

As confidentially submitted to the Securities and Exchange Commission on February 27, 2026.
This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

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

**FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

Seaport Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)

Seaport Therapeutics, Inc.
101 Seaport Blvd., Floor 12
Boston, Massachusetts 02210
(617) 807-4062

99-2235719
(I.R.S. Employer
Identification Number)

(Address, including zip code, and telephone number, including area code, of registrant’s principal executive offices)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box: ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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 7(a)(2)(B) of the Securities Act. ☐

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

PRELIMINARY PROSPECTUS

Shares



Common Stock

This is an initial public offering of shares of common stock of Seaport Therapeutics, Inc. We are offering shares of our common stock.

Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price per share will be between \$ and \$. We have applied to list our common stock on the Nasdaq Global Market under the symbol “SPTX.” We believe that upon the completion of this offering, we will meet the standards for listing on the Nasdaq Global Market, and the completion of this offering is contingent upon such listing.

We are an “emerging growth company” and “smaller reporting company” as defined under the U.S. federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements in this prospectus. For additional information, see the section titled “Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company.”

Investing in our common stock involves a high degree of risk. See the section titled “Risk Factors” beginning on page 15 to read about factors you should consider before deciding to invest in shares of our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions (1)	\$	\$
Proceeds, before expenses, to Seaport Therapeutics, Inc.	\$	\$

(1) For additional information regarding compensation payable to the underwriters, see the section titled “Underwriting.”

We have granted the underwriters the option to purchase up to an additional shares of common stock from us, at the initial public offering price, less the underwriting discounts and commissions.

At our request, the underwriters have reserved up to % of the shares offered by this prospectus for sale, at the initial public offering price, to our directors, officers, certain employees and certain other persons associated with us. See the section “Underwriting—Directed Share Program.”

The underwriters expect to deliver the shares against payment on or about , 2026.

Goldman Sachs & Co. LLC J.P. Morgan Leerink Partners Citigroup Stifel

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.¹

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Unless otherwise indicated, all references in this prospectus to “Seaport,” the “company,” “we,” “our,” “us”, or similar terms refer to Seaport Therapeutics, Inc. and its wholly owned subsidiaries, or either or all of them as the context may require.

Neither we nor the underwriters have authorized anyone to provide you any information or make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations, and prospects may have changed since that date.

For investors outside of the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of our common stock, and the distribution of this prospectus outside of the United States.

We own, have applied for, or have rights to use one or more registered and common law trademarks, service marks, and/or trade names in connection with our business in the United States, which may be used throughout this prospectus. This prospectus also includes trademarks, tradenames, and service marks of third parties which are the property of their respective owners. Our use or display of third-parties’ trademarks, service marks,

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tradenames, or products in this prospectus and our other public filings is not intended to, and does not imply a relationship with, or endorsement or sponsorship by us. Solely for convenience, the trademarks, service marks, logos and trade names referred to in this prospectus and our other public filings may appear without the ®, TM or SM symbols, but the omission of such references is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the rights of the applicable owner of or licensor to these trademarks, service marks, and trade names.

MARKET, INDUSTRY, AND OTHER DATA

The market data and certain other statistical information used throughout this prospectus are based on independent industry publications, governmental publications, reports by market research firms, or other independent sources that we believe to be reliable sources. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosures contained in this prospectus, and we believe that these sources are reliable; however, we have not independently verified the information contained in such publications. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section titled “Risk Factors” and elsewhere in this prospectus. Some data are also based on our good faith estimates.

BASIS OF PRESENTATION

We were incorporated under the laws of the State of Delaware as SP Therapeutics, Inc. on April 1, 2024 and changed our name to Seaport Therapeutics, Inc. on April 2, 2024. Our wholly owned subsidiary, SPTX, Inc., was a result of the incorporation of a predecessor company under the laws of the State of Delaware in February 2024 under the name Seaport Therapeutics, Inc., which subsequently changed its name to Seaport Therapeutics Holdings, Inc. in March 2024 and to SPTX, Inc. in April 2024. In April 2024, we entered into a share exchange agreement, or the Share Exchange Agreement, with SPTX, Inc., which resulted in SPTX, Inc. becoming our wholly owned subsidiary. On April 8, 2024, or the Asset Transfer Date, we entered into an Asset Transfer Agreement as amended in December 2025, or the Asset Transfer Agreement, with PureTech Health LLC, or PureTech Health, and PureTech LYT Inc., or PureTech LYT, pursuant to which PureTech Health and PureTech LYT agreed to contribute, convey, assign, transfer, and deliver to us all of their right, title, and interest in, to and under the assets related to its Glyph™ technology or products, subject to the terms set forth in the Asset Transfer Agreement.

The financial statements presented in this prospectus for periods prior to the Asset Transfer Date, which are included in the consolidated financial statements for the year ended December 31, 2024, have been prepared on a “carve-out” basis from the financial statements of PureTech Health plc, or PureTech, to represent our financial position and performance as if we had existed on a standalone basis. The financial statements presented in this prospectus for periods from and after the Asset Transfer Date reflect our financial position and performance as a standalone entity. All of our assets, liabilities and expenses as of and for the periods prior to the Asset Transfer Date were identified based on the assets and liabilities contributed to us from PureTech, as well as indirect costs that were not specifically identifiable to us or our related programs but were considered necessary to operate as a standalone company. Management believes the assumptions underlying our carve-out financial statements are reasonable. Nevertheless, the carve-out financial statements may not include all of the actual expenses that would have been incurred had we operated as a standalone company during the periods presented, and may not reflect our results of operations, financial position, and cash flows had we operated as a standalone company during the periods presented. Actual costs that would have been incurred if we had operated as a standalone company would depend on multiple factors, including organizational structure and strategic decisions made in various areas.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including the sections of this prospectus titled “Risk Factors,” “Special Note Regarding Forward-Looking Statements,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus, before making an investment decision.

Overview

We are a clinical-stage therapeutics company focused on inventing and developing new medicines for patients with depression, anxiety, and other debilitating neuropsychiatric disorders. Through our differentiated approach, we identify clinically validated mechanisms with established efficacy and safety profiles which had historically been limited by high first-pass metabolism, low bioavailability, and/or side effects. We apply our proprietary Glyph™ platform to overcome those limitations and invent innovative oral therapies. Glyph is a lymphatic-targeting prodrug technology which is designed to bypass first-pass metabolism and thereby enhance a drug’s oral bioavailability and reduce side effects. This process, which we call “Glyphing,” also creates new composition of matter intellectual property. Our experienced team of industry leaders has a proven track record in neuropsychiatry drug discovery and development and delivering successful business outcomes. We aim to develop novel, leading treatment options that will make a significant impact for patients and their families.

Our lead product candidate, GlyphAllo™ (SPT-300 or Glyph Allopregnanolone), is a novel, Glyphed oral prodrug of allopregnanolone, an endogenous molecule that has been clinically validated in third-party trials for the treatment of postpartum depression, or PPD, a form of major depressive disorder, or MDD, that shares symptomatology with MDD, as a rapidly acting antidepressant with anxiolytic and sleep-promoting effects. GlyphAllo is designed to overcome bioavailability limitations of allopregnanolone and deliver rapid and durable efficacy in MDD. We have demonstrated in a Phase 1 clinical trial that GlyphAllo reaches therapeutically relevant exposures with oral dosing, and in a Phase 2a clinical trial, GlyphAllo demonstrated initial proof-of-concept with an objective biomarker of stress in healthy volunteers and a favorable tolerability profile. We have initiated the Phase 2b BUOY-1 trial in patients with MDD with or without anxious distress and anticipate topline data in .

Our second product candidate, GlyphAgo™ (SPT-320 or Glyph Agomelatine), is a novel, Glyphed oral prodrug of agomelatine, a clinically validated anxiolytic and antidepressant that is approved for the treatment of generalized anxiety disorder, or GAD, in Australia and MDD in Australia and the European Union, or EU. We have initiated a proof-of-concept Phase 1 trial for the treatment of GAD and expect topline data in .

We are also advancing Glyph2BLSD™ (SPT-348 or Glyph 2-bromo-LSD), a novel, Glyphed oral prodrug of the non-hallucinogenic LSD analog 2-bromo-LSD, in preclinical studies for depressive disorders, including treatment-resistant depression, or TRD, post-traumatic stress disorder, or PTSD, and headache disorders.

Globally, over one billion people are living with mental illness as of 2021, comparable in prevalence to obesity or hypertension. According to the World Health Organization, as of 2021, depression affects approximately 332 million people worldwide and anxiety affects approximately 359 million people worldwide, and there is a significant need for novel treatment options. Currently approved drugs for MDD and GAD have significant limitations, including modest efficacy, slow onset of action, and unfavorable side effects. Advancement of novel therapies has been limited by a lack of understanding of disease pathophysiology, poor drug-like properties, and challenges in clinical trial design and execution leading to high clinical development failure rates.

Our differentiated approach

We are uniquely positioned to overcome the challenges of developing medicines for depression, anxiety, and other neuropsychiatric disorders by leveraging our differentiated, three-pillar approach:

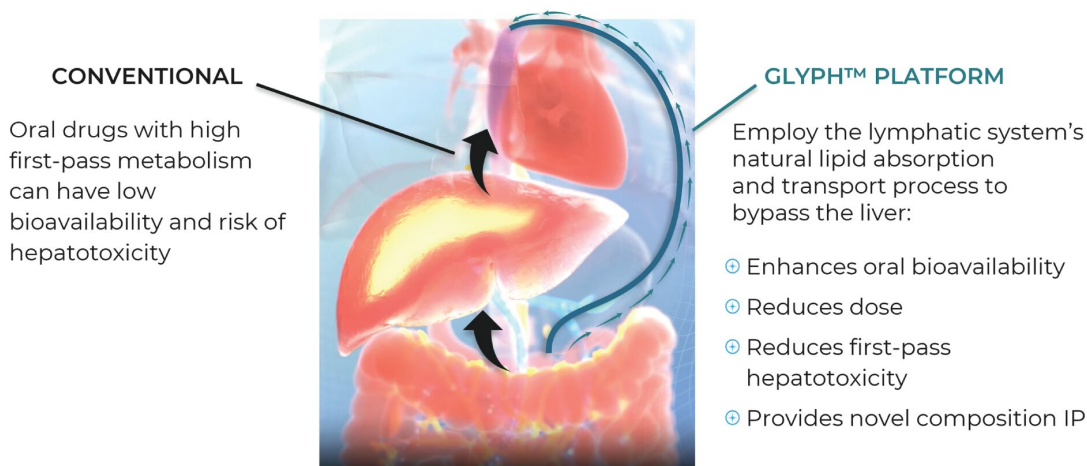
Identify clinically validated mechanisms held back by issues that can be addressed by our proprietary Glyph platform. We select our product candidates based on well-established clinical data, defined as demonstrated meaningful benefits compared to placebo in multiple randomized, placebo-controlled clinical trials in a large number of patients. We identify drugs matching this profile where clinical and commercial potential have been limited by high first-pass metabolism, low bioavailability, and/or side effects. We advance candidates that have the potential to be novel medicines and to impact a large number of patients.

Create novel medicines with strong intellectual property using Glyph. Glyph is our proprietary technology platform which uses the lymphatic system to enable and enhance the oral administration of drugs. Typically, non-Glyphed oral small molecules undergo first-pass metabolism, where the concentration of drug is significantly reduced by metabolic enzymes in the liver prior to systemic circulation. First-pass metabolism can lead to low bioavailability (i.e., reduced concentration of active drug available to target organs) and/or side effects, including liver enzyme elevations or hepatotoxicity. Glyph leverages a separate absorption path taken by dietary fats. A Glyphed molecule uses this alternative route via the intestinal lymphatic system to bypass first-pass metabolism and transit directly into systemic circulation. The Glyph platform has the potential to be widely applied to many therapeutic molecules that have high first-pass metabolism. For each program, we use Glyph to create unique sets of prodrugs with differentiated profiles, and evaluate these prodrugs as potential candidates to advance into preclinical and clinical studies. Glyph has been applied to create novel product candidates for our pipeline resulting in new intellectual property, including composition of matter patents.

Benefits of Our Proprietary Glyph Platform

Glyph™ Leverages the Lymphatic System to Unlock New Medicines

Proprietary platform advances active drugs previously limited by high first-pass metabolism

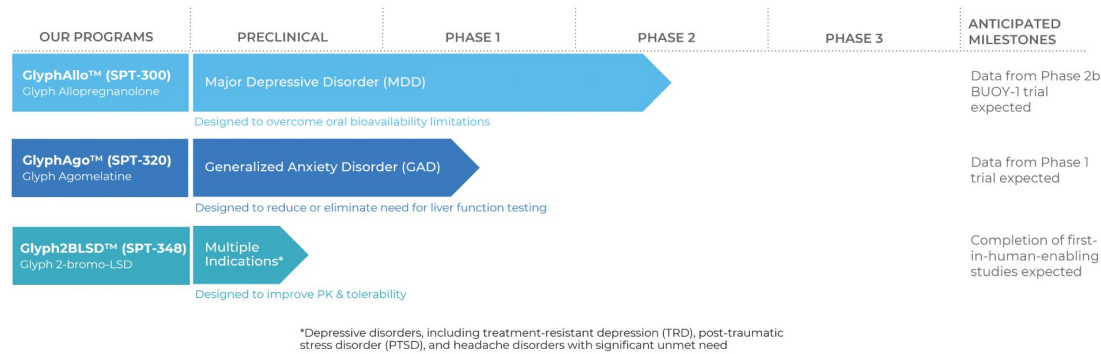


Apply our team's expertise to optimize the design and execution of clinical trials and drive successful business outcomes. Our team is comprised of industry leaders with a proven track record of building successful companies that have developed and commercialized innovative neuropsychiatric medicines. This includes

Zyprexa®, Cymbalta®, Latuda®, Zurzuvae®, and Cobenfy™ (xanomeline-trospium or KarXT), which was approved by the FDA in September 2024 and is the first new class of medicines in over 30 years for patients living with schizophrenia. Leveraging our team’s track record of success in neuropsychiatry discovery and clinical development is important as we select new product candidates and as we implement key design elements in our clinical trials to optimize treatment effect and duration and reduce placebo response. In parallel, we apply our deep experience in building successful companies to establish clear goals, drive strategic decision-making, and maintain financial discipline. Drawing on our track record of success in neuropsychiatry, we aim to drive successful outcomes for patients and shareholders.

Our Pipeline

We are developing a pipeline of novel potential treatments for neuropsychiatric disorders with significant unmet need. We retain exclusive, worldwide development and commercialization rights to all of our product candidates and discovery programs.



Glyph aims to unlock the therapeutic potential of drugs in CNS and beyond. In addition to our three lead candidates, we have robust discovery programs and multiple pipeline programs underway.

GlyphAllo: Potential Differentiated Therapy for MDD

GlyphAllo is a novel, Glyphed oral prodrug of allopregnanolone, an endogenous neurosteroid and gamma-aminobutyric acid A, or GABA_A, positive allosteric modulator, or PAM. Allopregnanolone is a naturally occurring molecule that reduces stress, with levels that peak during the third trimester of pregnancy. An intravenous infusion formulation of allopregnanolone was approved for the treatment of PPD, a form of MDD. Allopregnanolone has been clinically validated in two third-party trials, which were sponsored by Sage Therapeutics in the United States for the treatment of PPD and powered for statistical significance, as a rapidly acting antidepressant with anxiolytic and sleep-promoting effects. Due to the shared symptomatology between MDD and PPD, we believe data for MDD are relevant from such third-party trials. In each trial, allopregnanolone demonstrated statistically significant results on the primary endpoint of change in baseline at 60 hours in the Hamilton Depression Rating Scale-17, or HAM-D-17, a regulatory-standard depression severity rating scale. However, its scope of clinical use has been constrained by oral bioavailability limitations that the Glyph platform is uniquely designed to solve.

In our Phase 1 clinical trial conducted in Australia in 99 participants, GlyphAllo demonstrated therapeutically relevant exposures with a favorable tolerability profile that supports chronic dosing. Oral dosing of GlyphAllo has resulted in a greater than nine-fold increase in bioavailability compared to the bioavailability of oral allopregnanolone. Specifically, in preclinical studies in non-human primates, or NHPs, oral dosing of GlyphAllo resulted in such increase in bioavailability compared to oral unmodified allopregnanolone over 24 hours. In these preclinical studies, evaluation of GlyphAllo and unmodified allopregnanolone were conducted

simultaneously or sequentially using the same species. Consistent with these preclinical data, oral administration of GlyphAllo in our Phase 1 trial of GlyphAllo resulted in plasma exposure levels with an AUC_{inf} of 6.6 ng*hr/mL per 1 mg of allopregnanolone dosed. A previous third-party trial showed that oral administration of allopregnanolone resulted in plasma exposure levels with an AUC_{inf} of 0.7 ng*hr/mL per 1 mg of allopregnanolone dosed. No clinical head-to-head studies have been conducted comparing the results of our Phase 1 trial to oral allopregnanolone.

No treatment-related severe or serious adverse events were reported. GlyphAllo has also demonstrated initial proof-of-concept in a Phase 2a randomized, placebo-controlled trial conducted in Australia in 80 participants, using the Trier Social Stress Test, or TSST, a validated clinical model of anxiety in healthy volunteers. No severe or serious adverse events were reported. Based on these Phase 1 and Phase 2a data, we believe GlyphAllo has the potential to become a leading treatment for MDD. We advanced GlyphAllo into what we believe is a registration-enabling Phase 2b BUOY-1 trial conducted in the US and EU in July 2025. BUOY-1 is a global, randomized, double-blind, placebo-controlled trial evaluating the efficacy, safety, and tolerability of GlyphAllo in adults with MDD, with or without anxious distress. MDD with anxious distress is a form of MDD characterized by significant anxiety. Approximately 60% of patients with MDD meet the criteria for anxious distress. This trial is expected to enroll up to approximately 360 patients, randomized 1:1 to receive either GlyphAllo or placebo once-daily over a six-week treatment period. This randomized, double-blind, multiregional, placebo-controlled trial is designed to be registration-enabling, subject to review by the FDA and other comparable regulatory authorities, as an adequate and well-controlled investigation that seeks to help provide substantial evidence of effectiveness by assessing GlyphAllo's efficacy and safety in several hundred patients. Additional clinical trials may be required prior to the submission of a new drug application even if this trial is successful or positive. The primary endpoint of the trial is the change from baseline at six weeks in HAM-D-17. Following the initial treatment period, eligible patients may enter an open-label extension trial, in which all participants will receive GlyphAllo for up to six additional weeks.

Previous clinical development of allopregnanolone and its synthetic analog, which has been evaluated by Sage Therapeutics in multiple late-stage clinical trials for the treatment of MDD, has been generally hindered by poor oral bioavailability, safety concerns, and clinical trial design limitations. GlyphAllo is designed to enhance the oral bioavailability of allopregnanolone and achieve systemic exposures comparable to an intravenous infusion of allopregnanolone, with once-daily oral dosing. We believe our ongoing Phase 2b BUOY-1 trial improves upon the design of previous third-party clinical trials that evaluated a synthetic analog of allopregnanolone in several important ways.

We are improving durable efficacy by treating patients for the full six-week duration of the primary endpoint time frame, as opposed to previous trials that treated patients for only the first two weeks and assessed efficacy after six weeks. As allopregnanolone also has an anxiolytic effect, we are also enrolling patients that have MDD with or without anxious distress. To reduce placebo response, we are optimizing the frequency of clinician-administered assessments, as our comprehensive meta-analysis of recent antidepressant trials demonstrated that the frequency of these assessments is positively correlated with the magnitude of the placebo response in MDD trials. We are also including a single treatment arm and will flex dose to a target dose, similar to the strategy implemented at Karuna Therapeutics, since the number of active arms is positively associated with increased placebo response. Additionally, we are scrutinizing site selection and patient enrollment to ensure appropriate diagnosis and exclude inappropriate patients, including those with inflated baseline ratings and those who are concurrently participating in other studies. We expect topline data from the Phase 2b BUOY-1 trial in

GlyphAgo: Potential Differentiated Therapy for GAD

GlyphAgo is a novel, Glyphed oral prodrug of agomelatine that we are advancing in a key Phase 1 proof-of-concept trial for the treatment of GAD in Australia, in which we plan to enroll up to approximately

190 participants. Agomelatine, a clinically validated MT1/MT2 melatonin receptor agonist and serotonin 2C (5-HT2C) receptor antagonist, is an effective anxiolytic and antidepressant approved for the treatment of GAD in Australia and MDD in Australia and the EU. In GAD, agomelatine has demonstrated statistically significant separation from placebo in four third-party placebo-controlled studies¹. Based on two of the largest non-head-to-head literature meta-analyses of clinical trials of pharmacological agents for the treatment of GAD, agomelatine has been shown to have favorable efficacy and tolerability relative to other therapeutic agents. Specifically, in the first of these meta-analyses, which included two of the placebo-controlled studies of agomelatine, agomelatine was observed to have better efficacy and tolerability than certain standard-of-care drugs, like selective serotonin-reuptake inhibitors, or SSRIs, which can result in sexual dysfunction and weight gain, and benzodiazepines, which can result in dependence and abuse. In the second of these meta-analyses, which included three of the placebo-controlled studies of agomelatine, agomelatine was found to be the most favorable drug in terms of both efficacy and tolerability among the analyzed competitors (venlafaxine, escitalopram, paroxetine, duloxetine, and pregabalin). However, despite this positive profile, over 90% of unmodified agomelatine is lost to first-pass liver metabolism and its use has been limited by dose-dependent liver enzyme elevations. Its label in both Australia and the EU requires liver function testing before initiating treatment, during treatment, and upon increasing the dose. Agomelatine is not approved in the United States.

Using our proprietary Glyph platform, GlyphAgo is designed to avoid first-pass liver metabolism and increase systemic exposure of agomelatine, enabling exposure levels of agomelatine that are effective in GAD but at a lower dose that reduces liver exposure and reduces or eliminates the need for liver function testing. Based on internal analyses, we believe a two-fold increase in the bioavailability of agomelatine with GlyphAgo dosing will reduce or eliminate liver enzyme elevations. In preclinical studies in NHPs we showed that oral dosing of GlyphAgo increased plasma exposure of agomelatine versus agomelatine alone above this two-fold target. Therefore, based on the data we have generated to date, we believe GlyphAgo has the potential to become a leading treatment for GAD. The ongoing Phase 1 trial will be conducted in multiple parts to evaluate the safety, tolerability, and pharmacokinetics of GlyphAgo and compare the pharmacokinetics of GlyphAgo to agomelatine alone. It will include single- and multiple-ascending dose cohorts, as well as a food-effect crossover portion, using both open-label and placebo-controlled designs. We expect topline data from our Phase 1 trial of GlyphAgo in

Although the development and commercialization of GlyphAgo for the treatment of GAD is our primary focus, as part of our longer-term growth strategy, we may evaluate GlyphAgo in other indications as well, including MDD.

Glyph2BLSD and Additional Applications of the Glyph Platform

Glyph2BLSD is our novel, Glyphed oral prodrug of 2-bromo-LSD, a differentiated non-hallucinogenic neuroplastogen. Glyph2BLSD is designed to harness the differentiated and non-hallucinogenic profile of 2-bromo-LSD, which has rapidly acting clinical activity and is not expected to exhibit the fibrosis, cardiovascular effects, or hallucinations characteristic of some other neuroplastogens. Glyph2BLSD is designed to improve the pharmacokinetic and tolerability profile of 2-bromo-LSD while maintaining therapeutic exposure levels.

¹ The statements above relating to the placebo-controlled studies of agomelatine in GAD are based on the following, which represents a complete list of all placebo-controlled studies of agomelatine in GAD: Dan J. Stein, et al., Efficacy and safety of agomelatine (10 or 25 mg/day) in non-depressed out-patients with generalized anxiety disorder: A 12-week, double-blind, placebo-controlled study, *European Neuropsychopharmacology*, Volume 27, Issue 5, 2017 (Also included in meta-analyses); Dan J. Stein, et al., Agomelatine in Generalized Anxiety Disorder: An Active Comparator and Placebo-Controlled Study, *J Clin Psychiatry* 2014;75(4):362-368 (Also included in meta-analyses); Dan J. Stein, et al., Agomelatine Prevents Relapse in Generalized Anxiety Disorder: A 6-Month Randomized, Double-Blind, Placebo-Controlled Discontinuation Study, *J Clin Psychiatry* 2012;73(7):1002-1008; Dan J. Stein, et al., *Journal of Clinical Psychopharmacology* 28(5):p 561-566, October 2008 (Also included in meta-analyses).

Glyph2BLSD's non-hallucinogenic profile unlocks the potential to enable convenient outpatient and repeat dosing to improve efficacy. We are advancing Glyph2BLSD through preclinical studies and are developing Glyph2BLSD for the treatment of depressive disorders, including TRD, PTSD, and headache disorders with significant unmet need. We are currently conducting first-in-human-enabling studies of Glyph2BLSD.

We are also leveraging the power of the Glyph platform to explore additional applications in central nervous system, or CNS, and non-CNS diseases and advance programs that address significant unmet needs in these areas.

Our Team

Seaport was founded by pioneers in the neuropsychiatry field and is led by a team of seasoned industry veterans with a shared mission to transform the treatment of neuropsychiatric disorders and improve patients' lives. We have assembled an experienced group of individuals with a proven track record of building successful companies that have developed and commercialized innovative neuropsychiatric medicines. Members of our leadership team have collaborated successfully over several decades on the discovery, development, and commercialization of neuropsychiatric medicines including Cobenfy, Latuda, Zyprexa, Cymbalta, and Zurzuvae. Our co-founders, Daphne Zohar and Dr. Steven Paul, were central to the success of Karuna Therapeutics, which invented and advanced the first-in-class medicine Cobenfy, and was acquired by Bristol Myers Squibb in March 2024 for \$14 billion. Cobenfy was approved by the FDA in September 2024 and is the first drug to provide a new mechanism of action for schizophrenia in over 30 years. Cobenfy is estimated to achieve annual peak sales of over \$5 billion. Despite the prior experience of our team, our limited operating history as a standalone company makes any reliance on past performance uncertain.

Since our inception, we have raised \$325 million in net proceeds from leading life science investors, including shareholders with holdings greater than 5%: ARCH Venture Partners, General Atlantic, Sofinnova Investments, Third Rock Ventures, and our founder, PureTech. Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and in certain cases received their shares in prior offerings at prices lower than the price offered to the public in this offering.

Our Strategy

We founded our company with a mission to develop life-changing treatments for patients with depression, anxiety, and other neuropsychiatric disorders. The key elements of our business strategy are to:

- Successfully advance GlyphAllo through clinical development for the treatment of patients with MDD with or without anxious distress.
- Successfully advance GlyphAgo through clinical development for the treatment of patients with GAD.
- Develop a robust pipeline of differentiated programs for neuropsychiatric and other CNS disorders by leveraging our Glyph platform.
- Opportunistically pursue strategic partnerships to maximize the value of our Glyph platform.

Our Differentiated Approach

We are uniquely positioned to develop novel medicines that will make a significant impact for patients and their families through our differentiated, three-pillar approach: 1) identify clinically validated mechanisms held back by issues that can be addressed by our proprietary Glyph platform, 2) create novel medicines with strong intellectual property using Glyph, and 3) apply our team's expertise to optimize the design and execution of clinical trials and drive successful business outcomes. We believe our approach will enable us to develop transformative treatments for patients and build a leading neuropsychiatry company.

Risks Associated With Our Business

Our business is subject to a number of risks of which you should be aware before making an investment decision. These risks include, but are not limited to, the following:

- We are a clinical-stage therapeutics company with a limited operating history, which may make it difficult to evaluate our current business and predict our future success and viability. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.
- Even if this offering is successful, we will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Our business is highly dependent on the success of our product candidates, particularly GlyphAllo for the treatment of MDD with or without anxious distress and GlyphAgo for the treatment of generalized anxiety disorder, or GAD, and MDD. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.
- Clinical and preclinical development involves a lengthy and expensive process and is highly uncertain. Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.
- The regulatory approval processes of the FDA and other comparable regulatory authorities are lengthy, time-consuming, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- The determination of whether the BUOY-1 clinical trial will be registration-enabling lies solely within the discretion of the FDA and/or other comparable regulatory authorities, based on whether such body views this trial as an adequate and well-controlled clinical investigation that can support regulatory decision making, and whether the resulting data from the trial provide substantial evidence of effectiveness. There can be no assurance that our clinical trials will ultimately be successful or support further clinical development of our product candidates, and we may have to complete multiple additional clinical trials, which may be differently designed than prior clinical trials, to support a submission for marketing authorization for this product candidate.
- Our proprietary Glyph platform is based on a novel approach that may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.
- If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.
- We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Our product candidates may be associated with adverse events, or AEs, or other undesirable properties or safety risks, which could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials or abandon a product candidate, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained, or result in other significant negative consequences that could severely harm our business, financial condition, results of operations, and prospects.

- We have concentrated our research and development efforts on the treatment of disorders of the brain and central nervous system, a field that faces certain challenges in drug development.
- Existing and potential future competitive products may reduce or eliminate the commercial opportunity for our product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.
- Our ability to develop product candidates, leverage our Glyph platform and our future growth depends on attracting, hiring, and retaining our key personnel and recruiting additional qualified personnel.
- We rely on third parties to assist in conducting our clinical trials and preclinical studies. If they do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.
- Our commercial success depends on our ability to obtain, maintain, enforce, and otherwise protect our intellectual property and proprietary technology, and if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products and product candidates similar to ours and our ability to successfully develop and commercialize our product candidates may be adversely affected.
- We are heavily reliant upon the Amended and Restated License Agreement with Monash University, or the Monash License Agreement, pursuant to which we have been granted an exclusive, royalty-bearing license to certain patent rights that are important or necessary to the development of our proprietary technology and product candidates.
- While we may in the future seek designations for our product candidates with the FDA and other comparable regulatory authorities that are intended to confer benefits such as a faster development process, an accelerated regulatory pathway or regulatory exclusivity, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.
- Our results of operations for the period from January 1, 2024 to April 7, 2024, which are included in the consolidated financial statements for the year ended December 31, 2024, have been prepared on a “carve-out” basis based on management estimates, assumptions, and judgments about appropriate allocation and may not be indicative of what they would have been had we actually been an independent standalone entity throughout such period.
- There has been no prior public market for our common stock, and an active trading market may not develop or be sustained.

The summary risk factors described above should be read together with the text of the full risk factors in the section titled “Risk Factors” and the other information set forth in this prospectus, including our consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission, or the SEC. The risks summarized above or described in full elsewhere in this prospectus are not the only risks that we face. Additional risks and uncertainties not presently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

Corporate Information

We were incorporated under the laws of the State of Delaware as SP Therapeutics, Inc. on April 1, 2024 and changed our name to Seaport Therapeutics, Inc. on April 2, 2024. Our wholly owned subsidiary, SPTX, Inc., was a

result of the incorporation of a predecessor company under the laws of the State of Delaware in February 2024 under the name Seaport Therapeutics, Inc., which subsequently changed its name to Seaport Therapeutics Holdings, Inc. in March 2024 and to SPTX, Inc. in April 2024. In April 2024, we entered into a share exchange agreement, or the Share Exchange Agreement, with SPTX, Inc., which resulted in SPTX, Inc. becoming our wholly owned subsidiary. At the time of the Share Exchange Agreement, we were a wholly-owned subsidiary of PureTech. Our principal executive offices are located at 101 Seaport Blvd., Floor 12, Boston, Massachusetts 02210, and our telephone number is (617) 807-4062. We have three subsidiaries, Seaport Therapeutics Securities Corporation, formed in December 2024 under the laws of the Commonwealth of Massachusetts, SPTX, Inc., formed in February 2024 under the laws of the State of Delaware, and Seaport Therapeutics Australia Pty Ltd, formed in February 2025 under the laws of Australia. Our website address is www.seaporttx.com. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- being permitted to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this prospectus;
- reduced disclosure about our executive compensation arrangements;
- not being required to hold advisory votes on executive compensation or to obtain stockholder approval of any golden parachute arrangements not previously approved;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on the financial statements.

We may remain an emerging growth company for up to five years from the date of the first sale in this offering. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1.235 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Additionally, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we may not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result of this election, our financial statements may not be comparable to those of other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We have in the past chosen and may in the future choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We are also a “smaller reporting company,” meaning that the market value of our shares held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than \$700 million and our annual revenue was less than \$100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our shares held by non-affiliates is less than \$250 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than \$700 million measured on the last business day of our second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

THE OFFERING

Common stock offered by us	shares
Option to purchase additional shares of common stock offered by us	We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of common stock from us at the public offering price, less underwriting discounts and commissions on the same terms as set forth in this prospectus.
Common stock to be outstanding immediately after this offering	shares (or shares if the underwriters exercise their option to purchase additional shares of common stock in full)
Use of proceeds	We estimate that the net proceeds from the sale of our common stock in this offering will be approximately \$ million (or approximately \$ million if the underwriters exercise their option to purchase additional shares of common stock in full), based on the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds we receive from this offering, together with our existing cash, cash equivalents, and investments, to advance development of GlyphAllo™ (SPT-300), GlyphAgo™ (SPT-320), and Glyph2BLSD™ (SPT-348), as well as to fund research and development activities for additional programs, and the remainder for working capital and general corporate purposes. For additional information, see the section titled “Use of Proceeds.”
Directed share program	At our request, the underwriters have reserved up to % of the shares of common stock being offered by this prospectus for sale at the initial public offering price to our directors, officers, certain employees, and certain other persons associated with us. We do not know if these persons will choose to purchase all or any portion of these reserved shares, but any purchases they do make will reduce the number of shares of common stock available to the general public. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of common stock. Except for reserved shares purchased by our executive officers and directors, these reserved shares will not be subject to the lock-up restrictions described elsewhere in this prospectus. For additional information, see the section titled “Underwriting—Directed Share Program.”
Risk factors	For a discussion of factors you should carefully consider before deciding whether to invest in our common stock, see the section titled “Risk Factors.”
Proposed Nasdaq Global Market trading symbol	“SPTX”

Unless otherwise noted, the number of shares of our common stock that will be outstanding after this offering is based on 122,072,236 shares of common stock (which includes 486,114 shares of unvested restricted common stock) outstanding as of December 31, 2025, after giving effect to the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 113,921,036 shares of common stock immediately prior to the completion of this offering, or the Preferred Stock Conversion, and excludes:

- 27,633,144 shares of common stock issuable upon exercise of outstanding stock options as of December 31, 2025, which includes 718,500 performance-based awards that have not yet been deemed granted for accounting purposes, under our 2024 Equity Incentive Plan, as amended, or the 2024 Plan, with a weighted-average exercise price of \$1.52 per share, and 3,023,510 shares of common stock issuable upon exercise of outstanding stock options granted after December 31, 2025 pursuant to our 2024 Plan, with a weighted-average exercise price of \$3.28 per share;
- 4,722,667 shares of common stock reserved for future issuance as of December 31, 2025 under the 2024 Plan, which will cease to be available for issuance at the time that our 2026 Stock Option and Incentive Plan, or the 2026 Plan, becomes effective;
- shares of our common stock to be granted to an executive officer and a director under the 2026 Plan, issuable upon the exercise of stock options, with an exercise price that is equal to the initial public offering price in this offering, or a number of shares of restricted common stock, as applicable, or the IPO Grants, equal to approximately 12.5% of the number of shares of our common stock to be outstanding upon the closing of this offering calculated on a fully diluted basis; see the sections titled “Executive Compensation—Narrative disclosure to the 2025 Summary Compensation Table—Equity Incentive Compensation” and “Director Compensation” for more information on such grants, including a description of how the number of shares issuable pursuant to such grants will be determined;
- shares of our common stock that will become available for future issuance under our 2026 Plan, including shares reserved for the IPO Grants, which will become effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2026 Plan and any shares underlying outstanding stock awards granted under the 2024 Plan that expire or are repurchased, forfeited, cancelled, or withheld; and
- shares of common stock reserved for future issuance under our 2026 Employee Stock Purchase Plan, or the ESPP, which will become effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

Unless otherwise indicated, the information in this prospectus reflects or assumes the following:

- a 1-for- reverse stock split of our common stock, which will become effective prior to the completion of this offering;
- the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 113,921,036 shares of common stock immediately prior to the completion of this offering;
- no exercise of the outstanding stock options described above after December 31, 2025;
- no exercise of the underwriters’ option to purchase up to an additional shares of common stock in this offering;
- no purchases by existing stockholders or their affiliates pursuant to the directed share program; and
- the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the completion of this offering and the adoption of our amended and restated bylaws to be in effect upon the effectiveness of the registration statement of which this prospectus forms a part.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated statements of operations data for the years ended December 31, 2025 and 2024 and our summary consolidated balance sheet data as of December 31, 2025. We have derived the summary consolidated statements of operations data for years ended December 31, 2025 and 2024, and the summary consolidated balance sheet data as of December 31, 2025, from our audited consolidated financial statements included elsewhere in this prospectus. The historical results for the period from January 1, 2024 to April 7, 2024, which are included in the consolidated financial statements for the year ended December 31, 2024, have been prepared on a “carve-out” basis and are not necessarily indicative of results that may be expected in the future, nor are our other historical results necessarily indicative of the results that may be expected for any period in the future. You should read the following summary financial data together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes included elsewhere in this prospectus. The summary consolidated financial data included in this section are not intended to replace the consolidated financial statements and are qualified in their entirety by our consolidated financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,	
	2025	2024
	(in thousands, except share and per share data)	
Statement of Operations Data:		
Operating expenses		
Research and development (including stock-based compensation expense of \$2.3 million and \$0.7 million for 2025 and 2024, respectively) ⁽¹⁾	\$ 66,313	\$ 25,070
General and administrative (including stock-based compensation expense of \$4.6 million and \$15.2 million for 2025 and 2024, respectively) ⁽²⁾	20,981	27,346
Total operating expenses	87,294	52,416
Loss from operations	(87,294)	(52,416)
Other income (expense), net		
Interest income, net	11,403	5,537
Research and development tax credit	1,898	—
Other (expense), net	(115)	—
Total other income, net	13,186	5,537
Loss before income taxes	(74,108)	(46,879)
Income tax provision	773	—
Net loss	\$ (74,881)	\$ (46,879)
Net loss per share, basic and diluted ⁽³⁾	\$ (10.04)	\$ (15.83)
Weighted-average common shares outstanding, basic and diluted ⁽³⁾	7,456,011	2,961,543
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) ⁽⁴⁾	\$	
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited) ⁽⁴⁾		

- (1) Includes related-party amounts of \$0.3 million and \$14.2 million for research and development expenses for the years ended December 31, 2025 and 2024, respectively. See Note 17 to our consolidated financial statements included elsewhere in this prospectus.
- (2) Includes related-party amounts of \$0.1 million and \$5.8 million for general administrative expenses for the years ended December 31, 2025 and 2024, respectively. See Note 17 to our consolidated financial statements included elsewhere in this prospectus.
- (3) See Notes 2 and 16 to our consolidated financial statements included elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders.
- (4) Pro forma basic and diluted net loss per share attributable to common stockholders has been prepared to give effect to adjustments to our capital structure arising in connection with the completion of this offering and is calculated by dividing the pro forma net loss attributable to common stockholders by the pro forma weighted-average common shares outstanding for the period. Pro forma weighted-average common shares outstanding is computed by adjusting the weighted-average common shares outstanding to give pro forma effect to the Preferred Stock Conversion as if such conversion had occurred on January 1, 2025. Pro forma basic and diluted net loss per share attributable to common stockholders does not include the effect of the shares expected to be sold in this offering.

	As of December 31, 2025		
	Actual	Pro Forma (1)	Pro Forma As adjusted (2)
(in thousands)			
Balance Sheet Data			
Cash, cash equivalents, and investments	\$ 46,042	\$	\$
Working capital (3)	210,448		
Total assets	249,009		
Total liabilities	16,226		
Convertible preferred stock	325,328		
Accumulated deficit	(114,109)		
Total stockholders' (deficit) equity	(92,545)		

- (1) The pro forma balance sheet data give effect to (i) the Preferred Stock Conversion and (ii) the filing and effectiveness of our amended and restated certificate of incorporation in Delaware immediately prior to the completion of this offering.
- (2) The pro forma as adjusted balance sheet data give effect to (i) the pro forma adjustments set forth in footnote (1) above and (ii) the issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Pro forma as adjusted balance sheet data is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents, and investments, working capital, total assets, and total stockholders' equity by approximately \$, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each 1,000,000 increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents, and investments, working capital, total assets and total stockholders' equity by approximately \$ million, assuming no change in the assumed initial offering price per share, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) We define working capital as current assets less current liabilities. See our consolidated financial statements appearing elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should consider and read carefully all of the risks and uncertainties described below, as well as the other information in this prospectus, including our consolidated financial statements and the related notes included elsewhere in this prospectus and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” before deciding whether to invest in our common stock. The risks described below are not the only ones facing us. The following risks or additional risks and uncertainties not presently known to us or that we currently believe to be immaterial could materially and adversely affect our business, financial condition, results of operations, and growth prospects. In such an event, the trading price of our common stock could decline, and you may lose all or part of your investment. This prospectus also contains forward-looking statements and estimates that involve risks and uncertainties not presently known to us or that we currently deem immaterial that also may impair our business operations. Our actual results could differ materially from those anticipated in our forward-looking statements as a result of specific factors, including the risks and uncertainties described below.

Risks Related to Our Limited Operating History, Financial Condition, and Need for Additional Capital

We are a clinical-stage therapeutics company with a limited operating history, which may make it difficult to evaluate our current business and predict our future success and viability. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.

We are a clinical-stage therapeutics company with a limited operating history. We were formed by PureTech Health plc, or PureTech, in April 2024 and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, advancing our Glyph™ platform and technology, identifying potential product candidates, securing intellectual property rights, and planning and undertaking preclinical studies and clinical trials. Our Glyph platform was being developed by members of our current team during their tenure at PureTech up to the date of our entry into an Asset Transfer Agreement, or the Asset Transfer Agreement, with PureTech Health LLC, or PureTech Health, and PureTech LYT, Inc., or PureTech LYT, at which time we became a standalone company. As such, our results of operations for the period from January 1, 2024 to April 7, 2024, which are included in the consolidated financial statements for the year ended December 31, 2024, have been carved out from the results of operations of PureTech that were attributable to operations related to our Glyph platform and our product candidates, based on management estimates, assumptions, and judgments about appropriate allocation and may not be indicative of what they would have been had we actually been an independent standalone entity throughout such period, nor are they necessarily indicative of our future results of operations, financial position, and cash flows.

At Seaport, we have not yet demonstrated an ability to generate product or collaboration revenues, obtain regulatory approvals, manufacture any product on a commercial scale or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. All preclinical and early clinical development of GlyphAllo™ (SPT-300), certain preclinical development of GlyphAgo™ (SPT-320) and our other candidates prior to our formation was conducted when we were part of PureTech. Despite our affiliation with PureTech, and members of our current team’s involvement in the development of the Glyph platform while at PureTech, our limited operating history as a standalone company makes any reliance on past performance uncertain. We will encounter risks and difficulties frequently experienced by early-stage therapeutics companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business will suffer.

The success of our business depends primarily upon our ability to identify, develop, and commercialize product candidates based on our Glyph platform. We do not know whether we will be able to develop any product candidates that succeed through clinical development or to develop products of commercial value. We

have no products approved for commercial sale and have not generated any revenue from product sales or collaboration arrangements to date. We will continue to incur significant research and development and other expenses related to our preclinical and clinical development and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net losses totaled \$74.9 and \$46.9 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we have not yet generated product or collaboration revenue and had an accumulated deficit of \$114.1 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful initiation and completion of preclinical studies with favorable results, including toxicology and other studies designed to be compliant with good laboratory practice, or GLP, requirements;
- allowance to proceed with clinical trials under Investigational New Drug applications, or INDs, by the United States Food and Drug Administration, or the FDA, or of similar regulatory submissions by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates;
- successful initiation, enrollment, and completion of clinical studies in accordance with good clinical practice, or GCPs, requirements and other applicable rules and regulations;
- the frequency and severity of adverse events, or AEs, observed in clinical trials;
- maintaining and establishing relationships with contract research organizations, or CROs, and clinical sites for the clinical development of our product candidates;
- demonstrating the safety and efficacy of our product candidates to the satisfaction of the FDA and other applicable regulatory authorities;
- receipt of regulatory approvals from applicable regulatory authorities, including approvals of New Drug applications, or NDAs, from the FDA, and maintaining any such approvals;
- making arrangements with third-party manufacturers for, or establishing, clinical or commercial manufacturing capabilities;
- establishing sales, marketing, and distribution capabilities and launching commercial sales of our product candidates, if and when approved, either alone or in collaboration with others;
- obtaining, establishing, and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- maintaining an acceptable safety profile of our product candidates following regulatory approval, if any;
- maintaining and growing an organization of people who can develop and, if approved, commercialize, market and sell our product candidates, if approved; and
- acceptance of our product candidates, if approved, by patients, the medical community and third-party payors.

We anticipate that our expenses will increase substantially if, and as, we:

- advance our product candidates through preclinical and clinical development, including advancing GlyphAllo and GlyphAgo through later-stage clinical trials, and other candidates through discovery and early clinical and preclinical stages;
- seek regulatory approvals for our product candidates that successfully complete clinical trials from the U.S. Food and Drug Administration, or the FDA, and/or other foreign comparable regulatory authorities;

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- hire additional clinical, quality control, medical, scientific, and other technical personnel to support the clinical development of our product candidates;
- expand our internal capabilities to support clinical-stage development;
- increase our headcount as we expand our research and development organization, and pre-commercial planning activities;
- undertake any activities to establish sales, marketing, and distribution capabilities in preparation for commercialization, as applicable, including hiring additional personnel to support such operations;
- seek to identify, acquire, and develop additional product candidates where we can leverage our Glyph platform, including through business development efforts to invest in or in-license other technologies or product candidates;
- maintain, expand, and protect our intellectual property portfolio;
- experience heightened regulatory scrutiny;
- make milestone, royalty, or other payments due under the Asset Transfer Agreement and/or the License Agreement with Monash University, or the Monash License Agreement, and any future in-license or collaboration agreements with third parties; and
- incur additional legal, accounting, and other expenses associated with operating as a public company.

Therapeutic product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access, and reimbursement and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, you should consider our prospects, factoring in the costs, uncertainties, delays, and difficulties frequently encountered by companies in clinical development, especially clinical-stage therapeutics companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays, and other known or unknown factors in achieving our business objectives.

Additionally, our expenses could increase beyond our expectations if we are required by the FDA or other comparable regulatory authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for or in completing our clinical trials or the development of any of our product candidates.

Even if this offering is successful, we will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing therapeutic products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that takes years to complete. We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek regulatory approval for, our product candidates. Even if our current or future product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. To date, we have funded our operations principally through private financings. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the clinical and preclinical development of our product candidates, continue to identify additional targets using our Glyph platform, commence additional preclinical studies and clinical trials, and continue to identify and develop additional product candidates either through internal development or through acquisitions or in-licensing product candidates.

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As of December 31, 2025, we had \$233.7 million of cash, cash equivalents and investments. Based upon our current operating plan, we believe that our existing cash, cash equivalents, and investments, together with the net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements through . We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We may also raise additional financing on an opportunistic basis in the future. For example, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. Our future capital requirements will depend on many factors, including but not limited to:

- the scope, timing, progress, costs, and results of discovery, preclinical development and clinical trials for our current or future product candidates and effectiveness of our Glyph platform;
- the number of clinical trials required for regulatory approval of our current or future product candidates;
- the costs, timing, and outcome of regulatory review of any of our current or future product candidates;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties or other payments due in connection with our acquisitions and licenses, as applicable;
- the cost of manufacturing clinical and commercial supplies of our current or future product candidates;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire, and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of macroeconomic trends including inflation, tariffs, and fluctuating interest rates;
- addressing any potential supply chain interruptions or delays;
- the effect of competing technological, and market developments; and
- the extent to which we acquire or invest in businesses, products, and technologies.

Because of the numerous risks and uncertainties associated with research and development of product candidates, we are unable to predict the timing or amount of our working capital requirements. In addition, if we obtain regulatory approval for our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales, and distribution which make it difficult to predict when or if we will be able to achieve or maintain profitability. Furthermore, upon the completion of this offering, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain

substantial additional funding in order to support our continuing operations. Our ability to raise additional funds will depend on financial, economic, political and market conditions and other factors, over which we may have no or limited control. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce, or terminate our product development programs, future commercialization efforts or other operations.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations with our existing cash, cash equivalents, and investments, the net proceeds from this offering, any future equity, debt, royalty, or other financings and upfront and milestone and royalty payments, if any, received under any future licenses or collaborations. If we raise additional capital through the sale of equity or convertible debt securities, or issue any equity or convertible debt securities in connection with a collaboration agreement or other contractual arrangement, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. In addition, the possibility of such issuance may cause the market price of our common stock to decline. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, or acquiring, selling, or licensing intellectual property rights or assets, which could adversely impact our ability to conduct our business. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams, or product candidates, or grant licenses on terms that may not be favorable to us. We could also be required to seek funds through arrangements with collaborators, or others at an earlier stage than otherwise would be desirable. Attempting to secure additional financing may also divert management from our day-to-day activities. Any of these occurrences may have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Our Business

Our business is highly dependent on the success of our product candidates, particularly GlyphAllo for the treatment of major depressive disorder, or MDD, with or without anxious distress and GlyphAgo for the treatment of generalized anxiety disorder, or GAD, and MDD. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed.

To date, as an organization, we have not completed the development of any product candidates and nearly all of our candidates remain in early-stage clinical or preclinical development. Our future success and ability to generate revenue from our product candidates is dependent on our ability to successfully develop, obtain regulatory approval for, and commercialize one or more of our product candidates. All of our product candidates that we pursue will require substantial additional investment for clinical development, regulatory review, and approval in one or more jurisdictions. If any of our product candidates, particularly GlyphAllo for MDD with or without anxious distress, and GlyphAgo for GAD and MDD, encounters safety or efficacy problems, development delays or regulatory issues, or other problems, our development plans and business would be materially harmed.

We may not have the financial resources to continue development of our product candidates if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including:

- our inability to demonstrate to the satisfaction of the FDA or other comparable regulatory authorities that our product candidates are safe and effective;

- insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- negative or inconclusive results from our clinical trials, preclinical studies, or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies, or abandon a program;
- product-related AEs experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidates;
- delays in submitting an IND application, a New Drug Application, or an NDA, or other regulatory submission to the FDA or other comparable regulatory authorities, delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension, termination, or hold, of a clinical trial once commenced;
- conditions imposed by the FDA or other comparable regulatory authorities regarding the scope or design of our clinical trials;
- poor effectiveness of our product candidates during clinical trials;
- delays in enrolling subjects in our clinical trials;
- high drop-out rates of subjects from our clinical trials;
- inadequate supply or quality of product candidates or other materials necessary for the conduct of our clinical trials;
- higher than anticipated clinical trial or manufacturing costs;
- unfavorable FDA or other comparable regulatory authority inspection and review of our clinical trial sites, manufacturing sites, or those of our partners;
- failure of our third-party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all;
- competition with existing platforms, product candidates, or therapies;
- delays and changes in regulatory requirements, policies, and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular;
- insufficiency of our financial and other resources to complete the necessary activities to prepare for launch, commercialization and/or resources to address coverage and reimbursement matters to the extent any of our products receive approval; or
- varying interpretations of data by the FDA or other comparable regulatory authorities.

Clinical and preclinical development involves a lengthy and expensive process and is highly uncertain. Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.

Before obtaining approval from regulatory authorities for the commercialization of any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate in humans. Before we can initiate clinical trials for any product candidates, we must submit the results of preclinical studies to the FDA or other comparable regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls, and our proposed clinical trial protocol, as part of an IND or similar regulatory submission. The FDA or other comparable regulatory authorities may require us to conduct additional preclinical studies for any product candidate before it allows us

to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs. Moreover, even if we commence clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our ongoing and planned clinical trials for our product candidates could significantly affect our product development timelines and product development costs and harm our financial position.

We do not know whether our planned clinical trials will begin on time or be completed on schedule, if at all. The timing for commencement, data readouts, and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- obtaining allowance or approval from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or other comparable regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting, and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards, or IRBs, or ethics committees at clinical trial sites;
- IRBs refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with GCP requirements or applicable regulatory rules and guidelines in other countries;
- manufacturing sufficient quantities of our product candidates for use in clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials;
- patients choosing an alternative product for the indications for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue a clinical trial or costs being greater than we anticipate;
- subjects experiencing severe or serious unexpected drug-related AEs;
- occurrence of serious AEs in trials of the same class of agents conducted by other companies that could be considered similar to our product candidates;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization, or CMO, delays or failure by our CMOs or us to make any necessary changes to such manufacturing process, or failure of our CMOs to produce clinical trial materials in accordance with current Good Manufacturing Practice, or cGMP, regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

Clinical trials must be conducted in accordance with the FDA and other comparable regulatory authorities' legal requirements, regulations, and guidelines, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. 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 other comparable regulatory 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 applicable clinical trial protocols, adverse findings from inspections of clinical trial sites by the FDA or other comparable regulatory authorities, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, 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 regulators or to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we are currently doing and may do for our current or future product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects 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 schemes, and political and economic risks, including war, relevant to such foreign countries.

In addition, many of the factors that cause or lead to the termination, suspension of, or a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition, results of operations, and prospects.

Due to the significant resources required for the development of our pipeline and uncertainty regarding our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.

We seek to invent and develop new medicines for patients with depression, anxiety, and other debilitating neuropsychiatric disorders. Our lead product candidate, GlyphAllo for the treatment of MDD, with or without anxious distress, has been evaluated in Phase 1 and Phase 2a studies in healthy volunteers and is currently in Phase 2b clinical development in our BUOY-1 trial. Our second product candidate, GlyphAgo, is being evaluated in a key proof-of-concept Phase 1 clinical study, our third product candidate, Glyph2BLSD is in preclinical studies and our other programs are at various stages of discovery and preclinical development.

Due to the significant resources required for the development of our product candidates, we must decide which product candidates and indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management, and financial resources toward particular product candidates, therapeutic areas, or indications may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, in particular for disorders of the brain and nervous system, our business, financial condition, and results of operations could be materially and adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later

prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing, or royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

We, third parties on which we rely, and our service providers are, or may become, subject to a variety of stringent and evolving privacy and data security laws, regulations, and rules, contractual obligations, industry standards, policies, and other obligations related to privacy and data security. Any actual or perceived failure to comply with such obligations could expose us to significant fines or other penalties and otherwise harm our business and operations.

In the ordinary course of our business, we and the third parties upon which we rely (such as our third-party CROs, and other contractors and consultants) collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share, or, collectively, process, personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, sensitive third-party data, business plans, transactions, financial information, and data we collect about trial participants in connection with clinical trials, or, collectively, sensitive data. Our data processing activities subject us to numerous evolving privacy and data security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to privacy and data security.

The legislative and regulatory framework for the processing of personal data worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Numerous federal, state, and local laws and regulations, including federal and state information security and data breach notification laws and regulations, federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws) govern the processing of health-related and other personal data. Many of these laws and regulations differ from each other and from the Health Insurance Portability and Accountability Act of 1996, or HIPAA, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties, private litigation, and injunctive relief. In the event that we are subject to or affected by HIPAA 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.

At the state level, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording individuals certain rights concerning their personal data. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While the comprehensive privacy laws that are in effect at the state level generally exempt certain data processed in the context of clinical trials, the continued development of new privacy laws at the state level may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Further proposed privacy legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of data and information that could be of potential use to the growth and development of our business, and could result in increased compliance costs and/or the necessity of making changes in our business practices and policies. The continued further development of privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

Additionally, we may be subject to new laws governing the privacy of certain specific types of data, including, most notably, consumer health data. For example, Washington State's My Health My Data Act broadly defines consumer health data, creates a private right of action to allow individuals to sue for violations of the law, imposes stringent consent requirements, and grants consumers certain rights with respect to their health data, including to request deletion of their information. Connecticut and Nevada have also passed similar laws

regulating consumer health data. State laws are changing rapidly and there is ongoing discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we would likely become subject, if enacted. These various privacy and data security laws may impact our business activities, including our identification of research subjects, relationships with business partners, and ultimately the marketing and distribution of our products.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern privacy and data security. For example, the European Union's General Data Protection Regulation, or EU GDPR, and the United Kingdom's, or UK's, GDPR, or UK GDPR, impose strict requirements for processing personal data. The EU GDPR and the UK GDPR, or together, GDPR, establish stringent requirements regarding the processing of personal data, including strict requirements relating to processing of sensitive data (such as health data), ensuring there is a legal basis or condition to justify the processing of personal data, where required strict requirements relating to obtaining consent of individuals, expanded disclosures about how personal data is to be used, limitations on retention of information, implementing safeguards to protect the security and confidentiality of personal data, where required providing notification of data breaches, maintaining records of processing activities, and documenting data protection impact assessments where there is high risk processing and taking certain measures when engaging third-party processors.

Under GDPR, companies may face temporary or definitive bans on data processing and other corrective activities, fines of up to €20 million (£17.5 million GBP) or 4% of annual global revenues, whichever is greater, and 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. Non-compliance could also result in a material adverse effect on our business, financial condition, and results of operations.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. 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, or EEA, and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally 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 and UK to the United States in compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework, and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), 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 (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines, and penalties, the inability to transfer data and work with partners, vendors, and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition to privacy and data security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to privacy and data security, and our efforts to comply with such obligations may not be successful. We may publish privacy policies and marketing materials, and other statements, such as compliance

with certain certifications or self-regulatory principles, regarding privacy and data security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences. Obligations related to privacy and data security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our privacy and data security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable privacy and data security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, financial condition, or results of operations, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Risks Related to the Discovery and Development of Our Current or Future Product Candidates

The regulatory approval processes of the FDA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We are not permitted to commercialize, market, promote, or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Other comparable regulatory authorities impose similar requirements. The time required to obtain approval by the FDA or other comparable regulatory authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. For instance, jurisdictions outside of the United States, such as the EU, may have different requirements for regulatory approval, which may require us to conduct additional clinical, nonclinical, or chemistry, manufacturing, and control studies. To date, we have not submitted an NDA to the FDA or similar drug approval submissions to other comparable regulatory authorities for any product candidate. We must complete additional preclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is inherently uncertain as to outcome. We cannot guarantee that our clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our initial and potential additional product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to

demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of AEs that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or other comparable regulatory authorities that a product candidate may not continue development or is not approvable. It is possible that even if any of our product candidates have a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct, or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious AEs or other AEs, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or other comparable regulatory authorities may disagree as to the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or other comparable regulatory 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 other comparable regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or other comparable regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or other submission or to obtain regulatory approval in the United States, the European Union or elsewhere;
- the FDA or other comparable regulatory authorities may find deficiencies with or 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 other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would substantially harm our business, results of operations and prospects. The FDA and other comparable regulatory authorities have substantial discretion in the approval process and determining when or whether regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or other comparable regulatory authorities. Furthermore, the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies, and decisions may become subject to increasing legal challenges, delays, and/or changes.

Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the

successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

In addition, FDA and foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and Council of the EU and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may, however, have a significant impact on the pharmaceutical industry and our business in the long term.

The FDA or other comparable regulatory authorities may disagree with our regulatory plan for our product candidates.

The general approach for FDA approval of a new drug is dispositive data from two or more adequate and well-controlled clinical trials of the product candidate in the relevant patient population. Adequate and well-controlled clinical trials typically involve a large number of patients, have significant costs and take years to complete. The FDA or other comparable regulatory authorities may disagree with us about whether a clinical trial is adequate and well-controlled or may request that we conduct additional clinical trials prior to regulatory approval. In addition, there is no assurance that the doses, endpoints, and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. For instance, if we elect to pursue an indication of MDD with anxious distress, we will need to be able to reliably and consistently identify this sub-population of MDD patients, and we will need to demonstrate that GlyphAllo has a differentiated effect in these patients. However, the FDA may not agree with our proposed development plans, and our clinical trial results may not support approval of our product candidates for our target indications. In addition, our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- the FDA or other comparable regulatory authorities may not file or accept our NDA or marketing application for substantive review;
- the FDA or other comparable regulatory authorities may disagree with the dosing regimen, design, or implementation of our clinical trials;
- the FDA or other comparable regulatory authorities may determine there is not substantial evidence of effectiveness to support approval;
- we may be unable to demonstrate to the satisfaction of the FDA or other comparable regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of our clinical trials may not meet the level of statistical significance required by the FDA or other comparable regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or other comparable regulatory 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 sufficient to the satisfaction of the FDA or other comparable regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;

- the FDA or other comparable regulatory authorities may find deficiencies with or 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 other comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Our proprietary Glyph platform is based on a novel approach that may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval.

A key element of our strategy is utilizing our proprietary Glyph platform, which is designed to leverage the lymphatic system to enable and enhance the oral administration of drugs, avoid first-pass liver metabolism and reduce side effects that have previously impeded the development of certain active drugs. Despite favorable results in third-party clinical trials of the active moiety that is chemically identical to the active moiety within our product candidates and the favorable results in clinical trials of our molecules and mechanisms to date, the scientific research that forms the basis of our approach is still ongoing. Each of our current product candidates utilizes our Glyph platform. As a result, we are exposed to a number of unforeseen risks related to our Glyph platform, and these risks could impact each of our product candidates.

Although our research and development efforts to date have resulted in a development portfolio of programs and product candidates, we may not be able to discover or identify additional candidates that could appropriately utilize our Glyph platform and thus not be able to develop product candidates to expand our development portfolio. Even if we are successful in continuing to build and expand our development portfolio, the potential product candidates that we identify may not be successful in clinical development. For example, even though our Glyph platform is intended to reduce certain side effects, our product candidates may nonetheless be shown to have harmful side effects or other characteristics that indicate that they are unlikely to offer an improvement over standard of care or receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to obtain drug revenues in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates.

The results observed from preclinical studies or early-stage clinical trials of our product candidates may not necessarily be predictive of the results of later-stage clinical trials that we conduct. Similarly, positive results from such preclinical studies or early-stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. For instance, results seen in preclinical animal models may not translate to similar results in patients, and results from our initial studies in healthy volunteers may not translate to clinical trials in patients with MDD or GAD.

There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported AEs. Additionally, GlyphAllo is a novel, Glyphed oral prodrug of allopregnanolone, an endogenous neurosteroid with a well-established, clinically validated antidepressant, anxiolytic, and sleep-promoting effect, and GlyphAgo is a novel, Glyphed oral prodrug of agomelatine, a clinically validated antidepressant and anxiolytic. We may be unable to replicate the previous clinical efficacy observed with such molecules in clinical trials utilizing our Glyph platform.

Additionally, we may in the future utilize an “open-label” clinical trial design for certain of our future clinical trials. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results of a product candidate when studied in a controlled environment with a placebo or active control.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or other comparable regulatory authority approval.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. We have and may in the future experience delays in our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an IND or similar foreign authorization (e.g. regulatory hold), or not approving or delaying approval for any clinical trial grant or similar approval we need to initiate a clinical trial or a hold on an ongoing clinical trial. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including:

- regulators, IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, to conduct, or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;
- the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which may be required to resubmit to an IRB and regulatory authorities for re-examination;
- regulators or other reviewing bodies may find deficiencies with, fail to approve, or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter

into agreements for clinical and commercial supplies, or the supply or quality of any product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate, or not available at an acceptable cost, or we may experience interruptions in supply; and

- the potential for approval policies or regulations of the FDA, or other comparable regulatory authorities to significantly change in a manner rendering our clinical data insufficient for approval.

Regulators or IRBs of the institutions in which clinical trials are being conducted may suspend, limit, or terminate a clinical trial, or data monitoring committees may recommend that we suspend or terminate a clinical trial, 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 other comparable regulatory authorities resulting in the imposition of a clinical hold, 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. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of our product candidates in such other indications. We do not know whether any clinical trials that we conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates for the indications that we are pursuing. If later-stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates will be adversely impacted.

Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would significantly harm our business. Our product candidate development costs will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure or otherwise modify our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates may be associated with adverse side effects, AEs, or other undesirable properties or safety risks, which could delay or prevent their regulatory approval, cause us to suspend or discontinue clinical trials or abandon a product candidate, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained, or result in other significant negative consequences that could severely harm our business, financial condition, results of operations, and prospects.

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label, the inclusion of a Risk Evaluation and Mitigation Strategy, or REMS, or the delay or denial of regulatory approval by the FDA or other comparable regulatory authorities. Any treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial, or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition, and prospects significantly.

We may observe safety or tolerability issues beyond those we anticipate with our product candidates in ongoing or future clinical trials. For example, to date, we have only completed clinical studies evaluating GlyphAllo in healthy volunteers, and it is possible that serious AEs related to GlyphAllo may occur in this clinical program or in our clinical programs for other product candidates. Additionally, it is possible that human subjects with MDD may experience greater side effects in our clinical program for GlyphAllo than observed in

healthy volunteers. We continue to learn more about our product candidates, and unfavorable profiles could lead to adverse outcomes or concerns by the FDA or other comparable regulatory authorities.

Many compounds that initially showed promise in clinical or earlier-stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound. Results of future clinical trials of our product candidates could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, despite a favorable tolerability profile observed in earlier-stage testing. At any time, we may decide to terminate or greatly narrow the target population for a clinical development program due to unacceptable side effects or safety concerns.

If unacceptable side effects arise in the development of our product candidates, we, the FDA or other comparable regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, could suspend, limit, or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit, or terminate our trials, or the FDA or other comparable regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. We may be unable to overcome any such suspensions or holds that are placed on our clinical trials. Treatment-emergent side effects that are deemed to be drug-related could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that are administered our product candidates. Any of these occurrences may materially adversely affect our business, financial condition, results of operations, and prospects.

Moreover, clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects.

In addition, some of our product candidates utilize prodrugs of drugs that have been approved by regulatory authorities, such as the FDA and other comparable regulatory authorities, which if such approval is revoked, could negatively impact the success of our own products. For example, GlyphAllo is an oral prodrug of allopregnanolone, and brexanolone, a synthetic formulation of allopregnanolone, is currently approved by FDA for the treatment of postpartum depression. GlyphAgo is an oral prodrug of agomelatine, which has been approved for the treatment of GAD in Australia and MDD in Australia and Europe. It is possible that one or more of the active moieties of our product candidates has also been approved by FDA or other comparable regulatory authorities. In addition, even if our product candidates were to receive marketing approval or be commercialized, we would continue to be subject to the risks that the FDA or other comparable regulatory authorities could revoke approval of an active moiety that is chemically identical to the active moiety within our product candidates or any active moiety as our product candidates, if applicable, or that efficacy or safety issues could arise with any active moiety that is chemically identical to the active moiety within our product candidates or active moiety as our product candidates, if applicable, which could negatively impact the commercial opportunity for our own products.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient

education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone. Other potentially significant negative consequences associated with AEs include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or change their approvals of a product;
- regulatory authorities may require additional warnings on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies;
- we may be required to change the way a product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- a product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain, and may prevent us from obtaining approvals for the commercialization of our product candidates.

Any product candidate we develop and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other comparable regulatory authorities in the United States, and by other comparable foreign regulatory authorities. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval.

Our team expects to rely, in addition to in-house regulatory personnel, on third-party CROs and regulatory consultants to assist us in submitting and supporting the applications necessary to gain marketing approvals. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude its obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays

in the approval or rejection of an application. The FDA and other comparable regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

Interim, topline, and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes 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 publish interim, topline, or preliminary data from our clinical trials and preclinical studies. Such announcements or publications are typically based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline, or preliminary results that we report may differ from future results of the same studies or trials, 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 published. As a result, topline, and preliminary data should be viewed with caution until the final data are available.

Interim data from clinical trials that we may complete are further 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 interim, topline, or preliminary data, and final data could significantly harm our business prospects. Further, disclosure of such data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is 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 candidate or our business. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations, and prospects.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the development and commercialization of our product candidates may be delayed, and our business, financial condition, and results of operations may be harmed.

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations

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regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA and other comparable regulatory authorities and the timing thereof;
- other actions, decisions, or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used to manufacture our product candidates;
- the efforts of our collaborators with respect to the commercialization of our product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business, financial condition, and results of operations may be harmed.

We have concentrated our research and development efforts on the treatment of disorders of the brain and central nervous system, a field that faces certain challenges in drug development.

We have focused our research and development efforts on addressing disorders of the brain and central nervous system. Developing a product candidate for treatment of these diseases is difficult and subjects us to a number of challenges specific to central nervous system, or CNS, companies. In particular, many neuropsychiatric disorders, such as MDD and GAD, rely on subjective patient-reported outcomes as key clinical endpoints. This makes them more vulnerable to the placebo effect as compared to evaluating outcomes with more objective endpoints. For example, our Phase 2b BUOY-1 trial of GlyphAllo is using endpoints based on subjective assessment scales such as the HAMD-17 and the Clinical Global Impressions-Severity scale.

Moreover, given the history of clinical failures in this field, future clinical or regulatory failures by us or others may result in further negative perception of the likelihood of success in this field, which may significantly and adversely affect the market price of our common stock. We intend to work closely with the FDA and other comparable regulatory authorities to perform the requisite scientific analyses and evaluation in an effort to obtain regulatory approval for our product candidates; however, the process of developing our product candidates may be complex and time-consuming for the reasons described herein. We cannot be certain that our approach will lead to the development of product candidates that effectively and safely address the underlying diseases.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor impacting the duration of our clinical trials, along with treatment duration and completion of required follow-up periods. We may experience difficulties in patient enrollment in

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

Patient enrollment is affected by many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the severity of the disease under investigation;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- patient misrepresentation of their eligibility or non-compliance with the clinical trial protocol, resulting in the need to drop such patients from the clinical trial, increase the needed enrollment size for the clinical trial, or extend the clinical trial's duration;
- approval of new indications for existing therapies or approval of new therapies in general;
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications that we are investigating;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- continued enrollment of prospective patients by clinical trial sites;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in our clinical trials will drop out of the trials before completion.

We may experience challenges in recruiting principal investigators and patients to participate in ongoing and future clinical trials for such product candidates if we are unable to sufficiently demonstrate the potential of such product candidates to them. Furthermore, we may experience difficulties in reliably and consistently identifying the subpopulation of MDD patients with anxious distress, which may delay our recruitment efforts for our Phase 2b BUOY-1 trial. We also plan to take additional screening steps for patients beyond what certain other sponsors have done in similar trials, which may further narrow the eligible population of patients for our trials and cause delays in our recruitment efforts. In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Furthermore, if significant AEs or other side effects are observed in any of our clinical trials, we may have difficulty recruiting patients to our trials and patients may drop out of our trials. Additionally, patients, including patients in any control groups, may withdraw from the clinical trial for various reasons, including but not limited to if they are not experiencing improvement in their underlying disease or condition, or if they experience other difficulties or issues relating to their underlying disease or condition. Participants with neuropsychiatric disorders such as MDD and GAD constitute a vulnerable patient population and may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition or if they experience other difficulties or issues relating to their underlying disease or condition or otherwise, which may or may not be related to our product candidate in clinical trial. Withdrawal of patients from our clinical trials may compromise the quality of our data.

We also rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we will have limited influence over their actual performance. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials or our development efforts altogether. Delays in patient enrollment may result in increased costs, affect the timing or outcome of the planned clinical trials, product candidate development and approval process, and jeopardize our ability to seek and obtain the regulatory approval required to commence product sales and generate revenue, which could prevent completion of these trials, adversely affect our ability to advance the development of our product candidates, cause our value to decline, and limit our ability to obtain additional financing if needed.

We may conduct clinical trials for our product candidates outside of the United States and the FDA may not accept data from such trials, in which case our development plans may be delayed, which could materially harm our business.

We have conducted and are conducting clinical trials for our product candidates outside the United States. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or other comparable regulatory authorities 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 regulatory 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 regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the study was not otherwise subject to an IND, the FDA will not accept the data as support for an application for regulatory 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 requirements for clinical data gathered outside of their respective jurisdictions. 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 other comparable regulatory authorities will accept data from trials conducted outside of the United States or the relevant jurisdiction. If the FDA or any other comparable regulatory authority does not accept such data, it may 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.

Even if any of our product candidates receives regulatory approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.

We have never commercialized a product, and even if any of our product candidates are approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to achieve sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. The commercial success of any of our product candidates will depend significantly on the broad adoption and use of the resulting product by these individuals and organizations for approved indications. For example, Glyph2BLSD™ (SPT-348), in development for the treatment of depressive disorders, including treatment-resistant depression, or TRD, post-traumatic stress disorder, or PTSD, and headache disorders, is a Glyphed oral prodrug of the non-hallucinogenic neuroplastogen, 2-bromo-LSD. There has been recent interest in psychedelics in part because of their potential to demonstrate therapeutic effects in neuropsychiatric disorders. Although Glyph2BLSD is not a psychedelic, there is a risk that it will be viewed as such by investors and the public, or could be classified as such by regulatory authorities based on its final structure. Treatments containing controlled substances or drugs

that have similar effects or characteristics of controlled substances may generate public controversy or unfavorable views, which could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of such types of therapeutic candidates. For more information on controlled substances, see subsection titled “—Certain of our product candidates may be regulated as controlled substances, the making, use, sale, importation, exportation, and distribution of which are subject to significant regulation by the U.S. Drug Enforcement Administration and other regulatory agencies.”

Many of the indications for our product candidates have well-established standards of care that physicians, patients and payors are familiar with and, in some cases, are available generically. Even if our product candidates are successful in registrational clinical trials, they may not be successful in displacing these current standards of care if we are unable to demonstrate superior efficacy, safety, ease of administration, and/or cost-effectiveness. For example, physicians may be reluctant to take their patients off their current medications and switch their treatment regimen to our product candidates. Further, patients often acclimate to the treatment regimen that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch due to inadequate coverage or reimbursement by third-party payors. Even if we are able to demonstrate our product candidates’ safety and efficacy to the FDA and other comparable regulatory authorities, safety or efficacy concerns in the medical community may hinder market acceptance.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources, including management time, and financial resources, and may not be successful. If any product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product, including as compared to any more-established products or other alternative products that may later be approved;
- the potential advantages of the product compared to competitive therapies;
- the indications for which the product is approved, if any;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product’s convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with the product in the absence of sufficient third-party coverage and adequate reimbursement;
- the product’s acceptance into standard of care treatment algorithms by medical societies that could limit payor and physician uptake;
- limitations or warnings, including distribution or use restrictions contained in the product’s approved labeling;
- the strength of sales, marketing, and distribution support;
- changes in the standard of care for the targeted indications for the product;
- availability and adequacy of coverage and reimbursement from government payors, managed care plans, and other third-party payors, including any price concessions required by third-party payors to obtain coverage;

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- potential product liability claims; and
- unfavorable publicity relating to the product, or favorable publicity about competitive products.

Any failure by one or more of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects.

If we fail to discover, develop, and commercialize other product candidates, we may be unable to grow our business and our ability to achieve our strategic objectives would be impaired.

Although the development and commercialization of our current product candidates are our initial focus, as part of our longer-term growth strategy, we may seek to develop other product candidates leveraging our Glyph platform. We intend to evaluate internal opportunities from our existing product candidates or other potential product candidates, and also may choose to in-license or acquire other product candidates to treat patients suffering from other disorders with significant unmet medical needs and limited treatment options. Any other potential product candidates will require additional, time-consuming development efforts prior to commercial sale, including preclinical studies, clinical trials, and approval by the FDA or other comparable regulatory authorities. All product candidates are prone to the risks of failure that are inherent in pharmaceutical product development, including the possibility that the product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot assure you that any such products that are approved will be manufactured or produced economically, successfully commercialized or widely accepted in the marketplace or be more effective than other commercially available alternatives.

In addition, we intend to devote capital and resources for basic research to discover and identify additional product candidates. These research programs require substantial technical, financial, and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates that we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

In the future, we may also seek to in-license or acquire product candidates or the underlying technology. The process of proposing, negotiating, and implementing a license or acquisition is lengthy and complex. Other companies, including some with substantially greater financial, marketing, and sales resources, may compete with us for the license or acquisition of product candidates. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses, and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

In addition, future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of management's time and attention to develop acquired products or technologies;
- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- higher than expected acquisition and integration costs;
- difficulty in combining the operations and personnel of any acquired businesses with our operations and personnel;
- increased amortization expenses;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership;
- risks associated with entering new markets in which we have limited or no experience; and
- inability to motivate key employees of any acquired businesses.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions using our common stock as consideration. Additional funds may not be available on terms that are favorable to us, or at all.

If we are unsuccessful in identifying and developing additional product candidates, either through internal development or licensing or acquisition from third parties, our potential for growth and achieving our strategic objectives may be impaired.

The number of patients with the diseases and disorders for which we are developing our product candidates has not been established with precision. If the actual number of patients with the diseases or disorders we elect to pursue with our product candidates is smaller than we anticipate, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. Even if such product candidates are successfully developed and approved, the markets for our product candidates may be smaller than we expect and our revenue potential and ability to achieve profitability may be materially adversely affected.

Our pipeline includes product candidates for a variety of neuropsychiatric disorders, including MDD and GAD. There is no precise method of establishing the actual number of patients with any of these disorders in any geography over any time period. With respect to many of the indications in which we have developed, are developing, or plan to develop our product candidates, we have estimates of the prevalence of the disease or disorder. Our estimates as to prevalence may not be accurate, and the actual prevalence or addressable patient population for some or all of those indications, or any other indication that we elect to pursue, may be significantly smaller than our estimates. In estimating the potential prevalence of indications we are pursuing, or may in the future pursue, including our estimates as to the prevalence of MDD and GAD, we apply assumptions to available information that may not prove to be accurate. In each case, there is a range of estimates in the published literature and in marketing studies, which include estimates within the range that are lower than our estimates. The actual number of patients with these disease indications may, however, be significantly lower than we believe. Even if our prevalence estimates are correct, our product candidates may be developed for only a subset of patients with the relevant disease or disorder or our product candidates, if approved, may be indicated for or used by only a subset. In the event the number of patients with the diseases and disorders we are studying is significantly lower than we expect, we may have difficulties in enrolling patients in our clinical trials, which may delay or prevent development of our product candidates. If any of our product candidates are approved and

our prevalence estimates with respect to any indication or our other market assumptions are not accurate, the markets for our product candidates for these indications may be smaller than we anticipate, which could limit our ability to generate revenues and achieve profitability or to meet our expectations with respect to the foregoing.

Competitive products may reduce or eliminate the commercial opportunity for our product candidates, if approved. If our competitors develop technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective or safer than ours, our ability to develop and successfully commercialize our product candidates may be adversely affected.

The clinical and commercial landscapes for the treatment of neuropsychiatric disorders are highly competitive and subject to rapid and significant technological change. We face competition with respect to our indications for our product candidates and will face competition with respect to any other drug 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 drugs or are pursuing the development of drug candidates for the treatment of the CNS indications that we are pursuing. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

We are aware that a significant number of product candidates are currently under development for MDD, GAD, and other indications that we are currently pursuing and may pursue, and some or all may become commercially available in the future for the treatment of conditions for which we are trying or may try to develop product candidates. Additionally, if our product candidates were to be approved, they would likely compete with historical standard of care therapies. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical and generic drug companies, academic institutions, government agencies, and research institutions. For examples of the competition that our product candidates face, see the section titled “Business—Competition” included elsewhere in this prospectus.

In most cases, we do not currently plan to run head-to-head clinical trials evaluating our product candidates against the current standards of care, which may make it more challenging for our product candidates to compete against the current standards of care due to the lack of head-to-head clinical trial data.

Our competitors may have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals, and reimbursement, and marketing approved products than we do. Accordingly, our competitors may be more successful than we may be in obtaining regulatory approval for therapies and achieving widespread market acceptance. Our competitors’ products may be more effective, or more effectively marketed and sold, than any product candidate we may commercialize and may render our therapies obsolete or non-competitive before we can recover development and commercialization expenses. If any of our product candidates are approved, it could compete with a range of therapeutic treatments that are in development. In addition, our competitors may succeed in developing, acquiring, or licensing technologies and drug products that are more effective or less costly than our product candidates, which could render our product candidates obsolete and noncompetitive.

If we obtain approval for any of our product candidates, we may face competition based on many different factors, including the efficacy, safety, and tolerability of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage, and patent position. Existing and future competing products could present superior treatment alternatives, including being more effective, safer, 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. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

In addition, our competitors may obtain patent protection, regulatory exclusivities, or FDA approval and commercialize products more rapidly than we do, which may impact future approvals or sales of any of our product candidates that receive regulatory approval. If the FDA approves the commercial sale of any product candidate, we will also be competing with respect to marketing capabilities and manufacturing efficiency. We expect competition among products will be based on product efficacy and safety, the timing and scope of regulatory approvals, availability of supply, marketing and sales capabilities, product price, reimbursement coverage by government and private third-party payors, regulatory exclusivities, and patent position. Our profitability and financial position will suffer if our product candidates receive regulatory approval but cannot compete effectively in the marketplace.

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 and management personnel and establishing clinical trial sites, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we are unable to develop our sales, marketing, and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.

We currently have no marketing, sales, or distribution capabilities. We intend to establish a sales and marketing organization, either on our own or in collaboration with third parties, with technical expertise and supporting distribution capabilities to commercialize one or more of our product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our or third parties' internal sales, marketing, and distribution capabilities would adversely impact the commercialization of our product candidates.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or our failure to educate an adequate number of physicians on the benefits of any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United

States or overseas. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Risks Related to Employee Matters and Managing Growth

We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2025, we had 54 full-time employees. We expect to experience significant growth in the number of our employees and the scope of our operations over time. To manage these growth activities, we must continue to implement and improve our managerial, operational, quality, and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Our management may need to devote a significant amount of its attention to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion or relocation of our operations, retain key employees, or identify, recruit, and train additional qualified personnel. Our inability to manage the expansion or relocation of our operations effectively may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could also require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If we are unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate revenues could be reduced and we may not be able to implement our business strategy, including the successful commercialization of our product candidates.

Our ability to develop product candidates, leverage our Glyph platform and our future growth depends on attracting, hiring, and retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management and scientific personnel, many of whom have been instrumental for us and have substantial experience with developing therapies, identifying potential product candidates and building the technologies related to the clinical development of our product candidates. Given the specialized nature of neuropsychiatric disorders and our approach, there is an inherent scarcity of experienced personnel in these fields. As we continue developing our product candidates in our pipeline, we will require personnel with medical, scientific, or technical qualifications specific to each program. The loss of key personnel, in particular our Co-Founder and Chief Executive Officer, Co-Founder, and Chair of the Board, Chief Financial Officer, Chief Medical Officer, Co-Founder and Chief Scientific Officer, Chief Operating Officer, General Counsel, and clinical development personnel, would delay our research and development activities. The competition for qualified personnel in the therapeutics, biotechnology and biopharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions, and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which would have a material adverse effect on our business.

In addition, our clinical operations and research and development programs depend on our ability to attract and retain highly skilled employees across multiple functions, particularly in Massachusetts. There is powerful competition for skilled personnel in this geographical market, and we have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we do, and any of our employees may terminate their employment with us at any time. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. Furthermore, job candidates and existing employees often consider the value of the stock

awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

Risks Related to Our Dependence on Third Parties

We rely on third parties to assist in conducting our clinical trials and preclinical studies. If they do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business could be substantially harmed.

We have relied upon and plan to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and preclinical studies and expect to rely on these third parties to conduct clinical trials and preclinical studies of any other product candidate that we develop. Our ability to complete clinical trials in a timely fashion depends on a number of key factors. These factors include protocol design, regulatory, and IRB approval, patient enrollment rates, and compliance with GCPs. In most cases, we use the services of third parties, including CROs, to carry out our clinical trial-related activities and rely on such parties to accurately report their results. Our reliance on third parties for clinical development activities may impact or limit our control over the timing, conduct, expense, and quality of our clinical trials. Moreover, the FDA requires us to comply with GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. The FDA enforces these GCPs through periodic inspections of clinical trial sponsors, principal investigators, clinical trial sites, and IRBs. For certain commercial prescription drug products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen, and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States.

We remain responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. Our failure or the failure of third parties to comply with the applicable protocol, legal and regulatory requirements and scientific standards can result in rejection of our clinical trial data or other sanctions. If we or our third-party clinical trial providers or third-party CROs do not successfully carry out these clinical activities, our clinical trials, or the potential regulatory approval of a product candidate may be delayed or be unsuccessful. Additionally, if we or our third-party contractors fail to comply with applicable GCPs for any reason, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with GCPs.

Furthermore, the third parties conducting clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we cannot control whether or not they devote sufficient time, skill, and resources to our ongoing development programs. Moreover, many CROs, including some of those that we have engaged to conduct our clinical trials, are experiencing enrollment challenges as a result of, among other things, high employee turnover driven by macroeconomic environment and the inexperience of new employees. Additionally, at clinical trial sites, the availability of staff and trial participants has been limited due to a decrease in the number of clinical investigative sites across the globe. These contractors 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 impede their ability to devote appropriate time to our clinical programs. If these third parties, including clinical investigators, do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates. If that occurs, we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be delayed, impaired, or foreclosed. In addition, principal investigators for our clinical trials may be asked to serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or foreign regulatory authorities conclude that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA or foreign regulatory authorities of any NDA or foreign application we submit. Any such delay or rejection could prevent us from commercializing our product candidates.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or regulatory approval of our product candidates or commercialization of any resulting products, producing additional losses, and depriving us of potential product revenue.

Any of the third-party organizations we utilize may terminate their engagements with us under certain circumstances. The replacement of an existing CRO or other third party may result in the delay of the affected trials or otherwise adversely affect our efforts to obtain regulatory approvals and commercialize our product candidates. We may not be able to enter into alternative arrangements or do so on commercially reasonable terms. In addition, even if there are suitable replacements for one or more of these service providers, there is a natural transition period when a new service provider begins work. As a result, delays may occur, which could negatively impact our ability to meet our expected clinical development timelines and harm our business, financial condition, results of operations, and prospects.

In addition, we currently and may in the future rely on foreign CROs and CMOs. Such foreign CROs and CMOs may be subject to U.S. legislation, sanctions, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. For example, in January 2024, there was congressional activity, including the introduction of the BIOSECURE Act (H.R. 7085) in the House of Representatives and a substantially similar Senate bill (S.3558). In September 2024, the U.S. House of Representatives passed a version of the BIOSECURE Act (H.R. 8333), however, the Senate did not approve that legislation. In October 2025, both the U.S. House of Representatives and Senate passed their respective versions of the National Defense Authorization Act of 2026 (NDAA), each including an amendment often referred to as “BIOSECURE 2.0.” While BIOSECURE 2.0 has not yet been enacted and must still be reconciled in conference, the current text would establish federal government contracting, grant, and loan restrictions similar in effect to prior BIOSECURE proposals. However, unlike earlier versions of BIOSECURE that named specific Chinese companies, BIOSECURE 2.0 would implement a process-based designation system through which biotechnology companies “of concern” would be identified based on whether companies fall within statutorily define categories, including entities identified on the Department of Defense’s Section 1260H list of “Chinese military companies” and other entities that are subject to the direction, control, or jurisdiction of a foreign adversary’s government which pose national security risks based on specified criteria. If BIOSECURE 2.0 becomes law or similar laws are passed, they would have the potential to severely restrict the ability of therapeutics companies like us to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies “of concern” without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We do business with companies in China, and it is possible some of our contractual counterparties could be impacted by this legislation.

Our use of third parties to manufacture our product candidates, including those located outside of the United States, may increase the risk that we will not have sufficient quantities of our product candidates, raw materials, active pharmaceutical ingredients, or APIs, or drug products when needed or at an acceptable cost.

We do not own or operate manufacturing facilities for the production of clinical or commercial quantities of our product candidates, and we lack the resources and the capabilities to do so. Our current strategy is to outsource all manufacturing of our product candidates to third parties, including in jurisdictions outside of the United States.

We currently rely on and engage third-party manufacturers to provide all of the API and the final drug product formulation of all of our product candidates that are being used in our clinical trials and preclinical studies. If we were to need an alternate manufacturer, we would incur added costs and delays in identifying and qualifying any such replacement. In addition, we typically order raw materials, API, and drug product and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. We may not be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. We may be unable to conclude agreements for commercial supply with third-party manufacturers or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of our product candidates, and the costs of manufacturing could be prohibitive.

Some of the third-party manufacturers we rely on have only recently begun working with us and have limited experience manufacturing our API and final drug products. If our manufacturers have difficulty or suffer delays in successfully manufacturing material that meets our specifications, it may limit supply of our product candidates and could delay our clinical trials.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third-party manufacturer to comply with applicable regulatory requirements and reliance on third parties for manufacturing process development, regulatory compliance, and quality assurance;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- limitations on supply availability resulting from capacity and scheduling constraints of third parties;
- the failure of the third-party manufacturer to produce materials with acceptable quality on a larger scale;
- the possible breach of manufacturing agreements by third parties because of factors beyond our control;
- the possible termination or non-renewal of the manufacturing agreements by the third party, at a time that is costly or inconvenient to us; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

If we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities, which could delay or impair our ability to obtain regulatory approval for our product candidates. If we do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other comparable regulatory authorities.

Additionally, if any third-party manufacturer with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different manufacturer. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our product candidates may be proprietary to the original manufacturer and we may have difficulty, or there may be contractual restrictions prohibiting us from transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change third-party 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. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or other comparable regulatory authorities. We may be unsuccessful in demonstrating the comparability of clinical supplies, which could require the conduct of additional clinical trials. The delays associated with the verification of a new third-party manufacturer could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a third-party manufacturer may possess technology related to the manufacture of our product candidate that such third party owns independently. This would increase our reliance on such third-party manufacturer or require us to obtain a license from such third-party manufacturer in order to have another third party manufacture our product candidates.

If any of our product candidates is approved by any regulatory agency, we intend to utilize arrangements with third-party contract manufacturers for the commercial production of those products. This process is difficult and time-consuming and we may face competition for access to manufacturing facilities as there are a limited number of contract manufacturers operating under cGMPs that are capable of manufacturing our product candidates. Consequently, we may not be able to reach agreement with third-party manufacturers on satisfactory terms, which could delay our commercialization.

Some of our manufacturers are located outside of the United States. There is currently significant uncertainty about the future relationship between the United States and various other countries with respect to trade policies, treaties, government regulations, and tariffs. Increased tariffs or pending legislation that would impose federal contracting or federal funding limitations on parties directly using or connected to those using the services or equipment of certain foreign entities with known or alleged associations with foreign adversaries could potentially disrupt our existing supply chains and impose additional costs on our business. Additionally, it is possible further tariffs may be imposed that could affect imports of any APIs used in our product candidates in the future, or our business may be adversely impacted by retaliatory trade measures taken by China or other countries, including restricted access to such raw materials used in our product candidates. Given the uncertainty regarding how the U.S. or foreign governments will act with respect to tariffs, international trade agreements, and policies, further governmental action related to tariffs, additional taxes, contracting matters, regulatory changes, or other retaliatory trade measures in the future could occur with a corresponding detrimental impact on our business and financial condition.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product candidates, operating restrictions, and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be evaluated by the FDA and are required to register their facilities with the FDA, subjecting them to inspections to assess whether these facilities are in compliance with cGMPs.

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs and comparable foreign requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other comparable regulatory authorities, we may not be able to secure

and/or maintain regulatory approval for our product candidates manufactured at these facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance, and qualified personnel. If the FDA finds deficiencies or the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP and comparable foreign requirements. Any failure to comply with cGMP requirements or other FDA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved.

Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA and other comparable regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products following approval, if obtained.

Furthermore, should we decide to use any APIs in any of our product candidates that are proprietary to one or more third parties, we would need to maintain licenses to those APIs from those third parties. If we are unable to gain or continue to access rights to such APIs prior to conducting preclinical toxicology studies intended to support clinical trials, we may need to develop alternate product candidates from these programs by either accessing or developing alternate APIs, resulting in increased development costs and delays in commercialization of these product candidates. If we are unable to gain or maintain continued access rights to the desired APIs on commercially reasonable terms or develop suitable alternate APIs, we may not be able to commercialize product candidates from these programs.

We may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

We may in the future opportunistically pursue strategic partnerships or collaborations, as the advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. If we believe that partnerships or collaborations can accelerate the development or maximize the market potential of our product candidates, we will consider entering into product, target and/or geographic specific strategic partnerships or collaborations on an opportunistic basis. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies, and biotechnology companies. In addition, if we are able to obtain regulatory approval for product candidates from foreign regulatory authorities, we may enter into partnerships or collaborations with international biotechnology or pharmaceutical companies for the commercialization of such product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a partnership or collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed partnerships or collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our product candidate from competing product candidates, design, or results of clinical trials, the likelihood of approval by the FDA or other comparable regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients, and the potential of competing products. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for partnership or collaboration and whether such a partnership or collaboration could be more attractive than the one with us for our product candidate. If we elect to increase our expenditures to fund development 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 product candidates or bring them to market and generate product revenue.

Partnerships and collaborations are each complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Any partnership or collaboration agreements that we enter into in the future may contain restrictions on our ability to enter into potential partnerships or collaborations or to otherwise develop specified product candidates. We may not be able to negotiate partnerships or collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce, or delay its development program or one or more of our other development programs, delay its potential commercialization, reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense.

Furthermore, if conflicts arise between our collaborators and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Our collaborators could conduct multiple product development efforts and could develop, either alone or with others, products in related fields that are competitive with the product candidates we may develop that are the subject of these partnerships or collaborations with us.

Competing products may preclude us from entering into partnerships or collaborations with their competitors, fail to obtain timely regulatory approvals, prevent us from obtaining timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the partnership or collaboration efforts, including development, delivery, manufacturing, and commercialization of products. Any of these developments could harm our company and product development efforts.

If we enter into collaborations with third parties for the development and/or commercialization of our product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations.

We may enter into collaborations with third parties for the development and/or commercialization of certain of our product candidates. If we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates.

Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and/or commercialization of our product candidates or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, which divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;

- disagreements with collaborators, including disagreements over proprietary rights, including trade secrets and intellectual property rights, contract interpretation, or the preferred course of development might cause delays or termination of the research, development, or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination, it could decide to delay, diminish, or terminate the development or commercialization of any product candidate licensed to it by us.

If any third-party manufacturer of our product candidates is unable to increase the scale of its production of our product candidates or increase the product yield of its manufacturing, then our manufacturing costs may increase and commercialization may be delayed.

In order to produce sufficient quantities to meet the demand for clinical trials and, if approved, subsequent commercialization of our product candidates, our third-party manufacturers will be required to increase their production and optimize their manufacturing processes while maintaining the quality of our product candidates. The transition to larger scale production could prove difficult. In addition, if our third-party manufacturers are not able to optimize their manufacturing processes to increase the product yield for our product candidates, or if they are unable to produce increased amounts of our product candidates while maintaining the same quality then we may not be able to meet the demands of clinical trials or market demands, which could decrease our ability to generate profits and have a material adverse impact on our business, financial condition, and results of operations.

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

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval and similar foreign notifications and approvals. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials, or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates, and jeopardize our ability to commence sales and generate revenue.

Risks Related to Government Regulation

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

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure

or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, the European Commission or comparable foreign regulatory authorities must also approve the manufacturing and marketing of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

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

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

If any of our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, distribution, AE reporting, advertising, promotion, sampling, import, export, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP (and comparable foreign requirements) and GCP requirements for any clinical trials that we conduct post-approval.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. Certain endpoint data we hope to include in any approved product labeling also may not make it into such labeling, including exploratory or secondary endpoint data such as patient-reported outcome measures. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. In addition, if the FDA or other comparable regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA may impose consent decrees or 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 our product candidates, including AEs of unanticipated severity or frequency, or with our third-party manufacturers or 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 our products, withdrawal of the product from the market, or voluntary product recalls;

- fines, warning letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or withdrawal of approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. The policies of the FDA and other comparable regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory 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 lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

While we may in the future seek designations for our product candidates with the FDA and other comparable regulatory authorities that are intended to confer benefits such as a faster development process, an accelerated regulatory pathway, or regulatory exclusivity, there can be no assurance that we will successfully obtain such designations. In addition, even if one or more of our product candidates are granted such designations, we may not be able to realize the intended benefits of such designations.

The FDA and other comparable regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations may confer benefits such as additional interaction with regulatory authorities, a potentially accelerated regulatory pathway and priority review. However, there can be no assurance that we will successfully obtain such designations for our product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for our product candidates, there can be no assurance that we will realize their intended benefits.

For example, we may seek a Fast Track Designation for future product candidates we develop. If a product is intended for the treatment of a serious or life-threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. The FDA may rescind the Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development activities.

We may seek Breakthrough Therapy Designation for any product candidate that we develop. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval and priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe a product candidate we develop meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review, or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if any product candidate we develop qualifies as a breakthrough therapy, the FDA may later decide that the drug no longer meets the conditions for qualification and rescind the designation.

Even in the absence of obtaining Fast Track and/or Breakthrough Therapy Designations, a sponsor can seek priority review at the time of submitting a marketing application. The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination, or substantial reduction of a treatment-limiting adverse reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months. Priority review designation may be rescinded if a product no longer meets the qualifying criteria.

Where appropriate, we may secure approval from the FDA or other comparable regulatory authorities through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA or other comparable regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or such other comparable regulatory authorities may seek to withdraw any accelerated approval we have obtained.

We may seek an accelerated approval pathway for our one or more of our therapeutic candidates from the FDA or other comparable regulatory authorities. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a therapeutic candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the therapeutic candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. Under FDORA, the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send status updates on such studies to the FDA every 180 days to be publicly posted by the agency, or if such post-approval studies fail to verify the drug's predicted clinical benefit. The FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress.

Prior to seeking accelerated approval, we would seek feedback from the FDA or other comparable regulatory authorities and would otherwise evaluate our ability to seek and receive such accelerated approval.

There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review, or approval. Similarly, there can be no assurance that after subsequent feedback from the FDA or other comparable regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review, or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval, there can be no assurance that such application will be accepted or that any approval will be granted on a timely basis, or at all. The FDA or other comparable regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type, including, for example, if other products are approved via the accelerated pathway and subsequently converted by FDA to full approval. A failure to obtain accelerated approval or any other form of expedited development, review, or approval for our therapeutic candidate would result in a longer time period to commercialization of such therapeutic candidate, could increase the cost of development of such therapeutic candidate, and could harm our competitive position in the marketplace.

Certain of our product candidates may be regulated as controlled substances, the making, use, sale, importation, exportation, and distribution of which are subject to significant regulation by the U.S. Drug Enforcement Administration and other regulatory agencies.

We do not yet fully understand the potential for GlyphAllo or Glyph2BLSD to be classified as controlled substances, but brexanolone is currently classified as a Schedule IV controlled substance under the Controlled Substances Act, or CSA and although non-hallucinogenic 2-bromo-LSD is not a controlled substance, it is an analogue of LSD, which is a Schedule I controlled substance under the CSA. Accordingly, we may need to conduct studies to assess the abuse potential of GlyphAllo and/or Glyph2BLSD, and pending the outcome of such evaluations, we may be required to provide a proposal for scheduling by the Drug Enforcement Administration, or the DEA, when submitting an NDA, which could cause delays in our development process or commercialization timing.

The DEA regulates controlled substances as Schedule I, II, III, IV, or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV, or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. If any of our product candidates were to become subject to DEA oversight, such product candidates would be subject to additional restrictions regarding their manufacture, shipment, storage, sale, and use, depending on the scheduling of the active ingredients, and may limit the commercial potential of any of our product candidates, if approved.

Various states also independently regulate controlled substances. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs as well. While some states automatically schedule a drug when the DEA does so, in other states there must be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could impair the commercial attractiveness of such product. If any of our product candidates is classified as a controlled substance, we or our collaborators would also be required to obtain separate state registrations in order to be able to obtain, handle, and distribute controlled substances for clinical trials or for commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

For any of our product candidates that may be classified as controlled substances, we and our suppliers, manufacturers, contractors, customers, and distributors are required to obtain and maintain applicable

registrations from state, federal, and foreign law enforcement and regulatory agencies and comply with state, federal, and foreign laws and regulations regarding the manufacture, use, sale, importation, exportation and distribution of controlled substances. There is a risk that DEA regulations may limit the supply of the compounds used in clinical trials for our product candidates, and, in the future, the ability to produce and distribute our products in the volume needed to meet commercial demand. Regulations associated with controlled substances govern manufacturing, labeling, packaging, testing, dispensing, production, and procurement quotas, recordkeeping, reporting, handling, storage, shipment and disposal. These regulations increase the personnel needs and the expense associated with development and commercialization of product candidates including controlled substances. The DEA, and some states, conduct periodic inspections of registered establishments that handle controlled substances. Failure to obtain and maintain required registrations or comply with any applicable regulations could delay or preclude us from developing and commercializing our product candidates containing controlled substances and subject us to enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In some circumstances, violations could lead to criminal proceedings. Because of their restrictive nature, these regulations could limit commercialization of any of our products or product candidates that are classified as controlled substances.

Our relationships with healthcare providers and physicians and third-party payors subject us to anti-kickback, fraud and abuse and other healthcare laws and regulations, which could increase our compliance costs, and expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits, and future earnings.

Our business operations and current and future arrangements with investigators, healthcare professionals, pharmacies, consultants, marketing personnel, third-party payors, patient organizations, and customers expose us to broadly applicable foreign, federal and state fraud and abuse, and other healthcare laws and regulations. These laws include foreign, federal, and state anti-kickback laws, false claims statutes, civil monetary penalties laws, healthcare data privacy, and security laws, and consumer protection and unfair competition laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers, and laws related to price reporting. Healthcare providers, physicians, and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute any product for which we obtain regulatory approval. For more information on healthcare laws and regulations that may impact our company, see the section titled “Business—Government Regulation—Other Healthcare Laws” included elsewhere in this prospectus.

Efforts to ensure that our current and future business arrangements both internally and with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices or arrangements might be challenged under one or more of these laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time-consuming, resource-intensive, and can divert a company’s attention from the business.

If our business practices or operations are found to be in violation of any of fraud and abuse, or other healthcare laws or governmental laws, regulations, agency guidance, or case law that may apply to us, we may be

subject to significant penalties, including administrative, civil, and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, such as Medicare and Medicaid, integrity oversight, and reporting obligations, contractual damages, individual imprisonment, reputational harm, diminished profits, and future earnings, and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, defending against any such actions can be costly and time consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians, or other providers, or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, our ability to operate our business and our results of operations could be adversely affected.

The successful commercialization of any of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell any approved product candidates profitably.

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Our ability to achieve coverage and acceptable levels of reimbursement for our product candidates by third-party payors will have an effect on our ability to successfully commercialize those products. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, any product that we may develop. For more information on the laws and regulations that may impact coverage and reimbursement of our product candidates, see the section titled “Business—Government Regulation—Coverage and Reimbursement” included elsewhere in this prospectus.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor’s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products, if approved, on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Furthermore, rules and regulations regarding reimbursement change frequently, and, in some cases, at short notice, and we believe that additional changes in these rules and regulations are likely.

Even if we obtain coverage for a given product, if approved, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require cost-sharing (e.g., co-payments or

coinsurance) that patients find unacceptably high. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by U.S. Centers for Medicare & Medicaid Services, or CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare, and private payors tend to follow CMS coverage determinations to a substantial degree. Additionally, third-party payors may not cover or provide adequate reimbursement for a given product or, long-term follow-up evaluations, or other ancillary services required following the use of product candidates, once approved. Some third-party payors may require pre-approval of coverage or implement prior authorization or step therapy programs for new or innovative drug therapies before they will reimburse patients who use such therapies which may be time-consuming or costly for patients and lead to a reduction in revenue. Patients are unlikely to use our product candidates, once approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of their cost. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Third-party payors increasingly are challenging prices charged for therapeutics products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and offer to reimburse patients only for a less expensive competitor product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our products, if approved. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products, if approved, and may not be able to obtain a satisfactory financial return on products that we may develop.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

Moreover, increasing efforts by governmental and other third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. If, for example, we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our products, if approved, would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions, and fines should we be found to be in violation of any applicable obligations thereunder. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products, if approved. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals or clearances of our product candidates, if any, may be.

In addition, in some foreign countries, the proposed pricing for a product must be approved before it may be lawfully marketed. The requirements governing product pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

Ongoing healthcare legislative and regulatory reform measures and cost containment initiatives may have a material adverse effect on our business and results of operations and increase the difficulty and cost for us to obtain coverage for and commercialize any of our current or future product candidates and may adversely affect the prices we may set.

Changes in regulations, statutes, or the interpretation of existing regulations could impact our business in the future by requiring, for example, (1) changes to our manufacturing arrangements, (2) additions or modifications to product labeling, (3) the recall or discontinuation of our products, or (4) additional record-keeping requirements. Current and future legislation and regulations may increase the difficulty and cost for us to commercialize our drugs, if approved, and affect the prices we may obtain, including changes in coverage and reimbursement policies in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably. If any such changes were to be imposed, they could adversely affect the operation of our business. See the section titled “Business—Current and Future U.S. Healthcare Reform” included elsewhere in this prospectus.

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. For example, in March 2010, the 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. Since its enactment, certain provisions of the ACA have been subject to judicial, executive, and legislative challenges and may be subject to additional challenges in the future.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2032 unless additional congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to apply significant funding pressure on state Medicaid budgets, decrease

the number of persons enrolled in Medicaid, and reduce the services covered by Medicaid, which could adversely affect our sales of any of our product candidates that we commercialize. These laws and regulatory changes may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on prescribers of our product candidates, if approved, and accordingly, our financial operations.

The containment of healthcare costs has become a priority of federal, state, and foreign governments, and the prices of products have been a focus in this effort. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage, and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products. For example, the American Rescue Plan Act of 2021 eliminated the Medicaid statutory rebate cap of 100% of average manufacturer price as of January 1, 2024. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business.

The cost of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States. There have been several Congressional inquiries, as well as legislative and regulatory initiatives and executive orders designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Most significantly, in August 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Part D coverage gap discount program with a new manufacturer discount program (beginning in 2025). CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and has published the list of the subsequent 15 drugs that will be subject to negotiation. The IRA permits the Secretary of the Department of Health and Human Services, or the HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. The impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, but is likely to be significant.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for product candidates, if approved. On the one hand, the Trump administration has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, although proposed regulations have not yet been published. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers. Additional drug pricing proposals could appear in future legislation and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our revenue generated from the sale of any approved products.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models.

In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal 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 pharmaceutical products. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

At the state level, state governments have become increasingly active in developing proposals, passing legislation, and implementing regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, formulary flexibility, restrictions on certain product access and marketing cost disclosure, drug price increase reporting, and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, while some states are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. These types of initiatives may result in additional reductions in Medicare, Medicaid, and other healthcare funding. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations, and prospects. 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. These measures could reduce the ultimate demand for any of our current and future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects.

We expect that these and other state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies, impose price controls, and additional downward pressure on the price that we receive for any approved product candidate for which we may obtain regulatory approval, and the frequency with which any such product candidate is prescribed or used. 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, changes in healthcare spending and policy, or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates, and materially affect our business. If additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. We cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations, or decisions, related to healthcare availability, the method of delivery, or payment for healthcare products and services could negatively impact our business, operations and financial condition.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. 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 candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired. For more details concerning the risks related to pricing and reimbursement in the EU, please refer to the discussion in the risk factor.

Similar political, economic, and regulatory developments are occurring in the EU and may affect the ability of pharmaceutical companies to profitably commercialize their products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in

significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product, i.e. oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings that may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceedings, investigations, or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, integrity oversight and reporting obligations, reputational damage and modifications of our business practices, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Even if such a proceeding, investigation, or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources.

Our employees, independent contractors, consultants, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our current and any future employees, independent contractors, consultants, CMOs, and vendors. Misconduct by these parties could include

intentional, reckless, and/or negligent conduct that fails to comply with the regulations set forth by the FDA or other comparable regulatory authorities, provide true, complete, and accurate information to the FDA and other comparable regulatory authorities, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately, or disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. 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 governmental investigations or other actions or lawsuits stemming from a failure to comply with such 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 material and adverse effect on our business, financial condition, results of operations, and prospects, including, without limitation, the imposition of significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits, and future earnings, 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 curtailment of our operations, any of which could adversely affect our business, financial condition, results of operations, and prospects.

The FDA and other comparable regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA strictly regulates marketing, labeling, advertising, and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA. While physicians in the United States may choose, and are generally permitted, to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we may only promote or market our products in a manner that is consistent with their FDA-approved labeling. Similar requirements may apply in foreign jurisdictions.

If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion any product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. In addition, any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our product candidates for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation.

Inadequate funding for the FDA or other comparable regulatory authorities or government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA 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 agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA or other comparable regulatory authorities or government 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, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, including as a result of reaching the debt ceiling, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

EU drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the EU Member States.

We intend to seek approval to market our product candidates in both the United States and potentially in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to reward improper performance generally is typically governed by the national anti-bribery laws of EU Member States and the Bribery Act 2010 in the United Kingdom. Infringement of these laws could result in substantial fines and imprisonment. EU Directive 2001/83/EC, which is the EU Directive governing medicinal products for human use, further provides that, where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered, or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy. This provision has been transposed into the Human Medicines Regulations 2012 and so remains applicable in the United Kingdom despite its departure from the European Union.

Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

In addition, in some foreign countries, including some countries in the European Union, the proposed pricing for a product must be approved before it may be lawfully marketed. The requirements governing product

pricing and reimbursement vary widely from country to country. For example, some EU Member States have the option to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU Member States, can further reduce prices. An EU Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for therapeutics products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected.

We are subject to export and import controls, economic sanctions, and anti-corruption laws and regulations of the United States and other jurisdictions. We can face criminal liability and other serious consequences for violations of these laws and regulations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control. Export controls and trade sanctions laws and regulations may restrict or prohibit altogether the provision, sale, or supply of our products to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions or an embargo. We are also subject to anti-corruption and anti-bribery laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, and other state and national anti-bribery laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

If we or any third-party manufacturer we engage now or in the future fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs or liabilities that could have a material adverse effect on our business.

We and third-party manufacturers we engage now are, and any third-party manufacturer we may engage in the future will be, 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. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. 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. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain general liability insurance as well as 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, development, or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties, or other sanctions.

Further, with respect to the operations of our current and any future third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations, or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm, or experience a disruption in the manufacture and supply of our product candidates or products. In addition, our supply chain may be adversely impacted if any of our third-party contract manufacturers become subject to injunctions or other sanctions as a result of their non-compliance with environmental, health, and safety laws and regulations.

Risks Related to Our Intellectual Property

Our commercial success depends on our ability to obtain, maintain, enforce, and otherwise protect our intellectual property and proprietary technology, and if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products and product candidates similar to ours and our ability to successfully develop and commercialize our product candidates may be adversely affected.

Our commercial success depends, in large part, on our ability to obtain and maintain intellectual property rights protection through patents, trademarks, and trade secrets in the United States and other countries with respect to our technology and product candidates. If we do not adequately protect our intellectual property rights, competitors or other third parties may be able to erode, negate or preempt any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we and our licensors have filed patent applications and may file other patent applications in the United States or abroad related to our product candidates that are important to our business. In particular, we are heavily reliant on patent rights we have exclusively in-licensed from Monash University pursuant to the Monash License Agreement. The patent application process is expensive, time-consuming and complex. We may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner.

We or our licensors may not be able to obtain patents on certain inventions if those inventions are publicly disclosed prior to our filing a patent application covering them. We enter into nondisclosure and confidentiality agreements with parties who have access to confidential information, including confidential information regarding inventions not yet disclosed in patent applications. We cannot guarantee that any of these parties will not breach these confidentiality agreements and publicly disclose any of our inventions before a patent application is filed covering such inventions. If such confidential information is publicly disclosed, we may not be able to successfully patent the inventions and consequently, we may not be able to prevent third parties from using such inventions.

If the scope of the patent protection we obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our owned or in-licensed patents have, or that any of our owned or in-licensed pending patent applications that mature into issued patents will include claims with a scope sufficient

to protect our product candidates or otherwise provide any competitive advantage. Other parties have developed or may develop technologies that may be related to or competitive with our approach, and may have filed or may file patent applications and may have been issued or may be issued patents with claims that overlap or conflict with our patent portfolio, either by claiming the same compounds, formulations, or methods or by claiming subject matter that could dominate our patent position. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after the first non-provisional patent application has been filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing, and regulatory review of product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to ours.

Even if they are unchallenged, our owned and in-licensed patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patent portfolio by developing similar or alternative product candidates in a non-infringing manner. For example, a third party may develop a product candidate that provides benefits similar to one of our product candidates but falls outside the scope of our owned or in-licensed patent rights. If the patent protection provided by the patent and patent applications we hold or pursue with respect to such product candidate is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidate could be negatively affected, which would harm our business.

We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patent portfolio may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our partners, collaborators, or licensees, whether now or in the future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, or licensees are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patent portfolio, such patents may be held to be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. 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 U.S. Patent and Trademark Office, or the USPTO, and various government patent agencies outside of the United States over the lifetime of our owned or licensed patents and patent applications. We rely on our outside counsel or our licensing partners to pay these fees due to U.S. and non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can, and in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations 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-compliant events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. The USPTO and various non-U.S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the U.S., China, India and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (e.g., items related to national security or national defense). In some, but not

all cases, for example in China and India, a foreign filing license cannot be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We may also be dependent on our licensors to take the necessary actions to comply with these requirements with respect to our licensed intellectual property. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The patent position of pharmaceutical and biotechnology companies carries uncertainty. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are characterized by uncertainty.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patent portfolio, or that we were the first to file for patent protection of such inventions. If third parties have filed prior patent applications on inventions claimed in our patent portfolio that were filed on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by our patent portfolio. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our invention was derived from theirs.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, any patents we may own or license may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all the potentially relevant prior art relating to our patent portfolio has been published or found. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patent portfolio, or that we were the first to file for patent protection of such inventions. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third-party submission of prior art to the USPTO, or to other patent offices around the world. Alternatively or additionally, we may become involved in post-grant review procedures, oppositions, derivation proceedings, ex parte reexaminations, inter partes review, supplemental examinations, or interference proceedings or challenges before the USPTO or in district court in the United States, or similar proceedings in various foreign jurisdictions, including both national and regional, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenge may result in loss of the patent or claims in the patent portfolio being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent portfolio, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products.

Our or our licensors' pending and future patent applications may not result in patents being issued that protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. For example, our or our licensors' provisional applications may never result in issued patents. A provisional patent application is not eligible to become an issued patent until, among other things, we or our licensors file a non-provisional patent application within 12 months of filing the provisional patent application. If we or our licensors do not timely file non-provisional patent applications, we or our licensors may lose the

priority dates with respect to such provisional patent applications and any patent protection on the inventions disclosed in such provisional patent applications. While we intend to timely file non-provisional patent applications relating to our current and future provisional patent applications, we cannot predict whether any of our or our licensors' non-provisional patent applications directed to our technology and product candidates will result in the issuance of patents that effectively protect our technology and product candidates. Further, competitors may be able to design around our patents. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries also 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 or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including jurisdictions that coincide with significant commercial markets, such as the European Patent Office, China, and Japan, restrict the patentability of methods of treatment of the human body more than United States law does, and India does not permit the patenting of methods of treatment at all. These differences in patent protection may have a material adverse effect on our ability to adequately protect our inventions against unauthorized use by third parties.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our future development partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance, whether intentional or not, can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case;
- patent applications may not result in any patents being issued, or even if issued may not provide adequate patent coverage to prevent a competitor from developing a competing product or otherwise provide us with any competitive advantage;
- company-owned or in-licensed patents that have been issued or may be issued in the future may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, some of which may have substantially greater resources, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use, and sell our product candidates, if approved;
- 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 less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products;
- countries other than the U.S. may, under certain circumstances, force us to grant a license under our patents to a competitor, thus allowing the competitor to compete with us in that jurisdiction or forcing us to lower the price of our drug in that jurisdiction; and
- there could also be delays at the USPTO caused by staffing cuts and other U.S. government actions as a result of the U.S. Department of Government Efficiency or other executive actions to reduce the size of the U.S. government.

Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our patents, or both, including by

filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors do not infringe our patents. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

We maintain certain information as company trade secrets. This information may relate to inventions that are not patentable or not optimally protected with patents. We use commercially acceptable practices to protect this information, including, for example, limiting access to the information and requiring passwords for our computers. Additionally, we execute confidentiality agreements with any third parties to whom we may provide access to the information and with our employees, consultants, scientific advisors, collaborators, vendors, contractors, and advisors. We cannot provide any assurances that all such agreements have been duly executed, and third parties may still obtain this information or may come upon this or similar information independently. It is possible that technology relevant to our business will be independently developed by a person who is not a party to such a confidentiality or invention assignment agreement. If any of our trade secrets were to be independently developed by a competitor or other third party, we would have no right to prevent such competitor or third party, or those to whom they communicate such independently developed information, from using that information to compete with us. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by contract manufacturers, consultants, collaborators, vendors, advisors, former employees and current employees. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Furthermore, if the parties to our confidentiality agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a consequence of such breaches or violations. Our trade secrets could otherwise become known or be independently discovered by our competitors. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. If any of these events occurs or if we otherwise lose protection for our trade secrets, our business, financial condition, results of operation and prospects may be materially and adversely harmed.

We are heavily reliant on in-licensed intellectual property, and if we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our current and future licensors, we could lose license rights that are important to our business.

We are heavily reliant upon the rights granted to us under the Asset Transfer Agreement and the Monash License Agreement pursuant to which, for the latter, we have been granted an exclusive, royalty-bearing license to certain patent rights that are important or necessary to the development of our proprietary technology and product candidates. Termination of the Asset Transfer Agreement or the Monash License Agreement or reduction or elimination of our licensed rights could lead to the loss of our ability to develop and commercialize our proprietary technology and product candidates.

In the future, we may need to obtain licenses to intellectual property rights necessary to develop and commercialize our product candidates or may need to amend existing or future licenses. If we are unable to obtain or amend such licenses at a reasonable cost or on reasonable terms, we may be unable to develop or commercialize our product candidates, which could harm our business significantly.

As noted above, the Monash License Agreement imposes, and we expect that future license agreements will impose, diligence obligations, milestone and royalty payments, indemnification and other obligations on us. If we fail to comply with our obligations under one or more of these licenses, our licensors, including Monash University, may have the right to terminate the license agreement at issue. If one or more of these licenses is terminated, we may be unable to develop or commercialize our product candidates. Termination of any of our current or future license agreements or reduction or elimination of our licensed rights may require us to negotiate new or reinstated licenses with less favorable terms, even if available at all.

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In addition, our license agreements are, and future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of the licensed rights, or increase what we believe to be our diligence, development, regulatory, commercialization, financial or other obligations under the relevant agreement. In addition, if disputes over the license agreements or the in-licensed intellectual property prevent or impair our ability to maintain our current license agreements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

License agreements we may enter into in the future may be non-exclusive, or may not include all territories or fields of use of interest to us. Accordingly, third parties may also obtain licenses from such licensors to the same intellectual property rights they have licensed to us. As a result, the licenses granted to us may not provide us with exclusive rights to use such patent and other intellectual property rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates, which may permit competitors to develop and commercialize a competitive product.

Furthermore, in some cases, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we in-license from third parties. Therefore, we cannot be certain that any in-licensed patent rights will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our future licensors or collaboration partners fail to obtain, maintain or protect any patents or patent applications licensed to us, decide not to pursue litigation against third-party infringers, fail to prosecute infringement, or fail to defend against counterclaims of patent invalidity and unenforceability, our rights to such patents and patent applications may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected.

Disputes may arise between us and our current or future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Despite our best efforts, our current or future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products, if approved, and technology covered by these license agreements. As a result, we

may be required to cease our development and commercialization of our product candidates and use of our proprietary technologies covered by the patent rights owned by the licensors. Furthermore, if the in-licensed patent rights fail to provide the intended exclusivity, competitors will have the freedom to seek regulatory approval of, and to market, products identical to ours. These events could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects. For a more complete description of our license agreements, see the section titled “Business—License Agreement.”

We may need to acquire or license additional intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of one or more third parties to commercialize our current and future product candidates.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development. If we are unable to acquire such intellectual property outright, or obtain licenses to such intellectual property from such third parties when needed or on commercially reasonable terms, our ability to commercialize our product candidates, if approved, would likely be delayed or we may have to abandon development of that product candidate and our business and financial condition could suffer.

If we in-license product candidates in the future, we might become dependent on proprietary rights from third parties with respect to those product candidates. Any termination of such licenses could result in the loss of significant rights and would cause material adverse harm to our ability to develop and commercialize any product candidates subject to such licenses. Even if we are able to in-license any such necessary intellectual property, it could be on nonexclusive terms, including with respect to the use, field or territory of the licensed intellectual property, thereby giving our competitors and other third parties access to the same intellectual property licensed to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to license such intellectual property, or if we are forced to license such intellectual property on unfavorable terms, our business could be materially harmed. In-licensing IP rights could require us to make substantial licensing and royalty payments. Patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings. If any in-licensed patents are invalidated or held unenforceable, we may not be able to prevent competitors or other third parties from developing and commercializing competitive products.

In addition, intellectual property rights that we may in-license in the future may be sublicensed under intellectual property owned by third parties, in some cases through multiple tiers. The actions of our licensors may therefore affect our rights to use our sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. Should our licensors or any of the upstream licensors fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to develop and commercialize our product candidates may be materially harmed.

We may not have the right to control the prosecution, maintenance, enforcement or defense of patents and patent applications that we license from third parties, and may not have sufficient ability to provide input into the patent prosecution, maintenance and defense process with respect to such patents. In such cases, we would be reliant on the licensor to take any necessary actions. We cannot be certain that such licensor would act with our best interests in mind, or in compliance with applicable laws and regulations, or that their actions would result in valid and enforceable patents. For example, it is possible that a licensor’s actions in enforcing and/or defending a

patent licensed by us may be less vigorous than had we conducted them ourselves. We cannot be certain that such activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control. This could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our present or future licensors may have relied upon or may rely upon third-party consultants or collaborators or on funds from third parties such that our present or future licensors may not be the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our present or future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Furthermore, government agencies may provide, funding or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights.” March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. If we choose to collaborate with academic institutions to accelerate our preclinical research or development, 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.

The risks described elsewhere pertaining to our intellectual property rights also apply to the intellectual property rights that we may own or in-license now or in the future, and any failure by us or our licensors to obtain, maintain, defend and enforce these rights could have an adverse effect on our business.

It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for our product candidates, as well as on successfully defending these patents against potential third-party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved and have in recent years been the subject of much litigation. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual

property. Over the past decade, U.S. federal courts have increasingly invalidated pharmaceutical and biotechnology patents during litigation often based on changing interpretations of patent law. Further, the determination that a patent application or patent claim meets all the requirements for patentability is a subjective determination based on the application of law and jurisprudence. The ultimate determination by the USPTO or by a court or other trier of fact in the United States, or corresponding foreign national patent offices or courts, on whether a claim meets all requirements of patentability cannot be assured. Although we have conducted searches for third-party publications, patents and other information that may affect the patentability of claims in our patent portfolio, we cannot be certain that all relevant information has been identified. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our own patent portfolio.

We cannot provide assurances that any of our or our licensors' pending patent applications will be found to be patentable, including over our own prior art publications or patent literature, or will issue as patents. Neither can we make assurances as to the scope of any claims of the issued patents that we own or in-licensed or any claims that may issue from our or our licensors' pending and future patent applications nor to the outcome of any proceedings by any potential third parties that could challenge the patentability, validity or enforceability of our patent portfolio in the United States or foreign jurisdictions. Any such challenge, if successful, could limit patent protection for our product candidates and/or materially harm our business.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we may not be able to generate sufficient data to support full patent applications that protect the entire breadth of developments in one or more of our programs;
- it is possible that one or more of our pending patent applications will not become an issued patent or, if issued, that the patent claims will not have sufficient scope to protect our technology, provide us with commercially viable patent protection or provide us with any competitive advantages;
- if our pending applications issue as patents, they may be challenged by third parties as invalid or unenforceable under United States or foreign laws;
- we may not successfully commercialize our product candidates, if approved, before our relevant patents expire;
- we may not be the first to file patent applications for the inventions covered by our patent portfolio; or
- we may not develop additional proprietary technologies that are separately patentable.

In addition, to the extent that we are unable to obtain and maintain patent protection for our product candidates, or in the event that such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of any of our product candidates for follow-on indications.

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

Patents have a limited term. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally twenty years from its earliest U.S. non-provisional filing date. The patent term of a U.S. patent may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent, or may be shortened if a patent is terminally disclaimed over another patent having an earlier expiration date. Even if patents covering our drug candidates are obtained, once the patent life has expired for a drug candidate, we may be open to competition from competitive medications, including generic versions. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents directed towards such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us

with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours for a meaningful amount of time, or at all.

Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized.

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a Patent Term Extension, or PTE, of up to five years beyond the normal expiration of the patent to compensate patent owners for loss of enforceable patent term due to the lengthy regulatory approval process. A PTE grant cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product approval. Further, PTE may only be applied once per product, and only with respect to an approved indication—in other words, only one patent (for example, covering the product itself, an approved use of said product, or a method of manufacturing said product) can be extended by PTE. Moreover, the scope of protection during the period of the PTE does not extend to the full scope of the claim, but instead only to the scope of the product as approved. We anticipate applying for PTE in the United States. Similar extensions may be available in other countries where we are prosecuting patents and we likewise anticipate applying for such extensions.

The granting of such patent term extensions is not guaranteed and is subject to numerous requirements. We might not be granted an extension because of, for example, failure to apply within applicable periods, failure to apply prior to the expiration of relevant patents, failure to exercise due diligence during the testing phase or regulatory review process or any other failure to satisfy any of the numerous applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, 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 this occurs, our competitors may be able to obtain approval of competing products following our patent expiration by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If this were to occur, it could have a material adverse effect on our ability to generate revenue.

Further, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If one of our product candidates is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application filed with the FDA to obtain permission to sell a generic version of such drug candidate. Where patents are listed, an ANDA or 505(b)(2) applicant seeking approval before patent expiry must submit a Paragraph IV certification; if we sue within 45 days of notice, approval of the ANDA or 505(b)(2) application may be stayed for up to 30 months, though the patent can still be invalidated or found not infringed.

Changes in the interpretation of patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the 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 intellectual property or narrow the scope of our

owned and licensed patents. The U.S. Congress is responsible for passing laws establishing patentability standards. As with any laws, implementation is left to federal agencies and the federal courts based on their interpretations of the laws. Interpretation of patent standards can vary significantly within the USPTO, and across the various federal courts, including the U.S. Supreme Court. Recently, the Supreme Court has ruled on several patent cases, generally limiting the types of inventions as well as the scope of inventions that can be patented.

In addition to increasing uncertainty with regard to our ability to obtain patents in the future, the legal landscape in the U.S. has created uncertainty with respect to the value of patents. Depending on any proposed or already implemented actions by U.S. Congress, and future decisions by the lower federal courts and the U.S. Supreme Court, along with interpretations by the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future as well as the cost associated with the filing, prosecution and maintenance of our or our licensors patent rights.

Patent reform legislation in the United States and other countries could increase those uncertainties and costs. For example, the Leahy-Smith America Invents Act of 2011, or the Leahy-Smith Act, included a number of significant changes to United States patent law, including 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, for example, via post grant review and inter partes review proceedings at the USPTO. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our owned or in-licensed patents or any patents we may license in the future that would not have been invalidated if first challenged by the third party as a defendant in a district court action. In addition, the Leahy-Smith Act transformed the United States patent system into a “first to file” system. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and 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 harm our business, results of operations and financial condition.

Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. The U.S. Supreme Court has ruled on several patent cases in recent years; these cases often narrow the scope of patent protection available to inventions in the pharmaceutical and biotechnology industries. We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. For example, in 2023, the Federal Circuit issued a decision in *In re Collect, LLC* involving the interaction of patent term adjustment, or PTA, terminal disclaimers, and obviousness-type double patenting which may affect the patent term of any issued patents that rely on any PTA. In 2022, the U.S. Congress passed the Inflation Reduction Act, or IRA, which authorizes the Secretary of the Department of Health and Human Services, or HHS, to negotiate prices directly with participating manufacturers for selected medicines covered by Medicare even if these medicines are protected by an existing patent. For small molecule medicines, the process begins seven years after initial approval by the FDA. While we do not believe that the IRA or its effects will impact our ability to obtain patents in the near future, we cannot be certain that it will not affect our patent strategy in the long run.

Further, a new court system recently became operational in the European Union. The Unified Patent Court, or UPC, began accepting patent cases on June 1, 2023. The UPC is a common patent court with jurisdiction over patent infringement and revocation proceedings effective for multiple member states of the European Union. The broad geographic reach of the UPC could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the individual European

Union member states in which the European patent is validated. Under the UPC, a successful revocation proceeding for a European Patent under the UPC would result in loss of patent protection in those European Union countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection in numerous European Union countries. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations. Moreover, the controlling laws and regulations of the UPC will develop over time and we cannot predict what the outcomes of cases tried before the UPC will be. The case law of the UPC may adversely affect our ability to enforce or defend the validity of our European patents. Patent owners have the option to opt-out their European Patents from the jurisdiction of the UPC, defaulting to pre-UPC enforcement mechanisms. We have not opted out our existing European patents and patent applications but we may in the future decide to opt out certain European patents and patent applications from the UPC. However, if certain formalities and requirements are not met, our European patents could be subject to the jurisdiction of the UPC. We cannot be certain that our European patents will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

We may not be able to seek or obtain patent protection throughout the world or enforce such patent protection once obtained.

Filing, prosecuting, enforcing, and defending patents protecting our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. The requirements for patentability may differ in certain countries, particularly in developing countries; thus, even in countries where we do pursue patent protection, there can be no assurance that any patents will issue with claims that cover our products. Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our technologies, products and product candidates.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Geopolitical actions in the United States and in foreign countries could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents or those of any current or future licensors. Many companies have encountered significant problems in protecting, enforcing and defending intellectual property rights in certain foreign jurisdictions, such as China and Russia. For example, further to the United States and foreign government actions related to Russia's invasion of Ukraine, the Kremlin issued Decree 299 stating that Russian companies and individuals can use patented inventions without the owner's permission or compensation, if the patent is held by owners from "unfriendly countries," which include the United States. As a result, we would not be able to enforce our otherwise valid patent rights against an infringer in Russia. These and other restrictions could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights in such countries.

Furthermore, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe or from selling or importing products made from our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and market their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights, whether successful or not, could result in substantial costs and divert our efforts and resources from other aspects of our business. Further, such proceedings could put our

patents at risk of being invalidated, held unenforceable or interpreted narrowly; put our pending patent applications at risk of not issuing; and provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products, if approved. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the U.S., but may issue as patents with claims of different scope or may even be refused in other jurisdictions.

In order to protect our competitive position around our product candidates, we may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful and which may result in our patents being found invalid or unenforceable.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. 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. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. 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 this case, we could ultimately be forced to cease use of such trademarks. We may find it impractical or undesirable to enforce our intellectual property against some third parties.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. 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.

Some of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing, misappropriating or otherwise violating our intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims could result in substantial costs and diversion of management resources,

which could harm our business. 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, or in-license needed technology.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing current and future product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, and market our current as well as any future product candidates, without infringing the intellectual property and other proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. If any third-party patents or patent applications are found to cover our current or any future product candidates or their methods of use, or other aspects of our current or future product candidates, we may not be free to manufacture or market such product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all, or we may incur significant legal fees or damages. 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 technology, including interference proceedings, post grant review and inter partes review 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. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as “patent trolls,” have acquired patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or “invitations to license,” or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the actual or threatened suit.

In spite of our efforts to avoid obstacles and disruptions arising from third-party intellectual property, it is impossible to establish with certainty that our programs directed to our current and any future product candidates will be free of claims by third-party intellectual property holders. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are 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. Even with modern databases and on-line search engines, literature searches are imperfect and may fail to identify relevant patents and published applications. Even when a third-party patent is identified, we may conclude upon a thorough analysis, that we do not infringe the patent or that the patent is invalid. 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. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party’s pending application will issue with claims of relevant scope. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. If the third-party patent owner disagrees with our conclusion and we continue with the business activity in question, patent litigation may be initiated against us. Alternatively, we might decide to initiate litigation in an attempt to have a court declare the third-party patent invalid or non-infringed by our activity. In either scenario, patent litigation typically is costly and time-consuming, and the outcome is uncertain. The outcome of patent litigation is subject to uncertainties that cannot be quantified in advance, for example, the credibility of expert witnesses who may disagree on technical interpretation of scientific data. Ultimately, in the case of an adverse outcome in litigation, we could be prevented from commercializing a product or using certain

aspects of our technology platform as a result of patent infringement claims asserted against us. This could have a material adverse effect on our business.

There is a substantial amount of intellectual property litigation in the pharmaceutical and biotechnology industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our current or future product candidates, including interference proceedings before the USPTO. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that any current or future product candidates, products, methods, processes, modeling or similar work either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

If we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product or cease some of our business operations, which could harm our business. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. 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 access to the same technologies licensed to us; alternatively or additionally it could include terms that impede or destroy our ability to compete successfully in the commercial marketplace. 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. We may be required to indemnify collaborators or contractors against such claims. A finding of infringement could prevent us from commercializing any future product candidates or force us to cease some 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.

Our involvement in litigation, and in, e.g., any interference, derivation, reexamination, inter partes review, opposition or post-grant proceedings or other intellectual property proceedings in the United States, or other jurisdictions, may divert management time from focusing on business operations, could cause us to spend significant amounts of money and may have no guarantee of success. Any current and potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, manufacturing or using our products in the United States or other jurisdictions that use the intellectual property at issue;
- obtain from a third party asserting its intellectual property rights, a license to sell or use the relevant technology, which license may not be available on reasonable terms, or at all, or may be non-exclusive thereby giving our competitors access to the same technologies licensed to us;
- redesign those products or processes that use any allegedly infringing or misappropriated technology, which may result in significant cost or delay to us, or which redesign could be technically infeasible; or
- pay damages, including the possibility of treble damages in a patent case if a court finds us to have willfully infringed certain intellectual property rights.

Others may challenge inventorship or claim an ownership interest in our intellectual property which could expose it to litigation and have a significant adverse effect on its prospects.

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 unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors or the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent. Furthermore, ownership disputes may arise from alleged contributions of third parties involved in developing our product candidates and may result in joint ownership of our inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Any disagreement over inventorship could result in our being forced to defend our determination of inventorship in a legal action which could result in substantial costs and be a distraction to our senior management and scientific personnel. 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 management and other employees.

While we typically require employees, consultants and contractors who may develop intellectual property on our behalf to execute agreements assigning such intellectual property to us, we may be unsuccessful in obtaining execution of assignment agreements with each party who in fact develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached. In either case, 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. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we are unsuccessful in obtaining assignment agreements from an employee, consultant or contractor who develops intellectual property on our behalf, the employee, consultant or contractor may later claim ownership of the invention. Any disagreement over ownership of intellectual property could result in our losing ownership, or exclusive ownership, of the contested intellectual property, paying monetary damages and/or being enjoined from clinical testing, manufacturing and marketing of the affected product candidate(s). Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

Any intellectual property litigation could lead to unfavorable publicity that could harm our reputation and cause the market price of our common stock to decline.

During the course of any patent litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs, or intellectual property could be diminished. In such event, the market price of our common stock may decline.

We may be subject to claims that our employees or we have misappropriated intellectual property from a competitor or third parties or claiming ownership of what we regard as our own intellectual property.

Many of our current and former employees and our licensors' current and former employees, including our senior management, were previously employed at other pharmaceutical or biotechnology companies, including some which may be competitors or potential competitors. Although we take commercially reasonable steps to ensure that our employees do not use the proprietary information, know-how or trade secrets of others in their work for us, including incorporating such intellectual property into our product candidates, we may be subject to claims that we or these employees have misappropriated the intellectual property of a third party.

If we or any of our employees are accused of misappropriating the proprietary information, know-how or trade secrets of a third party, we may be forced to defend such claims in litigation. If we are found to have misappropriated the intellectual property rights of a third party, we may be forced to pay monetary damages, sustain reputational damage, lose key personnel, or lose valuable intellectual property rights. Further, it may become necessary for us to obtain a license from such third party to commercialize any of our product candidates. Such a license may not be available on commercially reasonable terms or at all. Any of the aforementioned could materially affect the commercialization of any of our product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

Along with patent protection, we also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, certain aspects of our manufacturing processes. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, CROs, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants.

Trade secrets and confidential know-how are difficult to maintain as confidential. Although we use reasonable efforts to protect our trade secrets, any party with whom we have executed a confidentiality agreement may breach that agreement and disclose our proprietary information, including our trade secrets.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Accordingly, we may not be able to obtain adequate remedies for such breaches, despite any legal action that we might take against persons making such unauthorized disclosures. In addition, courts outside the United States sometimes are less willing than United States courts to protect trade secrets. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad.

If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed. For example, we may choose not to file a patent application for certain inventions, instead choosing to rely on trade secret protection, and a third party may subsequently file a patent application covering such intellectual property. Although certain defenses maybe available to us, those defenses may not be available to a commercial partner or acquiror.

Those with whom we collaborate on research and development related to current and future product candidates may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. We may also need to share our trade secrets and proprietary know-how with current or future 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.

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

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming, particularly for a company of our size. We may not be able to protect our rights to our trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. During trademark registration proceedings, we may receive rejections. 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. Moreover, any name we propose to use for our products 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 product names, we may be required to expend significant additional resources in an effort to identify a usable 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. 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.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;

- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators 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 or business risk;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product or products;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Related to this Offering and Ownership of Our Common Stock

There has been no prior public market for our common stock, and an active trading market may not develop or be sustained.

There has been no public market for our common stock prior to this offering. Although we have applied to list our common stock on The Nasdaq Global Select Market, an active or liquid market in our common stock may not develop upon closing of this offering or, if it does develop, it may not be sustainable. The initial public offering price for our common stock was determined through negotiations among the underwriters and us and may vary from the market price of our common stock following this offering. This price will not necessarily reflect the price at which investors in the market will be willing to buy and sell our shares following this offering. The lack of an active market may impair the value of your shares, your ability to sell your shares at the time you wish to sell them and the prices that you may obtain for your shares. An inactive market may also impair our ability to raise capital by selling our common stock and our ability to acquire other companies, products, or technologies by using our common stock as consideration.

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

The trading price of our common stock following this offering is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this section and elsewhere in this prospectus, these factors include:

- the commencement, enrollment, completion, or results of our current or future preclinical and clinical trials for our product candidates;
- any delay in identifying and advancing a clinical candidate for our other programs;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays, suspensions, or terminations in future preclinical studies or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;

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- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates, or the failure of a regulatory authority to accept data from preclinical studies or clinical trials conducted in other countries;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- changes in the structure of the healthcare payment systems;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish strategic partnerships or collaborations, if needed;
- our failure to commercialize our product candidates, if approved;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to any of our current or future product candidates;
- introduction of new products or services offered by us or our competitors;
- 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 product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- 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 stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for therapeutics 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 common stock, regardless of our actual operating performance. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your

investment in us and may lose some or all of your investment. 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.

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.

Our quarterly and annual operating results may fluctuate significantly, due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and, if approved, commercialization activities relating to our current and future product candidates, which may change from time to time;
- the timing and status of enrollment for clinical trials;
- the cost of manufacturing our product candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop, or commercialize additional product candidates and technologies;
- timing and amount of any milestone, royalty, or other payments due under any collaboration or license agreement, including the Asset Transfer Agreement and/or the Monash License Agreement;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the timing of receipt of approvals for our product candidates from regulatory authorities in the United States and internationally;
- exchange rate fluctuations;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products; and
- the level of demand for our product candidates, if approved, which may vary significantly over time.

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 future revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if any forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may

never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our common stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Our executive officers, directors, principal stockholders, and their respective affiliates own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Based on the beneficial ownership of our common stock as of February 15, 2026, prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 92.9% of our voting stock and, upon the completion of this offering, that same group will hold approximately % of our outstanding voting stock (assuming no exercise of the underwriters' option to purchase additional shares, no exercise of outstanding options and no purchases of shares in this offering by any of this group), in each case assuming the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock. In particular, PureTech will own approximately % of our common stock following this offering and will be our largest stockholder following this offering. As a result, PureTech along with stockholders who own more than 5% or more of our capital stock, if acting together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation, or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Future sales of our common stock in the public market could cause our stock price to fall.

Our stock price could decline as a result of sales of a large number of shares of common stock after this offering or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

Upon the completion of this offering, shares of common stock will be outstanding (or shares if the underwriters exercise their option to purchase additional shares from us in full), based on the number of shares outstanding as of , 2026.

All shares of common stock expected to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, unless held by our "affiliates" as defined in Rule 144 under the Securities Act. The resale of the remaining shares, or % of our outstanding shares of common stock following this offering, is currently prohibited or otherwise restricted, subject to certain limited exceptions, as a result of securities law provisions, market standoff agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with this offering. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning on the 181st day after the date of this prospectus. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements and/or lock-up

agreements, as well as Rules 144 and 701 under the Securities Act. For more information, see the section titled “Shares Eligible for Future Sale” included elsewhere in this prospectus.

Upon the completion of this offering, the holders of approximately _____ shares, _____ or _____ % of _____ our outstanding shares following this offering, of our common stock will have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. We also intend to register the offer and sale of all shares of common stock that we may issue under our equity compensation plans. Once we register the offer and sale of shares for the holders of registration rights and shares that may be issued under our equity incentive plans, these shares will be able to be sold in the public market upon issuance, subject to the lock-up agreements described under the section titled “Underwriting” included elsewhere in this prospectus.

In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

We will have broad discretion in how we use the proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds of this offering and, including for any of the purposes described in the section titled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. As a result, investors will be relying upon management’s judgment with only limited information about our specific intentions for the use of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

If you purchase shares of our common stock in our initial public offering, you will experience substantial and immediate dilution.

The assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, is substantially higher than the pro forma as adjusted net tangible book value per share of our outstanding common stock immediately following the completion of this offering. If you purchase shares of common stock in this offering, you will experience substantial and immediate dilution in the pro forma as adjusted net tangible book value per share of \$ _____ per share as of December 31, 2025. That is because the price that you pay will be substantially greater than the pro forma as adjusted net tangible book value per share of the common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares of our capital stock. You will experience additional dilution if the underwriters exercise their option to purchase additional shares in this offering, when those holding stock options exercise their right to purchase common stock under our equity incentive plans, upon the vesting of outstanding restricted stock awards or when we otherwise issue additional shares of common stock. For more information, see the section titled “Dilution” included elsewhere in this prospectus.

Participation in this offering by our existing stockholders and/or their affiliated entities will reduce the public float for our common stock.

To the extent our existing stockholders who are our affiliates or their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our common stock after this offering, which is the number of shares of common stock that are not held by our officers, directors, and affiliated stockholders. As a result, the number of freely tradeable shares of our common stock following this offering will

be reduced relative to what it would have been had these shares been sold to investors that were not existing stockholders, affiliates, or purchasers. This could adversely impact the liquidity of our common stock and depress the price at which you may be able to sell shares of common stock purchased in this offering.

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

We expect to issue additional capital stock in the future and to grant equity awards to employees, directors, and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. Additionally, as part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

We do not currently intend to pay dividends on our common stock and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation of the value of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. In addition, any future debt agreements may preclude us from paying dividends. As a result, any investment return on our common stock will depend upon increases in the value for our common stock, which is not certain. For more information on our dividend policy, see the section titled "Dividend Policy" included elsewhere in this prospectus.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, and our amended and restated bylaws, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, will contain provisions that may discourage, delay, or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;

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- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of not less than two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our amended and restated certificate of incorporation or amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our amended and restated bylaws that will become effective upon the effectiveness of this registration statement designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated bylaws that will become effective upon effectiveness of the registration statement of which this prospectus forms a part provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws (including the interpretation, validity or enforceability thereof) or (iv) any action asserting a claim that is governed by the internal affairs doctrine, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, or the Federal Forum Provision. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders’ ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. While the Delaware Supreme Court and other state courts have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

We may not be able to satisfy listing requirements of The Nasdaq Stock Market, or Nasdaq, or obtain or maintain a listing of our common stock on Nasdaq.

If our common stock is listed on Nasdaq, we must meet certain financial and liquidity criteria to maintain such listing. If we violate Nasdaq's listing requirements, our common stock may be delisted. If we fail to meet any of Nasdaq's listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of your investment.

Other General Risks

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price, and results of operations.

The global credit and financial markets have experienced extreme volatility and disruptions (including as a result of actual or perceived changes in interest rates, inflation, and macroeconomic uncertainties), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, global supply chain disruptions, and increases in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflicts in the Middle East and between Russia and Ukraine, terrorism, political unrest, or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for our drug candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. For example, there has been proposed U.S. legislation that may have the effect of restricting the ability of U.S. biopharmaceutical companies to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies that the government name as "companies of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We continue to assess the legislation as it develops to determine whether it could have an effect on our contractual relationships. Furthermore, any disruptions to our supply chain as a result of unfavorable global economic conditions, including due to geopolitical conflicts, political unrest, tariff, and other trade-related cost pressures or public health crises, could negatively impact the timely execution of our ongoing and future clinical trials. In addition, inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent events of political unrest and/or potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

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

Natural disasters or public health crises could severely disrupt our operations and the operations of our suppliers, CROs, and clinical sites, which would have a material adverse impact on our business, financial condition, results of operations, and prospects. If a natural disaster, power outage, public health crisis, or other event occurred that prevented us from conducting our clinical trials, releasing clinical trial results, or delaying

our ability to obtain regulatory approval for our product candidates, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

We are eligible to be treated as an “emerging growth company” and a “smaller reporting company” and our election of reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an “emerging growth company” as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements in addition to any required unaudited interim financial statements and a correspondingly reduced “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*” disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to of Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation;
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved; and
- exemptions from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on the financial statements.

In this prospectus, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company.

We could be an emerging growth company for up to five years following the completion of this offering, although circumstances could cause us to lose that status earlier, including if we are deemed to be a “large accelerated filer,” which occurs when the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter, or if we have total annual gross revenue of \$1.235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the last day of our fiscal year, or if we issue more than \$1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies.

In addition, the JOBS Act provides that an emerging growth company can also take advantage of an extended transition period for complying with new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we may 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 common stock 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 common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our

common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will incur significant 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 and corporate governance practices.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, which will 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 The Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of this offering. Stockholder 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 an adverse effect on our business. 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.

If we fail to establish and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be reevaluated frequently. 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 in accordance with generally accepted accounting principles. In connection with this offering, we began the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. Under current rules, we will be subject to these requirements beginning with our annual report on Form 10-K for the year ending 2026. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require

prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Internal control deficiencies could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company or a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act. We could be an emerging growth company for up to five years following completion of this initial public offering. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

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

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under 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, 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 a required related party transaction disclosure. 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.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

We maintain the majority of our cash, cash equivalents, and investments in accounts with major U.S. and multi-national financial institutions, and our cash equivalents are invested in U.S. government money market funds and our investments are invested in U.S. Treasury obligations. Our deposits at certain of these institutions exceed insured limits, unless subject to a "sweep." Market conditions and changes in financial regulations and policies can impact the viability of these institutions. Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that us, the financial institutions with which we may have future credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit, or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. In addition, changes in regulations governing financial institutions are beyond our control and difficult to predict; consequently, the impact of such changes on our business and results of operations is difficult to predict and may have an adverse effect on us.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

As of December 31, 2025, we had approximately \$53.4 million of federal net operating losses, or NOLs. Federal NOLs generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards in a taxable year is limited to 80% of our taxable income in such year. As of December 31, 2025, we had approximately \$53.7 million of state NOLs. As of December 31, 2025, we had approximately \$2.9 million of federal research and development tax credit carryforwards. Federal tax credit carryforwards expire at various dates beginning in 2044. As of December 31, 2025, we had approximately \$1.0 million of state research and development tax credit carryforwards. The state tax credits carryforwards expire at various dates beginning in 2039.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by “5 percent shareholders” over a three-year period, the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. A corporation that experiences an ownership change will generally be subject to an annual limitation on the use of its pre-ownership change NOLs equal to the value of the corporation immediately before the ownership change, multiplied by the long-term tax-exempt rate (subject to certain adjustments). We may have experienced ownership changes in the past and may experience ownership changes as a result of this offering and/or subsequent shifts in our stock ownership (some of which are outside our control). There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs by federal or state taxing authorities or other unforeseen reasons, portions of our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities. As a result, our ability to use our pre-change NOLs and tax credits to offset future taxable income, if any, or taxes could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

Changes in tax law could adversely affect our business and financial condition.

U.S. federal, state, local, and foreign tax laws, regulations and administrative guidance are subject to change as a result of the legislative process and review and interpretation by the U.S. Internal Revenue Service, the U.S. Treasury Department and other taxing authorities. Changes to tax laws (which changes may have retroactive application), including with respect to net operating losses and research and development tax credits, could adversely affect us or holders of our common stock. For example, on July 4, 2025, President Donald Trump signed the One Big Beautiful Bill Act into law. Key tax provisions included the restoration of 100% bonus depreciation for certain qualified property, immediate expensing for domestic research and experimental expenditures and the ability to make elective adjustments for prior years, changes to the Section 163(j) interest limitations and updates to net CFC tested income (formerly GILTI) and FDII rules. In recent years, many other such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, financial condition, results of operations, or cash flow. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

Our information technology systems and infrastructure, or those of our collaborators and service providers, or our data, may be subject to cyberattacks, security breaches, compromises or other incidents, which could impact the confidentiality, integrity, and availability of our operational system and result in additional costs, loss of revenue, significant liabilities, harm to our brand, material disruption of our development programs and operations, or other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely, process sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats that could cause

cyber-attacks, security breaches, compromises, or other incidents that impact the confidentiality, integrity, and availability of our operational systems. Although we, and the third parties upon which we rely, take steps to develop and maintain systems and controls designed to protect our sensitive data, systems, and infrastructure, there can be no assurance that our internal technology systems, and infrastructure, or those of third parties upon which we rely, will be sufficient to protect against a cyber-attack, security breach, compromise, or other incident such as an industrial espionage attack, ransomware, or insider threat attack, which may compromise the confidentiality, integrity, and availability of our system infrastructure, or those of third parties upon which we rely, or lead to the loss, destruction, alteration, or dissemination of, or damage to, our sensitive data. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

The risk of a cyber-attack, security breach, compromise, or other adverse impact to our and our third-party service provider’s information technology systems and sensitive data has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Such risks come from a variety of evolving threats, including but not limited to, social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware errors (including vulnerabilities in commercial software that is integrated into our information technology systems and those of third parties upon which we rely), failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats.

Individuals engage in and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely, may be vulnerable to a heightened risk of cyber-attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell, and distribute our products and services.

We also face increased risks of a cyber-attack, security breach, compromise, or adverse impact to our and our third-party service provider’s information technology systems and sensitive data incident due to our reliance on internet technology and the number of our employees who work on a hybrid basis at home, in the office, or other public spaces. This may create additional opportunities for cybercriminals to exploit vulnerabilities. Additionally, business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies that were not found during due diligence of such acquired or integrated entities.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks. We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts and our ability to monitor these third parties’ information security practices is limited. These third parties may not have adequate information security measures in place and if our third-party service providers experience a cyber-attack, security breach, compromise or incident, or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

We may be unable to detect vulnerabilities in our information technology systems and infrastructure on a timely basis or until after a cyber-attack, security breach, compromise, or other incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to adequately address any such identified vulnerabilities. In addition, we may be unable to comprehensively apply patches or confirm that

measures are in place to mitigate all such vulnerabilities, or that patches will be applied before vulnerabilities are exploited by a threat actor. If attackers are able to exploit critical vulnerabilities before patches are installed or mitigating measures are implemented, significant compromises could impact our and our customers' systems and data. Any integration of artificial intelligence in our or any third party's operations, products, or services is expected to pose new or unknown cybersecurity risks and challenges.

There can also be no assurance that our cybersecurity risk management program and processes, including our policies, controls, or procedures, will be fully implemented, complied with, or effective in protecting our information technology systems (and those of third parties upon which we rely) and sensitive data. We and certain of our third-party service providers regularly experience cyberattacks and other incidents, and we expect such attacks and incidents to continue in varying degrees. While to date no incidents have had a material impact on our operations or financial results, we cannot guarantee that material incidents will not occur in the future. We may in the future experience additional threats, compromises, breaches, or incidents. If we, or a third party upon whom we rely, experience a cyber-attack, security breach, compromise, or other adverse impact to the confidentiality, integrity and availability of our system infrastructure, or those of third parties upon which we rely, or sensitive data, or are perceived to have experienced a cyber-attack, security breach, compromise, or other adverse impact to our and our third-party service provider's information technology systems and sensitive data, we may experience adverse consequences, such as government enforcement actions (e.g., investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including individual and class action claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); significant incident response, system restoration, or remediation and future compliance costs; financial loss; and other potentially significant harms. 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 privacy and data security obligations. Additionally, we cannot guarantee that any costs and liabilities incurred in relation to an attack or incident will be covered by our existing insurance policies or that applicable insurance will be available to us in the future on economically reasonable terms or at all.

Further, applicable privacy and data security obligations may require us to notify relevant stakeholders of a cyber-attack, security breach, compromise, or other adverse impact to our and our third-party service provider's information technology systems and sensitive data. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. In addition, cyber-attacks, security breaches, compromises, or other incidents may cause stakeholders (including investors and potential customers) to stop supporting our business, deter new customers from using our products, and negatively impact our ability to grow and operate our business.

If we were to experience a cyber-attack, security breach, compromise, or other adverse impact to our and our third-party service provider's information technology systems and sensitive data that causes interruptions in our operations, it could result in a material disruption of our product development programs, business, financial condition, and results of operations.

We may use artificial intelligence in our business, and challenges with properly managing its use, as well as uncertainty regarding the legal landscape surrounding the use of AI could result in reputational harm, competitive harm, legal liability, and adversely affect our results of operations.

We may use artificial intelligence, or AI, machine learning, and automated decision-making technologies, or, collectively, AI Technologies, throughout our business, and are making investments in this area. We expect that increased investment will be required in the future to continuously improve our use of AI Technologies. As with many technological innovations, there are significant risks involved in developing, maintaining and deploying these technologies, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of

AI or other emerging technologies increases regulatory, cybersecurity and other significant risks. There can be no assurance that the usage of, or our investments in such technologies will always enhance our products or services or be beneficial to our business, including our efficiency or profitability.

In particular, if the models underlying our AI Technologies are: incorrectly designed or implemented; trained or reliant on incomplete, inadequate, inaccurate, biased or otherwise poor quality data, or on data to which we do not have sufficient rights or in relation to which we and/or the providers of such data have not implemented sufficient legal compliance measures; used without sufficient oversight and governance to ensure their responsible use; and/or adversely impacted by unforeseen defects, technical challenges, cybersecurity threats or material performance issues, the performance of our products, services and business, as well as our reputation, could suffer or we could incur liability resulting from the violation of laws or contracts to which we are a party or civil claims.

We may not be successful in our development and maintenance of these technologies in the face of novel and evolving technical, reputational and market factors. Our efforts to develop proprietary AI models in the future could increase our operating costs. Our future ability to develop proprietary AI models may be limited by our access to processing infrastructure or training data, and we may be dependent on third party providers for such resources.

If we fail to keep pace with rapidly evolving AI Technologies, especially in the medical device industry, our competitive position and business results may suffer. The introduction and use of AI Technologies, particularly generative AI, into new or existing offerings may result in new or expanded risks and liabilities, including due to enhanced governmental or regulatory scrutiny, litigation, compliance issues, ethical concerns, confidentiality or security risks, as the well as other factors that could adversely affect our reputation, as the well as our business, operating results, and financial condition. For example, AI Technologies can lead to unintended consequences, including generating content that appears correct but is factually inaccurate, misleading, or otherwise flawed, which could negatively impact our customers, harm our reputation and business, and expose us to liability.

We use AI Technologies from third parties. If we are unable to obtain or maintain rights to use these AI Technologies on commercially reasonable terms, or if any such third-party AI tools become incompatible with our products, we may be forced to acquire or develop alternate AI Technologies, which may limit or delay our ability to provide competitive offerings and may increase our costs. These AI Technologies also may incorporate data from third party sources, which may expose us to risks associated with data rights and protection. The legal and regulatory landscape surrounding AI Technologies is rapidly evolving and uncertain, including with respect to intellectual property ownership and license rights, cybersecurity, and data protection laws, among others, and has not yet been fully addressed by courts or regulators. The evolving legal, regulatory, and compliance framework for AI Technologies may also impact our ability to protect our own data and intellectual property against infringing use.

The regulatory framework for AI Technologies is rapidly evolving as many federal, state, and foreign government bodies and agencies have introduced or are currently considering additional laws and regulations and we expect to see increasing government and supranational regulation related to AI use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. In the U.S., a number of states have proposed and passed laws regulating various uses of AI, and federal regulators have issued guidance affecting the use of AI in regulated sectors. The FDA, for example, also issued guidance on the use of AI in medical devices, requiring detailed risk management and review processes to obtain approvals. If we develop or use AI systems governed by these laws or regulations, we will need to apply significant resources to design, develop, test and maintain such systems in accordance with applicable laws and regulations, with the potential for significant enforcement or litigation in the event of any perceived non-compliance. It is possible that new laws and regulations will be adopted in the U.S. and in other non-U.S. jurisdictions, or that existing laws and regulations, including competition and antitrust laws, may be interpreted in ways that would limit our ability to use AI Technologies for our business, or require us to change the way we use AI Technologies in a manner that

negatively affects the performance of our products, services, and business and the way in which we use AI Technologies. We may need to expend resources to adjust our products or services in certain jurisdictions if the laws, regulations, or decisions are not consistent across jurisdictions. Further, the cost to comply with such laws, regulations, or decisions and/or guidance interpreting existing laws, could be significant and would increase our operating expenses (such as by imposing additional reporting obligations regarding our use of AI Technologies). Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could adversely affect our business, financial condition and results of operations.

Even in the absence of dedicated AI laws and regulations, we may be subject to novel legal and business risks relating to our adoption of these new technologies. Vendors may in turn incorporate AI tools into their own offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Our use of AI Technologies may also, in the future, result in cybersecurity incidents that implicate the personal information of customers or patients. Any such cybersecurity incidents related to our use of AI applications could adversely affect our reputation and results of operations.

Clinical trial and product liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of clinical trial and product liability exposure related to the testing of our product candidates in clinical trials, and we will face an even greater risk if we commercially sell any products that we develop. While we currently have no products that have been approved for commercial sale, the ongoing, planned, and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trials;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Although we currently hold clinical trial liability insurance, we will need to maintain such insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to obtain and maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

We may become involved in litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

From time to time we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal data, contractual relations with collaborators and licensors, and intellectual property rights. In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, the announcement of negative events, such as negative results from clinical trials, or periods of volatility in the market price of a company's securities. These events may also result in or be concurrent with investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned preclinical studies and clinical trials, results of preclinical studies, clinical trials, research and development costs, regulatory approvals, commercial strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “would,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “believe,” “estimate,” “predict,” “potential,” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the initiation, timing, progress and results of our current and future clinical trials, preclinical studies, and research and development programs;
- the timing of announcement of results from clinical trials;
- our ability to successfully complete our clinical trials;
- our ability to advance other product candidates that we may identify and successfully complete any clinical studies, including the manufacture of any such product candidates;
- our ability to quickly leverage programs within our initial target indications and to progress additional programs to further develop our pipeline;
- the prevalence of certain disorders we intend to treat and the size of the market opportunity for our product candidates;
- estimates of the number of patients with certain disorders we intend to treat and the number of patients that we will enroll in our clinical trials;
- the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates;
- the timing of our investigational new drug applications, or INDs, submissions;
- the implementation of our strategic plans for our business, platform, and our programs;
- the scope of protection we are able to establish and maintain for intellectual property rights;
- developments related to our competitors and our industry;
- the success of competing therapies that are or may become available;
- our ability to leverage the clinical, regulatory, and manufacturing advancements to accelerate our clinical trials and approval of product candidates;
- our ability to meet future regulatory standards with respect to our product candidates, if approved;
- our ability to maintain our existing license agreements and identify and enter into future license agreements and collaborations;
- our reliance on third parties to conduct clinical trials of our product candidates;
- our reliance on third parties for the manufacture of our product candidates;
- developments related to our platform;

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- regulatory developments in the United States and foreign countries;
- our commercialization, marketing, and manufacturing capabilities;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act or a smaller reporting company;
- our ability to attract and retain key scientific and management personnel; and
- our anticipated cash runway, use of proceeds from this offering, our financial performance, estimates of our expenses, capital requirements, and needs for additional financing.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described in “*Risk Factors*” and elsewhere in this prospectus. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events, or otherwise. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures, or investments that we may make or enter into.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of our common stock in this offering will be approximately \$ million (or approximately \$ million if the underwriters exercise their option to purchase additional shares of our common stock in full) based on an assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover of this prospectus, would increase or decrease, as applicable, the net proceeds to us from this offering by \$ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1.0 million shares in the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, would increase or decrease, as applicable, the net proceeds to us from this offering by \$ million, assuming the assumed initial public offering price of \$ per share remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to create a public market for our common stock and thereby facilitate future access to the public equity markets, increase our visibility in the marketplace, and obtain additional capital to support our operations. We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents, and investments, as follows:

- approximately \$ million to advance development of GlyphAllo™ (SPT-300) through ;
- approximately \$ million to advance development of GlyphAgo™ (SPT-320) through ; and
- the remainder to fund development of Glyph2BLSD™ (SPT-348), as well as research and development activities for additional programs, and working capital and general corporate purposes.

We may use a portion of the remaining net proceeds and our existing cash, cash equivalents, and investments to in-license, acquire, or invest in complementary businesses, technologies, products, or assets. However, we have no current commitments, agreements, understandings, or obligations to do so.

We believe, based on our current operating plan, that the net proceeds from this offering, together with our existing cash, cash equivalents and investments, will be sufficient to fund our operations through . We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We do not have any committed external source of funds.

Our expected use of proceeds from this offering along with our existing cash, cash equivalents, and investments described above represents our current intentions based on our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the actual amounts that we will spend on the uses set forth above. We expect that we will require additional funds in order to fully accomplish the specified uses of the proceeds of this offering. The amounts and timing of our actual expenditures will depend on numerous factors, including progress of our research and development, the status of and results from preclinical studies and clinical trials that we are conducting or may conduct in the future, and other factors described in the section titled “Risk Factors,” as well as the amount of cash used in our operations and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. Moreover, our estimates of the costs to fund our trials are based on the current designs of the trials. If we were to modify the design of any of these trials, for instance, to increase the number of patients in the trials, our costs to fund the trials could increase. We may find it necessary or advisable to use the net proceeds for other purposes.

We will have broad discretion over how to use the net proceeds to us from this offering and investors will be relying on the judgment of our management regarding the application of the net proceeds. Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term and long-term interest-bearing instruments, investment-grade securities, and direct or guaranteed obligations of the U.S. government. We cannot predict whether the proceeds invested will yield a favorable return.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws, and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects, and other factors our board of directors may deem relevant. Investors should not purchase our common stock with the expectation of receiving cash dividends. In addition, our ability to pay cash dividends on our capital stock in the future may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

CAPITALIZATION

The following table sets forth our existing cash, cash equivalents, and investments and our capitalization as of December 31, 2025:

- on an actual basis;
- on a pro forma basis, giving effect to (i) the Preferred Stock Conversion and (ii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the completion of this offering; and
- on a pro forma as adjusted basis, giving effect to (i) the pro forma adjustments set forth above and (ii) the issuance and sale of shares of common stock in this offering at the assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only, and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. Cash, cash equivalents, and investments are not components of our capitalization.

You should read this information together with our consolidated financial statements and the related notes included elsewhere in this prospectus, and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	As of December 31, 2025		
	Actual	Pro Forma	Pro Forma As adjusted ⁽¹⁾
	(in thousands, except share and per share data)		
Cash, cash equivalents, and investments	\$ 233,653	\$ _____	\$ _____
Convertible preferred stock (Series A and B), \$0.0001 par value; 113,921,040 shares authorized and 113,921,036 shares issued and outstanding, actual; no shares authorized, issued, or outstanding, pro forma and pro forma as adjusted	\$ 325,328	\$ _____	\$ _____
Stockholders’ equity (deficit):			
Preferred stock, \$0.0001 par value; no shares authorized, issued, or outstanding, actual; shares authorized, and no shares issued, or outstanding, pro forma and pro forma as adjusted			
Common stock, \$0.0001 par value; 159,070,000 shares authorized and 8,151,200 shares issued and outstanding, actual; 159,070,000 shares authorized, 122,072,236 issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	1		
Additional paid-in capital	21,262		
Accumulated other comprehensive income	301		
Accumulated deficit	(114,109)		
Total stockholders’ (deficit) equity	(92,545)		
Total capitalization	\$ 249,009	\$ _____	\$ _____

- (1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents, and investments, additional paid-in capital, total stockholders' equity and total capitalization by \$ _____ million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares of common stock offered by us would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents, and investments, additional paid-in capital, total stockholders' equity and total capitalization by \$ _____ million, assuming no change in the assumed initial public offering price per share, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock that will be outstanding after this offering on a pro forma and pro forma as adjusted basis is based on 122,072,236 shares of common stock (which includes 486,114 shares of unvested restricted common stock) outstanding as of December 31, 2025, after giving effect to the Preferred Stock Conversion, and excludes:

- 27,633,144 shares of common stock issuable upon exercise of outstanding stock options as of December 31, 2025, which includes 718,500 performance-based awards that have not yet been deemed granted for accounting purposes, under our 2024 Plan, with a weighted-average exercise price of \$1.52 per share, and 3,023,510 shares of common stock issuable upon exercise of outstanding stock options granted after December 31, 2025 pursuant to our 2024 Plan, with a weighted-average exercise price of \$3.28 per share;
- 4,722,667 shares of common stock reserved for future issuance as of December 31, 2025 under the 2024 Plan, which will cease to be available for issuance at the time that our 2026 Plan becomes effective;
- _____ shares of our common stock issuable upon the exercise or grant of the IPO Grants, equal to approximately 12.5% of the number of shares of our common stock to be outstanding upon the closing of this offering calculated on a fully diluted basis (after giving effect to the number of shares of our common stock to be sold in this offering, not including the exercise in full of the underwriters' option to purchase additional shares), to be granted to an executive officer and a director under the 2026 Plan; see the sections titled "Executive Compensation—Narrative Disclosure to the 2025 Summary Compensation Table—Equity Incentive Compensation" and "Director Compensation" for more information on such grants, including a description of how the number of shares issuable pursuant to such grants will be determined;
- _____ shares of our common stock that will become available for future issuance under our 2026 Plan, including shares reserved for the IPO Grants, which will become effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2026 Plan and any shares underlying outstanding stock awards granted under the 2024 Plan that expire or are repurchased, forfeited, cancelled, or withheld; and
- _____ shares of common stock reserved for future issuance under the ESPP, which will become effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) as of December 31, 2025 was \$(93,784) million, or \$(12.24) per share of our common stock. Our historical net tangible book value (deficit) represents the amount of our total tangible assets less our total liabilities and the carrying value of our convertible preferred stock, which is not included within stockholders' deficit. Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by 7,665,086 shares of our common stock outstanding (which excludes 486,114 shares of unvested restricted common stock) as of December 31, 2025.

Our pro forma net tangible book value (deficit) as of December 31, 2025 was \$ million, or \$ per share. Pro forma net tangible book value (deficit) per share represents the amount of our total tangible assets less our total liabilities, divided by the number of shares of our common stock outstanding as of December 31, 2025, after giving effect to (i) the Preferred Stock Conversion and (ii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the completion of this offering. Pro forma net tangible book value (deficit) per share represents pro forma net tangible book value (deficit) divided by the total number of shares outstanding (which excludes 486,114 shares of unvested restricted common stock) as of December 31, 2025, after giving effect to the pro forma adjustments described above.

After giving further effect to the issuance and sale of shares of common stock that we are offering at the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value (deficit) as of December 31, 2025 would have been \$ million, or \$ per share. This amount represents an immediate increase in pro forma net tangible book value (deficit) of \$ per share to our existing stockholders and an immediate dilution in pro forma net tangible book value (deficit) of \$ per share to new investors purchasing shares of common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value (deficit) per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Assumed initial public offering price per share	\$
Historical net tangible book value (deficit) per share as of December 31, 2025	\$(12.24)
Increase per share as of December 31, 2025 attributable to the pro forma adjustment described above	<u> </u>
Pro forma net tangible book value (deficit) per share as of December 31, 2025	
Increase in pro forma as adjusted net tangible book value (deficit) per share attributable to new investors participating in this offering	<u> </u>
Pro forma as adjusted net tangible book value (deficit) per share after this offering	
Dilution per share to new investors participating in this offering	<u><u>\$</u></u>

The dilution information discussed above is illustrative only and may change based on the actual initial public offering price and other terms of this offering. Each \$1.00 increase or decrease, as applicable, in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease, as applicable, the pro forma as adjusted net

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tangible book value per share after this offering by \$, and dilution per share to new investors purchasing common stock in this offering by \$, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease, as applicable, of 1.0 million shares in the number of shares of common stock offered by us would increase or decrease, as applicable, our pro forma as adjusted net tangible book value (deficit) per share after this offering by \$ per share, in each case, and increase or decrease, as applicable, the dilution to investors participating in this offering by \$ per share, assuming no change in the assumed initial public offering price, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares of our common stock in full, our pro forma as adjusted net tangible book value (deficit) after the offering would be \$ per share, representing an immediate increase in pro forma as adjusted net tangible book value (deficit) of \$ per share to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value (deficit) of \$ per share to new investors, in each case assuming an initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes on the pro forma as adjusted basis described above, as of December 31, 2025, the total number of shares of common stock purchased from us on an as-converted basis, the total consideration paid or to be paid to us, and the average price per share paid by existing stockholders or to be paid by new investors in this offering, based on the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. New investors purchasing shares of our common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percentage	Amount	Percentage	
Existing stockholders		%	\$	%	\$
New investors purchasing shares in this offering					
Total		100.0%	\$	100.0%	\$

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters exercise their option to purchase additional shares of common stock from us in full, our existing stockholders would own %, and new investors purchasing shares of our common stock in this offering would own %, of the total number of shares of our common stock outstanding immediately after the completion of this offering.

The number of shares of our common stock that will be outstanding after this offering is based on 121,586,122 shares outstanding as of December 31, 2025 (which excludes 486,114 shares of unvested restricted common stock), after giving effect to the Preferred Stock Conversion, and excludes:

- 27,633,144 shares of common stock issuable upon exercise of outstanding stock options as of December 31, 2025, which includes 718,500 performance-based awards that have not yet been deemed granted for accounting purposes, under our 2024 Plan, with a weighted-average exercise price of \$1.52 per share, and 3,023,510 shares of common stock issuable upon exercise of outstanding stock options granted after December 31, 2025 pursuant to our 2024 Plan, with a weighted-average exercise price of \$3.28 per share;

- 4,722,667 shares of common stock reserved for future issuance as of December 31, 2025 under the 2024 Plan, which will cease to be available for issuance at the time that our 2026 Plan, becomes effective;
- shares of our common stock issuable upon the exercise or grant of the IPO Grants, equal to approximately 12.5% of the number of shares of our common stock to be outstanding upon the closing of this offering calculated on a fully diluted basis (after giving effect to the number of shares of our common stock to be sold in this offering, not including the exercise in full of the underwriters' option to purchase additional shares), to be granted to an executive officer and a director under the 2026 Plan; see the sections titled "Executive Compensation—Narrative Disclosure to the 2025 Summary Compensation Table—Equity Incentive Compensation" and "Director Compensation" for more information on such grants, including a description of how the number of shares issuable pursuant to such grants will be determined;
- shares of our common stock that will become available for future issuance under our 2026 Plan, including shares reserved for the IPO Grants, which will become effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2026 Plan and any shares underlying outstanding stock awards granted under the 2024 Plan that expire or are repurchased, forfeited, cancelled, or withheld; and
- shares of common stock reserved for future issuance under our ESPP, which will become effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the ESPP.

To the extent any outstanding options are exercised, new options or other equity awards are issued under our equity incentive plans, or we issue additional shares of common stock in the future, there will be further dilution to new investors. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our audited consolidated financial statements and related notes and other financial information included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon our current plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, strategies, objectives, expectations, intentions, and beliefs. Financial results through April 8, 2024, which are included in the consolidated financial statements for the year ended December 31, 2024, have been prepared on a "carve-out" basis and our full year results for the year ended December 31, 2024 are not necessarily indicative of results that may be expected in the future, nor are our other historical results necessarily indicative of the results that may be expected for any period in the future. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements." Unless otherwise indicated, all references in this section to "Seaport," the "company," "we," "our," "us," or similar terms refer to Seaport Therapeutics, Inc. and its wholly owned subsidiaries, or either or all of them, before the Asset Transfer (as defined below) and after the Asset Transfer, as applicable and as the context may require.

Overview

We are a clinical-stage therapeutics company focused on inventing and developing new medicines for patients with depression, anxiety, and other debilitating neuropsychiatric disorders. Through our differentiated approach, we identify clinically validated mechanisms with established efficacy and safety profiles which had historically been limited by high first-pass metabolism, low bioavailability, and/or side effects. We apply our proprietary Glyph platform to overcome those limitations and invent innovative oral therapies. Our lead product candidate, GlyphAllo (SPT-300 or Glyph Allopregnanolone), is a novel, Glyphed oral prodrug of allopregnanolone, an endogenous molecule that has been clinically validated in two third-party trials in the United States for the treatment of postpartum depression, or PPD, a form of major depressive disorder, or MDD, as a rapidly acting antidepressant with anxiolytic and sleep-promoting effects. We have initiated the Phase 2b BUOY-1 trial in patients with MDD with or without anxious distress and anticipate topline data in . Our second product candidate, GlyphAgo (SPT-320 or Glyph Agomelatine), is a novel, Glyphed oral prodrug of agomelatine, a clinically validated anxiolytic and antidepressant that is approved for the treatment of generalized anxiety disorder, or GAD, in Australia and MDD in Australia and the European Union, or EU. We have initiated a proof-of-concept Phase 1 trial for the treatment of GAD and expect topline data in . We are also advancing Glyph2BLSD (SPT-348 or Glyph 2-bromo-LSD), a novel, Glyphed oral prodrug of the non-hallucinogenic LSD analog 2-bromo-LSD, in preclinical studies for depressive disorders, including treatment-resistant depression, or TRD, post-traumatic stress disorder, or PTSD, and headache disorders.

We were incorporated in April 2024 by PureTech LYT Inc., or PureTech LYT, as our sole stockholder, and upon formation we entered into an asset transfer agreement, as amended in December 2025, or the Asset Transfer Agreement, with PureTech LYT and PureTech Health LLC, or PureTech Health, pursuant to which PureTech Health and PureTech LYT agreed to contribute, convey, assign, transfer, and deliver to us all of its right, title, and interest in, to, and under the assets related to its Glyph technology or products, including the Monash License Agreement (as defined below), subject to the terms set forth in the Asset Transfer Agreement or the Asset Transfer. See subsection titled "Asset Transfer Agreement and Financings" below. Our historical consolidated financial statements up to April 8, 2024, or the Asset Transfer Date, have been prepared on a "carve-out" basis and are derived from the financial statements of PureTech Health plc and its consolidated subsidiaries, or PureTech, to represent our financial position and performance as if we had existed on a standalone basis. Prior to the Asset Transfer, our combined financial statements included the assets, liabilities, and expenses of PureTech

that management determined were specifically identifiable to us and our related programs, as well as indirect costs that were not specifically identifiable to us or our related programs but were considered necessary to operate as a standalone company. Management believes the assumptions underlying our carve-out financial statements are reasonable. Nevertheless, the carve-out financial statements may not include all of the actual expenses that would have been incurred, and may not reflect our results of operations, financial position, and cash flows, had we operated as a standalone company for the period prior to the Asset Transfer. Effective April 8, 2024, our financial statements are presented on a consolidated basis, as PureTech Health LLC and PureTech LYT completed the transfer of the Glyph platform business, or the Seaport Business, on such date. The audited financial statements presented, including our historical results prior to April 8, 2024, are referred to as the consolidated financial statements. Our consolidated financial statements are presented in conformity with accounting principles generally accepted in the U.S., or GAAP. For additional information on the preparation and basis of presentation of the consolidated financial statements, see Note 1—Nature of Business and Basis of Presentation, in the notes to the consolidated financial statements appearing elsewhere in this prospectus.

We have devoted substantially all of our efforts to organizing and staffing our company, business planning, research and development activities, building and strengthening our intellectual property portfolio, and providing general and administrative support for these operations. Subsequent to the Asset Transfer Date and to date, we have funded our operations with proceeds from the issuance and sale of convertible preferred stock, including the \$100.1 million gross proceeds we received in April 2024 from our Series A-2 Financing (as defined below) and the \$226.0 million gross proceeds we received in October 2024 from our Series B Financing (as defined below).

We have incurred significant operating losses since the inception of our business and expect to continue to generate operating losses for the foreseeable future. Our ability to generate product revenue sufficient to achieve profitability will depend on the successful development and eventual commercialization of any product candidates we may develop. During the years ended December 31, 2025 and 2024, we had a net loss of \$74.9 million and \$46.9 million, respectively. As of December 31, 2025, we had an accumulated deficit of \$114.1 million. We expect our expenses and operating losses will increase substantially as we:

- advance our product candidates through preclinical and clinical development, including advancing GlyphAllo and GlyphAgo through later-stage clinical trials, and other candidates through discovery and clinical and preclinical stages;
- seek regulatory approvals for our product candidates that successfully complete clinical trials from the U.S. Food and Drug Administration, or the FDA, and/or other foreign comparable regulatory authorities;
- hire additional clinical, quality control, medical, scientific, and other technical personnel to support the clinical development of our product candidates;
- expand our internal capabilities to support clinical-stage development;
- increase our headcount as we expand our research and development organization, and pre-commercial planning activities;
- undertake any activities to establish sales, marketing, and distribution capabilities in preparation for commercialization, as applicable, including hiring additional personnel to support such operations;
- seek to identify, acquire, and develop additional product candidates where we can leverage our Glyph platform, including through business development efforts to invest in or in-license other technologies or product candidates;
- maintain, expand, and protect our intellectual property portfolio;
- experience heightened regulatory scrutiny;
- make milestone, royalty, or other payments due under the Asset Transfer Agreement and/or the Monash License Agreement (as defined below), and any future in-license or collaboration agreements with third parties; and
- incur additional legal, accounting, and other expenses associated with operating as a public company.

Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our preclinical studies and planned clinical trials and our expenditures on other research and development activities.

We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our potential future product candidates, which may not be for at least the next several years, if ever. If we obtain regulatory approval for any of our existing or future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. Accordingly, until such time as we can generate significant revenue from our existing or future product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses, and other similar arrangements. See the section titled “Liquidity and Capital Resources.” However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our inability to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market potential future product candidates that we would otherwise prefer to develop and market ourselves.

We believe, based on our current operating plan, that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements through . See sections titled “Use of Proceeds”, “Liquidity and Capital Resources”, and “Risk Factors—Risks Related to Our Limited Operating History, Financial Condition and Need for Additional Capital.”

Asset Transfer Agreement and Financings

We were incorporated in April 2024 by PureTech LYT, as our sole stockholder, and upon formation issued 1,000 shares of our common stock to PureTech LYT. In April 2024, we entered into an Asset Transfer Agreement, or the Asset Transfer Agreement, with PureTech Health LLC, or PureTech Health and PureTech LYT Inc., or PureTech LYT, pursuant to which PureTech Health and PureTech LYT agreed to contribute, convey, assign, transfer, and deliver to us all of PureTech Health’s and PureTech LYT’s right, title, and interest in, to, and under the assets related to its Glyph technology or products, including the Monash License Agreement, subject to the terms set forth in the Asset Transfer Agreement. In exchange, we issued 40,000,000 shares of our Series A-1 convertible preferred stock and 949,000 shares of our common stock to PureTech LYT.

In connection with the Asset Transfer Agreement, we have agreed to make milestone payments of up to an aggregate of \$10.0 million for the first product covered by assets transferred through the Asset Transfer Agreement, or the Seaport Glyph Product, of \$2.0 million for the first patient dosed in the first phase 3 clinical trial, \$4.0 million for the first commercial sale in the United States, \$2.0 million for the first commercial sale in a major European market, and \$2.0 million for the first commercial sale in Japan, and for each subsequent Seaport Glyph Product, we have agreed to make milestone payments of \$1.0 million for the first patient dosed in the first phase 3 clinical trial, \$2.0 million for the first commercial sale in the United States, \$1.0 million for the first commercial sale in a major European market, and \$1.0 million for the first commercial sale in Japan. In addition, we are obligated to pay royalties between 3% and 5% on the annual net sales of each Seaport Glyph Product and a percentage of net income generated by us from third parties on any products licensed under the Glyph intellectual property which was transferred to us as part of the Asset Transfer Agreement. The royalty term will expire on a country-by-country basis as to each Seaport Glyph Product on the later of the ten year anniversary of the first commercial sale of such Seaport Glyph Product in such country or the date on which the last valid claim of patent rights of such Seaport Glyph Product expires in such country. For additional information, see “Business—Agreements—Asset Transfer Agreement with PureTech.”

Concurrently, upon entry into the Asset Transfer Agreement, we entered into a stock purchase agreement with PureTech LYT and other third-party investors, pursuant to which we issued 26,342,102 shares of our Series A-2 convertible preferred stock, or the Series A Financing, of which 8,421,052 shares were issued and sold to PureTech LYT, at a purchase price of \$3.80 per share for gross aggregate proceeds of \$100.1 million. PureTech LYT remained a majority investor of Seaport, until the completion of our Series B convertible preferred stock financing, or the Series B Financing, in October 2024, upon which we issued and sold an aggregate amount of 47,578,934 shares of its Series B convertible preferred stock, of which 3,031,578 shares were issued to PureTech LYT, and an aggregate of 494,734 shares issued to certain of our management and Board of Directors, or the Board, at a purchase price of \$4.75 per share, for gross aggregate proceeds of \$226.0 million.

License and Collaboration Agreements

Monash License Agreement

In April 2024, PureTech Health exclusively assigned to us, and we assumed, all rights and obligations under a license agreement entered into in August 2017 between PureTech Health and Monash University, or the Original License Agreement. In March 2025, we entered into the Monash License Agreement and amended and restated license agreement with Monash University, which amended and restated the Original License Agreement, or the Monash License Agreement. Pursuant to the Monash License Agreement, Monash University has granted us (i) a worldwide, exclusive, sublicensable license under certain Monash University intellectual property rights, including patent rights related to the Glyph platform, or the Licensed Patents, know-how, and intellectual property stemming from joint research and development activities, for the purpose of developing and commercializing products in all fields with one exception, (ii) a worldwide, non-exclusive, sublicensable license under certain background technology and certain other intellectual property strictly to the extent necessary to exercise the license described in subclause (i) above, and (iii) a first right and an exclusive option to obtain an exclusive license to any invention generated by Monash University outside of the Licensed Patents and pertaining to certain prodrug technology. Additionally, we and Monash University agreed to collaborate in conducting research and development activities.

Under the Monash License Agreement, we have agreed to use reasonable commercial endeavors to (i) develop at least one Licensed Product (as defined therein), (ii) seek regulatory approval for at least one Licensed Product, and (iii) after receipt of such regulatory approval in the United States or Europe, promote and develop the sale of at least one Licensed Product in such territory. Monash University has agreed to provide reasonable technical assistance and advice based on Monash University's know-how relating to the technology licensed under the Monash License Agreement. We have granted Monash University a non-exclusive, perpetual, royalty-free license under the Licensed Patents, related know-how, and intellectual property stemming from joint research and development activities solely for academic, teaching, and non-commercial collaborative research uses, which includes the right to sublicense for non-commercial collaborative research to other academic institutions or non-commercial research entities.

For additional discussion around the obligations under the Monash License Agreement, see the subsection titled “—Contractual Obligations and Commitments” and “Business—Agreements—Monash University Exclusive License Agreement” included elsewhere in this prospectus

Components of Results of Operations

Historically, our operations were managed as part of PureTech prior to the Asset Transfer Date. Accordingly, certain shared costs have been allocated to us and reflected as expenses in our standalone consolidated financial statements, as described in greater detail in the notes to our consolidated financial statements appearing elsewhere in this prospectus. We considered the allocation methodologies used to be a reasonable and appropriate reflection of the historical PureTech expenses attributable to us for purposes of our standalone consolidated financial statements. The expenses reflected in our consolidated financial statements

may not be indicative of expenses that will be incurred by us in the future. The following discussion summarizes the key factors we believe are necessary for an understanding of our consolidated financial statements.

Revenue

To date, we have not recognized any revenue and do not expect to generate any revenue from the sale of products in the near term, if at all. If our development efforts for our current or potential future product candidates are successful and result in regulatory approval or if we enter into additional license or collaboration agreements with third parties, we may generate revenue in the future from product sales, payments from such license or collaboration agreements, or any combination thereof. However, there can be no assurance as to when we will generate such revenue, if at all.

Operating Expenses

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of costs incurred in connection with the discovery, non-clinical development, and clinical development of our lead product candidates and potential future product candidates. R&D expenses include direct costs specifically attributable to our programs including external fees to conduct certain clinical and non-clinical research and development activities, preclinical and early discovery assets, such as costs paid to contract research and manufacturing organizations, consulting fees, laboratory services and supplies, and costs incurred in connection with the Monash License Agreement, as well as indirect costs that are not directly attributable to a specific program such as personnel related expenses, including stock-based compensation, facility expenses, depreciation, and information technology costs. Prior to the Asset Transfer Date, R&D expenses also included allocated indirect R&D costs from PureTech, including personnel related expenses, stock-based compensation, facility expenses, depreciation, and information technology costs.

We expense research and development costs as incurred. We recognize direct development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors or our estimate of the level of service that has been performed at each reporting date. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our consolidated financial statements as prepaid or accrued research and development expenses.

Due to the inherently unpredictable nature of preclinical and clinical development, we do not allocate all of our internal research and development expenses on a program-by-program basis as these expenses primarily relate to personnel and other overhead costs that are deployed across multiple programs under development. Our research and development expenses also include external costs, which we do track on a program-by-program basis following the program's nomination as a product candidate. We began tracking such external costs upon the nomination for GlyphAllo in 2020, GlyphAgo at the end of our fiscal year ended December 31, 2023 and Glyph2BLSD at the end of our fiscal year ended December 31, 2024.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we advance our current and any future product candidates into and through clinical development and as we continue to develop additional product candidates.

General and Administrative Expenses

General and administrative expenses consist of salaries and personnel-related costs, including stock-based compensation expense, for our personnel in executive, business development, legal, finance and accounting, human resources and other administrative functions, consulting fees, facility costs not otherwise included in R&D expenses, fees paid for accounting and tax services, insurance expenses, legal costs consisting of general

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corporate legal fees and patent legal fees, and allocated expenses from PureTech prior to our formation in April 2024. Allocated PureTech expenses included employee-related costs, including salaries, bonuses, benefits, and stock-based compensation expenses for PureTech personnel and our personnel in executive, finance, accounting, human resources, and other administrative functions. Allocated expenses from PureTech also included corporate overhead expenses and shared costs, such as general management and executive oversight, facilities, compliance, human resources, legal, including intellectual property costs, finance, risk management, and information technology all of which supported the operations of PureTech as a whole.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support the expansion of our business, particularly in support of development of product candidates and our continued research and clinical development activities. We will also incur significant costs associated with being a public company, including increased accounting, audit, legal, regulatory, compliance, and director and officer insurance costs, as well as expenses related to services associated with maintaining compliance with the requirements of the Nasdaq Stock Market, the Securities and Exchange Commission, and investor relations costs.

Through the completion of this offering, we continued to grant additional equity awards to certain individuals to maintain in total an aggregate of 12.5% ownership on a fully diluted basis as specified by underlying agreements. Upon the completion of the offering, we will issue equity awards to certain individuals to maintain an aggregate of 12.5% ownership and we will recognize total stock-based compensation expense of \$ over the remaining vesting period. In addition, certain individuals have accelerated vesting associated with the successful completion of an IPO which will result in equity awards vesting and recognition of stock-based compensation expense of .

Other income (expense), Net

Other income (expense), net consists primarily of interest income earned on our investments and cash and cash equivalents, research and development tax credits from the Australian government's tax incentive program, and realized and unrealized foreign currency gains and losses.

Provision for Income Taxes

Provision for income taxes consists of United States federal and state income taxes in jurisdictions in which we conduct business and foreign income taxes related to our Australian subsidiary. The provision for income taxes is based on our taxable income. Our loss before income taxes is adjusted for permanent and temporary tax differences, primarily related to capitalized non-U.S. research and development expenses, resulting in taxable income or loss. We recorded a full valuation allowance of our U.S. deferred tax asset position as of December 31, 2025 and 2024 as we believe it was more likely than not that we would not be able to utilize our deferred tax assets.

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Results of Operations

Comparison of the years ended December 31, 2025 and 2024

The following table summarizes our results of operations (in thousands):

	Year Ended December 31		
	2025	2024	\$ Change
Operating expenses:			
Research and development (including stock-based compensation expense of \$2.3 million and \$0.7 million for 2025 and 2024, respectively)	\$ 66,313	\$ 25,070	\$ 41,243
General and administrative (including stock-based compensation expense of \$4.6 million and \$15.2 million for 2025 and 2024, respectively)	20,981	27,346	(6,365)
Total operating expenses	87,294	52,416	34,878
Loss from operations	(87,294)	(52,416)	(34,878)
Other income (expense), net			
Other income, net	13,186	5,537	7,649
Total other income, net	13,186	5,537	7,649
Loss before income taxes	(74,108)	(46,879)	(27,229)
Income tax provision	773	—	773
Net loss and comprehensive loss	<u>\$ (74,881)</u>	<u>\$ (46,879)</u>	<u>\$ (28,002)</u>

Research and Development Expenses

The following table summarizes our research and development expenses (in thousands):

	Year Ended December 31,		
	2025	2024	\$ Change
Direct costs:			
GlyphAllo	\$25,858	\$ 7,396	\$18,462
GlyphAgo	13,546	5,204	8,342
Glyph2BLSD	6,437	—	6,437
Preclinical and early discovery assets	3,856	5,903	(2,047)
Indirect costs:			
Employee compensation (excluding stock-based compensation)	12,557	5,022	7,535
Stock-based compensation	2,272	677	1,595
Other research and development	1,787	868	919
Total research and development expenses	<u>\$66,313</u>	<u>\$25,070</u>	<u>\$41,243</u>

Research and development expenses increased by \$41.2 million from \$25.1 million for the year ended December 31, 2024 to \$66.3 million for the year ended December 31, 2025. The increase in research and development expenses was primarily attributable to:

- \$18.5 million of increased costs associated with our lead program GlyphAllo, which was primarily due to commencing our Phase 2b BUOY-1 trial in July 2025;
- \$8.3 million of increased costs associated with our GlyphAgo program, which was primarily due to commencing our Phase 1 trial in July 2025;

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- \$6.4 million of increased costs associated with our Glyph2BLSD program, which was nominated as a development candidate in late 2024;
- \$7.5 million of increased costs associated with employee compensation primarily due to increased headcount to support our operations;
- \$1.6 million of increased costs associated with stock-based compensation costs primarily due to additional equity grants under our Plan; and
- \$0.9 million of increased costs associated with other research and development expenses primarily due to increased facility costs associated with our lab space lease, which commenced in January 2025;

These increases were partially offset by:

- \$2.0 million of decreased costs associated with preclinical and other early discovery assets as Glyph2BLSD was nominated as a development candidate in late 2024.

General and Administrative Expenses

The following table summarizes our general and administrative expenses (in thousands):

	Year Ended December 31,		\$ Change
	2025	2024	
Stock-based compensation	\$ 4,611	\$ 15,181	\$ (10,570)
Employee compensation (excluding stock-based compensation)	8,189	5,480	2,709
Professional fees	5,039	5,158	(119)
Facilities, depreciation, IT, and other	3,142	1,527	1,615
Total general and administrative expenses	<u>\$20,981</u>	<u>\$ 27,346</u>	<u>\$ (6,365)</u>

General and administrative expenses decreased by \$6.4 million from \$27.3 million for the year ended December 31, 2024 to \$21.0 million for the year ended December 31, 2025. The decrease in general and administrative expenses was primarily attributable to:

- \$10.6 million of decreased stock-based compensation expense primarily due to a one-time charge recorded during the year ended December 31, 2024 due to accelerated vesting of equity awards related to the closing of our Series B Financing;

These decreases were partially offset by:

- \$2.7 million of increased employee compensation, excluding stock-based compensation due to increased headcount to support our operations;
- \$1.6 million of increased facilities, depreciation, IT, and other costs primarily due to increased facility costs associated with our corporate office lease which commenced in December 2024.

Other Income, Net

Other income, net increased by \$7.6 million from \$5.5 million for the year ended December 31, 2024 to \$13.2 million for the year ended December 31, 2025. The increase in other income, net was primarily attributed to a \$5.9 million increase in interest income on our investments and cash equivalents due to the amount of funds invested in interest bearing accounts and a \$1.9 million increase in our research and development tax credit as a result of qualifying research and development spend in Australia.

Liquidity and Capital Resources

Sources of Liquidity

The primary source of liquidity for our business prior to our formation was funding by PureTech of the expenses allocated to the Seaport Business. Prior to the Asset Transfer Date, transfers of cash to and from PureTech have been reflected in net transfers from PureTech in the statement of cash flows and net parent investment in the statement of convertible preferred stock and stockholders' deficit. Since the Asset Transfer Date, we have funded our operations with the aggregate gross proceeds of \$326.1 million from the Series A and Series B Financings.

Cash Flows

The following table provides information regarding our cash flows for the period presented (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	\$ (77,942)	\$ (29,629)
Net cash used in investing activities	(184,245)	(113)
Net cash (used in) provided by financing activities	(873)	339,295
Effect of exchange rate changes on cash and cash equivalents ⁽¹⁾	3	—
Net (decrease) increase in cash, cash equivalents, and restricted cash	<u>\$(263,057)</u>	<u>\$ 309,553</u>

- (1) The balance sheet is affected by spot exchange rates used to translate local currency amounts into U.S. dollars. In accordance with U.S. GAAP, we have eliminated the effect of foreign currency throughout our cash flow statement, except for its effect on our cash and cash equivalents.

Net Cash Used in Operating Activities

During the year ended December 31, 2025 net cash used in operating activities was \$77.9 million, compared to \$29.6 million for the year ended December 31, 2024. Cash used in operating activities increased by \$48.3 million primarily due to increased operating expenses as we continue to advance our product candidates through preclinical and clinical developments.

Net Cash Used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2025 was \$184.2 million, compared to net cash used in investing activities of \$0.1 million for the year ended December 31, 2024. Cash used in investing activities increased by \$184.1 million due to the purchases and maturities of U.S. treasuries during fiscal year 2025.

Net Cash (Used In) Provided by Financing Activities

Net cash used in financing activities for the year ended December 31, 2025 was \$0.9 million, primarily due to payment of deferred offering costs, as compared to cash provided of \$339.3 million for the year ended December 31, 2024. Cash provided by financing activities decreased by \$340.2 million due to the absence of financing transactions in fiscal year 2025. Financing activities during the year ended December 31, 2024 included \$100.1 million of gross proceeds received in April 2024 from our Series A financing and \$226.0 million of gross proceeds received in October 2024 from our Series B financing, partially offset by \$0.8 million of issuance cost payments. In addition, PureTech managed our cash and financing arrangements through April 8, 2024, and financing activities for the year ended December 31, 2024 included \$14.0 million of net transfers from PureTech.

Future Funding Requirements

As of December 31, 2025, we had cash and cash equivalents, and investments of \$233.7 million. We expect that our cash and cash equivalents as of December 31, 2025, will be sufficient to fund our operating expenses and capital expenditure requirements through at least 12 months from the date our consolidated financial statements were available to be issued. We believe that the net proceeds from this offering, together with our existing cash, cash equivalents, and investments will enable us to fund our operations and capital expenditure requirements through . We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Due to the inherently unpredictable nature of preclinical and clinical development and given the early stage of our programs and product candidates, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain any marketing approval, and commercialize our products, if and when approved. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations. In addition, we cannot forecast which products, if approved, may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. We will need to raise substantial additional capital in the future.

Our primary uses of capital are to fund research and development activities, compensation and related expenses, and general overhead costs. We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance our current and future product candidates through discovery, preclinical studies, and clinical trials.

Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including:

- the scope, timing, progress, costs, and results of discovery, preclinical development and clinical trials for our current or future product candidates and effectiveness of our Glyph platform;
- the number of clinical trials required for regulatory approval of our current or future product candidates;
- the costs, timing, and outcome of regulatory review of any of our current or future product candidates;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any milestones, royalties, or other payments due in connection with our acquisitions and licenses, as applicable;
- the cost of manufacturing clinical and commercial supplies of our current or future product candidates;
- the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire, and retain skilled personnel;
- the costs of operating as a public company;

- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of macroeconomic trends including inflation, tariffs, and fluctuating interest rates;
- addressing any potential supply chain interruptions or delays;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products, and technologies.

Until such time, if ever, that we can generate substantial product revenue, we expect to finance our operations through a combination of public and private equity offerings, debt and royalty financings, or other sources of capital, which may include additional collaborations with other companies, or licensing arrangements with third parties, or other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt or royalty financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures, or declaring dividends. If we raise additional funds through additional collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional capital or obtain adequate funding when needed or on acceptable terms, we may be required to delay, scale back, or discontinue our research, 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.

Contractual Obligations and Commitments

Asset Transfer Agreement and Transition Services Agreement with PureTech

As part of the Asset Transfer Agreement, we have agreed to contingent payments to PureTech Health upon successful development and commercialization of products developed using the Glyph platform. For more information, refer to the subsection titled “Asset Transfer Agreement and Financings” above.

In connection with entry into the Asset Transfer Agreement, we also entered into a Transition Services Agreement, or the TSA, with PureTech Health and PureTech LYT, or the PureTech TSA Parties, pursuant to which the PureTech TSA Parties agreed to provide us with certain services and resources related to corporate functions for an initial 12 month period following the Asset Transfer Date, subject to extension. Under the TSA, we were obligated to pay to the PureTech TSA Parties \$0.5 million upon closing of the Asset Transfer. We further agreed to pay the PureTech TSA Parties monthly fees for services that were mutually agreed upon by us and the PureTech TSA Parties as provided under the TSA, which were based on the PureTech TSA Parties’ cost of providing the services, throughout the term of the TSA. In 2025, the TSA was amended to extend through July 2026 to provide ad-hoc support as needed; however, the services to be provided under the amended TSA are expected to be de minimis. For more information, refer to the subsection titled “Transition From PureTech and Costs to Operate as an Independent Company.”

Monash License Agreement

Under the Monash License Agreement, we have agreed to use reasonable commercial endeavors to (i) develop at least one Licensed Product, (ii) seek regulatory approval for at least one Licensed Product, and (iii) after receipt of such regulatory approval in the United States or Europe, promote and develop the sale of at least one Licensed Product in such territory. Monash University agrees to provide reasonable technical assistance and advice based on Monash University’s know-how relating to the technology licensed under the Monash License Agreement.

As consideration for the licenses granted by Monash University, we are required to pay Monash University: (i) low-single digit royalties with a rate based on net sales per calendar year (subject to certain reductions); (ii) a low-double digit percentage (within the range of 5-15%) of any net income received under a sublicense (subject to a license payment stacking reduction) with the percentage varying based on the development stage of the licensed products at the time the sublicense is granted during the term of the Monash License Agreement; (iii) an agreed upon research funding amount to progress mutually agreed research and development or commercialization activities; (iv) a mid-five-figure annual maintenance fee during the term of the agreement commencing on the third anniversary of the execution date of the Original License Agreement until the first commercial sale of a Licensed Product creditable against net income sharing, royalties, and milestone payments; (v) milestone payments in the event of successful development milestones of up to \$1.075 million per Licensed Product for the first three Licensed Products; and (vi) milestone payments in the event of successful commercial milestones of up to \$7.25 million per Licensed Product for the first three Licensed Products. We are also obligated to (a) pay all costs incurred for the prosecution and maintenance of the Licensed Patents and patent filings stemming from collaboration activities and (b) reimburse Monash University for all patent prosecution costs of the Licensed Patents prior to the execution date of the Original License Agreement.

The Monash License Agreement commenced on the execution date of the Original License Agreement and will expire seven years after the last of the Licensed Patents expires, unless terminated earlier. Either party may terminate for due cause, including for material breach and bankruptcy. Monash University may terminate if we fail to meet our diligence requirements. Either party may terminate the Monash License Agreement if we determine that the activities are no longer commercially viable.

As of December 31, 2025, the first two development milestones for a total of \$0.2 million were achieved and paid by PureTech as they occurred prior to our formation, and we have paid the third development milestone of \$0.1 million as well as annual maintenance fees. No other milestones have occurred or have been paid under the Monash License Agreement as of December 31, 2025.

For additional information see the section titled “Business—Agreements—Monash License Agreement”, included elsewhere in this prospectus.

Purchase and Other Obligations

We enter into contracts in the normal course of business with contract research organizations, or CROs, and other third-party vendors for preclinical and commercial supply manufacturing, support for pre-commercial activities, research, and development activities, and other services and products for our operations. These contracts are generally cancelable upon written notice. Payments due upon cancellation consist generally of payments for services provided and expenses incurred up to the date of cancellation.

Lease Obligations

In November 2024, we entered into a lease agreement with a third party for our corporate office space located in Boston, Massachusetts. The lease commenced in December 2024 and has an initial term of approximately six years, expiring in October 2030. The aggregate payments under the full lease total approximately \$6.1 million, which will be recognized over the term of the lease.

In December 2024, we entered into a laboratory license with a third party for lab space located in Boston, Massachusetts. The license commenced in January 2025 and is for an initial term of 24 months from the commencement date. The aggregate payments under the full license total approximately \$1.2 million.

For additional information on our contractual obligation and commitments please see Note 8—Monash License Agreement and Note 14—Commitments and Contingencies, to our consolidated financial statements included elsewhere in this prospectus.

Critical Accounting Estimates and Significant Judgments

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the related disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and judgments on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included elsewhere in this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. This process involves reviewing open contracts and purchase orders, communicating with internal personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We periodically confirm the accuracy of our estimates with our service providers and make adjustments if necessary. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. The financial terms of agreements with these service providers are subject to negotiation, vary from contract-to-contract and may result in uneven payment flows. In circumstances where amounts have been paid in excess of costs incurred, we record a prepaid expense.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized that are expected to vest over the requisite service period of the awards, which is usually the vesting period of the respective award. For stock-based awards with service-based vesting conditions, we recognize compensation expense on a straight-line basis. For stock-based awards with performance-based vesting conditions, we recognize compensation expense over the requisite service period using the accelerated attribution method, commencing when achievement of the performance condition becomes probable. Subsequent to our formation and the Asset Transfer, we estimated the fair value of stock option awards using the Black-Scholes option pricing model. Estimating the fair value of equity awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of variables, including the risk-free interest rate, the expected stock price volatility, the expected term of stock options, the expected dividend yield and the fair value of the underlying common stock on the date of grant. These inputs are subjective and generally require significant analysis and judgment to develop. Forfeitures are accounted for as they occur. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. The fair value of time-vesting restricted stock unit awards is equal to the common stock price on the date of grant.

The stock-based compensation expense we recognized in our financial statements prior to our formation and the Asset Transfer Date, and separate from our 2024 Plan, has been determined based on the fair value of the underlying award as determined by PureTech, the total expense calculated for the period under GAAP, and the relative amount allocated to Seaport associated with each employee. The assumptions used in the Black-Scholes option pricing model for these awards were those of PureTech, including the fair value of PureTech's common stock, expected volatility, expected term, expected dividend yield, and risk-free interest rates as of the grant date. Seaport employees continued to vest in their PureTech equity awards up until the completion of our Series B Financing in October 2024 at which time PureTech no longer maintained a controlling interest.

Determination of the Fair Value of Common Stock

As there has been no public market for our common stock subsequent to the Asset Transfer and to date, the estimated fair value of our common stock has been determined by our Board, as of the date of each option grant with input from management, considering our most recently available third-party valuations of common stock, and our Board's assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our common stock valuation was prepared using a market approach to estimate our enterprise value and either an option pricing method, OPM, or a hybrid method to allocate value to the common stock. The OPM treats common stock and convertible preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the convertible preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. The hybrid method is a probability-weighted expected return method, or PWERM, where the equity value in one or more of the scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of the future value of our common stock, assuming various outcomes. The value of a share of common stock is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. In each case, a discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

These third-party valuations were performed at various dates, which resulted in valuations of our common stock of \$2.35 per share as of October 18, 2024, \$2.53 per share as of July 16, 2025 and \$3.28 per share as of January 14, 2026. Given the absence of a public trading market, our Board, with input from management, considered the results of these third-party valuations in addition to numerous objective and subjective factors to determine the fair value of common stock. The factors included, but were not limited to:

- the prices at which we sold convertible preferred stock to new and existing investors and the rights and preferences of the convertible preferred stock relative to our common stock at the time of each grant;
- our ability to raise future financings;
- the progress of our research and development efforts, including the status of clinical development for our product candidates;
- the lack of liquidity of our equity as a private company;
- our stage of development and business strategy and the material risks related to our business and industry;
- the achievement of enterprise milestones, including entering into license agreements;

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- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- any external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- the likelihood of achieving a liquidity event for the holders of our convertible preferred stock and holders of our common stock, such as an initial public offering, or a sale of our company, given prevailing market conditions; and
- the analysis of initial public offerings and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations were highly complex and subjective and represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different. Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our Board to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

The following table summarizes by grant date the number of shares subject to awards granted under our equity incentive plan from January 1, 2025 through the date of this prospectus, the per share exercise price of the awards and weighted average grant date fair value on each grant date:

<u>Grant Date</u>	<u>Type of Award</u>	<u>Number of Shares Subject to Award</u>	<u>Per Share Exercise of Award</u>	<u>Weighted Average Grant Date Fair Value</u>
January 26, 2025	Stock Option	270,940	\$ 2.35	\$ 1.81
February 25, 2025	Stock Option	641,500	\$ 2.35	\$ 1.80
March 3, 2025	Stock Option	241,966	\$ 2.35	\$ 1.79
March 25, 2025	Stock Option	391,000	\$ 2.35	\$ 1.81
May 15, 2025	Stock Option	395,000	\$ 2.35	\$ 1.81
June 11, 2025	Stock Option	482,000	\$ 2.35	\$ 1.80
October 7, 2025	Stock Option	415,000	\$ 2.53	\$ 1.94
January 27, 2026	Stock Option	909,325	\$ 3.28	\$ 2.51
February 24, 2026	Stock Option	2,114,185	\$ 3.28	\$ 2.51

In connection with this offering, we plan to grant equity awards to executive officers and directors. For additional information, see the section titled "Executive Compensation—Narrative Disclosure to the 2025 Summary Compensation Table—Equity Incentive Compensation", "Executive Compensation—Employee Benefit and Equity Compensation Plans" and "Director Compensation".

Transition From PureTech and Costs to Operate as an Independent Company

Prior to our formation and the Asset Transfer, the financial statements reflect our operating results and financial position as our business was operated by PureTech, rather than as an independent company. We may incur additional ongoing operating expenses to operate as an independent company. These costs will include the cost of various corporate functions, incremental information technology-related costs and incremental costs to operate standalone accounting, legal and other administrative functions. We may also incur non-recurring expenses and non-recurring capital expenditures.

As part of building our administrative infrastructure, we entered into the TSA in connection with the Asset Transfer with PureTech that provided us with certain services and resources related to corporate functions for an initial 12 month period following the Transfer Date as amended. We pay PureTech fees for the services as

mutually agreed upon by us and PureTech as provided under the TSA, which fees are based on PureTech's cost of providing the services. This TSA allowed us to operate our business independently prior to completing the establishment of a standalone infrastructure. Actual costs that would have been incurred if we operated as a standalone company during these periods would have depended on various factors, including organizational design, outsourcing, and other strategic decisions related to corporate functions, information technology and back-office infrastructure.

Transactions with Related Parties

Following the Asset Transfer Date, we began incurring additional operating expenses necessary to operate as an independent company, including various corporate functions and incremental costs to operate standalone accounting, legal, and other administrative functions. These functions were provided to us from PureTech prior to the Asset Transfer Date and continued under the TSA discussed above. Substantially all of these activities will be performed using our own resources at this time. The terms of the TSA are discussed in the section captioned "Certain Relationships and Related Person Transactions."

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the Jumpstart Our Business Startups Act, or the JOBS Act. As such, we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including:

- being permitted to provide only two years of audited financial statements in addition to any required unaudited interim financial statements and a correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation;
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved; and
- exemptions from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act of 1934, as amended, or the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. We have elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, will adopt the new or revised standard whenever such adoption is required for private companies. We may also choose to early adopt any new or revised accounting standards whenever such early adoption is permitted. This may make comparison of our financial statements with another public company, which is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period, difficult or impossible because of the potential differences in accounting standards used.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the completion of this initial public offering, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.235 billion, (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of the common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year, or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

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 (i) the market value of our voting and non-voting common stock held by non-affiliates is less than \$250.0 million measured on the last business day of our second fiscal quarter, or (ii)(a) our annual revenue is less than \$100.0 million during the most recently completed fiscal year, and (b) the market value of our voting and non-voting common stock held by non-affiliates is less than \$700.0 million measured on the last business day of our second fiscal quarter.

BUSINESS

Overview

We are a clinical-stage therapeutics company focused on inventing and developing new medicines for patients with depression, anxiety, and other debilitating neuropsychiatric disorders. Through our differentiated approach, we identify clinically validated mechanisms with established efficacy and safety profiles which had historically been limited by high first-pass metabolism, low bioavailability, and/or side effects. We apply our proprietary Glyph™ platform to overcome those limitations and invent innovative oral therapies. Glyph is a lymphatic-targeting prodrug technology which is designed to bypass first-pass metabolism and thereby enhance a drug's oral bioavailability and reduce side effects. This process, which we call "Glyphing," also creates new composition of matter intellectual property. Our experienced team of industry leaders has a proven track record in neuropsychiatry drug discovery and development and delivering successful business outcomes. We aim to develop novel, leading treatment options that will make a significant impact for patients and their families.

We are leveraging our proprietary Glyph platform to advance a pipeline of novel therapies to address the significant unmet needs in depression and anxiety. Our lead product candidate, GlyphAllo™ (SPT-300 or Glyph Allopregnanolone), is a novel, Glyphed oral prodrug of allopregnanolone, an endogenous molecule that has been clinically validated in third-party trials for the treatment of postpartum depression, or PPD, a form of major depressive disorder, or MDD, that shares symptomatology with MDD, as a rapidly acting antidepressant with anxiolytic and sleep-promoting effects. GlyphAllo is designed to overcome bioavailability limitations of allopregnanolone and deliver rapid and durable efficacy in MDD. We have demonstrated in a Phase 1 clinical trial that GlyphAllo reaches therapeutically relevant exposures with oral dosing, and in a Phase 2a clinical trial, GlyphAllo demonstrated initial proof-of-concept with an objective biomarker of stress in healthy volunteers and a favorable tolerability profile. We have initiated the Phase 2b BUOY-1 trial in patients with MDD with or without anxious distress and anticipate topline data in .

Our second product candidate, GlyphAgo™ (SPT-320 or Glyph Agomelatine), is a novel, Glyphed, oral prodrug of agomelatine, a clinically validated anxiolytic and antidepressant that is approved for the treatment of generalized anxiety disorder, or GAD, in Australia and MDD in Australia and the European Union, or EU. Due to extensive liver first-pass metabolism, agomelatine can cause dose-dependent liver enzyme elevations, and its use has been limited by the need for frequent liver function testing. GlyphAgo is designed to overcome this limitation by avoiding first-pass metabolism and achieving therapeutic exposures of agomelatine while reducing or eliminating the need for liver monitoring. We have initiated a proof-of-concept Phase 1 trial for the treatment of GAD and expect topline data in . We are also advancing Glyph2BLSD™ (SPT-348 or Glyph 2-bromo-LSD), a novel, Glyphed oral prodrug of the non-hallucinogenic LSD analog 2-bromo-LSD, in preclinical studies for depressive disorders, including treatment-resistant depression, or TRD, post-traumatic stress disorder, or PTSD, and headache disorders.

Globally, over one billion people are living with mental illness as of 2021, comparable in prevalence to obesity or hypertension. According to the World Health Organization, as of 2021, depression affects approximately 332 million people worldwide and anxiety affects approximately 359 million people worldwide, and there is a significant need for novel treatment options. Currently approved drugs for MDD and GAD have significant limitations, including modest efficacy, slow onset of action, and unfavorable side effects. Advancement of novel therapies has been limited by a lack of understanding of disease pathophysiology, poor drug-like properties, and challenges in clinical trial design and execution leading to high clinical development failure rates.

Our differentiated approach

We are uniquely positioned to overcome the challenges of developing medicines for depression, anxiety, and other neuropsychiatric disorders by leveraging our differentiated, three-pillar approach:

Identify clinically validated mechanisms held back by issues that can be addressed by our proprietary Glyph platform. We select our product candidates based on well-established clinical data, defined as

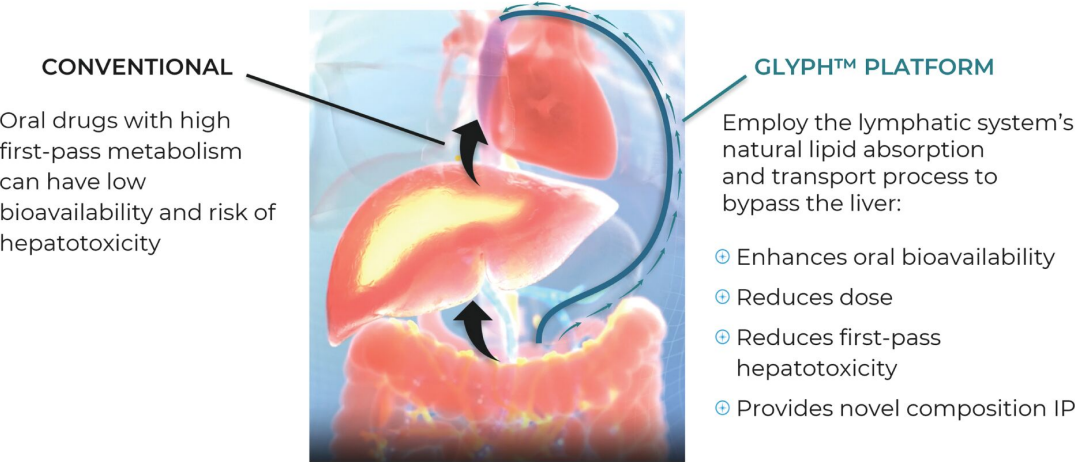
demonstrated meaningful benefits compared to placebo in multiple randomized, placebo-controlled clinical trials in a large number of patients. We identify drugs matching this profile where clinical and commercial potential have been limited by high first-pass metabolism, low bioavailability, and/or side effects. We advance candidates that have the potential to be novel medicines and to impact a large number of patients.

Create novel medicines with strong intellectual property using Glyph. Glyph is our proprietary technology platform which uses the lymphatic system to enable and enhance the oral administration of drugs. Typically, non-Glyphed oral small molecules undergo first-pass metabolism, where the concentration of drug is significantly reduced by metabolic enzymes in the liver prior to systemic circulation. First-pass metabolism can lead to low bioavailability (i.e., reduced concentration of active drug available to target organs) and/or side effects, including liver enzyme elevations or hepatotoxicity. Glyph leverages a separate absorption path taken by dietary fats. A Glyphed molecule uses this alternative route via the intestinal lymphatic system to bypass first-pass metabolism and transit directly into systemic circulation. The Glyph platform has the potential to be widely applied to many therapeutic molecules that have high first-pass metabolism. For each program, we use Glyph to create unique sets of prodrugs with differentiated profiles, and evaluate these prodrugs as potential candidates to advance into preclinical and clinical studies. Glyph has been applied to create novel product candidates for our pipeline resulting in new intellectual property, including composition of matter patents.

Benefits of Our Proprietary Glyph Platform

Glyph™ Leverages the Lymphatic System to Unlock New Medicines

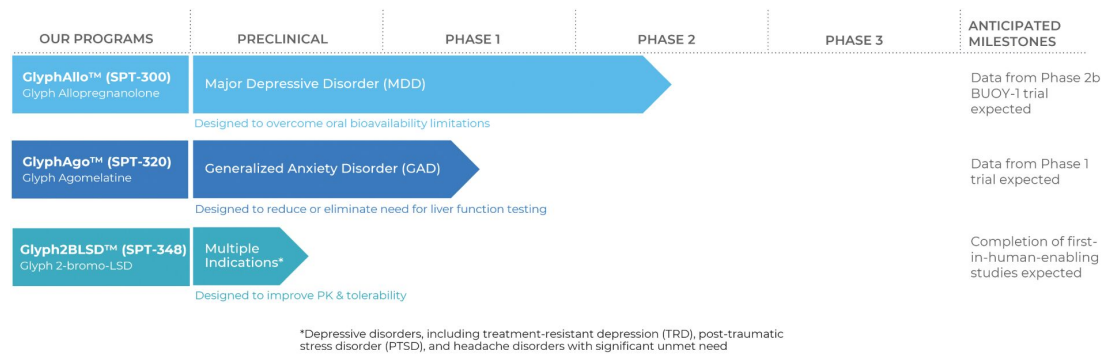
Proprietary platform advances active drugs previously limited by high first-pass metabolism



Apply our team's expertise to optimize the design and execution of clinical trials and drive successful business outcomes. Our team is comprised of industry leaders with a proven track record of building successful companies that have developed and commercialized innovative neuropsychiatric medicines. This includes Zyprexa®, Cymbalta®, Latuda®, Zurzuvae®, and Cobenfy™ (xanomeline-trospium or KarXT), which was approved by the FDA in September 2024 and is the first new class of medicines in over 30 years for patients living with schizophrenia. Leveraging our team's track record of success in neuropsychiatry discovery and clinical development is important as we select new product candidates and as we implement key design elements in our clinical trials to optimize treatment effect and duration and reduce placebo response. In parallel, we apply our deep experience in building successful companies to establish clear goals, drive strategic decision-making, and maintain financial discipline. Drawing on our track record of success in neuropsychiatry, we aim to drive successful outcomes for patients and shareholders.

Our Pipeline

We are developing a pipeline of novel potential treatments for neuropsychiatric disorders with significant unmet need. We retain exclusive, worldwide development and commercialization rights to all of our product candidates and discovery programs.



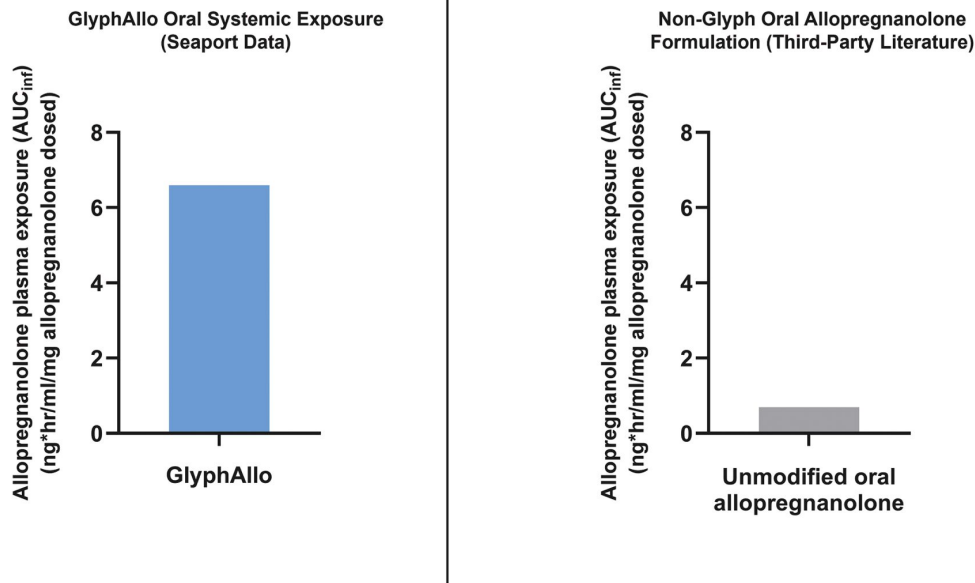
Glyph aims to unlock the therapeutic potential of drugs in CNS and beyond. In addition to our three lead candidates, we have robust discovery programs and multiple pipeline programs underway.

GlyphAllo: Potential Differentiated Therapy for MDD

GlyphAllo is a novel, Glyphed oral prodrug of allopregnanolone, an endogenous neurosteroid and gamma-aminobutyric acid A, or GABA_A, positive allosteric modulator, or PAM. Allopregnanolone is a naturally occurring molecule that reduces stress, with levels that peak during the third trimester of pregnancy. An intravenous infusion formulation of allopregnanolone was approved for the treatment of PPD, a form of MDD. Allopregnanolone has been clinically validated in two third-party trials, which were sponsored by Sage Therapeutics in the United States for the treatment of PPD and powered for statistical significance, as a rapidly acting antidepressant with anxiolytic and sleep-promoting effects. Due to the shared symptomatology between MDD and PPD, we believe data for MDD are relevant from such third-party trials. In each trial, allopregnanolone demonstrated statistically significant results on the primary endpoint of change in baseline at 60 hours in the Hamilton Depression Rating Scale-17, or HAMD-17, a regulatory-standard depression severity rating scale. However, its scope of clinical use has been constrained by oral bioavailability limitations that the Glyph platform is uniquely designed to solve.

In our Phase 1 clinical trial conducted in Australia in 99 participants, GlyphAllo demonstrated therapeutically relevant exposures with a favorable tolerability profile that supports chronic dosing. Oral dosing of GlyphAllo has resulted in a greater than nine-fold increase in bioavailability compared to the bioavailability of oral allopregnanolone. Specifically, in preclinical studies in non-human primates, or NHPs, oral dosing of GlyphAllo resulted in such increase in bioavailability compared to oral unmodified allopregnanolone over 24 hours. In these preclinical studies, evaluation of GlyphAllo and unmodified allopregnanolone were conducted simultaneously or sequentially using the same species. Consistent with these preclinical data, oral administration of GlyphAllo in our Phase 1 trial of GlyphAllo resulted in plasma exposure levels with an AUC_{inf} of 6.6 ng*hr/mL per 1 mg of allopregnanolone dosed. A previous third-party trial showed that oral administration of allopregnanolone resulted in plasma exposure levels with an AUC_{inf} of 0.7 ng*hr/mL per 1 mg of allopregnanolone dosed. No clinical head-to-head studies have been conducted comparing the results of our Phase 1 trial to oral allopregnanolone. Each of these plasma exposure levels are illustrated in the figure below.

GlyphAllo Oral Systemic Exposure and Literature Data



No head-to-head clinical trials have been conducted. The graphic is presented for illustrative purposes and presents clinical information from the phase 1 trial alongside publicly available information from other therapies and includes information from different clinical trials, conducted by different parties, at different points in time, with differences in trial designs and patient populations and is included to provide key context for why there has not historically been an oral version of allopregnanolone available, and to demonstrate the meaningful potential difference of “Glyphing”, as compared to traditional delivery. Comparing the results from different trials may be unreliable due to factors such as protocol design and trial objectives varying between the trials. Therefore, cross-study comparisons provide limited information about the effectiveness of a product candidate.

No treatment-related severe or serious adverse events were reported. GlyphAllo has also demonstrated initial proof-of-concept in a Phase 2a randomized, placebo-controlled trial conducted in Australia in 80 participants, using the Trier Social Stress Test, or TSST, a validated clinical model of anxiety in healthy volunteers. No severe or serious adverse events were reported. Based on these Phase 1 and Phase 2a data, we believe GlyphAllo has the potential to become a leading treatment for MDD. We advanced GlyphAllo into what we believe is a registration-enabling Phase 2b BUOY-1 trial conducted in the US and EU in July 2025. BUOY-1 is a global, randomized, double-blind, placebo-controlled trial evaluating the efficacy, safety, and tolerability of GlyphAllo in adults with MDD, with or without anxious distress. MDD with anxious distress is a form of MDD characterized by significant anxiety. Approximately 60% of patients with MDD meet the criteria for anxious distress. This trial is expected to enroll up to approximately 360 patients, randomized 1:1 to receive either GlyphAllo or placebo once-daily over a six-week treatment period. This randomized, double-blind, multiregional, placebo-controlled trial is designed to be registration-enabling, subject to review by the FDA and other comparable regulatory authorities, as an adequate and well-controlled investigation that seeks to help provide substantial evidence of effectiveness by assessing GlyphAllo’s efficacy and safety in several hundred patients. Additional clinical trials may be required prior to the submission of a new drug application even if this trial is successful or positive. The primary endpoint of the trial is the change from baseline at six weeks in HAM-D-17. Following the initial treatment period, eligible patients may enter an open-label extension trial, in which all participants will receive GlyphAllo for up to six additional weeks.

Previous clinical development of allopregnanolone and its synthetic analog, which has been evaluated by Sage Therapeutics in multiple late-stage clinical trials for the treatment of MDD, has been generally hindered by poor oral bioavailability, safety concerns, and clinical trial design limitations. GlyphAllo is designed to enhance the oral bioavailability of allopregnanolone and achieve systemic exposures comparable to an intravenous infusion of allopregnanolone, with once-daily oral dosing. We believe our ongoing Phase 2b BUOY-1 trial improves upon the design of previous third-party clinical trials that evaluated a synthetic analog of allopregnanolone in several important ways.

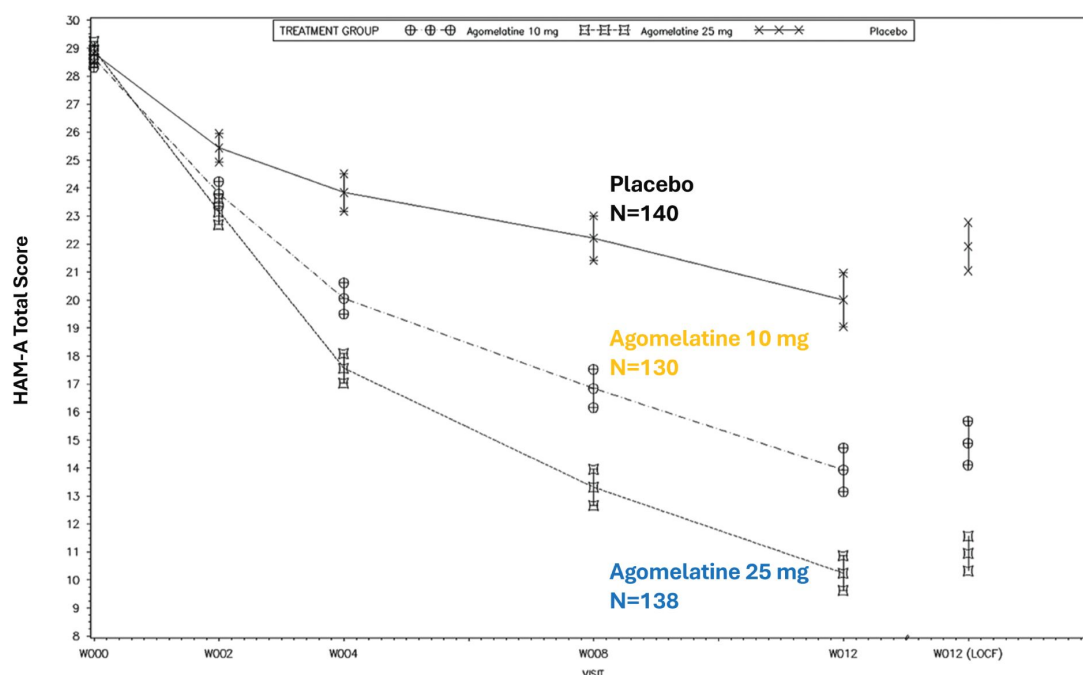
We are improving durable efficacy by treating patients for the full six-week duration of the primary endpoint time frame, as opposed to previous trials that treated patients for only the first two weeks and assessed efficacy after six weeks. As allopregnanolone also has an anxiolytic effect, we are also enrolling patients that have MDD with or without anxious distress. To reduce placebo response, we are optimizing the frequency of clinician-administered assessments, as our comprehensive meta-analysis of recent antidepressant trials demonstrated that the frequency of these assessments is positively correlated with the magnitude of the placebo response in MDD trials. We are also including a single treatment arm and will flex dose to a target dose, similar to the strategy implemented at Karuna Therapeutics, since the number of active arms is positively associated with increased placebo response. Additionally, we are scrutinizing site selection and patient enrollment to ensure appropriate diagnosis and exclude inappropriate patients, including those with inflated baseline ratings and those who are concurrently participating in other studies. We expect topline data from the Phase 2b BUOY-1 trial in

GlyphAgo: Potential Differentiated Therapy for GAD

GlyphAgo is a novel, Glyphed oral prodrug of agomelatine that we are advancing in a key Phase 1 proof-of-concept trial for the treatment of GAD in Australia, in which we plan to enroll up to approximately 190 participants. Agomelatine, a clinically validated MT1/MT2 melatonin receptor agonist and serotonin 2C (5-HT_{2C}) receptor antagonist, is an effective anxiolytic and antidepressant approved for the treatment of GAD in Australia and MDD in Australia and the EU. In GAD, agomelatine has demonstrated statistically significant separation from placebo in four third-party placebo-controlled studies⁽¹⁾. Based on two of the largest non-head-to-head literature meta-analyses of clinical trials of pharmacological agents for the treatment of GAD, agomelatine has been shown to have favorable efficacy and tolerability relative to other therapeutic agents. Specifically, in the first of these meta-analyses, which included two of the placebo-controlled studies of agomelatine, agomelatine was observed to have better efficacy and tolerability than certain standard-of-care drugs, such as selective serotonin-reuptake inhibitors, or SSRIs, which can result in sexual dysfunction and weight gain, and benzodiazepines, which can result in dependence and abuse. In the second of these meta-analyses, which included three of the placebo-controlled studies of agomelatine, agomelatine was found to be the most favorable drug in terms of both efficacy and tolerability among the analyzed competitors (venlafaxine, escitalopram, paroxetine, duloxetine, and pregabalin). However, despite this positive profile, over 90% of unmodified agomelatine is lost to first-pass liver metabolism and its use has been limited by dose-dependent liver enzyme elevations. Its label in both Australia and the EU requires liver function testing before initiating treatment, during treatment, and upon increasing the dose. Agomelatine is not approved in the United States.

⁽¹⁾ The statements above relating to the placebo-controlled studies of agomelatine in GAD are based on the following, which represents a complete list of all placebo-controlled studies of agomelatine in GAD: Dan J. Stein, et al., Efficacy and safety of agomelatine (10 or 25 mg/day) in non-depressed out-patients with generalized anxiety disorder: A 12-week, double-blind, placebo-controlled study, *European Neuropsychopharmacology*, Volume 27, Issue 5, 2017 (also included in the meta-analyses); Dan J. Stein, et al., Agomelatine in Generalized Anxiety Disorder: An Active Comparator and Placebo-Controlled Study, *J Clin Psychiatry* 2014;75(4):362-368 (also included in the meta-analyses); Dan J. Stein, et al., Agomelatine Prevents Relapse in Generalized Anxiety Disorder: A 6-Month Randomized, Double-Blind, Placebo-Controlled Discontinuation Study, *J Clin Psychiatry* 2012;73(7):1002-1008; Dan J. Stein, et al., *Journal of Clinical Psychopharmacology* 28(5):p 561-566, October 2008 (also included in the meta-analyses).

Agomelatine Significantly Reduces Anxiety in Patients with GAD



Using our proprietary Glyph platform, GlyphAgo is designed to avoid first-pass liver metabolism and increase systemic exposure of agomelatine, enabling exposure levels of agomelatine that are effective in GAD but at a lower dose that reduces liver exposure and reduces or eliminates the need for liver function testing. Based on internal analyses, we believe a two-fold increase in the bioavailability of agomelatine with GlyphAgo dosing will reduce or eliminate liver enzyme elevations. In preclinical studies in NHPs we showed that oral dosing of GlyphAgo increased plasma exposure of agomelatine versus agomelatine alone above this two-fold target. Therefore, based on the data we have generated to date, we believe GlyphAgo has the potential to become a leading treatment for GAD. The ongoing Phase 1 trial will be conducted in multiple parts to evaluate the safety, tolerability, and pharmacokinetics of GlyphAgo and compare the pharmacokinetics of GlyphAgo to agomelatine alone. It will include single- and multiple-ascending dose cohorts, as well as a food-effect crossover portion, using both open-label and placebo-controlled designs. We expect topline data from our Phase 1 trial of GlyphAgo in .

Although the development and commercialization of GlyphAgo for the treatment of GAD is our primary focus, as part of our longer-term growth strategy, we may evaluate GlyphAgo in other indications as well, including MDD.

Glyph2BLSD and Additional Applications of the Glyph Platform

Glyph2BLSD is our novel, Glyphed oral prodrug of 2-bromo-LSD, a differentiated non-hallucinogenic neuroplastogen. Glyph2BLSD is designed to harness the differentiated and non-hallucinogenic profile of 2-bromo-LSD, which has rapidly acting clinical activity and is not expected to exhibit the fibrosis, cardiovascular effects, or hallucinations characteristic of some other neuroplastogens. Glyph2BLSD is designed to improve the pharmacokinetic and tolerability profile of 2-bromo-LSD while maintaining therapeutic exposure levels. Glyph2BLSD's non-hallucinogenic profile unlocks the potential to enable convenient outpatient and repeat dosing to improve efficacy. We are advancing Glyph2BLSD through preclinical studies and are developing Glyph2BLSD for the treatment of depressive disorders, including TRD, PTSD, and headache disorders with significant unmet need. We are currently conducting first-in-human-enabling studies of Glyph2BLSD.

We are also leveraging the power of the Glyph platform to explore additional applications in CNS and non-CNS diseases and advance programs that address significant unmet needs in these areas.

Our Team

Seaport was founded by pioneers in the neuropsychiatry field and is led by a team of seasoned industry veterans with a shared mission to transform the treatment of neuropsychiatric disorders and improve patients' lives. We have assembled an experienced group of individuals with a proven track record of building successful companies that have developed and commercialized innovative neuropsychiatric medicines. Members of our leadership team have collaborated successfully over several decades on the discovery, development, and commercialization of neuropsychiatric medicines including Cobenfy, Latuda, Zyprexa, Cymbalta, and Zurzuvae. Our co-founders, Daphne Zohar, and Dr. Steven Paul, were central to the success of Karuna Therapeutics, which invented and advanced the first-in-class medicine Cobenfy, and was acquired by Bristol Myers Squibb in March 2024 for \$14 billion. Cobenfy was approved by the FDA in September 2024 and is the first drug to provide a new mechanism of action for schizophrenia in over 30 years. Cobenfy is estimated to achieve annual peak sales of over \$5 billion. The core members of our leadership team include:

- **Daphne Zohar**, Founder, Chief Executive Officer and Board Member, previously founded and led PureTech Health for 20 years as CEO. She also co-founded PureTech's entities, including Karuna Therapeutics, which was acquired by Bristol Myers Squibb for \$14 billion. Ms. Zohar was a key driver in PureTech's productive R&D engine, which led to 28 new medicines and a clinical success rate at PureTech and founded entities that was around six times better than the industry average during her tenure. PureTech programs, including Cobenfy (invented at PureTech) and deupirfenidone, met with clinical success pursuing the same three pillar strategy of identifying clinically validated medicines with previous issues that held back their development, applying new technology to address previous limitations, and leveraging the team's expertise to optimize the design and execution of clinical trials and drive successful business outcomes.
- **Steven Paul, M.D.**, Co-founder and the Chair of the board of directors, brings over 40 years of experience as a physician-scientist specializing in CNS drug discovery and development and was previously the President, Chief Executive Officer, and Chair of the Board and Chief Scientific Officer and President of Research and Development at Karuna Therapeutics. He was also formerly the Executive Vice President for Science and Technology and President of the Lilly Research Laboratories at Eli Lilly. Prior to his tenure at Eli Lilly, Dr. Paul spent 18 years at the National Institute of Health and served as the Scientific Director of the National Institute of Mental Health. Dr. Paul played a key role in the development of several important neuropsychiatric drugs, including Zyprexa, Cymbalta, Cobenfy, and Zurzuvae.
- **Antony Loebel, M.D.**, Chief Medical Officer and President of Clinical Development, brings over 20 years of leadership experience in the biopharmaceutical industry and is a board-certified psychiatrist. He was formerly the President and Chief Executive Officer and Chief Medical Officer of Sunovion Pharmaceuticals. Dr. Loebel was instrumental in the growth of Sunovion to a company with over \$3.5 billion in total revenue and played a key role in the development and commercialization of Latuda for the treatment of patients with bipolar depression and schizophrenia.
- **Michael Chen, Ph.D.**, Co-founder and Chief Scientific Officer, has over 20 years of experience in various research and leadership roles in the neuropsychiatry field. He was formerly the Head of Innovation at PureTech Health where he oversaw the rapid advancement of neuropsychiatric medicines and Glyph platform translation and validation that led to the founding of Seaport Therapeutics. At PureTech, Dr. Chen played a key role in the clinical advancement of deupirfenidone, which recently demonstrated strong and durable efficacy with favorable tolerability as a monotherapy in a Phase 2b trial in idiopathic pulmonary fibrosis. Dr. Chen was previously Co-founder and Head of Research and Strategy at Sonde Health, a leader in voice-based health monitoring developing artificial intelligence powered-vocal biomarkers for depression and other neuropsychiatric disorders.

- **Lauren White**, Chief Financial Officer, has over 22 years of corporate finance, accounting, strategic partnering and investor relations experience. Most recently, she served as the Chief Financial Officer at ImmunoGen prior to and through its acquisition by AbbVie for \$10.1 billion in 2024. Before that she was the Chief Financial Officer, Treasurer, and Principal Accounting Officer at C4 Therapeutics, responsible for developing and leading the company's financial and capital strategies. Prior to that, Ms. White spent ten years at Novartis in various finance roles. Ms. White started her career at General Electric and Boston Consulting Group in strategy and marketing roles.
- **Lana Gladstein, J.D.**, General Counsel, has over 25 years of legal expertise including corporate governance and M&A transactions, licensing and partnerships, and intellectual property matters. Most recently, Ms. Gladstein was the Group General Counsel at APRINOIA Therapeutics, a clinical-stage company developing therapeutics and diagnostics for neurodegenerative diseases. Prior to APRINOIA, she was Chief Legal Officer at Arranta Bio and Executive Vice President and General Counsel at Brammer Bio until their acquisitions.
- **Eric Green**, Chief Operating Officer, has diverse expertise with over 25 years of experience across R&D process engineering, pharmaceutical manufacturing, operations, and global development and commercialization strategy. Most recently, he was Senior Vice President, Head of Development Programs at Alnylam Pharmaceuticals where he led a team responsible for global development and pre-commercialization activities for a portfolio of development stage programs.

Our board of directors brings together seasoned leaders in the biopharmaceutical industry, with expertise spanning neuropsychiatry research and development, regulatory affairs, financial operations, and commercialization. Our team is united by a shared commitment to develop transformative treatments for patients to address the significant unmet need in neuropsychiatry. Despite the prior experience of our team, our limited operating history as a standalone company makes any reliance on past performance uncertain.

Since our inception, we have raised \$325 million in net proceeds from leading life science investors, including shareholders with holdings greater than 5%: ARCH Venture Partners, General Atlantic, Sofinnova Investments, Third Rock Ventures, and our founder, PureTech. Prospective investors should not rely on the investment decisions of our existing investors, as these investors may have different risk tolerances and in certain cases received their shares in prior offerings at prices lower than the price offered to the public in this offering. See the sections titled "Certain Relationships and Related Person Transactions" and "Principal Stockholders" for more information.

Our Strategy

We founded our company with a mission to develop life-changing treatments for patients with depression, anxiety, and other neuropsychiatric disorders. The key elements of our business strategy are to:

- **Successfully advance GlyphAllo through clinical development for the treatment of patients with MDD with or without anxious distress.** GlyphAllo is a novel, Glyphed oral prodrug of allopregnanolone, an endogenous molecule that has been clinically validated in two third-party trials as a rapidly acting antidepressant with anxiolytic and sleep-promoting effects. GlyphAllo is designed to overcome bioavailability limitations of allopregnanolone and deliver rapid and durable efficacy in MDD. We have demonstrated in a Phase 1 clinical trial that GlyphAllo reaches therapeutically relevant exposures with oral dosing, and in a Phase 2a clinical trial, GlyphAllo demonstrated initial proof-of-concept with an objective biomarker of stress in healthy volunteers and a favorable tolerability profile that supports chronic dosing. We have initiated the Phase 2b BUOY-1 trial in patients with MDD with or without anxious distress and anticipate topline data in .
- **Successfully advance GlyphAgo through clinical development for the treatment of patients with GAD.** GlyphAgo is a novel, Glyphed oral prodrug of agomelatine, a clinically validated anxiolytic and antidepressant that is approved for the treatment of GAD in Australia and MDD in Australia and the EU. Due to extensive first-pass metabolism, agomelatine can cause dose-dependent liver enzyme elevations, and

its use has been limited by the need for frequent liver function testing. GlyphAgo is designed to overcome this limitation by avoiding first-pass metabolism and achieving therapeutic exposures of agomelatine while reducing or eliminating the need for liver monitoring. We have initiated a proof-of-concept Phase 1 trial for the treatment of GAD and expect topline data in .

- **Develop a robust pipeline of differentiated programs for neuropsychiatric and other CNS disorders by leveraging our Glyph platform.** We have used Glyph to create over 24 different small molecules based on the broad compatibility of our platform with a range of small molecule physicochemical properties. Given the novel prodrug modifications to these drugs and resulting improvements in drug properties, we create new composition of matter intellectual property for these therapies. In addition to GlyphAllo and GlyphAgo, we have multiple preclinical programs, including Glyph2BLS, and are also evaluating the application of our Glyph platform in therapeutic areas beyond neuropsychiatry. Our team has a track record of building revolutionary biopharmaceutical companies that have developed successful medicines for neuropsychiatric disorders, and we believe that our scientific expertise and world-class technical capabilities will enable us to identify and develop high value targets in the future.
- **Opportunistically pursue strategic partnerships to maximize the value of our Glyph platform.** We have exclusive global rights to develop and commercialize our product candidates and pursue various discovery programs using our Glyph platform. We may seek strategic collaborations where we believe the resources and expertise of third-party biopharmaceutical companies could accelerate the clinical development or maximize the commercial potential of our product candidates and/or discovery programs, or where such collaborations could expand the capabilities of our Glyph platform. We may also opportunistically evaluate partnerships in therapeutic areas outside neuropsychiatry where our Glyph platform has demonstrated potential applicability, such as oncology, immunology and inflammation, metabolic disease, and obesity.

Unmet Patient Need in Neuropsychiatry

According to the World Health Organization, as of 2021, depression affects approximately 332 million people worldwide and anxiety affects approximately 359 million people worldwide. Quality of life can be severely impacted and the societal economic burden of MDD totals over \$300 billion in the United States alone as of 2023. According to the National Institute of Mental Health, MDD affects approximately 21 million adults in the United States, as of 2021. According to the National Institute of Mental Health, approximately 4 in 10 people with MDD do not receive treatment, and for those that do, currently approved drugs often have significant limitations, including modest efficacy, slow onset of action, and unfavorable side effects. Anxiety disorders are even more prevalent than MDD and affect approximately 350 million people worldwide. Of these, approximately 100 million adults suffer from GAD, including more than seven million adults in the United States, according to JAMA Psychiatry, as of 2017. There have been no new therapies approved for GAD in almost two decades, and the medicines currently used for GAD have modest efficacy, slow onset, and/or unfavorable side effects.

Despite the shortcomings of existing therapies, there has been limited innovation in neuropsychiatric treatment options over the last 30 years and there remains a significant need for novel mechanisms and additional treatment options. The unmet need for improved therapies to treat depression and anxiety is so great that even approved drugs with limited efficacy and significant tolerability issues have become widely prescribed drugs. For instance, standard-of-care therapies, such as Zoloft®, Zyprexa, and Cymbalta, have each generated \$3 billion to \$5 billion in peak annual sales between 2005 and 2012, despite significant limitations, such as modest efficacy, slow onset, and undesirable side effects. SSRIs and serotonin-norepinephrine reuptake inhibitors, or SNRIs, both first-line treatments for MDD and GAD, can take weeks to improve symptoms, and often do not lead to complete remission of symptoms. In addition, patients with MDD with anxious distress, a subtype of MDD representing approximately 60% of patients with MDD, have even lower rates of treatment response and remission, and there are no approved therapies indicated for MDD with anxious distress. Patients with MDD have an increased likelihood of both suicidal ideation and suicide attempts, which is further increased in patients with MDD with anxious distress. Even for patients who benefit from standard-of-care drugs, many experience challenging side effects, such as unintended weight gain, sexual dysfunction, and sleep disturbances.

GAD is characterized by excessive anxiety and worry that is difficult to control, and presents with associated symptoms such as restlessness, sleep disturbance, and irritability. More than half of GAD patients are untreated, and of those that are treated, only half respond to standard-of-care treatments like SSRIs and SNRIs. Current therapies provide limited efficacy and can cause significant adverse effects, including weight gain, sexual dysfunction, and sleep disturbances. There is a clear unmet need for novel therapies that provide improved efficacy and reduce unfavorable side effects for patients suffering from GAD.

Challenges in Neuropsychiatric Drug Development

Despite the significant unmet need in neuropsychiatry, over 90% of neuropsychiatry product candidates fail in clinical trials, according to the Biotechnology Innovation Organization. The challenges that have held back the development of novel treatments for neuropsychiatric disorders include:

- **Fundamental pathophysiology is unknown:** High failure rates in clinical trials evaluating investigational therapies without prior clinical validation can reflect an incomplete understanding of the underlying pathophysiology of depression and anxiety. Translation of data from animal models to humans is difficult due to the complexity of the CNS.
- **Poor drug-like properties:** Drugs for neuropsychiatric disorders have had low oral bioavailability and/or significant side effects due in part to poor drug-like properties, often due to high first-pass metabolism in the liver.
- **Challenges with clinical trial design and execution:** Suboptimal trial design and execution of neuropsychiatry clinical trials can lead to failed studies and prevent drug approvals. A key challenge in neuropsychiatry clinical development is the placebo effect, which can be impacted by the frequency of clinician-administered assessments, the number of treatment arms, the number of sites, and the inclusion of inappropriate patients, including those with inflated baseline ratings and those who are concurrently participating in other studies.

Our Differentiated Approach

We are uniquely positioned to develop novel medicines that will make a significant impact for patients and their families through our differentiated, three-pillar approach: 1) identify clinically validated mechanisms held back by issues that can be addressed by our proprietary Glyph platform, 2) create novel medicines with strong intellectual property using Glyph, and 3) apply our team's expertise to optimize the design and execution of clinical trials and drive successful business outcomes. We believe our approach will enable us to develop transformative treatments for patients and build a leading neuropsychiatry company.

1) Identify clinically validated mechanisms held back by issues that can be addressed by our proprietary Glyph platform.

We use our team's deep expertise in neuropsychiatry drug discovery and development to analyze data generated from prior clinical trials of investigational therapies for depression, anxiety, and other neuropsychiatric disorders. Of the investigational therapies that have demonstrated clinical efficacy, we analyze the factors that have held these molecules back from achieving regulatory or commercial success and identify those that we can address with our Glyph platform, including poor oral bioavailability and/or liver-related adverse events.

We select product candidates that have the potential to become high-impact, leading therapies and design and conduct early proof-of-concept studies that address key development questions and validate the fundamental hypotheses underlying each program. Molecules that meet all the above criteria become candidates for our Glyph platform.

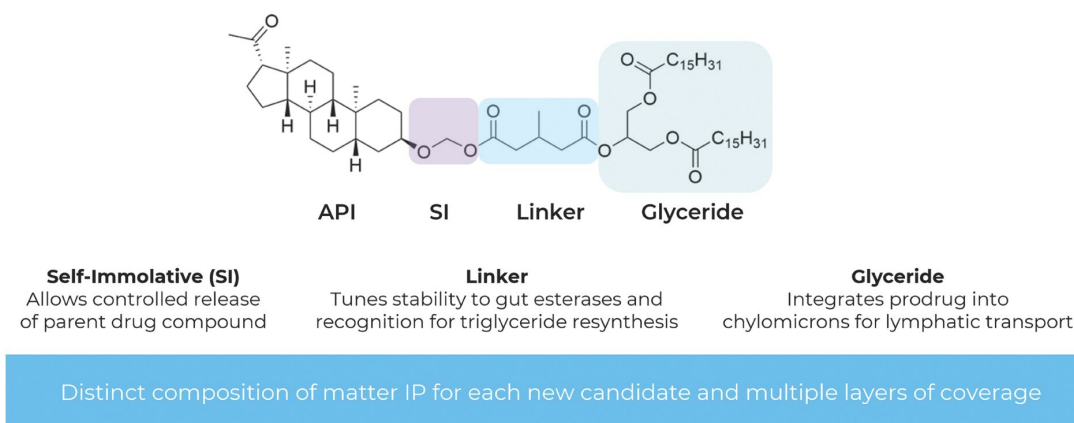
2) Create novel medicines with strong intellectual property using Glyph.

Glyph is a lymphatic-targeting prodrug platform that has shown clinical proof of concept in our Phase 1 and Phase 2a clinical trials of GlyphAllo. We can apply Glyph to molecules to overcome limitations such as low oral bioavailability, liver related adverse events, and other side effects. Importantly, every time we Glyph a molecule, it results in the creation of a novel molecule and, therefore, new composition of matter intellectual property.

The development of the Glyph platform has been a culmination of over 50 years of work since researchers began exploring the potential of lymphatic transport to improve drug delivery. Since the 1970s, research has been conducted on highly lipophilic molecules, or molecules that can be dissolved in lipids or fats, that could take advantage of the lymphatic route to bypass first-pass metabolism and target lymphatic tissues. However, this approach was limited by the need for chemical properties like lipophilicity, which can negatively affect drug absorption and metabolism. To overcome these limitations, Dr. Christopher Porter, the co-inventor of Glyph and Director of the Monash Institute of Pharmaceutical Sciences, advanced cleavable prodrugs with lipophilic moieties to promote lymphatic transport and the release of parent drug. Simple triglyceride-based prodrugs with direct conjugation of a desired drug with a lipophilic moiety were explored but did not fully capture the potential of lymphatic targeting prodrugs.

Dr. Porter, in collaboration with our Head of Chemistry, Dr. Jamie Simpson, then invented our Glyph platform, which advanced the creation of a new type of prodrug that significantly improved lymphatic transport. This proprietary prodrug chemistry is designed to promote enhanced lymphatic uptake while maintaining gut stability and the release of the parent drug. Our Glyph platform enables the design of various linkers, glyceride moieties, and self-immolative groups tailored for each active pharmaceutical ingredient, or API, candidate, to allow for the release of the API. An illustration of an exemplary lymphatic targeting lipid prodrug is below.

EXAMPLE OF LYMPHATIC-TARGETING LIPID PRODRUG



When taken orally, conventional small molecule drugs are absorbed in the gut, enter the portal vein, and travel to the liver, where they can undergo high first-pass metabolism before entering systemic circulation. This can result in low bioavailability, or very little of the drug actually circulating in the body or brain and can also increase the risk of liver-related adverse events. In contrast, dietary fats enter systemic circulation through a completely different pathway: they enter the mesenteric lymphatic system of the gut and traffic into the thoracic duct, bypassing the liver on their way into systemic circulation. With Glyph, we cloak drugs so that the body recognizes them as if they were dietary fats, and traffics them through the lymphatic system, avoiding the liver and transporting them directly into the bloodstream. This improves a molecule's bioavailability and thereby enables drugs that otherwise need to be given intravenously, to be dosed orally. Glyph also helps to overcome other issues—such as liver toxicity—by avoiding the liver on the first pass and reducing dose while maintaining

therapeutic exposure levels. Glyph is, to our knowledge, the only clinically validated lymphatic-targeting platform. Previous examples of oral lymphatic-targeting therapies have yet to result in efficient lymphatic transport, generalized across molecules, or translated to humans.

We have pioneered the use of preclinical models to test and validate our lymphatic transport approach. We are able to use a streamlined series of *in vitro* and *in vivo* assays, which are efficient, repeatable, and highly translatable, and customize prodrug chemistry to each unique active drug. The translatability of these models is illustrated by our GlyphAllo program, which was predicted to have enhanced bioavailability based on our preclinical data. This was confirmed in a Phase 1 trial of GlyphAllo in healthy volunteers, which demonstrated therapeutically relevant exposures following dosing of GlyphAllo. Although no head-to-head studies have been conducted comparing GlyphAllo to oral allopregnanolone, oral administration of GlyphAllo in the Phase 1 trial of GlyphAllo resulted in greater bioavailability compared to previously reported bioavailability of oral allopregnanolone.

We have used Glyph to create over 24 different small molecules based on our Glyph platform's compatibility with a range of physiochemical properties of small molecules. Our Glyph platform can be used with a range of small molecules, including for indications beyond neuropsychiatry, including oncology, immunology and inflammation, metabolic disease, and obesity.

3) Apply our team's expertise to optimize the design and execution of clinical trials and drive successful business outcomes.

Our experienced team has a proven track record of building successful companies that have developed and commercialized innovative neuropsychiatric medicines. We are led by the team that discovered and advanced Cobenfy, which was first approved by the FDA in September 2024 and is the first new mechanism in over 30 years for patients living with schizophrenia. Within each of our programs, we are implementing key learnings from our collective experience to improve the probability of success. For instance, to optimize the design and execution of the Phase 2b BUOY-1 trial of GlyphAllo in MDD, we aim to implement learnings from the prior trials of allopregnanolone and its synthetic analogs such as zuranolone. These include key design elements to improve durable efficacy and reduce the placebo effect, namely treating patients for the full duration of the primary endpoint, limiting the frequency of clinical assessments, randomizing patients 1:1 to either a single active treatment arm or placebo, and using rigorous patient inclusion criteria. Our strategy to optimize the frequency of clinical assessments is supported by a recent meta-analysis we conducted of major MDD trials over the last 10 years to identify clinical design factors associated with the magnitude of the placebo response. A key finding from this analysis was that the number and frequency of clinician-administered assessments were significantly associated with greater placebo response. Thus, reducing the number and frequency of clinician-administered assessments may decrease the placebo response in MDD trials.

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The table below summarizes the key design elements we are incorporating into our clinical trials to improve durable efficacy and minimize the placebo effect.

	Challenges in Prior Neuropsychiatry Clinical Trials	Seaport's Approach
Clinical assessments	High frequency of clinical assessments that may amplify placebo effect	Optimize frequency of clinical assessments to reduce placebo effect
Patient inclusion criteria	Inflated baseline ratings or unfit participants that skew results	Implement specific patient inclusion criteria to scrutinize enrollment and filter out inappropriate participants
Control arm design	Multiple or imbalanced treatment arms that may amplify placebo effect	1:1 randomization to a single treatment arm or a single placebo control arm to minimize placebo effect
Treatment duration	Shorter treatment duration that limits efficacy and durability of response	Longer treatment duration to improve efficacy and durability of response

Product Candidates

We are leveraging our Glyph platform to advance a pipeline of novel candidates to address the significant unmet need for patients with depression and anxiety. Our lead product candidates include GlyphAllo for the treatment of MDD and GlyphAgo for the treatment of GAD.

GlyphAllo: Potential Differentiated Therapy for MDD

GlyphAllo, is a novel, Glyphed oral prodrug of allopregnanolone, an endogenous neurosteroid and GABA_A PAM that has been clinically validated in two third-party trials, which were sponsored by Sage Therapeutics in the United States for the treatment of PPD and powered for statistical significance, as a rapidly acting antidepressant with anxiolytic and sleep-promoting effects. In each trial, allopregnanolone demonstrated statistically significant results on the primary endpoint of change in baseline at 60 hours in the HAM-D-17. However, its scope of clinical use has been constrained by oral bioavailability limitations that the Glyph platform is uniquely designed to solve.

We are currently advancing GlyphAllo in the Phase 2b BUOY-1 trial in MDD with or without anxious distress, that we believe will be registration-enabling, subject to review by the FDA and/or other comparable regulatory authorities, as the trial is an adequate and well-controlled investigation that seeks to help provide substantial evidence of effectiveness by definitively assessing GlyphAllo's efficacy and safety in several hundred patients. We believe that GlyphAllo has the potential to be a leading treatment for MDD.

Background on MDD and Market Opportunity

MDD is one of the most disabling neuropsychiatric disorders and ranks among the leading causes of disease burden worldwide. As of 2023, 29% of adults in the United States reported having been diagnosed with depression at some point in their life, more than diabetes (16%) or chronic kidney disease (14%). Depression is often characterized by persistent low mood or anhedonia—loss of interest in normally enjoyable activities—as well as changes in sleep, appetite, cognition, psychomotor function, fatigue, feelings of worthlessness,

inappropriate guilt, or suicidal ideation. Depression can be debilitating to daily functioning, including school, work, and interpersonal relationships, and it significantly reduces quality of life. Individuals with depression are 20 times more likely to commit suicide than those without depression. In 2022, suicide was the second leading cause of death for people ages 10-14 and 20-34, and the third leading cause of death for people ages 15-19.

MDD is a highly heterogeneous disease that manifests in myriad ways, with variations in symptoms, severity, and duration. Furthermore, the underlying causes are multifaceted, encompassing genetic, biological, environmental, and psychological factors. For example, according to The American Journal of Psychiatry, more than half of adults diagnosed with MDD also experience notable concurrent anxiety. Individuals with MDD with anxious distress have worse depressive symptoms, higher likelihood of suicidal ideation, and attempted suicide, increased functional and physical impairment, reduced quality of life, and lower response to treatments for MDD. In recognition of the clinical impact of anxious distress, the DSM-5 added in 2013 a specifier for anxious distress in the context of MDD. There are no drugs specifically approved for MDD patients with anxious distress.

Limitations of the Current Standard of Care in MDD

Although there are multiple approved antidepressant therapies, only 61% of adults with MDD in the United States received treatment in 2021, according to the National Institute of Mental Health. Of MDD patients who do receive treatment, approximately one-half fail to achieve remission with first-line therapies. Current standard of care for those who respond poorly to initial antidepressant monotherapy treatment relies on polypharmacy and treatment-switching strategies between current options including SSRIs, SNRIs, dopaminergic/noradrenergic drugs, and atypical antipsychotics. Current treatments are also in many cases associated with significant negative side effects such as sexual dysfunction, weight gain, gastrointestinal issues, insomnia, fatigue, nausea, emotional blunting, and others, which limit medication adherence and can negatively impact treatment outcomes. Even when patients achieve symptom remission, standard-of-care therapies may take weeks to yield effect and can even make symptoms like insomnia worse. Therefore, there is a significant unmet need for novel therapies that are more effective and better tolerated for the treatment of people with MDD.

Validation of Allopregnanolone and GABA Modulation in MDD

Allopregnanolone is an endogenous neurosteroid that is synthesized in the periphery and brain and binds selectively with high affinity to GABA_A receptors. Allopregnanolone has a rapid onset of action and a well-established, clinically validated antidepressant, anxiolytic, and sleep-promoting effect. GlyphAllo retains the activity and potency of endogenous allopregnanolone in oral form. Levels of allopregnanolone peak during the third trimester of pregnancy, and an intravenous infusion formulation of allopregnanolone was approved for the treatment of PPD.

GABA is the primary inhibitory neurotransmitter in the brain and is a pivotal component of the etiology of depression and anxiety disorders. Reduced GABA levels in the brain are associated with MDD, and cerebrospinal fluid, or CSF, GABA levels are highly correlated with anxiety in patients with MDD and tend to normalize with successful treatment. Other drugs that target GABA, such as benzodiazepines, have been investigated for MDD; however, these have been largely ineffective as they lack antidepressant effects driven by specific GABA receptor subtypes and can lead to dependence and abuse. Importantly, allopregnanolone binds to GABA_A receptors at distinct sites compared to benzodiazepines and thereby modulates GABA_A signaling in a manner distinct from benzodiazepines.

Prior Clinical Studies of Allopregnanolone and its Synthetic Analogs

Allopregnanolone and its synthetic analogs, including zuranolone, have been tested in multiple studies in MDD and PPD and have demonstrated rapidly acting antidepressant and anxiolytic effects. An IV formulation of allopregnanolone, brexanolone, was developed and approved by the FDA in 2019 for the treatment of PPD and marketed under the trade name Zulresso. In two positive Phase 3 trials, brexanolone demonstrated statistically significant and clinically meaningful and rapid reductions in HAM-D-17 as compared to placebo in patients with

PPD. In addition, brexanolone demonstrated rapid and statistically significant anxiolytic effects and improvement in insomnia symptoms from baseline, according to pooled post-hoc analyses of three placebo-controlled trials of brexanolone in PPD.

After oral administration, unmodified allopregnanolone is rapidly and nearly completely metabolized via liver first-pass metabolism, resulting in only a small percentage reaching the systemic circulation and CNS. As a result, oral administration of allopregnanolone does not produce adequate exposure levels for efficacy and is poorly suited for chronic treatment of depression and anxiety disorders. Due to the poor oral bioavailability of allopregnanolone, brexanolone was only available via a 60-hour IV infusion, requiring the presence of a health care provider to continuously monitor the patient.

To overcome the poor bioavailability of brexanolone and the challenges associated with IV administration, an oral synthetic analog of allopregnanolone, zuranolone, was developed. In two Phase 3 studies in PPD conducted by Sage Therapeutics, zuranolone met the primary endpoint and also demonstrated a statistically significant improvement in symptoms of anxiety. Zuranolone was approved by the FDA for the treatment of PPD in 2023 and is marketed under the trade name Zurzuvae.

In addition to its development in PPD, zuranolone was tested in four placebo-controlled clinical trials in patients with MDD. In these trials, patients received either zuranolone or placebo once daily for two weeks. The primary endpoint in these trials was change from baseline in HAMD-17 score at Day 15 or Day 3. Change from baseline in HAMD-17 score was also assessed at Day 42, when patients had not received treatment for four weeks. Zuranolone demonstrated a rapid antidepressant effect that deepened while patients were on drug and met the primary endpoint in three of the four trials. In the trial that did not meet its primary endpoint, zuranolone showed statistically significant reductions in HAMD-17 total score at Days 3, 8 and 12, but not at Day 15. Zuranolone also demonstrated a statistically significant anxiolytic effect in the WATERFALL trial. We believe the negative results of these trials at Day 42 was primarily due to two key factors related to clinical trial design and execution. First, as patients received treatment for only the first two weeks of the study, patients had not received treatment for approximately four weeks when HAMD-17 score was assessed at Day 42. Second, these studies showed a high placebo response, likely driven by the elevated frequency of clinician-administered assessments. Indeed, according to our meta-analysis of recent antidepressant trials, zuranolone's WATERFALL trial had approximately double the placebo response and double the frequency of clinician-administered assessments compared to typical antidepressant trials. Zuranolone was generally safe and well tolerated in 2,005 treated patients across seven randomized control trials, with the most common treatment-emergent adverse event being somnolence, an on-target effect of GABA_A. Despite its demonstrated antidepressant and anxiolytic activity, zuranolone was not approved in MDD by the FDA during its review of the product.

GlyphAllo Overcomes Limitations of Allopregnanolone and its Synthetic Analogs

GlyphAllo is a novel, Glyphed oral prodrug of allopregnanolone designed to increase the oral bioavailability of allopregnanolone. After oral dosing, GlyphAllo is metabolized to the parent API, allopregnanolone, chemically identical to the endogenous neurosteroid, which we believe can overcome safety limitations of synthetic analogs of allopregnanolone. Additionally, we believe GlyphAllo may have additional benefits compared to other MDD drugs, including a rapid onset of action, anxiolytic activity, and sleep-promoting effects. Paired with our expertise in designing and executing neuropsychiatry clinical trials, we believe we can overcome the historical limitations seen in the development of allopregnanolone and its synthetic analogs.

GlyphAllo Phase 1 and Phase 2a Trial in Healthy Volunteers

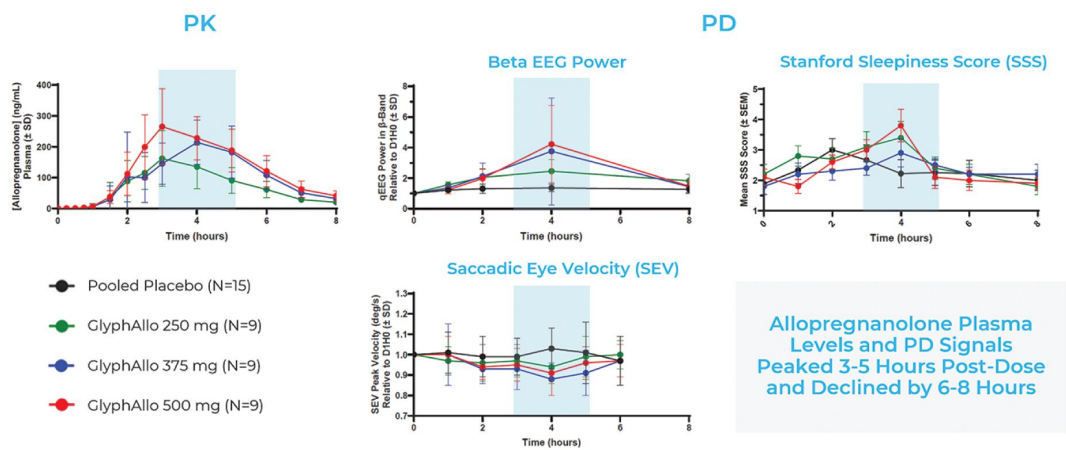
As initial proof of concept for GlyphAllo, we conducted a trial in 179 healthy volunteers to evaluate the safety, tolerability and pharmacokinetics of GlyphAllo, which included both Phase 1 and Phase 2a portions. Phase 1 was a multi-part trial with single ascending, multiple ascending, and food effect parts with doses ranging from 70 mg to 1,000 mg daily for up to 7 days. The primary endpoints of the Phase 1 portion of the trial were safety and tolerability. The goal of this trial was to demonstrate that orally dosed GlyphAllo can safely achieve

therapeutically relevant exposures and demonstrate pharmacodynamic effects consistent with allopregnanolone activity in the brain.

In the Phase 1 trial, we observed that GlyphAllo resulted in dose-dependent levels of allopregnanolone in plasma with no accumulation and minimal evidence of a clinically meaningful food effect. Across dose groups, the estimated time to peak exposure was between three to four hours, and the terminal half-life after single or multiple doses was approximately 24 hours. Unlike synthetic analogs of allopregnanolone that can exhibit delayed elimination rates compared to endogenous allopregnanolone, levels of allopregnanolone dropped to 15% of Cmax by eight hours post-dose following administration of GlyphAllo, which we believe will reduce or eliminate next-day somnolence or drowsiness. Although no head-to-head studies have been conducted, oral administration of GlyphAllo in the Phase 1 trial of GlyphAllo achieved exposures that are nine-fold greater than those reported without Glyph, reaching therapeutically relevant levels that are comparable to those that occur naturally during the third trimester of pregnancy.

At these therapeutically relevant levels, GlyphAllo also demonstrated pharmacodynamic effects consistent with allopregnanolone activity in the brain. These additional measures include increased beta electroencephalogram, or beta EEG, power versus placebo and reduced saccadic eye velocity, or SEV, at four hours post dose, consistent with the pharmacology of IV allopregnanolone. Both allopregnanolone blood concentrations and brain activity signals peaked at 3-5 hours post-dose and declined by 6-8 hours.

GlyphAllo Provided Therapeutically Relevant Allopregnanolone Exposures and Demonstrated Pharmacodynamic Effects

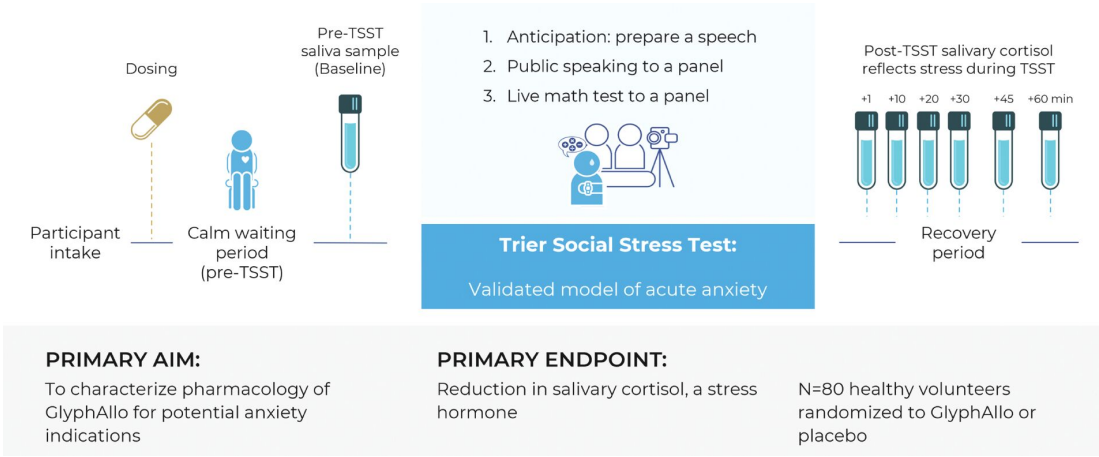


On the primary endpoints of safety and tolerability, GlyphAllo was generally well-tolerated with no serious or severe adverse events, or AEs, including no events of excessive sedation, altered state of consciousness, loss of consciousness, pre-syncope, syncope, falls, or suicidal ideation or behavior. These data were consistent with the safety profile seen in our extensive non-clinical dog toxicity studies. All treatment-related AEs were transient, mild or moderate, and were consistent with the known pharmacology profile of allopregnanolone. These events were generally dose- and time-dependent, occurring more frequently at high doses and early in dosing. The most common AE was mild and transient somnolence, an on-target effect of GABA_A. Furthermore, Stanford Sleepiness Score, or SSS, scores returned to baseline by six hours post-dosing, and this effect decreased after Day 1.

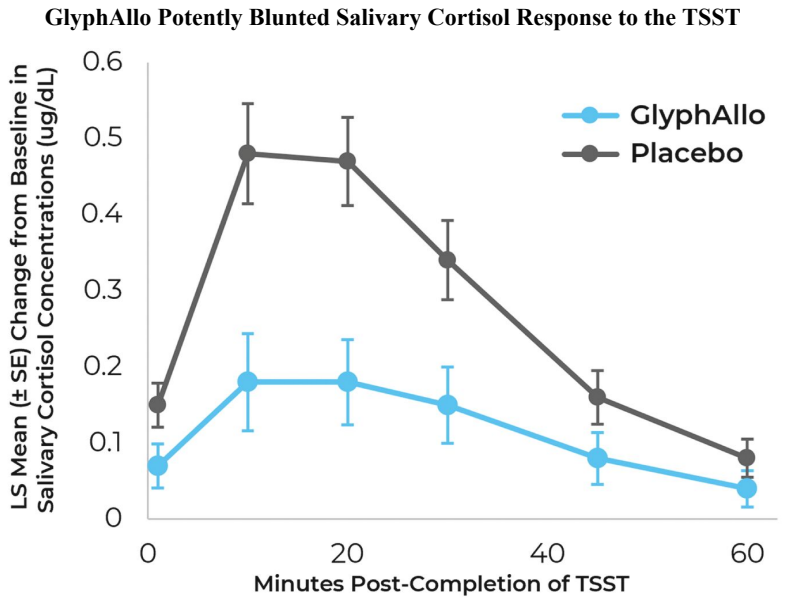
Based on the demonstration of therapeutically relevant plasma exposures of allopregnanolone and pharmacodynamic markers of allopregnanolone activity in the brain observed in Phase 1, we evaluated an active, well-tolerated dose of GlyphAllo in an initial proof-of-concept trial in healthy volunteers. As allopregnanolone is an anti-stress hormone and has demonstrated clinical efficacy in PPD, a form of major depression that is also characterized by high anxiety, we conducted a Phase 2a initial proof-of-concept trial in Australia using a

validated clinical model of anxiety in healthy volunteers called the Trier Social Stress Test, or TSST. This randomized, double-blind, placebo-controlled trial evaluated a single dose of GlyphAllo (375 mg) or placebo given in the morning to 80 healthy volunteers. The TSST involves preparing a speech and delivering it in front of a panel of judges, followed by a mental math test judged by the panel. Typically, participants will have a robust increase in salivary cortisol, the body’s primary stress hormone, in response to the TSST.

Design of Phase 2a Trial of GlyphAllo Using the TSST in Healthy Volunteers



In this trial, individuals receiving placebo exhibited a robust increase in salivary cortisol in response to the TSST. In contrast, this increase in the physiological stress response was potentially blunted by a single dose of GlyphAllo, with a p-value of 0.0001, meeting the primary endpoint. To date, the only compound to demonstrate reduced salivary cortisol levels in response to the TSST is alprazolam, a benzodiazepine that has been marketed as Xanax.

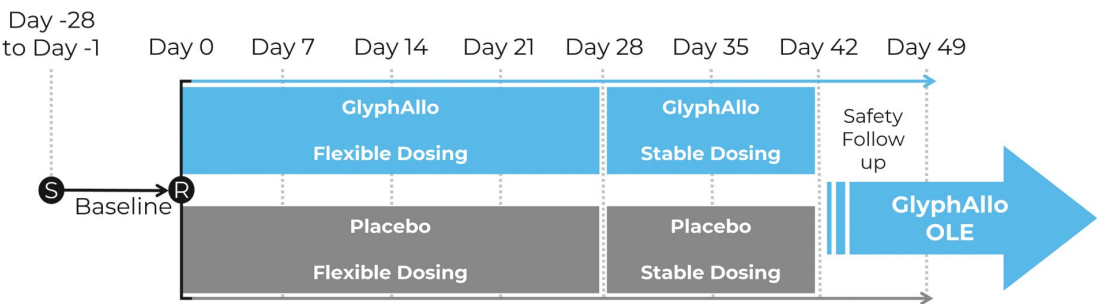


Self-reported assessments of anxiety were also collected using the State-Trait Anxiety Inventory which confirmed that the TSST transiently and modestly increased self-reported anxiety in both the placebo and GlyphAllo groups. These results are consistent with previous data showing that healthy volunteers are less likely to self-report anxiety symptoms following the TSST compared to patients with an anxiety disorder, who may experience a heightened negative psychological response to social stress. These results are also consistent with previously published self-reported assessments during the TSST using known anxiolytic drugs such as alprazolam in healthy volunteers, in which self-reported anxiety increased in both drug and placebo groups in response to the TSST. Treatment-emergent related adverse events occurring at >5% were somnolence (29% GlyphAllo vs. 13% placebo) dizziness (20% GlyphAllo vs. 3% placebo), and headache (7.3% GlyphAllo vs. 7.7% placebo), all of which were transient and mild or moderate in severity. No treatment-related severe or serious adverse events (AEs) were reported. The results of these Phase 1 and Phase 2a trials support the continued development of GlyphAllo as a potential medicine for MDD with or without anxious distress.

GlyphAllo Phase 2b BUOY-1 Trial in MDD

In July 2025, we initiated the Phase 2b BUOY-1 trial of GlyphAllo in the United States and the EU in adults with MDD with or without anxious distress. BUOY-1 is a global, randomized, double-blind, placebo-controlled trial with an open-label extension to evaluate the efficacy, safety, and tolerability of GlyphAllo. Patients will be randomized to GlyphAllo or placebo during the double-blind period. In the active treatment arm, GlyphAllo will be administered once daily at bedtime at flexible fixed doses ranging from 125 mg to 375 mg. On Day 42, patients completing the double-blind period will be eligible to enter a six-week open label extension, or OLE, trial.

Design of Phase 2b BUOY-1 Trial of GlyphAllo in MDD



We expect topline data from the Phase 2b BUOY-1 trial in . Based on the results of our Phase 2b clinical trial, we intend to consult with the FDA about the potential to use this trial to support our registrational filing for MDD.

Opportunities to Expand the Potential for GlyphAllo in MDD and Other Indications

While the development and commercialization of GlyphAllo for the treatment of MDD with or without anxious distress is our primary focus, we plan to evaluate GlyphAllo in additional indications as part of our longer-term growth strategy. For instance, since allopregnanolone is a rapidly acting antidepressant with anxiolytic and sleep-promoting effects, we may also evaluate GlyphAllo as a treatment for other stress-related mood and anxiety disorders.

GlyphAgo: Potential Differentiated Therapy for GAD

GlyphAgo is a novel, Glyphed oral prodrug of agomelatine that we are developing for the treatment of GAD. We are currently progressing a key Phase 1 proof-of-concept trial of GlyphAgo in Australia in healthy

volunteers in which we plan to enroll up to approximately 190 participants. Agomelatine, a clinically validated melatonin receptor agonist and serotonin 2C receptor antagonist, is an effective anxiolytic and antidepressant approved for the treatment of GAD in Australia and MDD in Australia and the EU. With GlyphAgo, we aim to achieve the exposure levels of agomelatine that are effective in GAD, but at a lower dose that reduces or eliminates the need for liver function testing, while creating new composition of matter IP.

	Route of Absorption	Dose	Liver Exposure	Liver Function Tests	
 Agomelatine • Unique and validated mechanism: GAD (Australia) and MDD (Australia/EU) • No weight gain, sexual dysfunction, or emotional blunting	 Hepatic portal vein	 25-50 mg	 Extensive first-pass metabolism High liver exposure	 Dose-dependent ALT elevations and liver monitoring required	Limitations: First-pass metabolism and liver monitoring required
 GlyphAgo™ • Oral, lymphatic-targeted prodrug of agomelatine using the Glyph platform	 Intestinal lymphatics	 <25 mg	 Avoids first-pass metabolism Reduces liver exposure	 No ALT elevations predicted above placebo	Potential to overcome agomelatine limitations by bypassing first-pass metabolism, reducing liver exposure and thus hepatotoxicity

Background on GAD and Market Opportunity

According to the World Health Organization, anxiety disorders affect 359 million people worldwide, as of 2021. Of these, 100 million adults suffer from GAD, including more than seven million adults in the United States, according to JAMA Psychiatry as of 2017. As there have been no new approved therapies for GAD in almost two decades, and the current standards of care for GAD are characterized by modest efficacy, slow onset, and/or unfavorable side effects, there is a significant unmet need for novel treatments. GAD results in excessive, obsessive, and continuous stress to the point where patients are incapable of living normal lives or carrying out standard daily routines. GAD patients typically have uncontrollable symptoms of restlessness, fatigue, inability to focus, irritability, muscle tension, and sleep disturbance. GAD places substantial strain on the broader healthcare system, with patients with GAD having more than twice as many health care visits and almost nine times more mental health care visits than those without GAD.

Current Standard of Care and Limitations in GAD

According to the Anxiety & Depression Association of America, as of 2025, more than approximately half of GAD patients do not receive treatment, and those that do typically are prescribed SSRI or SNRI agents, which can have significant AEs including weight gain, sexual dysfunction, emotional blunting, and insomnia. These AEs, coupled with the observation that only half of patients respond to these medications, lead many patients to pursue augmentation therapies including benzodiazepines, buspirone, gabapentin, mirtazapine, or antipsychotics—each with its own risks. For example, benzodiazepines are widely used and can result in dependence and abuse in just a few weeks. Despite this, approximately 1 in 8 adults in the United States use benzodiazepines each year.

Clinical Validation of Agomelatine in GAD

Agomelatine is a clinically validated anxiolytic and antidepressant and is approved in Australia for the treatment of GAD. Agomelatine has demonstrated clinical efficacy compared to placebo in four out of four third-party, randomized, placebo-controlled studies in GAD, and its efficacy in GAD is better than standard-of-care drugs like benzodiazepines or SSRIs. These studies demonstrate a favorable efficacy and tolerability profile, with the only

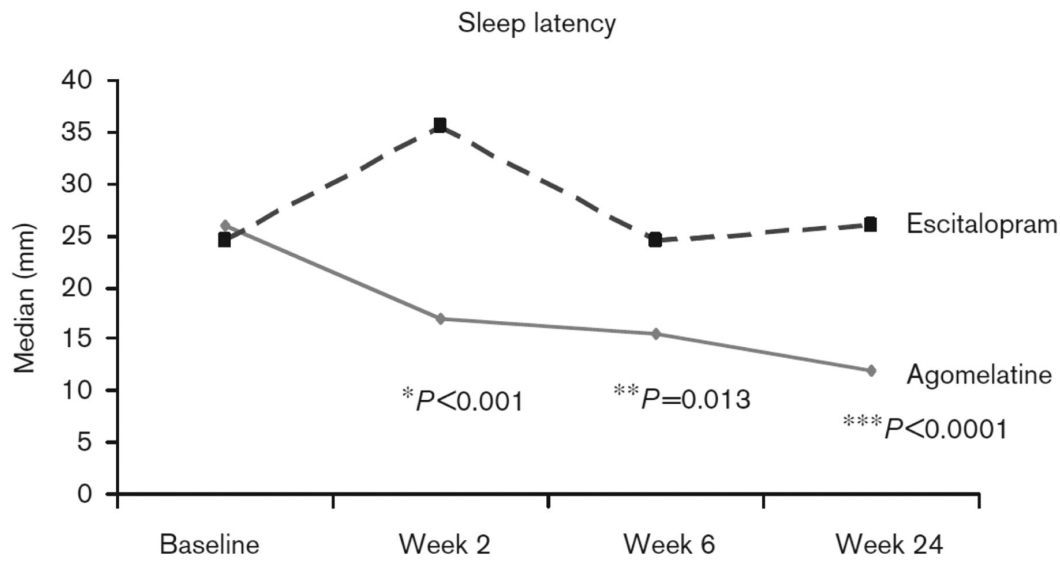
key exception being dose-dependent elevations in liver enzymes in a small but notable percentage of patients. As a result, frequent liver function testing is required prior to and during use of agomelatine. Agomelatine is also approved in the EU and Australia for the treatment of MDD, but it has never been approved in the United States.

The favorable efficacy and safety profile of agomelatine in GAD is supported by a recent meta-analysis of 22 pharmacological treatments evaluated in randomized trials of adult outpatients with GAD. This non-head-to-head, literature meta-analysis, which was based on data collected from 25,441 patients across 89 trials, including two placebo-controlled trials of agomelatine, found that agomelatine demonstrated superior efficacy compared to SSRIs and benzodiazepines. In addition, agomelatine demonstrated a superior tolerability profile compared to both benzodiazepines, which have abuse potential, and SSRIs, which can have significant AEs, including insomnia, sexual dysfunction, emotional blunting, weight gain, and even withdrawal symptoms in the event of discontinuation.

The favorable efficacy and safety profile of agomelatine in GAD is also supported by a recent systematic review and network meta-analysis that aimed to assess the efficacy and tolerability of agomelatine versus approved medications for the treatment of GAD. This non-head-to-head analysis was based on a total of 25 trials, including three placebo-controlled trials of agomelatine. Using the treatment rankings based on the network meta-analysis results, agomelatine was found to be the most favorable drug in terms of both efficacy (measured by remission rate) and tolerability (measured by discontinuation due to AEs) among the analyzed competitors (venlafaxine, escitalopram, paroxetine, duloxetine, and pregabalin).

Moreover, agomelatine's favorable tolerability profile consists of no statistically significant difference in overall adverse events or dropout rate and no association with clinically significant somnolence compared to placebo. Agomelatine does not cause sexual dysfunction. Specifically, no deleterious effect on sexual function was observed during agomelatine treatment over 12 or 24-week treatment periods in a specific sexual dysfunction comparative trial in remitted depressed patients. Agomelatine also does not exhibit the "hangover" effects (e.g., lethargy, fatigue, decreased motivation, anxiety, etc.) caused by various antidepressants and antipsychotics. Agomelatine, in a head-to-head study conducted by a third-party, also improves sleep latency, sleep architecture, and daytime sleepiness compared to escitalopram (SSRI), which can worsen sleep and cause insomnia. This makes agomelatine well-suited for GAD, where sleep disturbance is a core symptom.

Agomelatine Improves Sleep Compared to Escitalopram (SSRI)



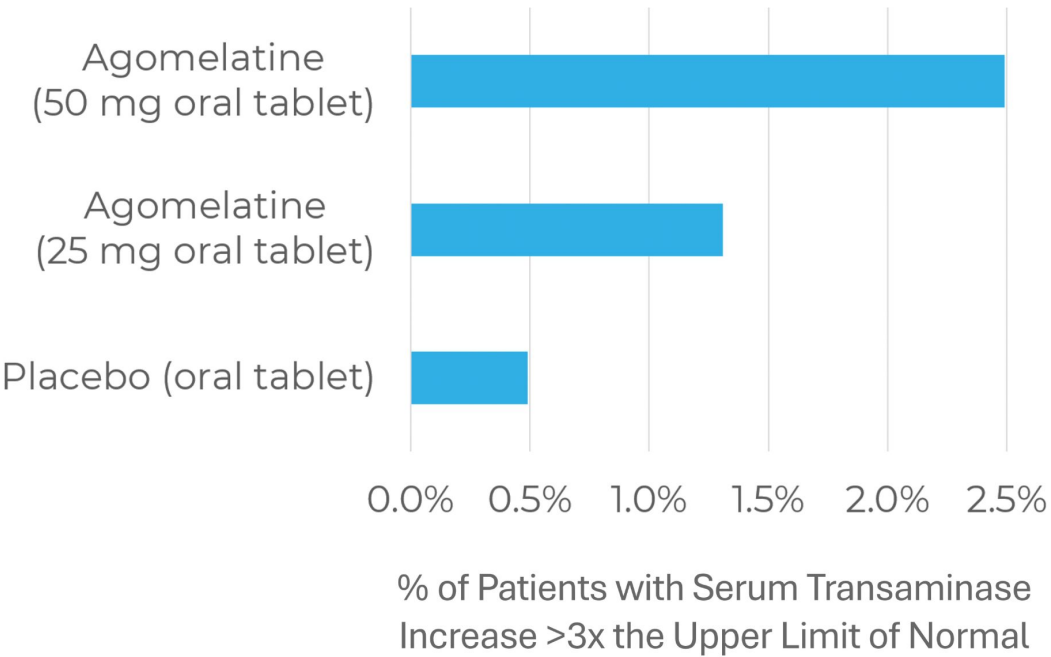
Sleep latency after 2, 6, and 24 weeks of treatment. * $P<0.001$, ** $P=0.013$, *** $P<0.001$ (Mann–Whitney test).

Quera-Salva, Maria-Antonia, et al. (2011) Comparison of agomelatine and escitalopram on nighttime sleep and daytime condition and efficacy in major depressive disorder patients. International clinical psychopharmacology, 26(5), 252-262

Despite the superior tolerability profile of agomelatine, clinical uptake has been limited by the requirement for frequent liver function monitoring. Due to extensive first-pass liver metabolism, the oral bioavailability of agomelatine is very low (~1%), and the frequency of liver transaminase elevations with agomelatine treatment is two to five-fold greater than placebo. As a result, patients in Australia and the EU—where agomelatine is approved—are required to undergo frequent liver function tests. Specifically, liver function tests must be performed before starting treatment, after 3, 6, 12, and 24 weeks, and when increasing dose. This burdensome liver testing, combined with a lack of patent protection, has limited clinical and commercial adoption of agomelatine.

Glyph enables bypass of liver first-pass metabolism, improving oral bioavailability and enabling the potential to achieve therapeutic exposures at a lower dose. As the increases in liver transaminase levels observed with agomelatine are dose-dependent, our goal is to achieve the exposure levels of agomelatine that are effective in GAD, but at a higher bioavailability and thus lower dose that reduces or eliminates the need for liver function testing. Based on internal analyses, we believe a two-fold increase in the bioavailability of agomelatine will reduce or eliminate liver enzyme elevations.

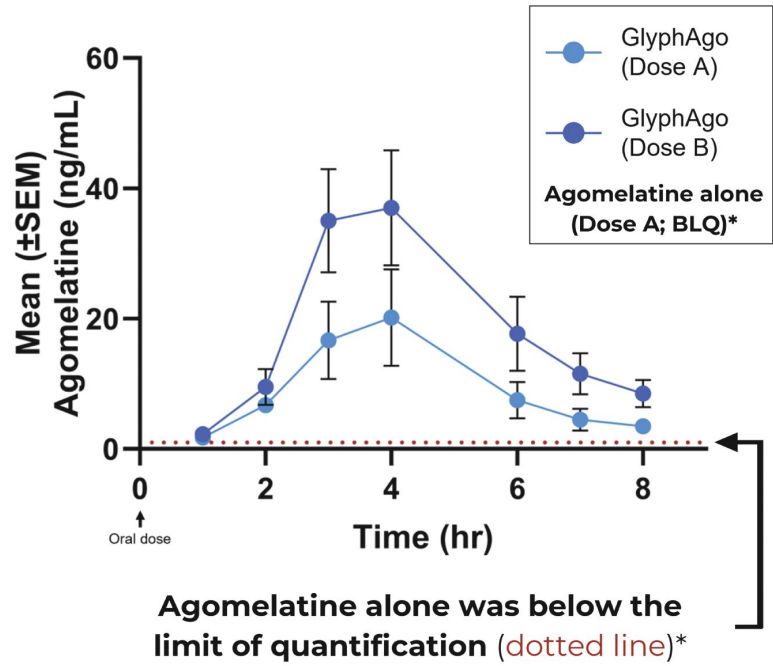
Agomelatine Can Cause Dose-Dependent Liver Enzyme Elevations



GlyphAgo in Preclinical Studies

As validation for GlyphAgo and further validation for our Glyph platform, we conducted in vivo studies in NHPs to evaluate the potential for GlyphAgo to achieve therapeutic exposure levels at a lower dose that may reduce or eliminate the need for liver function testing. In these studies, we dosed NHPs with either GlyphAgo or an equivalent (i.e., equimolar) amount of agomelatine alone (Dose A), or a greater dose of GlyphAgo (Dose B). GlyphAgo was shown to enhance lymphatic absorption and provide significantly higher systemic exposures of agomelatine compared to agomelatine alone. Oral dosing of GlyphAgo in a rat model resulted in over 50% of agomelatine being transported through the mesenteric lymphatics versus less than 1% for orally dosed agomelatine alone. Following administration of agomelatine alone, levels of agomelatine in plasma were below the limit of quantification, consistent with the low oral bioavailability of agomelatine in humans and NHPs (Valdoxan EPAR). In contrast, administration of GlyphAgo substantially increased plasma exposures of agomelatine compared with agomelatine alone, demonstrating the potential of GlyphAgo to achieve therapeutic exposures of agomelatine while minimizing the dose impacting the liver.

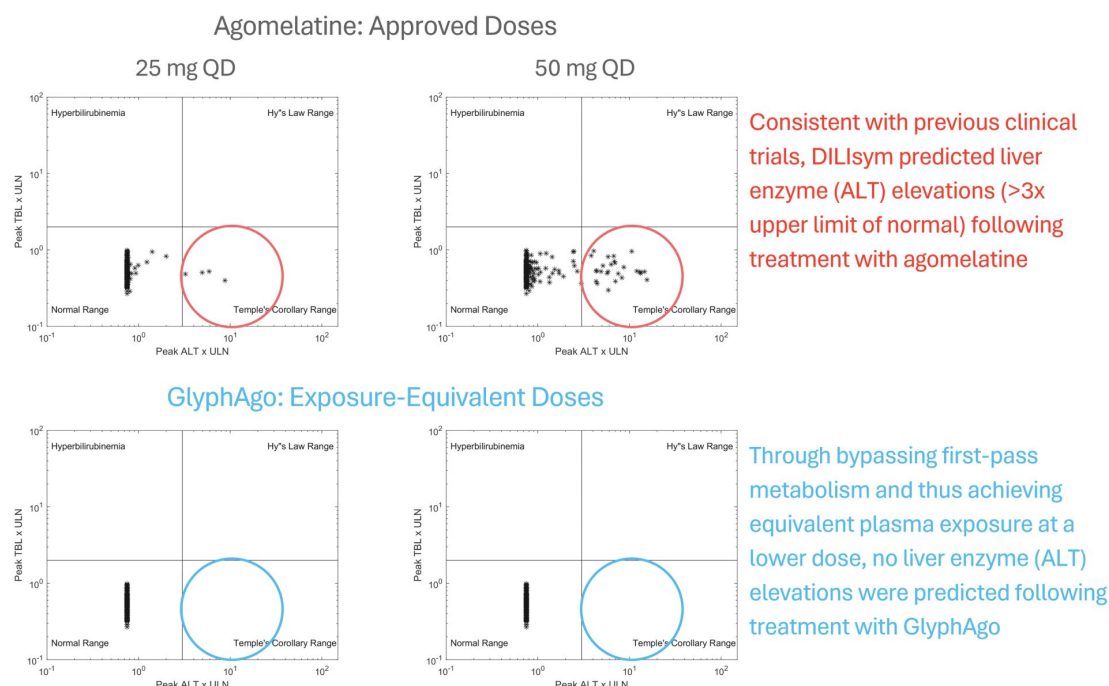
GlyphAgo Substantially Increased Plasma Agomelatine Levels in Non-Human Primates



Following the therapeutic exposures achieved with GlyphAgo in our NHP studies, we modelled the clinical implications of these data with respect to potential liver enzyme elevations using DILIsym, an analytical, computational model-based software capable of predicting and explaining Drug-Induced Liver Injury, or DILI. The FDA uses and cites DILIsym in drug approvals as the standard software for the quantitative prediction and investigation of DILI.

One useful output of DILIsym is an eDISH (Evaluation of Drug-Induced Serious Hepatotoxicity) plot. eDISH plots are a standard way that the FDA evaluates liver safety of new drug candidates in clinical trials. eDISH graphs the peak serum alanine aminotransferase (ALT; a liver enzyme) value and peak serum bilirubin value observed in each patient (or simulated patient) in a clinical trial along the x-axis and y-axis, respectively. Each patient (or simulated patient) is represented by a single point on the graph, and liver enzyme elevations (>3x upper limit of normal) are indicated by the presence of points on the right half of the graph. We first simulated the relationship between agomelatine dose and liver enzyme elevations using available clinical data for two approved doses of agomelatine (25 and 50 mg). Next, we simulated potential liver enzyme elevations following administration of GlyphAgo at doses designed to generate comparable systemic exposures of agomelatine, using assumptions derived from our in vivo study in NHPs described above. The results are shown in the four eDISH plots below. The eDISH plots in the upper row represent approved doses of agomelatine (25 mg and 50 mg) and recapitulate the liver enzyme elevations observed in previous clinic trials of agomelatine. The eDISH plots in the lower row represent doses of GlyphAgo with enhanced bioavailability and thus lower doses of agomelatine, which in contrast show no liver enzyme elevations.

DILIsym Simulations Demonstrate that GlyphAgo is Not Projected to Cause Liver Enzyme Elevations



Therefore, our DILIsym simulations demonstrated that, with conservative estimates, clinically relevant doses of GlyphAgo are not projected to cause liver enzyme elevations.

Clinical Development Plan of GlyphAgo in GAD

We are advancing a Phase 1 proof-of-concept trial of GlyphAgo in healthy adult volunteers in which we plan to enroll up to approximately 190 participants, that we believe has the potential to be proof of concept, in addition to addressing key development questions for the GlyphAgo program. In this trial, we aim to demonstrate that GlyphAgo can achieve exposure levels that have demonstrated efficacy in GAD at a lower dose that does not cause an increase in liver enzymes and reduces or eliminates the need for liver function testing. This Phase 1 trial will be conducted in multiple parts to evaluate the safety, tolerability, and pharmacokinetics of GlyphAgo compared to agomelatine. The primary endpoints will be safety, tolerability, and pharmacokinetics. It will include single- and multiple-ascending dose phases, as well as a food-effect crossover portion, using both open-label and placebo-controlled designs. We expect topline data in .

Opportunities to Expand the Potential for GlyphAgo in GAD and Other Indications

Although the development and commercialization of GlyphAgo for the treatment of GAD is our primary focus, as part of our longer-term growth strategy, we may evaluate GlyphAgo in other indications as well, including MDD. Indeed, agomelatine is approved for MDD in Australia and the EU, but it is constrained by similar liver function testing requirements in MDD as well. As agomelatine also improves sleep latency, sleep quality, and daytime sleepiness compared to SSRIs, which can worsen sleep and cause insomnia, we may also evaluate GlyphAgo for the treatment of insomnia.

Glyph2BLSD: Non-Hallucinogenic Neuroplastogen

Glyph2BLSD is our novel, Glyphed oral prodrug of the non-hallucinogenic neuroplastogen 2-bromo-LSD, which we are developing for the treatment of depressive disorders, including TRD, PTSD, and headache disorders with significant unmet need. Neuroplastogens are compounds that enhance neuroplasticity, the brain's ability to form, reorganize, and strengthen neural connections, and include psychedelics and ketamine. They offer the potential to repair disrupted brain circuits and have demonstrated efficacy for treating neuropsychiatric disorders. However, significant challenges remain, including functional unblinding of clinical trials due to the production of hallucinations and sensory disturbances, the accompanying need for supervised administration, and concerns over long-term safety, such as the risk of fibrosis. Leveraging our Glyph platform, we have designed Glyph2BLSD to harness the differentiated and non-hallucinogenic profile of 2-bromo-LSD, which has rapidly acting clinical activity and is not expected to exhibit the risks of fibrosis, cardiovascular effects, or hallucinations characteristic of some other neuroplastogens. With Glyph2BLSD, we aim to improve the pharmacokinetic and tolerability profile of 2-bromo-LSD while maintaining therapeutic exposure levels, and enable the execution of placebo-controlled trials, outpatient dosing, and an enhanced dosing regimen to optimize efficacy.

Development Plan of Glyph2BLSD

This candidate is in the early stages of development. We are currently conducting first-in-human-enabling studies of Glyph2BLSD, including single- and repeat-dose toxicology studies, in addition to in vitro and in vivo assays to further characterize Glyph2BLSD. The company expects to complete first-in-human-enabling studies by . We then expect to initiate a Phase 1 trial to evaluate the safety, tolerability and pharmacokinetics of Glyph2BLSD in healthy volunteers.

Potential Indications for Glyph2BLSD

Approximately 3 million adults in the United States have TRD, according to The Journal of Clinical Psychiatry, as of 2021. Unlike MDD, which, according to the National Institute of Mental Health, as of 2021, impacts an estimated 21 million adults annually, TRD is characterized by the failure to achieve an adequate response after two or more antidepressant treatments. Patients with TRD face severe challenges, including a significantly lower likelihood of responding to subsequent therapies, a reduced quality of life, and an increased risk of attempting suicide, more than double the rate seen in non-resistant depression. Many of these individuals experience chronic disability, relying heavily on social support systems.

PTSD affects approximately 12 million individuals in the United States and is also characterized by significant unmet need. There are currently only two approved therapies for PTSD, both of which are SSRIs. We believe Glyph2BLSD has the potential to restore function and improve outcomes to address the significant unmet medical need in TRD and PTSD.

Trigeminal autonomic cephalalgias, notably cluster headaches, are severe neurological conditions linked to the trigeminal nerve. Cluster headaches affect approximately 150,000 patients in the United States and cause the most severe pain known to humans, greater than labor pain or gunshot wounds. Individuals with cluster headache experience intense pain and autonomic symptoms including eye watering, swelling, and redness, as well as nose congestion. Headache attacks may last for up to 3 hours per episode and occur up to 8 times a day, disrupting patients' lives. Cluster headache has also been called "suicide headache" due to the increased risk of suicide during headache periods.

A small trial by Karst et al. showed that three doses of 2-bromo-LSD over a 10-day period significantly reduced the frequency and intensity of chronic cluster headaches, with effects lasting weeks to months. Importantly, the treatment did not induce hallucinations, making it a safer alternative to traditional psychedelics. While the trial was not placebo-controlled, and thus requires additional clinical investigation, we believe that Glyph2BLSD has the potential to optimize the pharmacokinetics of 2-bromo-LSD to ensure precise and sustained dosing, while preserving its non-hallucinogenic profile.

Competition

We are a clinical-stage therapeutics company focused on inventing and developing novel medicines for patients with depression, anxiety, and other debilitating neuropsychiatric disorders. While we believe our Glyph platform can produce small molecules that offer an attractive alternative to branded and generic therapeutics treating neuropsychiatric diseases if they are approved, today we face competition from major pharmaceutical and biopharmaceutical companies, academic institutions, governmental agencies, consortiums, and public and private research institutions, among others. Many of our potential competitors, either alone or with collaboration partners, have significantly greater financial resources than we do, as well as equal or greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products, and the commercialization of those products. Accordingly, our potential competitors may be more successful than we are in achieving regulatory approvals and commercializing their neuropsychiatric products.

We believe the key competitive factors affecting the success of our lead product candidates GlyphAllo and GlyphAgo, that we are developing to address MDD and GAD, respectively, if approved, are likely to be efficacy, safety, and frequency of dosing, convenience, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors.

We are developing GlyphAllo for the treatment of MDD. We believe, if approved, that GlyphAllo would compete with several currently approved therapeutics, including: Caplyta and Spravato (marketed by Janssen Pharmaceuticals), Vraylar (AbbVie and Gideon Richert Plc.), Trintellix (Takeda Pharmaceuticals and Lundbeck), Auvelity (Axsome Therapeutics), and Rexulti and Abilify (Ostuka Pharmaceuticals). We are also aware of multiple potentially competitive late-clinical-stage assets, including azetukalner (Xenon Pharmaceuticals), ALTO-300 and ALTO-203 (Alto Neuroscience) and CYB003 (Cybin). We also face competition from branded and generic atypical antipsychotics and SSRI/SNRIs.

We are developing GlyphAgo for the treatment of GAD. We believe, if approved, that GlyphAgo would compete with several currently marketed therapeutics, including: Lyrica and Buspirone (marketed by Viatris) and marketed generic SSRI/SNRIs and benzodiazepines. In relation to both GlyphAgo and Glyph2BLSD, we are also aware of multiple potentially competitive late-clinical-stage assets, including an LSD program (Mind Medicine, MindMed), ENX-102 (Engrail Therapeutics), CYB004 (Cybin), and non-hallucinogenic neuroplastogens (Gilgamesh Pharma and AbbVie).

Intellectual Property

We strive to protect the proprietary technology, inventions and improvements that are commercially important to the development of our business, by seeking, maintaining and standing ready to defend patent rights, whether developed internally or licensed from third parties. We also rely on trademarks, trade secrets and other intellectual property rights relating to our proprietary Glyph platform and product candidates, and on continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain our proprietary and intellectual property position. We may also rely on regulatory and other protections afforded through data and marketing exclusivities, where available.

We seek to protect the intellectual property and proprietary technology that we consider important to our business by pursuing patent applications that cover our technologies (including the Glyph platform) and product candidates and methods of using the same, as well as any other relevant inventions and improvements that are considered commercially important to the development of our business. We likewise seek to protect the intellectual property to which we obtain rights through licenses and sublicenses and work collaboratively with our licensors to ensure patent prosecution and protection. Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for our product candidates, commercially important technologies (including the Glyph platform), inventions and trade secrets related to our business, defend and enforce our intellectual property rights, particularly our patent rights and any patents we may own or in-license in the future, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others.

The patent positions for therapeutics companies like us are generally uncertain and can involve complex legal, scientific and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that any of our product candidates will be protectable or remain protected by enforceable patents that we own or in-license now or in the future. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties. Notwithstanding the scope of the patent protection available to us, a competitor could develop competitive technologies and products that are not covered by our patents, and we may be unable to stop such competitor from commercializing such technologies and products.

Our patent portfolio includes a combination of patents and pending patent applications solely owned by us or co-owned with Monash University where Monash University's rights are exclusively licensed to us, and patents and pending patent applications owned by Monash University that are exclusively licensed to us. As of January 15, 2026, our owned and exclusively licensed patent estate contains eleven patent families comprising five issued U.S. patents, thirteen issued patents in Australia, Canada, China, Europe (validated in Great Britain and through a Unitary Patent in Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Romania, Slovenia, and Sweden), Japan and New Zealand, seven pending U.S. non-provisional patent applications, two allowed European applications, 37 pending patent applications in various jurisdictions outside of the U.S., as further described below, and four pending PCT international applications.

GlyphAllo Program

In addition to the Glyph platform patents and applications discussed below, as of January 15, 2026, with regard to the GlyphAllo program, we co-own with and exclusively license from Monash University one issued U.S. patent relating to composition of matter coverage of GlyphAllo, which is expected to expire in 2041. We also co-own with and exclusively license from Monash University three pending U.S. non-provisional patent applications, one allowed European application, one allowed Japanese application and 19 pending patent applications in Australia, Canada, China, Europe, Hong Kong, India, Israel, Japan, Korea, New Zealand, and Singapore, relating to the composition of matter and methods of treatment which, if issued, will be expected to expire between 2039 and 2041. The foregoing expiration dates may not account for potentially available patent term adjustments or extensions and terminal disclaimers, and assume payment of all appropriate maintenance, renewal, and annuity fees.

We also solely own two international patent applications filed under the Patent Cooperation Treaty (PCT), one directed to methods of treating MDD with and without anxious distress using our GlyphAllo product candidate and the other directed to an intermediate for GlyphAllo. We expect that any issued patents claiming priority to these applications will expire in 2044, without taking into account any possible patent term adjustments or extensions and if all maintenance and annuity fees are paid.

Neither we nor any other Company has composition of matter patent protection on the parent molecule or the unmodified, non-glyphed form of allopregnanolone. Allopregnanolone, a naturally occurring neuroactive steroid, has no composition-of-matter patent protection in the United States or globally.

GlyphAgo Program

In addition to the Glyph platform patents and applications discussed below, we also solely own one international patent application filed under the PCT, directed to the composition of matter of our GlyphAgo product candidate and its use. We expect that any issued patents claiming priority to the international patent application will expire in 2044, without taking into account any possible patent term adjustments or extensions and if all maintenance and annuity fees are paid.

Neither we nor any other Company has composition of matter patent protection on the parent molecule or the unmodified, non-glyphed form of agomelatine. The composition-of-matter patents for agomelatine have expired in the United States and worldwide between 2010 and 2012.

Glyph2BLSD Program

In addition to the Glyph platform patents and applications discussed below, we also solely own one international patent application filed under the PCT, directed to the composition of matter of our Glyph2BLSD product candidate and its use. We expect that any issued patents claiming priority to this international patent application will expire in 2044, without taking into account any possible patent term adjustments or extensions and if all maintenance and annuity fees are paid.

Glyph Platform

With regard to the Glyph platform, we exclusively license from Monash University two issued U.S. patents, twelve issued patents in Australia, Canada, China, Europe (validated in Great Britain and through a Unitary Patent in Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Romania, Slovenia and Sweden), Japan, and New Zealand, and one allowed European patent application, relating to platform coverage of GlyphAllo, GlyphAgo and Glyph2BLSD, as well as design-around coverage, which are expected to expire between 2035 and 2037. We also exclusively license from Monash University three pending U.S. non-provisional patent applications and 15 pending patent applications in Australia, Canada, China, Europe, Hong Kong, Japan, and New Zealand, relating to platform coverage of GlyphAllo, GlyphAgo and Glyph2BLSD, as well as design-around coverage, which are expected to expire between 2035 and 2036. We also co-own and exclusively license from Monash University one issued U.S. patent, two pending U.S. non-provisional patent applications and four pending patent applications in Australia, Canada, Europe, and Hong Kong, relating to platform coverage of Glyph2BLSD, as well as design-around coverage, which are expected to expire in 2039. The foregoing expiration dates may not account for potentially available patent term adjustments or extensions and terminal disclaimers, and assume payment of all appropriate maintenance, renewal, and annuity fees.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier expiring patent. Our patent applications may not issue as patents, and even if issued, the scope or term of any issued patent may not afford sufficient protection or competitive advantage to our existing or future products. See the section titled "Risk Factors—Risks related to our intellectual property" for a more comprehensive description of risks related to our intellectual property.

In the United States, the term of a patent covering an FDA-approved drug may be eligible for a patent term extension under the Hatch-Waxman Act as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years beyond the expiration of the patent, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended, and a given patent may only be extended once. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. If our product candidates receive FDA approval, we intend to apply for patent term extensions, if available, to extend the term of patents that cover the approved product candidates. We also intend to seek patent term extensions in any jurisdictions where they are available, however, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

As of January 15, 2026, we have no outstanding litigation related to our intellectual property nor any threat to initiate claims against us. In the future, we may need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know-how or to defend against claims of infringement of the rights of others. Such litigation could be costly and could divert our attention from other functions and responsibilities. We may not receive adequate remedies even if we prevail in such litigation and adverse determinations could subject us to significant liabilities to third parties, which could severely harm our business. See the section titled “Risk Factors—Risks related to our intellectual property” for a more comprehensive description of risks related to our intellectual property.

Although we rely on intellectual property rights, including patents, trademarks and trade secrets, as well as contractual protections to establish and protect our proprietary rights, we believe that factors such as the technological and creative skills of our personnel, creation of new solutions, features and functionality, and frequent enhancements to our platform are also essential to establishing and maintaining our technology leadership position.

In addition to patent protection, we also rely on know-how and trade secret protection for our proprietary information to develop and maintain our proprietary position. However, trade secrets can be difficult to protect. Although we take steps to protect our proprietary information, including restricting and monitoring access to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors and potential collaborators, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our know-how and trade secret information. See the section titled “Risk Factors—Risks related to our intellectual property” for a more comprehensive description of risks related to our intellectual property.

In addition, we plan to rely on regulatory protection based on orphan drug exclusivities, data exclusivities, and market exclusivities. See the section titled “—Government Regulation” for additional information.

Further, we have and will continue to pursue trademark protection for our company name and brand. As of January 27, 2026, we own eighteen pending trademark applications in the United States and foreign jurisdictions, including four allowed trademarks in the United States.

Agreements

Asset Transfer Agreement with PureTech

In April 2024, we entered into an Asset Transfer Agreement, as amended in December 2025, or the Asset Transfer Agreement, with PureTech Health LLC, or PureTech Health, and PureTech LYT, Inc., or PureTech LYT, pursuant to which PureTech Health and PureTech LYT agreed to contribute, convey, assign, transfer, and deliver to us all of PureTech Health’s and PureTech LYT’s right, title, and interest in, to, and under the assets related to its Glyph technology or products, including the Monash License Agreement and the exclusive patents thereunder, subject to the terms set forth in the Asset Transfer Agreement. In exchange, we issued 40,000,000 shares of our Series A-1 convertible preferred stock and 949,000 shares of our common stock to PureTech LYT.

In connection with the Asset Transfer Agreement, we have agreed to make milestone payments for the first product covered by assets transferred through the Asset Transfer Agreement, or the first Seaport Glyph Product, of \$2.0 million for the first patient dosed in the first phase 3 clinical trial, \$4.0 million for the first commercial sale in the United States, \$2.0 million for the first commercial sale in a major European market, and \$2.0 million for the first commercial sale in Japan, and for each subsequent Seaport Glyph Product, we have agreed to make milestone payments of \$1.0 million for the first patient dosed in the first phase 3 clinical trial, \$2.0 million for the first commercial sale in the United States, \$1.0 million for the first commercial sale in a major European market, and \$1.0 million for the first commercial sale in Japan. In addition, we are obligated to pay royalties between 3% and 5% on the annual net sales of each Seaport Glyph Product as follows: less than \$500 million: 3%;

\$500 million to \$1 billion: 3.5%; \$1 billion to \$2.5 billion: 4%; \$2.5 billion to \$3.5 billion: 4.5%; \$3.5 billion or greater: 5%. The royalty term will expire on a country-by-country basis as to each Seaport Glyph Product on the later of the ten year anniversary of the first commercial sale of such Seaport Glyph Product in such country or the date on which the last valid claim of patent rights of such Seaport Glyph Product expires in such country. As of the date of this filing, the last-to-expire patents under the Asset Transfer Agreement expire in 2044, not including any patent term extension or patent term adjustment. We may update or revise the year of the last-to-expire patents as the transferred assets under the Asset Transfer Agreement include patents exclusively licensed under the Monash License Agreement which covers, in addition to a prespecified list, any patent or patent application that claims new intellectual property created under any research agreement entered into with Monash University. Please refer to the Monash License Agreement summary below for further information.

In the event we license or sublicense to a third-party a product directed to an indication that is primarily affecting or manifesting in the brain, spinal cord, or peripheral nervous system (with the exception of and not including the enteric nervous system), including neurological, psychiatric, neuropsychiatric, pain, mental, and behavioral indications made using our Glyph platform under the Glyph intellectual property, transferred to us through the Asset Transfer Agreement, we have also agreed to pay a percentage of net income we receive from such third party under such a license within the range of 5%-7.5% and adjusted depending on the date such a license is granted, with the amount to be paid subject to certain reductions. Any such amount of net income are creditable against royalty payments.

Under the Asset Transfer Agreement, PureTech may from time to time request that we grant it a license under the Glyph technology to utilize certain products directed to an indication that is not primarily affecting or manifesting in the brain, spinal cord, or peripheral nervous system (such as, for example, neurological, psychiatric, neuropsychiatric, pain, mental, and behavioral indications) under license terms that have already been agreed to by PureTech and us in the Asset Transfer Agreement; provided that such products (i) are not subject to an agreement, or we are not actively engaged in negotiations, with a third party that would prevent us from granting such license, (ii) are not the subject of an internal research and development program, and (iii) have not been demonstrated or under experimental investigation by us to be potentially useful as a therapeutic for any disease, disorder, or condition primarily affecting or manifesting in the brain, spinal cord, or peripheral nervous system. PureTech's right to request such a license terminates upon a change of control of either PureTech or us.

Other than the upfront equity grant, we have not made any payments to date pursuant to the Asset Transfer Agreement. Should we sell our first controlled affiliate that has exclusive rights to utilize any Seaport Glyph Product, we will be obligated to pay a low double-digit percentage, within the range of 5% to 15%, of the value of the aggregate amount of all change of control consideration paid to us. We will not be obligated to pay any fee under the Asset Transfer Agreement in the event of a sale of the Company or any other subsequent controlled affiliate. The Asset Transfer Agreement closed on April 8, 2024, and it is not contractually permissible to terminate the Asset Transfer Agreement.

Monash University Exclusive License Agreement

In April 2024, PureTech Health exclusively assigned to us, and we assumed, all rights and obligations under the Original License Agreement. In March 2025, we entered Monash License Agreement. Pursuant to the Monash License Agreement, Monash University grants us (i) a worldwide, exclusive, sublicensable license under certain Monash University intellectual property rights, including patent rights related to the Glyph platform, or the Licensed Patents, know-how, and intellectual property stemming from joint research and development activities, for the purpose of developing and commercializing products in all fields with one exception, (ii) a worldwide, non-exclusive, sublicensable license under certain background technology and certain other intellectual property strictly to the extent necessary to exercise the license described in subclause (i) above, and (iii) a first right and an exclusive option to obtain an exclusive license to any invention generated by Monash University outside of the Licensed Patents and pertaining to certain prodrug technology. Additionally, we and Monash University agreed to collaborate in conducting research and development activities.

Under the Monash License Agreement, we have agreed to use reasonable commercial endeavors to (i) develop at least one Licensed Product, (ii) seek regulatory approval for at least one Licensed Product, and (iii) after receipt of such regulatory approval in the United States or Europe, promote and develop the sale of at least one Licensed Product in such territory. Monash University agrees to provide reasonable technical assistance and advice based on Monash University's know-how relating to the technology licensed under the Monash License Agreement. We grant Monash University a non-exclusive, perpetual, royalty-free license under the Licensed Patents, related know-how, and intellectual property stemming from joint research and development activities solely for academic, teaching, and non-commercial collaborative research uses, which includes the right to sublicense for non-commercial collaborative research to other academic institutions or non-commercial research entities.

As consideration for the licenses granted by Monash University, we are required to pay Monash University: (i) low-single digit royalties with a rate based on net sales per calendar year (subject to certain reductions); (ii) a low-double digit percentage (within the range of 5-15%) of any net income received under a sublicense (subject to a license payment stacking reduction) with the percentage varying based on the development stage of the Licensed Products at the time the sublicense is granted during the term of the Monash License Agreement; (iii) an agreed upon research funding amount to progress mutually agreed research and development or commercialization activities; (iv) a mid-five-figure annual maintenance fee during the term of the agreement commencing on the third anniversary of the execution date of the Original License Agreement until the first commercial sale of a Licensed Product creditable against net income sharing, royalties, and milestone payments; (v) milestone payments in the event of successful development milestones of up to \$1.075 million per Licensed Product for the first three Licensed Products; and (vi) milestone payments in the event of successful commercial milestones of up to \$7.25 million per Licensed Product for the first three Licensed Products. We are also obligated to (a) pay all costs incurred for the prosecution and maintenance of the Licensed Patents and patent filings stemming from collaboration activities and (b) reimburse Monash University for all patent prosecution costs of the Licensed Patents prior to the execution date of the Original License Agreement.

The Monash License Agreement commenced on the execution date of the Original License Agreement and will expire seven years after the last of the Licensed Patents expires, unless terminated earlier. Although the last-to-expire patent licensed under the Monash License Agreement currently expires in 2041, the year of the last-to-expire patent may change as the Monash License Agreement covers, in addition to a prespecified list, any patent or patent application that claims new intellectual property created under any research agreement entered into with Monash University. Either party may terminate for due cause, including for material breach and bankruptcy. Monash University may terminate if we fail to meet our diligence requirements. Either party may terminate the Monash License Agreement if we determine that the activities are no longer commercially viable.

As of December 31, 2025, the first two development milestones for a total of \$0.2 million were achieved and paid by PureTech as they occurred prior to our formation, and we have paid the third development milestone of \$0.1 million as well as annual maintenance fees. No other milestones have occurred or have been paid under the Monash License Agreement as of December 31, 2025.

Government Regulation

Government authorities in the United States, at the federal, state, and local level, and in other countries and jurisdictions, including the European Union, or EU, extensively regulate, among other things, the research, development, testing, manufacturing, quality control, safety, effectiveness, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs in the United States

In the United States, the FDA regulates drugs under the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The failure to comply with applicable U.S. requirements at any time during the product development process, approval process, or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, and other types of letters, product seizures, total or partial suspension of production or distribution, injunctions, fines, product recalls, and other post-market actions, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations, and penalties brought by the FDA and the U.S. Department of Justice or other governmental entities.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of nonclinical, or preclinical, laboratory tests, animal studies, and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, which must take effect before human clinical trials may begin;
- approval by an institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated at that site;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a New Drug Application, or NDA, and payment of user fees;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality, and purity;
- satisfactory completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data; and
- FDA review and approval of the NDA.

Preclinical Studies

Before an applicant begins testing a compound in humans, the drug candidate enters the preclinical testing stage. Preclinical studies include, among other things, laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient, or API, and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the potential safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of certain preclinical studies is subject to federal regulations and requirements, including GLP regulations. Some long-term preclinical testing, such as animal tests of reproductive adverse effects, or AEs, and carcinogenicity, may continue after the IND is submitted.

The IND and IRB Processes

An IND is an exemption from the FDCA that allows an investigational drug to be shipped in interstate commerce for use in a clinical trial and a request for FDA authorization to administer such investigational drug to humans. Such authorization must be secured prior to interstate shipment and administration of the investigational

drug. In an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments. In addition, the results of the preclinical tests, manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. The FDA also may impose a clinical hold or partial clinical hold after commencement of a clinical trial under an IND. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation (or full investigation in the case of a partial clinical hold) may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical trial is not conducted under an IND, the sponsor must ensure that the study is conducted in accordance with GCP, among other things, including review and approval by an independent ethics committee and obtaining informed consent from subjects. The GCP requirements are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. FDA must also be able to validate the data from the study through an on-site inspection if necessary.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review of the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides advice to the sponsor as to whether or not a trial may move forward at designated check points based on pre-specified criteria and access that only the group maintains to available data from the study. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on its ClinicalTrials.gov website.

Human Clinical Trials in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects, or their legal representative, provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- *Phase 1.* The product candidate is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage

tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness, and to determine maximal dosage.

- *Phase 2.* The product candidate is administered to a limited patient population with the specified disease or condition to identify possible AEs and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases or conditions and to determine dosage tolerance and optimal dosage.
- *Phase 3.* The product candidate is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials with the intent to generate enough data to evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product candidate and to provide adequate information for the labeling of the product.

Post-approval studies, sometimes referred to as Phase 4 studies, may be conducted after initial regulatory approval. These studies 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 4 clinical trials as a condition of approval of an NDA.

While the IND is active, progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA. In addition, within 15 calendar days after the sponsor determines that the information qualifies for reporting, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information.

Concurrent with clinical trials, companies often 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 product 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, the applicant must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. 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.

Review of an NDA by the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls, and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to a significant application user fee as well as annual prescription drug product program fees. These fees are typically increased annually. Certain exceptions and waivers are available for some of these fees.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, NDAs, and certain supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the product candidate is ready for approval

for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before any pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt, before accepting the NDA for filing, to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP compliant to assure and preserve the product's identity, strength, quality, and purity. Under the performance goals and policies implemented by the FDA under the Prescription Drug User Fee Act, or PDUFA, FDA has agreed to specified performance goals in the review process of NDAs. Applications for drugs containing new molecular entities are meant to be reviewed within 10 months from the date of filing, and applications for "priority review" products containing new molecular entities are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months if FDA requests or the applicant otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date or is otherwise deemed a "major amendment" to the application.

During its review of an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA, including drug component manufacturing (such as APIs), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an NDA unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

In addition, as a condition of approval, the FDA may require an applicant to develop a risk evaluation and mitigation strategy, or REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential AEs, and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates, and provides 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.

Fast Track, Breakthrough Therapy, and Priority Review

The FDA has a number of programs intended to facilitate and expedite development and review of investigational drugs if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. Three of these programs are referred to as Fast Track Designation, Breakthrough Therapy Designation, and priority review designation.

First, the FDA may designate a product candidate for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such disease or condition. For Fast Track product candidates, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product candidate's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product candidate may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track Designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product candidate may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other drugs products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy Designation includes all of the benefits associated with Fast Track Designation, including the potential for rolling review of an NDA submission. In addition, the FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate an NDA review for a priority review if it is for a product candidate that treats a serious or life-threatening disease or condition and, if approved, would provide a significant improvement in safety or effectiveness compared to available therapies. The FDA determines, on a case-by-case basis, whether the product candidate may represent a significant improvement when compared with other available therapies. Significant improvement may be illustrated, among other things, by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from 10 months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product candidate intended to treat a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly.

The accelerated approval pathway is typically contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's anticipated clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or other post-approval clinical trials to verify and describe the anticipated effect on the clinical endpoint. Under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Sponsors are also required to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must post this information publicly. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the sponsor fails to conduct such studies in a timely manner and send the necessary updates to the FDA, or if a confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA generally requires, unless otherwise informed by the agency, pre-approval of promotional materials for product candidates approved under accelerated regulations, which could adversely impact the timing of the commercial launch of the product.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of any inspections of the manufacturing facilities and select clinical trial sites, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If a complete response letter is issued, the applicant may resubmit the NDA to address all of the deficiencies identified in the letter, withdraw the application, or request a hearing. If the applicant resubmits the NDA, the FDA will issue an approval letter only when the deficiencies have been addressed to the FDA's satisfaction. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings, or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety or effectiveness after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising, and promotion, reporting of adverse experiences with the product and applicable product tracking and tracing requirements. After approval, many changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are annual prescription drug product program fee requirements for certain marketed products.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs, and those supplying products, ingredients, and components of them are required to register

their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the NDA holder and any third-party manufacturers that the NDA holder may decide to use. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and notify the FDA of counterfeit, diverted, stolen, and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the 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 AEs 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 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 voluntary product recalls;
- fines, warning, or untitled letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Hatch-Waxman Amendments

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A 505(b)(2) NDA is an application that contains full reports of investigations of safety and efficacy but where at least some of the information required for approval comes from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This regulatory pathway enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy for an existing product, or published literature, in support of its application. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference

drug. The FDA may then approve the new product candidate for all, or some, of the labeled indications for which the branded reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product, known as a reference listed drug, or RLD. ANDAs are termed “abbreviated” because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through *in vitro*, *in vivo*, or other testing. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product.

Non-Patent Exclusivity

Under the Hatch-Waxman Amendments, the FDA may not approve (or in some cases accept) an ANDA or 505(b)(2) application until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity, or NCE. For the purposes of this provision, an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, which states the proposed generic drug will not infringe one or more of the already approved product’s listed patents or that such patents are invalid or unenforceable, in which case the applicant may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of exclusivity for non-NCE drugs if the NDA or a supplement to the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application or supplement. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination, or indication, but it generally would not protect the original, unmodified product from generic competition. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs seeking approval for generic versions of the drug as of the date of approval of the original drug product; it only prevents FDA from approving such ANDAs.

A drug product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the active moiety and to patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection and patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued “Written Request” for such a study, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

Hatch-Waxman Patent Certification and the 30-Month Stay

In seeking approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant’s product or an approved method of using the product. Upon approval of an NDA, each of the patents listed in the application for the drug is published in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Upon

submission of an ANDA or 505(b)(2) NDA, an applicant is required to certify to the FDA concerning any patents listed for the RLD in the Orange Book that:

- no patent information on the drug product that is the subject of the application has been submitted to the FDA;
- such patent has expired;
- the date on which such patent expires; or
- such patent is invalid, unenforceable, or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted.

Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through the last type of certification, also known as a paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired. If the ANDA or 505(b)(2) NDA applicant has provided a paragraph IV certification, the applicant must send notice of the paragraph IV certification to the NDA and patent holders once the application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. If the paragraph IV certification is challenged by an NDA holder or the patent owner(s) asserts a patent challenge to the paragraph IV certification, the FDA may not approve that application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or settled, or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay. In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owner(s) regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation. If the drug has NCE exclusivity and the ANDA is submitted four years after approval, the 30-month stay is extended so that it expires seven and a half years after approval of the innovator drug, unless the patent expires or there is a decision in the infringement case that is favorable to the ANDA applicant before then.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Amendments, which permits a patent term restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date, provided the sponsor acted with diligence. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question and within 60 days of drug approval. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office, or USPTO, reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

U.S. Drug Enforcement Administration Regulation

Certain of our product candidates have the potential to be regulated as controlled substances by the U.S. Drug Enforcement Administration, or DEA. The Controlled Substances Act of 1970, or CSA, establishes registration, security, recordkeeping, reporting, storage, distribution, and other requirements administered by the DEA. The DEA

is concerned with the control of handlers of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. The DEA regulates controlled substances as Schedule I, II, III, IV, or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV, or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports, or exports any controlled substance. The registration is specific to the particular location, activity, and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized. The DEA typically inspects a facility to review its security measures prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA. Reports must also be made for thefts or losses of any controlled substance, and authorization must be obtained to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations can lead to criminal prosecution. Individual states also regulate controlled substances, and manufacturers are also subject to state regulation on distribution of these products.

Rest of the World Regulation

For other countries outside of the United States, such as those in Europe, Latin America, or Asia, the requirements governing product development, the conduct of clinical trials, product marketing, product licensing, pricing and reimbursement can vary from country to country. Failure to comply with applicable foreign regulatory requirements may subject sponsors, manufacturers, or marketers of pharmaceutical products to, among other things, fines, suspension, or withdrawal of regulatory authorizations and approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Review and Approval of Medicinal Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy, and governing, among other things, clinical trials, obtaining marketing authorization, or MA, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. Specifically, the process governing approval of medicinal products in the EU generally follows similar lines as in the United States. It entails satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission to the relevant competent authorities of an MA application, or MAA, and granting of an MA by these authorities before the product can be marketed and sold in the EU.

Non-clinical Studies and Clinical Trials

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, or ICH, guidelines on Good Clinical Practices, or GCP, as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU member states, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repealed the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allowed sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state’s decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practice, or GMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

In order to market our product candidates in the EU and many other foreign jurisdictions, we must obtain separate regulatory approvals. More concretely, in the EU, medicinal product candidates can only be commercialized after obtaining an MA. To obtain an MA, an applicant must submit an MAA either under a centralized procedure administered by the European Medicines Agency, or EMA, or one of the procedures administered by competent authorities in the EU member states (decentralized procedure or mutual recognition procedure) for obtaining an MA in multiple EU Member States.

“Centralized MAs” are issued by the European Commission through the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the EU. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products (gene therapy, somatic cell therapy and tissue-engineered products) and products with a new active substance indicated for the treatment

of certain diseases, including products for the treatment of HIV, AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific, or technical innovation or which are in the interest of public health in the EU.

Under the centralized procedure, the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions asked by the CHMP. Clock stops may extend the timeframe of evaluation of an MAA considerably beyond 210 days. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from a public health perspective and in particular from the point of view of therapeutic innovation. If the CHMP accepts such request, the time limit of 210 days will be reduced to 150 days, excluding clock stops, but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment. At the end of this period, the CHMP provides a scientific opinion on whether or not a marketing authorization should be granted in relation to a medicinal product. Within 67 days from the date of the CHMP opinion, the European Commission will adopt its final decision on the MAA.

“National MAs” are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for product candidates not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Periods of Authorization and Renewals

A MA has an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the relevant EU member state for a nationally authorized product. To this end, the MA holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety, and efficacy, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. Once renewed, the MA is valid for an unlimited period, unless the European Commission or the competent authorities of the relevant member states decide, on justified grounds relating to pharmacovigilance, to proceed with one further five year renewal period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for centrally-authorized products) or on the market of the authorizing EU member state (for nationally-authorized products) within three years after authorization ceases to be valid (the so-called “sunset clause”).

Data and Market Exclusivity

In the EU, innovative medicinal products approved on the basis of a complete and independent data package generally receive eight years of data exclusivity and an additional two years of market exclusivity upon grant of an MA. The data exclusivity period prevents applicants for authorization of generics or biosimilars of these innovative products from referencing the innovator’s preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar (abbreviated) MA, for a period of eight years from the date on which the reference product was first authorized in the EU. During an additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator’s data may be referenced, but no generic or biosimilar medicinal product can be placed on the EU market until the expiration of the market exclusivity. The overall 10-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit

in comparison with existing therapies. There is no guarantee that a product will be considered by the EMA to be an innovative medicinal product, and products may not qualify for data exclusivity. Even if a product is considered to be an innovative medicinal product so that the innovator gains the prescribed period of data exclusivity, another company nevertheless could also market another version of the product if such company obtained an MA based on an MAA with a complete and independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Orphan Medicinal Products

The criteria for designating an “orphan medicinal product” in the EU are similar in principle to those in the United States. A medicinal product can be designated as an orphan if its sponsor can establish that: (1) the product is intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition, (2) either (i) such condition affects no more than five in ten thousand persons in the EU when the application is made, or (ii) without the benefits derived from orphan status, it is unlikely that the marketing of the product in the EU would generate sufficient return to justify the necessary investment in its development; (3) there exists no satisfactory method of diagnosis, prevention, or treatment of the condition in question that has been authorized in the EU or, if such method exists, the product would be of significant benefit to those affected by that condition.

An orphan designation provides a number of benefits, including fee reductions, regulatory assistance, and the possibility to apply for a centralized EU MA. Upon grant of an MA, orphan medicinal products are entitled to a ten-year period of market exclusivity, which means that the EMA and the competent authorities of the EU member states cannot accept another MAA, or grant an MA, or accept an application to extend an MA for a similar medicinal product for the same indication for a period of ten years. A “similar medicinal product” is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed pediatric investigation plan, or PIP. No extension to any supplementary protection certificate, or SPC, can be granted on the basis of pediatric studies for orphan indications. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The orphan exclusivity period may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for which it received orphan destination, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar product for the same indication as an authorized orphan product at any time if (i) a second applicant can establish that its product, although similar to the authorized orphan product, is safer, more effective or otherwise clinically superior; (ii) the MA holder for the authorized orphan product consents to a second medicinal product application; or (iii) the MA holder for the authorized product cannot supply enough orphan medicinal product.

Pediatric Development

Regulation (EC) No 1901/2006 provides that prior to obtaining an MA in the EU, applicants have to demonstrate compliance with all measures included in a pediatric investigation plan, or PIP, agreed with the EMA’s Pediatric Committee, or PDCO, and covering all subsets of the pediatric population, unless the PDCO has granted (1) a product-specific waiver, (2) a class waiver, or (3) a deferral for one or more of the measures included in the PIP. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the product for which an MA is being sought. Products that are granted an MA with the results of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six-month extension of the protection under a SPC provided an application for such extension is made at the same time as filing the SPC application for the product, or at any point up to two years before the SPC expires, even where the trial results are negative. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be

available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the member states. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, or QPPV, who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAA must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product.

The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising, and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited in the EU. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the EU member states plus Norway, Liechtenstein, and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, authorization of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption, or with other applicable regulatory requirements may result in administrative, civil, or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant an MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing, or clinical trials, operating restrictions, injunctions, suspension of licenses, fines, and criminal penalties.

Reform of the Regulatory Framework in the European Union

The EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and Council of the EU and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026.

Brexit and the Regulatory Framework in the United Kingdom

Following the end of the Brexit transition period on January 1, 2021 and the implementation of the Windsor Framework on January 1, 2025, the United Kingdom, or UK, is not generally subject to EU laws in respect of medicines. The EU laws that have been transposed into UK law through secondary legislation remain applicable in the UK however, new legislation such as the (EU) CTR is not applicable in the UK.

Under the Medicines and Medical Devices Act 2021, the Secretary of State or an ‘appropriate authority’ have delegated powers to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials, and medical devices.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, is the UK’s standalone medicines and medical devices regulator. As a result of the Ireland/Northern Ireland protocol, different rules applied in Northern Ireland than in England, Wales, and Scotland (together, “Great Britain”, or GB), which continued to follow the EU regulatory regime. However, on January 1, 2025 a new arrangement called the “Windsor Framework” came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes and EU labeling and serialization requirements in relation to Northern Ireland and introduces a UK-wide licensing process for medicines.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the CTD, as implemented into UK national law through secondary legislation. In April 2025, the UK introduced the Medicines for Human Use (Clinical Trials) (Amendment) Regulations. These changes, which will take full effect from April 2026, aim to create a streamlined, risk-proportionate system that accelerates approvals while maintaining robust safety standards.

In addition, in October 2023, the MHRA announced a new Notification Scheme for clinical trials which enables a more streamlined and risk-proportionate approach to initial clinical trial applications for Phase 4 and low-risk Phase 3 clinical trial applications.

MAAs in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. All existing EU MAAs for centrally authorized products were automatically converted or grandfathered into UK MAAs, effective in GB (only), free of charge on January 1, 2021, unless the MA holder chose to opt-out. Under the terms of the Windsor Framework, these licenses became valid for the whole of the UK from January 1, 2025. In order to use the centralized procedure to obtain an MA that will be valid throughout the EEA, companies must be established in the EEA. Therefore, after Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized MAAs. In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, a 150-day assessment (subject to clock-stops) and a rolling review procedure. The rolling-review procedure permits the separate or joint submission of quality, non-clinical, and clinical data to the MHRA which can be reviewed on a rolling basis. After an application under the rolling-review procedure has been validated, the final decision should be received within 100 days (subject to clock-stops). In addition, since January 1, 2024, the MHRA may rely on the International Recognition Procedure, or IRP, when reviewing certain types of MAAs. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (e.g. the medicines regulatory authorities in Australia, Canada, Switzerland, Singapore, Japan, the U.S.A. and the EMA in the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is

considered insufficiently robust. Applications should be decided within a maximum of 60 days if there are no major objections identified that cannot be resolved within such 60 day period and the approval from the trusted regulatory partner selected has been granted within the previous 2 years. If there are such major objections identified or such approval hasn't been granted within the previous 2 years, then the relevant timeframe for the MHRA decision is within 110 days. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations, and renewals.

In the UK, the initial duration of an MA is five years and following renewal will be valid for an unlimited period unless the MHRA decides on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Any authorization which is not followed by the actual placing of the medicine on the market in the UK (or GB, if the MA is only valid in GB) within three (3) years shall cease to be in force.

There is no pre-MA orphan designation in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MA application. The criteria are essentially the same, but have been tailored for the market, i.e., the prevalence of the condition in the UK, rather than the EU, must not be more than five in 10,000. Should an orphan designation be granted, the period or market exclusivity will be set from the date of first approval of the product in the UK.

Other Healthcare Laws

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. The laws that may affect our ability to operate, and our proposed sales, marketing, and distribution strategies, include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons 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, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, or recommendation of any good, facility, item, or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. 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. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. 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, or FCA (discussed below);
- federal civil and criminal false claims laws, including the FCA and civil monetary penalty laws, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses,

representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating these statutes without actual knowledge of the statutes or specific intent to violate them;

- failing to take appropriate steps to keep consumers' personal information secure could constitute an unfair act or practice in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a) or similar state laws. The Federal Trade Commission, or FTC, and state regulators expect a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards;
- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, and its implementing regulations requires manufacturers of drugs, devices, biologicals, 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 Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other licensed healthcare professionals (i.e., physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, and certified nurse midwives), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal government price reporting laws, which require manufacturers to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales, and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; 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 that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations, and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives.

Federal, state, and foreign enforcement bodies are continuing to increase their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to significant penalties, including, without limitation, administrative, civil, and criminal penalties, damages, fines, disgorgement, contractual damages, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs, reputational harm, diminished profits and future earnings, and individual imprisonment.

Privacy and Data Security

In the ordinary course of business, we and the third parties upon which we rely collect, receive, store, or otherwise process personal data, including information we may collect about participants in our clinical trials. This personal data can also include data that is considered “sensitive” personal data under privacy laws, policies, or agreements to which we are subject. Accordingly, we are, or may become, subject to numerous, evolving privacy and data security obligations, including global, federal, state, and local laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations related to privacy and data security.

These privacy and data security laws are evolving and may impose potentially conflicting obligations. Such obligations may include, without limitation, federal health information privacy laws, state information security and data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., the Federal Trade Commission Act). At the state level, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording individuals certain rights concerning their personal data. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. Additionally, a smaller number of states have passed or are considering laws governing the privacy of consumer health data. While existing state consumer privacy laws provide exemptions for data processed in the context of clinical trials, the continued development of complex requirements at the state level may further complicate compliance efforts and may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products, and are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing, as more fully discussed in the section titled “Risk Factors.”

Additionally, to the extent we collect personal data outside of the United States, through clinical trials or otherwise, we are, or may become, subject to foreign data and data security laws, such as the European Union’s General Data Protection Regulation 2016/679, or EU GDPR, and other national data protection legislation in force in relevant EEA Member States, and the EU GDPR as it forms part UK law by virtue of section 3 of the European Union (Withdrawal) Act 2018, or UK GDPR. Foreign privacy and data security laws impose significant and complex compliance obligations on entities that are subject to those laws and may impose significant sanctions for non-compliance (including fines of up to the greater of 20 million Euros (17.5 million GBP for the UK) or 4% of worldwide annual revenue), as more fully discussed in the section titled “Risk Factors.”

Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the costs associated with their prescription. Therefore, adequate coverage and reimbursement from such third-party payors are critical to new and ongoing product acceptance. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels, for the product. Factors payors consider in determining coverage and reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective, and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Therefore, even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a return on our investment. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs.

There may be significant delays in obtaining coverage and reimbursement, as the process of determining coverage and reimbursement is often time consuming and costly. In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Moreover, coverage may be more limited than the purposes for which the product is approved by FDA or regulatory authorities in other countries. Additionally, companies may also need to provide discounts to purchasers, private health plans, or government healthcare programs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication. Third-party payors could determine that our product candidates are not medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and our financial condition.

The containment of healthcare costs has become a priority of federal, state, and foreign governments, and the prices of products have been a focus in this effort. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control, and other changes to the healthcare system in the United States including the relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

Further, third-party payors are increasingly reducing reimbursements for drugs and services and implementing measures to control utilization of drugs (such as requiring prior authorization or step therapy for coverage, among other things). Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the U.S. Centers for Medicare & Medicaid Services, or CMS, may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several U.S. Congressional inquiries and proposed and enacted state and federal 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 pharmaceutical products. Congress has indicated that it will continue to seek new legislative measures to control drug costs.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the EU Member States have the option to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic, and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States, and parallel trade, i.e., arbitrage between low-priced and high-priced EU Member States, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Current and Future Healthcare Reform

In the United States, there have been, and continue to be, a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. For example, in March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments, and changes to fraud and abuse laws. For example, the ACA, among other things:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 50% point-of-sale discount off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D (later increased to 70%); and

- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell “branded prescription drugs” to specified federal government programs.

Since its enactment, there have been judicial, administrative, executive, and legislative challenges to certain aspects of the ACA as well as executive orders related to the ACA’s implementation. It is unclear how healthcare reform measures of the current presidential administration or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers and health plans (including Part D prescription drug plans) of up to 2% per fiscal year, effective April 1, 2013, and which will stay in effect through 2032, unless Congress takes additional action. Additionally, American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Moreover, the One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid. These new laws and regulatory changes may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on prescribers of our drugs, if approved, and accordingly, our financial operations.

There has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, as of January 1, 2024, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap of 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs. More recently, the Inflation Reduction Act of 2022, or IRA, among other things, directed HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and created civil monetary penalties and an excise tax for manufacturers that fail to comply with the drug price negotiation requirements. The IRA also imposed rebates for certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation, and, beginning in 2025, replaced the Part D coverage gap discount program with a new discounting program. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 15, 2024, HHS announced the negotiated prices for the first ten drugs that will be subject to price negotiations, and on January 17, 2025, HHS announced 15 additional drugs subject to negotiations. The Medicare drug price negotiation program is currently subject to multiple legal challenges. The impact of these challenges, as well as any other future challenges, is uncertain, and it is unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry.

In addition, the Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for product candidates, if approved. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, although proposed regulations have not yet been published. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers.

In 2020, FDA released its implementing regulations regarding section 804 Importation Programs under the Medicare Prescription Drug Improvement and Modernization Act of 2003, which create a pathway for states to submit proposals to import certain drugs from Canada. On January 5, 2024, the FDA authorized a Florida program to import prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. If broadly implemented, importation of drugs under this program from Canada may materially and adversely affect the price we receive for any of our product candidates. Additionally, it is unclear what steps the current presidential administration will take with respect to increasing importation of drugs at the state or federal level.

Individual states have also been increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care 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, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare products and services.

Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current presidential administration may reverse or otherwise change these measures, both the current presidential administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

Similar political, economic, and regulatory developments are occurring in the EU and may affect the ability of pharmaceutical companies to profitably commercialize their products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could restrict or regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

In the EU, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing systems, parallel distribution, and parallel trade. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced countries. Reductions in the pricing of our medicinal products in one EU member state could affect the price in other EU member states and, thus, have a negative impact on our financial results.

Health Technology Assessment, or HTA, of medicinal products in the EU is an essential element of the pricing and reimbursement decision-making process in a number of EU member states. The outcome of HTA has a direct impact on the pricing and reimbursement status granted to the medicinal product. A negative HTA by a leading and recognized HTA body concerning a medicinal product could undermine the prospects to obtain reimbursement for such product not only in the EU member state in which the negative assessment was issued, but also in other EU member states.

In 2011, Directive 2011/24/EU was adopted at the EU level. This Directive establishes a voluntary network of national authorities or bodies responsible for HTA in the individual EU member states. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, on December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product, i.e. oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Facilities

We maintain a physical corporate office for administrative purposes and a small non-GxP lab space, which we do not view as material.

We believe our existing facilities arrangements are sufficient for our needs for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

Employees and Human Capital Resources

As of December 31, 2025, we had 54 full-time employees. Within our workforce, 35 employees are engaged in research and development and 19 are engaged in business development, finance, legal, and general management and administration. Our human capital resources objectives include 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. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors as of the date of this prospectus:

Name	Age	Position
<i>Executive Officers:</i>		
Daphne Zohar	55	Chief Executive Officer and Director
Michael C. Chen, Ph.D.	41	Chief Scientific Officer
Lana Gladstein, J.D.	50	General Counsel
Eric Green	51	Chief Operating Officer
Antony Loebel, M.D.	65	Chief Medical Officer
Lauren A. White	47	Chief Financial Officer
<i>Non-Employee Directors:</i>		
Steven M. Paul, M.D.	75	Director and Board Chair
Eric Elenko, Ph.D.	53	Director
James I. Healy, M.D., Ph.D.	61	Director
Robert J. Hombach	59	Director
Robert Nelsen	62	Director
Sandra E. Peterson	67	Director
Jason Pitts, Ph.D.	40	Director
Denice Torres, J.D.	66	Director
David Wheadon, M.D.	68	Director
Robert Lyne LLB	42	Director

- (1) Member of the compensation committee.
- (2) Member of the nominating and corporate governance committee.
- (3) Member of the audit committee.

Executive Officers

Daphne Zohar. Ms. Zohar was our founder and has served as our President and Chief Executive Officer and as a member of our board of directors since April 2024. Prior to joining us, Ms. Zohar served as Founder, Chief Executive Officer and as a member of the board of directors of PureTech (Nasdaq/LSE: PRTC), since its formation in June 2015 to April 2024, and since 2005 at PureTech’s predecessor entity. A successful entrepreneur, Ms. Zohar created PureTech, assembling a leading team and scientific network to help implement her vision for the company, and was a key participant in fundraising, business development and establishing the underlying programs and platforms that have resulted in PureTech’s substantial pipeline of products and product candidates. She also co-founded PureTech’s entities, including Karuna Therapeutics, Inc. (formerly Nasdaq: KRTX), which developed the groundbreaking antipsychotic drug, Cobenfy (KarXT). The FDA approval of Cobenfy in September 2024 marked the first new schizophrenia mechanism in 70 years. Following FDA approval of Cobenfy (invented by PureTech), Karuna was acquired by Bristol Myers Squibb for \$14 billion. Ms. Zohar was a key driver in PureTech’s productive R&D engine, which led to 28 new medicines and a clinical success rate at PureTech and founded entities that was around six times better than the industry average during her tenure. Ms. Zohar is a senior advisor to PureTech and founder & co-host of the weekly podcast “Biotech Hangout.” Ms. Zohar received a B.S. from Northeastern University. Our board of directors believes that Ms. Zohar is qualified to serve as a member of our board of directors because of her extensive experience and leadership in the biopharmaceutical industry and her role as our company’s founder and chief executive officer.

Michael C. Chen, Ph.D. Dr. Chen has served as our Chief Scientific Officer since May 2024. Prior to joining us, Dr. Chen served various roles at PureTech from 2016 to May 2024, most recently as Head of

Innovation from 2016 to May 2024, where he oversaw the rapid advancement of the neuropsychiatric medicines that led to our launch. From 2016 to 2019, Dr. Chen was also co-founder and Head of Research and Strategy at Sonde Health, Inc., a company developing vocal biomarkers for depression and other neuropsychiatric disorders. He was a postdoctoral fellow at Beth Israel Deaconess Medical Center and Harvard Medical School, Department of Neurology. Dr. Chen completed his Ph.D. at Stanford University, focusing on the neurobiological mechanisms of depression and sleep disorders. He received a B.A. from Yale University.

Lana Gladstein, J.D. Ms. Gladstein has served as our General Counsel since June 2024. Prior to joining us, she served as the Group General Counsel at APRINOIA Therapeutics, Inc. (Nasdaq: APRI) from May 2023 to June 2024. From June 2022 to May 2023, she also served as Chief Legal Officer of Recipharm AB North America from June 2022 to May 2023, Chief Legal Officer and General Counsel of Arranta Bio (acquired by Recipharm) from November 2019 to May 2023 and Executive Vice President and General Counsel of Brammer Bio (acquired by Thermo Fisher Scientific) from March 2017 to October 2019. Prior to that, Ms. Gladstein was a partner at the law firm of Nutter McClennen & Fish LLP and Pepper Hamilton LLP. Ms. Gladstein holds a J.D. from Northeastern University School of Law and a B.A. in Biology from Brandeis University.

Eric Green. Mr. Green has served as our Chief Operating Officer since May 2024. Prior to joining us, Mr. Green was Senior Vice President, Head of Development Programs at Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY), or Alnylam, from February 2021 to April 2024 where he led a team responsible for global development and pre-commercialization activities for a portfolio of development stage programs. From February 2019 to January 2021 he served as Senior Vice President, Global General Manager for the TTR Franchise at Alnylam. Mr. Green held former roles at biopharmaceutical companies such as Synageva BioPharma Corp., Infinity Pharmaceuticals, Inc., Genzyme Corporation, and Pfizer Inc. (NYSE: PFE). He received an M.B.A. from MIT Sloan School of Management and an M.S. in chemical engineering from MIT School of Engineering. He earned a B.S. in chemical engineering from University of Michigan.

Antony Loebel, M.D. Dr. Loebel has served as our Chief Medical Officer and President of Clinical Development since June 2024. He was previously the President and Chief Executive Officer of Sunovion Pharmaceuticals Inc. from April 2019 to June 2023, and served as Chief Medical Officer from 2011 to March 2019. During his tenure at Sunovion, Dr. Loebel played a key role in the company's growth to over \$3.5 billion in total revenue and was instrumental in the development and commercialization of Latuda for the treatment of bipolar depression and schizophrenia. Prior to his time at Sunovion, he held senior roles in research and development and medical affairs at Dainippon Sumitomo Pharma America and Pfizer Inc. (NYSE: PFE). Dr. Loebel earned his M.D. from the University of Washington in Seattle, completed his psychiatry residency at the Zucker Hillside Hospital in New York, and is board certified in psychiatry.

Lauren A. White. Ms. White has served as our Chief Financial Officer since November 2024. Prior to joining us, Ms. White served as the Chief Financial Officer and Treasurer of ImmunoGen, Inc. (formerly Nasdaq: IMGX), or ImmunoGen, from September 2023 to June 2024 prior to its acquisition by AbbVie. Prior to that, she served as Chief Financial Officer, Treasurer, and Principal Accounting Officer at C4 Therapeutics, Inc. (Nasdaq: CCC) from June 2021 to September 2023, and held roles of increasing responsibility at Novartis AG (NYSE: NVS), most recently as Vice President, Finance, and Global Head of Business Planning and Analysis at Novartis Institutes for BioMedical Research from July 2017 to June 2021. Ms. White earned an M.B.A. from Harvard Business School and a B.S. from the Carroll School of Management at Boston College.

Non-Employee Directors

Steven M. Paul, M.D. Dr. Paul has been a member and chair of our board of directors since April 2024. Dr. Paul was one of our founders and has also served as our senior advisor since February 2024. From August 2018 to January 2024, Dr. Paul served in senior leadership roles at Karuna Therapeutics, Inc. (Nasdaq: KRTX, prior to its recent acquisition by Bristol Myers Squibb Company), including as Chief Scientific Officer and President of Research and Development from January 2023 to January 2024, and President, Chief Executive

Officer, and Chairman of the board of directors from August 2018 to January 2023. Dr. Paul has also served as a Venture Partner at Third Rock Ventures since 2010. Dr. Paul is also board certified by the American Board of Psychiatry and Neurology. Dr. Paul has served on the board of directors of Rapport Therapeutics, Inc. (Nasdaq: RAPP) since December 2022 and Sage Therapeutics, Inc. (Nasdaq: SAGE) from September 2011 until June 2024 and is also the chairman of the board of directors of the Foundation for the National Institutes of Health (FNIH). Previously, Dr. Paul served on the boards of directors of Alnylam Pharmaceuticals, Inc. (Nasdaq: ALNY) from September 2010 to April 2022, Voyager Therapeutics, Inc. (Nasdaq: VYGR) from September 2014 to June 2022 and Karuna Therapeutics, Inc. from March 2018 to March 2024. Dr. Paul also previously spent 17 years at Eli Lilly and Company (NYSE: LLY), during which time he held several leadership roles, including Executive Vice President for Science and Technology, and President of the Lilly Research Laboratories. Prior to Lilly, Dr. Paul spent 18 years at the National Institute of Mental Health (NIMH) where he served as Scientific Director. Dr. Paul received a Bachelor of Arts degree in biology and psychology from Tulane University and Master of Science and Doctor of Medicine degrees from the Tulane University School of Medicine. Our board of directors believes that Dr. Paul is qualified to serve on our board of directors due to his numerous leadership roles and experience in the pharmaceutical industry and his expertise in neuroscience.

James I. Healy, M.D, Ph.D. Dr. Healy has been a member of our board of directors since April 2024. Dr. Healy has served as Managing Partner of Sofinnova Investments, Inc. since June 2000. Dr. Healy has served on the boards of directors of Rapport Therapeutics, Inc. (Nasdaq: RAPP) since August 2023, ArriVent Biopharma, Inc. (Nasdaq: AVBP) since March 2023 and BioAge Labs, Inc. (Nasdaq: BIOA) since February of 2024. , Previously, Dr. Healy served on numerous public company boards of directors including Bolt Biotherapeutics, Inc. (Nasdaq: BOLT) from January 2021 until September 2024, Natera, Inc. (Nasdaq: NTRA) from November 2014 until June 2025, Y-mAbs Therapeutics, Inc. (Nasdaq: YMAB) from November 2017 until September 2025, Ascendis Pharma A/S (Nasdaq: ASND) from November 2014 to May 2022, Amarin Corporation PLC (Nasdaq: AMRN) from May 2008 to December 2016, CinCor Pharma, Inc. (Nasdaq: CINC, prior to its recent acquisition by AstraZeneca PLC) from May 2019 to February 2023, Coherus BioSciences, Inc. (Nasdaq: CHRS) from February 2014 to February 2022, Karuna Therapeutics, Inc. (Nasdaq: KRTX, prior to its recent acquisition by Bristol Myers Squibb Company) from June 2019 to March 2024, Iterum Therapeutics plc (Nasdaq: ITRM) from November 2015 to February 2020, ObsEva SA (Nasdaq: OBSEF) from August 2013 to May 2021, and NuCana PLC (Nasdaq: NCNA) from March 2014 to April 2022. He also previously served as a director on the Board of the National Venture Capital Association (NVCA) and the Board of the Biotechnology Industry Organization (BIO). Dr. Healy holds Bachelor of Arts degrees in molecular biology and Scandinavian studies from the University of California, Berkeley, and Doctor of Medicine and Doctor of Philosophy degrees in immunology from Stanford University School of Medicine. Our board of directors believes that Dr. Healy is qualified to serve on our board of directors due to his extensive experience and leadership roles in the biopharmaceutical industry and expertise in healthcare investing.

Robert J. Hombach. Mr. Hombach has been a member of our board of directors since March 2025. Mr. Hombach served as the Executive Vice President, Chief Financial Officer and Chief Operations Officer of Baxalta (NYSE: BXLTL), a global biopharmaceutical company, until it was acquired by Shire plc. in 2016. Mr. Homach has served on the board of directors of Henry Schein Inc (Nasdaq: HSIC) since February, 2025, BioMarin Pharmaceutical Inc (Nasdaq: BMRN) since September 2017, Embecta Corp. (Nasdaq: EMBC) since April, 2022, Aptinyx Inc. from April, 2018 to December, 2023, CarMax Inc, (NYSE: KMX) from March, 2018 to June, 2022. He was instrumental in Baxalta's successful spin off from its parent company, Baxter (NYSE: BAX), where he previously served as Corporate Vice President and Chief Financial Officer. In addition to his board positions at BioMarin and Henry Schein, Mr. Hombach is the Chair of the Audit Committee at Embecta, a global diabetes care company spun out of Becton Dickinson, and has held previous board positions at several other companies including Naurex, Inc., which was acquired by Allergan in 2015. Mr. Hombach received an MBA from Northwestern University's J.L. Kellogg Graduate School of Management, and a BS in Finance cum laude from the University of Colorado. Our board of directors believes that Mr. Hombach is qualified to serve on our board of directors due to his significant leadership experience in the biopharmaceutical industry.

Robert Nelsen. Mr. Nelsen has been a member of our board of directors since April 2024. Mr. Nelsen co-founded ARCH Venture Partners, L.P., a venture capital firm focused on early-stage technology companies, in 1986 and has served as a Managing Director of ARCH Venture Partners or its affiliated entities since 1994. Mr. Nelsen has served on the board of directors of Prime Medicine, Inc. (Nasdaq: PRME) since September 2020, and Sana Biotechnology, Inc. (Nasdaq: SANA) since October 2018, each a U.S. publicly traded biotechnology company. Mr. Nelsen has served as the Chairman and as a member of the board of directors of Hua Medicine, Inc., a Hong Kong publicly listed drug development company, since April 2010 and currently serves on the board of directors of a number of private companies. Mr. Nelsen previously served on the board of directors of a number of public biotechnology companies, including Vir Biotechnology, Inc. from 2016 to 2025, Lyell Immunopharma, Inc. from 2018 to 2025, Bii Biosciences, Inc., from 2018 to 2024, Revolution Healthcare Acquisition Corp. from 2021 to 2022, Denali Therapeutics Inc. from 2015 to 2022, Unity Biotechnology, Inc. from 2015 to December 2020, Agios Pharmaceuticals, Inc. from 2007 to June 2017, Syros Pharmaceuticals, Inc. from 2012 to June 2018, Juno Therapeutics, Inc. (acquired by Celgene Corporation in January 2018) from 2013 to March 2018, Sienna Biopharmaceuticals, Inc. from 2015 to September 2018 and Gossamer Bio, Inc. from 2017 to December 2018 (prior to its initial public offering). Mr. Nelsen received his M.B.A. from the University of Chicago and his B.S. from the University of Puget Sound in Economics and Biology. Our board of directors believes that Mr. Nelsen is qualified to serve on the Board due to his significant venture capital experience as a director and investor in the biotechnology industry.

Sandra E. Peterson. Ms. Peterson has been a member of our board of directors since November 2024. She has served as an Operating Partner at Clayton Dubilier & Rice, or CD&R, a private investment firm, since April 2019 where she invests in life sciences and consumer companies and oversees technology initiatives to enhance performance of the firm's portfolio companies. Prior to joining CD&R, Ms. Peterson was the Group Worldwide Chair for Johnson & Johnson, or J&J, where she led J&J's consumer and medical devices businesses and was responsible for global operating infrastructure, technology, supply chain, quality, and key strategic initiatives from 2012 to 2018. Ms. Peterson currently serves as Lead Independent Director of Microsoft Corp. (Nasdaq: MSFT) since March 2023 and a member of its board of directors since December 2015. She also serves as Executive Chairwoman of the board of directors of Volastra Therapeutics since October 2019. Ms. Peterson received her M.P.A. from Princeton University and a B.A. from Cornell University. Our board of directors believes that Ms. Peterson is qualified to serve on our board of directors due to her extensive knowledge of strategy and business development in the life sciences industry and her wide-ranging experience in leadership positions.

Denice Torres, J.D. Ms. Torres has been a member of our board of directors since May 2024. Ms. Torres is the founder and Chief Executive Officer of The Ignited Company, a consulting firm she founded in November 2017, and is also the founder of The Mentoring Place, a nonprofit organization established in 2017. From December 2004 to December 2017, Ms. Torres served in senior leadership roles at Johnson & Johnson, including President of J&J Neuroscience, President of J&J Consumer Health, and Chief Strategy and Transformation Officer of the J&J Medical Device Sector. Prior to that, from 1990 to 2004, Ms. Torres held various leadership positions at Eli Lilly and Company, including Executive Director of Global Neuroscience and Director of U.S. Women's Health. Ms. Torres currently serves on the board of directors of Celldex Therapeutics Inc. (Nasdaq: CLDX), Glaukos Corp. (Nasdaq: GKOS), National Resilience Inc., and ByHeart Inc. Ms. Torres previously served on the boards of Karuna Therapeutics, Inc., 2seventy bio, Inc., Thirty Madison, bluebird bio, Inc., and Surface Oncology, Inc. Ms. Torres holds an M.B.A. from the University of Michigan, a J.D. from Indiana University School of Law, a B.S. in Psychology from Ball State University, and an M.A. in the Study of Happiness from Centenary University. She is currently pursuing a Ph.D. in Happiness Studies at Centenary University. Our board of directors believes that Ms. Torres is qualified to serve on our board of directors due to her extensive leadership experience in the pharmaceutical, biotechnology, and consumer health industries and her expertise in neuroscience, strategy, and business operations.

David Wheadon, M.D. Dr. Wheadon has been a member of our board of directors since July 2024. He served as Senior Vice President, Global Regulatory Affairs, Patient Safety, and Quality Assurance for AstraZeneca Pharmaceuticals from 2014 to 2019 and as Executive Vice President, Research and Advocacy at the Juvenile Diabetes Research Foundation from 2013 to 2014. From 2009 to 2013, Dr. Wheadon served as Senior Vice

President, Scientific and Regulatory Affairs and as a member of the Management Committee of the Pharmaceutical Research and Manufacturers of America, or PhRMA. Prior to his joining PhRMA, Dr. Wheadon held senior regulatory and clinical development leader roles at Abbott Laboratories and GlaxoSmithKline plc. Dr. Wheadon began his career as a clinical research physician in neuroscience at Eli Lilly & Company. Dr. Wheadon has served on the board of directors of Indivior, PLC (Nasdaq: INDV) since June 2024, Vaxart, Inc. (Nasdaq: VXRT) since April 2021, and Sotera Health, Inc. (Nasdaq: SHC) since May 2021. He formerly served on the board of directors of Assertio Holdings, Inc. (formerly Assertio Therapeutics, Inc.), Karuna Therapeutics, Inc., and Chemocentryx, Inc. Dr. Wheadon holds an A.B. from Harvard College and an M.D. from Johns Hopkins University School of Medicine. He completed his fellowship training in Psychiatry at the Tufts, New England Medical Center. Our board of directors believes that Dr. Wheadon is qualified to serve as a member of the board of directors due to his leadership roles in the pharmaceutical industry and his extensive experience in regulatory affairs.

Eric Elenko, Ph.D. Dr. Elenko has been a member of our board of directors since April 2024. Dr. Elenko is the co-founder of PureTech Health (Nasdaq: PRTC) where he has served as the President since April 2024. Prior to his current role, Dr. Elenko previously served as PureTech Health's Chief Innovation Officer from June 2015 through April 2024. Prior to serving as Chief Innovation Officer, Dr. Elenko held multiple other leadership roles within PureTech. Prior to joining PureTech Health, Dr. Elenko was a consultant with McKinsey and Company. Dr. Elenko has served on the Board of Directors of multiple PureTech portfolio companies during his tenure with PureTech. Dr. Elenko received his Ph.D. in biomedical sciences from the University of California, San Diego and his B.A. in biology from Swarthmore College. Our board of directors believes that Dr. Elenko is qualified to serve on our board of directors because of his extensive understanding of the biotechnology and pharmaceutical industries and his senior management experience.

Jason Pitts, Ph.D. Dr. Pitts has been a member of our board of directors since October 2024. Dr. Pitts has served as Principal at General Atlantic since December 2024, and prior to such role served in various roles, including Vice President, since March 2021 at General Atlantic, and focuses on investments in the life sciences sector. Prior to joining General Atlantic, he was a Principal at Sofinnova Investments focused on therapeutics investments from June 2019 to January 2021. Dr. Pitts has also served as a board member of Solve Therapeutics since December 2024, CinCor Pharma, Inc. from October 2021 to February 2023 and Bolt Biotherapeutics, Inc. from July 2020 to January 2021. He received his Ph.D. in neuroscience from The Rockefeller University and a B.S. in neuroscience from Cornell University. Our board of directors believes that Dr. Pitts is qualified to serve on our board of directors due to his extensive expertise in healthcare investing and experience as a board member of other biotechnology companies.

Robert Lyne, LLB. Mr. Lyne is the chief executive officer and chief portfolio officer at PureTech. Mr. Lyne is a seasoned executive with deep experience in life sciences, including his prior role as Chief Executive Officer at Arix Bioscience plc, a transatlantic venture capital company focused on investing in innovative biotechnology companies from April 2021 to December 2023. Mr. Lyne brings more than a decade of experience leading London-listed life science companies and portfolio management, with a strong track record in governance and executive team leadership. Mr. Lyne began his career as a lawyer at international law firm Bird & Bird LLP in London before moving to Touchstone Innovations, a London listed biotech and technology investor, which was acquired in 2017. Mr. Lyne has a BA from the University of Oxford and an LLB from Oxford Brookes University. Our board of directors believes that Mr. Lyne is qualified to serve as a member of the board of directors due to his extensive experience and leadership roles in the pharmaceutical industry.

Family Relationships

There are no family relationships among any of our executive officers or directors.

Composition of Our Board of Directors

Our business and affairs are managed under the direction of our board of directors, which currently consists of ten members. The primary responsibilities of our board of directors are to provide oversight, strategic guidance,

counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Certain members of our board of directors were elected under the provisions of our amended and restated certificate of incorporation and agreements with our stockholders. These board composition provisions will terminate upon the completion of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance committee’s and our board of directors’ priority in selecting board members is the identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, professional and personal experiences, and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, and our amended and restated bylaws, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, will also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Staggered Board

Our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, and our amended and restated bylaws, which will be effective upon the effectiveness of the registration statement of which this prospectus forms a part, will permit our board of directors to establish the authorized number of directors from time to time by resolution. Each director serves until the expiration of the term for which such director was elected or appointed, or until such director’s earlier death, resignation or removal. In accordance with our amended and restated certificate of incorporation, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to 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 will be divided among the three classes as follows:

- the Class I directors will be _____ and _____, and their terms will expire at our first annual meeting of stockholders following this offering, to be held in _____ ;
- the Class II directors will be _____ and _____, and their terms will expire at our second annual meeting of stockholders following this offering, to be held in _____ ; and
- the Class III directors will be _____ and _____, and their terms will expire at our third annual meeting of stockholders following this offering, to be held in _____ .

We expect that any additional directorships resulting from an increase in the number of directors 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.

Director Independence

Under the listing standards, requirements and rules of The Nasdaq Stock Market LLC, or the Nasdaq Listing Rules, independent directors must comprise a majority of our board of directors as a listed company within one

year of the listing date. In addition, the Nasdaq Listing Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation, and nominating and governance committees be independent within twelve months from the date of listing. Audit committee members must also satisfy additional independence criteria, including those set forth in Rule 10A-3 under the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under the Nasdaq Listing Rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (i) accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries, other than compensation for board service; or (ii) be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1 under the Exchange Act, the board of directors must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director, and whether the director is affiliated with the company or any of its subsidiaries or affiliates.

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning her or his background, employment, and affiliations, including family relationships, our board of directors has determined that _____, _____, and _____ do not have relationships that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Nasdaq Listing Rules. Our board of directors has determined that _____, _____, and _____ are not independent under applicable rules and regulations of the SEC and the Nasdaq Listing Rules. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director and the transactions described in the section titled "Certain Relationships and Related Person Transactions."

Board Policies

In connection with this offering, we intend to adopt policies and procedures for director candidates for our nominating and corporate governance committee, which will provide that factors, such as a candidate's character, judgment, skills, education, expertise, and absence of conflicts of interest should be considered in determining director candidates. Our priority in selection of board members will be identification of members who will further the interests of our stockholders through their established records of professional accomplishment, their ability to contribute positively to the collaborative culture among board members, and their knowledge of our business and understanding of the competitive landscape in which we operate and adherence to high ethical standards.

Board Leadership Structure and Board's Role in Risk Oversight

Currently, the role of chair of our board of directors is separated from the role of chief executive officer. We believe that separating these positions allows our chief executive officer to focus on our day-to-day business, while allowing the chairman of our board to lead the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that the chief executive officer is required to devote to her position in the current business environment, as well as the commitment required to serve as our chair of our board of directors, particularly as the board of directors' oversight responsibilities continue to grow. While our amended and restated bylaws and corporate

governance guidelines will not require that our board chair and chief executive officer positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance. Our board of directors will adopt, effective prior to the completion of this offering, corporate governance guidelines that will provide that the board of directors may appoint a lead independent director. The lead independent director will be responsible for calling and presiding over separate meetings of the independent directors. The lead independent director will preside over periodic meetings of independent directors, serve as a liaison between the chair and the independent directors and perform such additional duties as the board of directors may otherwise determine and delegate.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to our financial condition, development, and commercialization activities, operations, strategic direction, and intellectual property as more fully discussed in the section titled “Risk Factors.” Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees below and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairperson of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Committees of Our Board of Directors

Our board of directors will establish upon the completion of this offering an audit committee, a compensation committee, and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee will operate under a written charter that satisfies the application rules and regulation of the SEC and the Nasdaq Listing Rules, which we will post to our website at www.seaporttx.com upon the completion of this offering. Information contained on, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

Audit Committee

Upon the completion of this offering, our audit committee will consist of _____, _____ and _____, and the chair of our audit committee will be _____. Our board of directors has determined that each member of the audit committee is independent under Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Exchange Act and can read and understand fundamental financial statements in accordance with applicable requirements. Our board of directors has also determined that _____ is an “audit committee financial expert” within the meaning of SEC regulations. In arriving at these determinations, our board of directors has examined each audit committee member’s scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the audit committee will be to discharge the responsibilities of our board of directors with respect to our corporate accounting and financial reporting processes, systems of internal control

and financial-statement audits, and to oversee our independent registered public accounting firm. Specific responsibilities of our audit committee will include:

- helping our board of directors oversee our corporate accounting and financial reporting processes;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- managing the selection, engagement, qualifications, independence, and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- establishing insurance coverage for our officers and directors;
- overseeing the preparation of our annual proxy statement, reviewing with management our financial statements to be included in our quarterly reports to be filed with the SEC, and reviewing with management the “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosures in our periodic reports filed with the SEC;
- approving, or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm; and
- reviewing our major risk exposures, including financial, operational, cybersecurity, competition, legal, and regulatory exposures.

Our audit committee will operate under a written charter, which will be effective upon the completion of this offering, that satisfies the applicable Nasdaq Listing Rules.

Compensation Committee

Upon the completion of this offering, our compensation committee will consist of _____, _____ and _____, and the chair of our compensation committee will be _____. Our board of directors has determined that each member of the compensation committee is independent under the Nasdaq Listing Rules and is a “non-employee director” as defined in Rule 16b-3 promulgated under the Exchange Act.

The primary purpose of our compensation committee will be to discharge the responsibilities of our board of directors in overseeing our compensation policies, plans, and programs and to review and determine the compensation to be paid to our executive officers, directors, and other senior management, as appropriate. Specific responsibilities of our compensation committee will include:

- reviewing and approving the compensation of our chief executive officer, other executive officers, and senior management;
- reviewing and recommending to our board of directors the compensation paid to our directors;
- reviewing and approving the compensation arrangements with our executive officers and other senior management;
- administering our equity incentive plans and other benefit programs;
- reviewing, adopting, amending, and terminating incentive compensation and equity plans, severance agreements, profit sharing plans, bonus plans, change-of-control protections, and any other compensatory arrangements for our executive officers and other senior management;

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- reviewing, evaluating, and recommending to our board of directors succession plans for our executive officers; and
- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation philosophy.

Our compensation committee will operate under a written charter, which will be effective upon the completion of this offering, that satisfies the applicable Nasdaq Listing Rules.

Nominating and Corporate Governance Committee

Upon the completion of this offering, our nominating and corporate governance committee will consist of _____, _____ and _____, and the chair of our nominating and corporate governance committee will be _____. Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the Nasdaq Listing Rules, a non-employee director, and free from any relationship that would interfere with the exercise of his or her independent judgment.

The primary purpose of the nominating and corporate governance committee will be to discharge the responsibilities of our board of directors with respect to our corporate governance functions and to identify, communicate with, evaluate and recommend candidates for our board of directors. Specific responsibilities of our nominating and corporate governance committee will include:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on our board of directors;
- considering and making recommendations to our board of directors regarding the composition and chairmanship of the committees of our board of directors;
- instituting plans or programs for the continuing education of our board of directors and orientation of new directors;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing periodic evaluations of the board of directors' performance, including committees of the board of directors and management.

Our nominating and corporate governance committee will operate under a written charter, which will be effective upon the completion of this offering, that satisfies the applicable Nasdaq Listing Rules.

Code of Business Conduct and Ethics

In connection with this offering, we intend to adopt a written code of business conduct and ethics that applies to all our employees, officers, and directors. This includes our principal executive officer, principal financial officer, and principal accounting officer or controller, or persons performing similar functions. The full text of our code of business conduct and ethics will be posted on our website at www.seaporttx.com. We intend to disclose on our website any future amendments of our code of business conduct and ethics or waivers that exempt any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions, or our directors from provisions in the code of business conduct and ethics. Information contained on, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference.

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 officers or employees. None of our officers currently serves, or has served during the last calendar year, 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 compensation committee.

Compensation Recovery

In connection with this offering, we intend to adopt a compensation recovery policy that is compliant with the Nasdaq Listing Rules, as required by the Dodd-Frank Act, to be effective in connection with the effectiveness of the registration statement of which this prospectus forms a part.

Limitations on Liability and Indemnification Agreements

As permitted by Delaware law, provisions in our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to the completion of this offering and upon the effectiveness of the registration statement of which this prospectus forms a part, respectively, limit or eliminate the personal liability of directors and officers for a breach of their fiduciary duty of care as a director or officer. The duty of care generally requires that, when acting on behalf of the corporation, a director and, or officer exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, a director or officer will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director or officer, except for liability for:

- any breach of the director or officer's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- for our directors, unlawful payments of dividends or unlawful stock repurchases, or redemptions as provided in Section 174 of the Delaware General Corporation Law, or DGCL;
- for our officers, any derivative action by or in the right of the corporation; or
- any transaction from which the director or officer derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder's rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter a director or officer's liability under other laws, such as the federal securities laws or other state or federal laws. Our amended and restated certificate of incorporation that will become effective upon the closing of this offering also will authorize us to indemnify our officers, directors, and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws to be effective immediately upon effectiveness of the registration statement will provide that:

- we will indemnify our directors, officers, employees, and other agents to the fullest extent permitted by law;
- we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated bylaws will also permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our amended and restated bylaws permit such indemnification. We intend to obtain such insurance.

In addition to the indemnification that will be provided for in our amended and restated certificate of incorporation and amended and restated bylaws, we plan to enter into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification provisions contained in the DGCL. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines, and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is attached as an exhibit to the registration statement of which this prospectus forms a part.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

EXECUTIVE COMPENSATION

The following discussion contains forward-looking statements that are based on our current plans, considerations, expectations, and determinations regarding future compensation programs. The actual amount and form of compensation and the compensation policies and practices that we adopt in the future may differ materially from the programs as summarized in this discussion.

As an emerging growth company and a smaller reporting company, we have opted to comply with the executive compensation disclosure rules applicable to “smaller reporting companies,” as such terms are defined in the rules promulgated under the Securities Act. The compensation provided to our named executive officers for the fiscal year ended December 31, 2025, or Fiscal Year 2025, is detailed in the 2025 Summary Compensation Table and accompanying footnotes and narrative that follow.

Our named executive officers for Fiscal Year 2025 are:

- Daphne Zohar, our Founder, Chief Executive Officer, President and Board Member;
- Michael Chen, Ph.D., our Co-Founder and Chief Scientific Officer; and
- Antony Loebel, M.D., our Chief Medical Officer and President of Clinical Development.

To date, the compensation of our named executive officers has consisted of a combination of base salary, cash incentive compensation, and long-term incentive compensation, as more fully described below. Our executive officers, like all full-time employees, are eligible to participate in our health, welfare, and retirement benefit plans. As we transition from a private company to a publicly traded company, we intend to evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require.

2025 Summary Compensation Table

The following table shows the total compensation earned by, or paid to, our named executive officers for services rendered to us in all capacities during Fiscal Year 2025.

Name and Principal Position	Year	Salary (\$)	Option Awards ⁽¹⁾ (\$)	Non-Equity Incentive Plan Compensation ⁽²⁾ (\$)	All Other Compensation ⁽³⁾ (\$)	Total (\$)
Daphne Zohar <i>Founder, Chief Executive Officer, President and Board Member</i>	2025	768,922	—	481,000	10,500	1,260,422
Michael Chen, Ph.D. <i>Co-Founder and Chief Scientific Officer</i>	2025	414,000	490,462	180,000	10,500	1,094,962
Antony Loebel, M.D. <i>Chief Medical Officer and President of Clinical Development</i>	2025	465,750	—	194,000	10,500	670,250

(1) The amount reported represents the aggregate grant date fair value of a stock option award granted to Dr. Chen in Fiscal Year 2025, computed in accordance with FASB ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures related to service-based vesting. The assumptions used in calculating the grant date fair values of the option awards reported in this column are set forth in Note 10 of our consolidated financial statements for Fiscal Year 2025, included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for these option awards and do not correspond to the actual economic value that may be received by Dr. Chen upon the exercise of the option awards or any sale of the underlying securities.

(2) Annual cash incentive bonuses for performance during Fiscal Year 2025.

- (3) The amounts reported represent 401(k) employer matching contributions made by us.

Narrative Disclosure to the 2025 Summary Compensation Table

2025 Base Salaries

Our named executive officers each receive a base salary to compensate them for services rendered to us. Base salaries are intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role, and responsibilities. Base salaries are expected to be reviewed annually, typically in connection with our annual performance review process, approved by our board of directors or the compensation committee of the board of directors, and may be adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance, and experience.

For Fiscal Year 2025, the base salaries for Ms. Zohar, Dr. Chen, and Dr. Loebel were \$768,922, \$414,000 and \$465,750, respectively.

2025 Cash Bonuses

Our named executive officers are eligible to receive annual performance-based cash bonuses, which are designed to provide appropriate incentives to our executives to achieve corporate performance goals and to reward our executives for individual achievement towards these goals. For Fiscal Year 2025, each of the named executive officers was eligible to earn an annual performance bonus based on the achievement of certain corporate performance and individual performance goals, with any such bonus expected to be paid in February 2026. For Fiscal Year 2025, the target annual bonus for Ms. Zohar, Dr. Chen, and Dr. Loebel was 50%, 35% and 35% of base salary, respectively.

Equity Incentive Compensation

Although we do not yet have a formal policy with respect to the grant of equity incentive awards to our executive officers, we believe equity grants provide our executives with a strong link to our long-term performance, create an ownership culture, and help to align the interests of our executives and our stockholders. In addition, we believe equity grants promote executive retention because they incentivize our executive officers to remain in our service during the vesting period.

During Fiscal Year 2024, we granted each of our named executive officers options to purchase common stock of the Company under our 2024 Equity Incentive Plan, as amended from time to time, or the 2024 Plan. In addition, Ms. Zohar received a grant of 3,750,000 shares of restricted stock, which vested in full in December 2024, and she paid \$1.8 million to cover the tax liability associated with such grant.

During Fiscal Year 2025, we granted Dr. Chen an option to purchase common stock of the Company under the 2024 Plan, but none of our other named executive officers received any equity awards in Fiscal Year 2025. For additional information regarding outstanding equity awards held by our named executive officers as of December 31, 2025, see the "Outstanding Equity Awards at 2025 Fiscal Year End" table below.

401(k) Plan and Health and Welfare Benefits

We currently maintain a tax-qualified 401(k) retirement savings plan, or the 401(k) Plan, for our employees, including our named executive officers, who satisfy certain eligibility requirements. Our named executive officers are eligible to participate in the 401(k) Plan on the same terms as other full-time employees. Our 401(k)

Plan is intended to qualify for favorable tax treatment under Section 401(a) of the Code and contains a cash or deferred feature that is intended to meet the requirements of Section 401(k) of the Code. We provide nondiscretionary contributions under the 401(k) Plan of 3% of the employee's annual eligible compensation, subject to the safe harbor limit. We believe that providing a vehicle for tax-deferred retirement savings through our 401(k) Plan adds to the overall desirability of our executive compensation package and further incentivizes our employees, including our named executive officers, in accordance with our compensation policies. Other than the 401(k) plan, we do not provide any qualified or non-qualified retirement or deferred compensation benefits to our employees, including our named executive officers.

All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including medical dental, and vision benefits, short-term and long-term disability insurance, and basic life and AD&D insurance.

Employment Arrangements for Named Executive Officers

We entered into offer letters with each of our named executive officers in connection with their commencement of employment, which set forth the terms and conditions of their employment, including base salary, target annual bonus opportunity, initial equity awards and eligibility to participate in our employee benefit plans generally offered to our employees.

Daphne Zohar

On April 8, 2024, we entered into an offer letter with Ms. Zohar for the position of Chief Executive Officer, which provides for Ms. Zohar's at-will employment. Ms. Zohar's offer letter was amended on September 13, 2024. We refer to the offer letter with Ms. Zohar, as amended, as the Zohar Offer Letter. Pursuant to the Zohar Offer Letter, Ms. Zohar is eligible to receive an annual base salary, subject to annual review for merit increases at the sole discretion of our board of directors, and an annual performance bonus, as determined by our board of directors based on her individual performance and the performance of the Company. Ms. Zohar is also eligible to participate in the employee benefit plans generally available to our employees, subject to the terms of those plans.

Additionally, Ms. Zohar received an initial equity award in the form of an option to purchase a number of shares of our common stock equal to 7.5% of then fully diluted capitalization of the Company. 1/18th of the shares subject to this option vested on April 16, 2024, with the remaining shares vesting in 34 equal monthly installments thereafter. 50% of the then-unvested shares subject to this option accelerated and became fully vested upon the first closing of the Series B preferred stock financing, which occurred on October 18, 2024. The remaining 50% of the unvested shares subject to this option will further accelerate and become fully vested upon the closing of this offering, subject to Ms. Zohar's continued service relationship as our Chief Executive Officer through such closing. In addition, for so long as Ms. Zohar remains our Chief Executive Officer up to and including our initial public offering (but excluding any shares issued pursuant to any over-allotment option), Ms. Zohar shall be entitled to receive additional equity grants (either in the form of stock options or restricted stock) so that her share ownership shall remain at 7.5% of the fully diluted capitalization of the Company.

Pursuant to the Zohar Offer Letter, in the event that Ms. Zohar's employment is terminated by us without "cause" or by Ms. Zohar for "good reason" (each as defined in the Zohar Offer Letter), subject to Ms. Zohar's execution of a general release of claims in favor of us and our affiliates, Ms. Zohar is entitled to receive (i) continuation of her then-current base salary for a period of 12 months, (ii) up to 12 months of COBRA premium payments at the same rate we pay for active and similarly-situated employees, (iii) a prorated portion of her annual performance bonus based on actual performance, or the Prorated Bonus; and (iv) an extension of the exercise period for Ms. Zohar's outstanding stock options granted pursuant to the Zohar Offer Letter to the one-year anniversary of the termination date.

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In addition, in the event that Ms. Zohar's employment is terminated by us without cause or by Ms. Zohar for good reason, in each case, within 12 months following a "sale event" (as defined in the Zohar Offer Letter), Ms. Zohar shall be entitled to the same payments and benefits set forth above, except that in lieu of the Prorated Bonus, Ms. Zohar shall be entitled to receive a lump sum payment of 100% of her annual performance bonus for the year in which the termination occurs.

In addition, the Zohar Offer Letter provides that if any executive officer enters into an employment agreement that provides for any termination or severance benefits that are more favorable, the Company shall seek to amend the Zohar Offer Letter to provide the more favorable benefits.

Michael Chen

On April 29, 2024, we entered into an offer letter with Dr. Chen for the position of Chief Scientific Officer, which provides for Dr. Chen's at-will employment. We refer to the offer letter with Dr. Chen, as the Chen Offer Letter. Pursuant to the Chen Offer Letter, Dr. Chen is eligible to receive an annual base salary, subject to annual review for merit increases at the sole discretion of our board of directors, and an annual performance bonus, as determined by our board of directors based on his individual performance and the performance of the Company. Dr. Chen is also eligible to participate in the employee benefit plans generally available to our employees, subject to the terms of those plans.

Additionally, Dr. Chen received an initial equity award in the form of an option to purchase 1,258,222 shares of our common stock. 25% of Dr. Chen's initial equity award vested on April 9, 2025, with the remaining shares vesting in 36 equal monthly installments thereafter.

Pursuant to the Chen Offer Letter, in the event that Dr. Chen's employment is terminated by us without "cause" or by Dr. Chen for "good reason" (each as defined in the Chen Offer Letter), subject to Dr. Chen's execution of a general release of claims in favor of us and our affiliates, Dr. Chen is entitled to receive (i) continuation of his then-current base salary for a period of 6 months, and (ii) up to six months of COBRA premium payments at the same rate we pay for active and similarly-situated employees.

In addition, in the event that Dr. Chen's employment is terminated by us without cause or by Dr. Chen for good reason, in each case, within 12 months following a "change in control" (as defined in the Chen Offer Letter), in lieu of the above benefits, Dr. Chen is entitled to receive (i) continuation of his then-current base salary for a period of 12 months, (ii) up to 12 months of COBRA premium payments at the same rate we pay for active and similarly-situated employees, and (iii) accelerated vesting of the initial equity award.

Antony Loebel, M.D.

On June 11, 2024, we entered into an offer letter with Dr. Loebel, or the Loebel Offer Letter, for the position of Chief Medical Officer and President of Clinical Development, which provides for Dr. Loebel's at-will employment. Pursuant to the Loebel Offer Letter, Dr. Loebel is eligible to receive an annual base salary, subject to annual review for merit increases at the sole discretion of our board of directors, and an annual performance bonus, as determined by our board of directors based on his individual performance and the performance of our Company. Dr. Loebel is also eligible to participate in the employee benefit plans generally available to our employees, subject to the terms of those plans.

Additionally, Dr. Loebel received an initial equity award in the form of an option to purchase 1,693,760 shares of our common stock. 25% of Dr. Loebel's initial equity award vested on July 18, 2025, with the remaining shares vesting in 36 equal monthly installments thereafter.

Pursuant to the Loebel Offer Letter, in the event that Dr. Loebel's employment is terminated by us without "cause" or by Dr. Loebel for "good reason" (each as defined in the Loebel Offer Letter), subject to Dr. Loebel's

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execution of a general release of claims in favor of us and our affiliates, Dr. Loebel is entitled to receive (i) continuation of his then-current base salary for a period of 12 months, (ii) up to 12 months of COBRA premium payments at the same rate we pay for active and similarly-situated employees, (iii) a prorated portion of his annual performance bonus, and (iv) if the termination occurs after the first anniversary of his start date and on or prior to the second anniversary of his start date (or 12 months if such termination occurs after the first anniversary of his start date), accelerated vesting of his initial equity award such that he will vest in the portion of the award that would have vested during the six months following his termination date, or, if the termination occurs after the second anniversary of his start date, accelerated vesting of his initial equity award such that he will vest in the portion of the award that would have vested during the nine months following the termination date, in each case as if he had remained employed through such date.

In addition, in the event that Dr. Loebel's employment is terminated by us without cause or by Dr. Loebel for good reason occurs on or within 12 months following a "change in control" (as defined in the Loebel Offer Letter), subject to Dr. Loebel's execution of a general release of claims in favor of us and our affiliates, in lieu of the above benefits, Dr. Loebel is entitled to receive (i) 12 months of his then-current base salary, (ii) 12 months of COBRA premium payments at the same rate we pay for active and similarly-situated employees, (iii) a lump sum payment of 100% of his annual performance bonus, and (iv) accelerated vesting of Dr. Loebel's initial equity grant.

Outstanding Equity Awards at 2025 Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2025.

Name	Grant Date	Option Awards ⁽¹⁾				
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price (\$)	Option Expiration Date
Daphne Zohar	6/4/2024 ⁽²⁾	5,847,504	1,411,468		0.97	6/3/2034
	12/29/2024 ⁽²⁾	461,687	111,444		2.35	12/28/2034
Michael Chen, Ph.D.	6/4/2024 ⁽³⁾	524,259	733,963		0.97	6/3/2034
	12/24/2024 ⁽⁴⁾			170,000	2.35	12/23/2034
	01/26/2025 ⁽⁵⁾	—	270,940		2.35	01/25/2035
Antony Loebel, M.D.	8/12/2024 ⁽⁶⁾	599,873	1,093,887		0.97	8/11/2034
	12/24/2024 ⁽⁴⁾			50,000	2.35	12/23/2034

(1) All option awards were granted under our 2024 Plan, described below.

(2) The shares underlying this stock option vest as follows: 1/18th of the shares vested on April 16, 2024, and the remaining shares vest in 34 equal monthly installments thereafter. Additionally, 50% of the then-unvested shares would accelerate and become fully vested upon the first closing of the Series B preferred stock financing, which occurred on October 18, 2024. The remaining 50% of the unvested shares will further accelerate and become fully vested upon the closing of this offering, subject to Ms. Zohar's continued service relationship as our Chief Executive Officer through such closing.

(3) The shares underlying this stock option award vest as follows: 25% of the shares vested on April 9, 2025, and the remaining 75% of the shares vest in 36 equal monthly installments thereafter, subject to Dr. Chen's continued service relationship through the applicable vesting date.

(4) The shares underlying this stock option award vest as follows: 1/3rd of the shares will vest and become exercisable in 2026 based on annual performance metrics (starting with the 2025 annual Company goals) as

determined by our Chief Executive Officer in consultation with the Compensation Committee and the remaining shares will vest and become exercisable in 1/3rd increments upon each of the two subsequent annual performance metrics (based on the annual Company goals) as determined by our Chief Executive Officer in consultation with the Compensation Committee. For accounting purposes, this stock option award is not considered granted under FASB ASC Topic 718 as of the date hereof.

- (5) The shares underlying this stock option award vest as follows: 25% of the shares vest on the first anniversary of January 26, 2025, and the remaining 75% of the shares vest in 36 equal monthly installments thereafter, subject to Dr. Chen's continued service relationship through the applicable vesting date.
- (6) The shares underlying this stock option award vest as follows: 25% of the shares vested on the first anniversary of July 18, 2024, and the remaining 75% of the shares vest in 36 equal monthly installments thereafter, subject to the executive's continued service relationship through the applicable vesting date.

Employee Benefit and Equity Compensation Plans

2024 Equity Incentive Plan

The 2024 Plan, was approved by the Company's subsidiary's Board and Stockholders and became effective for the Company in April 2024 and was subsequently amended in April 2024 and October 2024 to increase the number of shares reserved for issuance thereunder. Under the 2024 Plan, as amended, we have reserved for issuance an aggregate of 38,607,011 shares of our common stock. These numbers are subject to adjustment in the event of a stock dividend, stock split, spin-off, recapitalization, or other similar equity restructuring. Our board of directors has determined not to issue any further awards under the 2024 Plan following the closing of this offering, but all outstanding awards under the 2024 Plan will continue to be governed by their existing terms. In connection with this offering, we intend to adopt a new incentive equity plan under which we will grant equity-based awards following this offering, as described below under "*2026 Equity Incentive Plan*." The following summary describes the material terms of the 2024 Plan. This summary is not a complete description of all provisions of the 2024 Plan and is qualified in its entirety by reference to the 2024 Plan, which is filed as an exhibit to the registration statement of which this prospectus is a part.

The shares of common stock underlying any awards that are expired, lapsed, terminated, surrendered, cancelled without having been fully exercised, or is forfeited in whole or in part (including repurchased by us at or below the original issuance price), and shares that are withheld upon exercise of an option or settlement of an award to cover the exercise price or tax withholding under our 2024 Plan are currently added back to the shares of common stock available for issuance under our 2024 Plan (and, following the completion of this offering, will be added back to the shares of common stock available for issuance under the 2026 Equity Incentive Plan, or the 2026 Plan).

Our board of directors has acted as administrator of the 2024 Plan. The administrator has full power to, among other things, select, from among the individuals eligible for awards, determine the specific terms and conditions of each award, and accelerate at any time the exercisability or vesting of any award, subject to the provisions of the 2024 Plan. Persons eligible to participate in our 2024 Plan are our employees, consultants and directors.

The 2024 Plan permits the granting of (1) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and (2) options that do not so qualify. The option exercise price of each option is determined by the administrator but may not be less than 100% of the fair market value of the common stock on the date of grant or, in the case of an incentive stock option granted to a 10% owner, the exercise price shall not be less than 110% of the fair market value of our common stock on the date of grant. The term of each option is fixed by the administrator and may not exceed ten years from the date of grant (or five years in the case of certain incentive stock option grants). The administrator determines at what time or times each option may be exercised.

The administrator of the 2024 Plan may award restricted shares of common stock and restricted stock units subject to such conditions and restrictions as it determines.

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The administrator of the 2024 Plan may also grant other stock-based awards to be delivered in the future. The awards may be paid in shares of common stock, cash, or other forms of property, as determined by the administrator.

In the event of certain equity restructuring, including stock dividend, stock split, spin-off, recapitalization or other similar change to the Company's capital structure, the administrator of the 2024 Plan shall make appropriate adjustments to the maximum number of shares reserved for issuance under the 2024 Plan, the number and type of securities subject to outstanding awards under the 2024 Plan, and the exercise price of any outstanding awards under the 2024 Plan.

The 2024 Plan provides that in the event of a "change in control" (as defined in the 2024 Plan), the administrator is authorized to take various actions, including, but not limited to: (i) canceling any award in exchange for cash or property, (ii) accelerating the vesting of any award, (iii) providing for the assumption or substitution of awards by the successor entity, (iv) adjusting the number and type of shares subject to outstanding awards, (v) replacing the award with other rights or property selected by the administrator, and (vi) terminating the award.

Our board of directors may amend, suspend or terminate the 2024 Plan at any time, subject to stockholder approval where required by applicable law. The administrator of the 2024 Plan may also amend, modify or terminate any outstanding award. The participant's consent to such action will be required unless (i) the administrator determines that the action would not materially and adversely affect the participant, or (ii) the change is permitted under the 2024 Plan.

No awards may be granted under our 2024 Plan after the date that is ten years from the date our 2024 Plan was adopted by our board of directors. As described above, our board of directors has determined not to issue any further awards under our 2024 Plan following the completion of this offering.

As of December 31, 2025, options to purchase up to 27,633,144 shares of common stock at a weighted average exercise price of \$1.52 per share and 6,250,000 shares of restricted stock were outstanding under the 2024 Plan.

2026 Equity Incentive Plan

The 2026 Plan was adopted by our board of directors on _____, 2026, approved by our stockholders on _____, 2026 and will become effective on the date immediately preceding the date on which the registration statement of which this prospectus is a part is declared effective by the SEC. The 2026 Plan will allow us to make equity-based and cash-based incentive awards to our officers, employees, directors, and consultants. The following summary describes the material terms of the 2026 Plan. This summary is not a complete description of all provisions of the 2026 Plan and is qualified in its entirety by reference to the 2026 Plan, which will be filed as an exhibit to the registration statement of which this prospectus is a part.

Authorized Shares. We have initially reserved _____ shares of our common stock for the issuance of awards under the 2026 Plan, or the Initial Limit. The 2026 Plan provides that the number of shares reserved and available for issuance under the 2026 Plan will automatically increase on January 1, 2027 and each January thereafter during the term of the 2026 Plan, by _____ % of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation committee, or the Annual Increase. The number of shares reserved for issuance under the 2026 Plan will be subject to adjustment in the event of a stock split, stock dividend, or other change in our capitalization.

The shares we issue under the 2026 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards under the 2026 Plan and the 2024 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire, or are otherwise terminated (other than by exercise) will be added back to the shares of common stock available for issuance under the 2026

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Plan. The maximum number of shares of common stock that may be issued pursuant to incentive stock options shall not exceed the Initial Limit, cumulatively increased on January 1, 2027 and on each January 1 thereafter by the lesser of the Annual Increase for such year or _____ shares of common stock.

Non-Employee Director Limit. The grant date fair value of all awards under the 2026 Plan and all other cash compensation paid by us to any non-employee director during any one calendar year for services as a non-employee director may not exceed \$ _____; provided, however, that such amount shall be \$ _____ for the calendar year in which the applicable non-employee director is initially elected or appointed to our board of directors.

Plan Administration. The 2026 Plan will be administered by our compensation committee. Our compensation committee will have full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted and the number of shares subject to such awards, to make any combination of awards to participants, to accelerate at any time the exercisability or vesting of any award, and to determine the specific terms and conditions of each award, subject to the provisions of the 2026 Plan. The compensation committee is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants without stockholder consent.

Eligibility. Persons eligible to participate in the 2026 Plan will be those employees, non-employee directors, and consultants selected from time to time by our compensation committee in its discretion.

Stock Options. The 2026 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant unless the option (i) is granted pursuant to a transaction described in and in a manner consistent with, Section 424(a) of the Code, (ii) is granted to an individual who is not subject to United States income tax, or (iii) complies with or is exempt from Section 409A of the Code. The term of each option will be fixed by our compensation committee and may not exceed ten years from the date of grant (or five years in the case of certain incentive stock options). Our compensation committee will determine at what time or times each option may be exercised.

Stock Appreciation Rights. Our compensation committee may award stock appreciation rights under the 2026 Plan subject to such conditions and restrictions as it determines. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right may not be less than 100% of the fair market value of our common stock on the date of grant unless the stock appreciation right (i) is granted pursuant to a transaction described in, and in a manner consistent with, Section 424(a) of the Code, (ii) is granted to an individual who is not subject to United States income tax, or (iii) complies with or is exempt from Section 409A of the Code. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Restricted Stock and Restricted Stock Units. Our compensation committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it determines. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment or other service relationship with us through a specified vesting period.

Unrestricted Stock Awards. Our compensation committee may grant shares of common stock that are free from any restrictions under the 2026 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

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Dividend Equivalent Rights. Our compensation committee may grant dividend equivalent rights to participants that entitle the recipient to receive credits for dividends that would be paid if the recipient had held a specified number of shares of common stock.

Cash-Based Awards. Our compensation committee may grant cash bonuses under the 2026 Plan to participants, subject to the achievement of certain performance goals.

Sale Event. The 2026 Plan provides that, upon the effectiveness of a “sale event” (as defined in the 2026 Plan), an acquirer or successor entity may assume, continue, or substitute outstanding awards under the 2026 Plan. To the extent that awards granted under the 2026 Plan are not assumed, continued, or substituted by the successor entity, the 2026 Plan and all awards granted under the 2026 Plan will terminate. In such case, except as may be otherwise provided in the relevant award agreement, all awards with time-based vesting, conditions, or restrictions will become fully vested and exercisable or nonforfeitable as of the effective time of the sale event and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and exercisable or nonforfeitable in connection with the sale event in the plan administrator’s discretion or to the extent specified in the relevant award agreement. In the event of such termination, (i) individuals holding options and stock appreciation rights will be permitted to exercise any options and stock appreciation rights (to the extent exercisable) within a specified time period, as determined by the compensation committee, prior to the sale event or (ii) we may make or provide for a payment, in cash or in kind, to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights; provided, that any options or stock appreciation rights with exercise prices equal to or greater than such per share consideration will be cancelled for no consideration. In addition, we may make or provide for a payment, in cash or in kind, to the participants holding other awards in an amount equal to the per share consideration payable to stockholders in the sale event multiplied by the number of vested shares of common stock under such awards.

Amendment. Our board of directors may amend or discontinue the 2026 Plan and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may materially and adversely affect rights under an award without the holder’s consent. Certain amendments to the 2026 Plan require the approval of our stockholders. The compensation committee is specifically authorized to exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants without stockholder consent.

No awards may be granted under the 2026 Plan after the date that is ten years from the effective date of the 2026 Plan. No awards have been made under the 2026 Plan prior to the date hereof.

2026 Employee Stock Purchase Plan

The ESPP was adopted by our board of directors on _____, 2026, approved by our stockholders on _____, 2026, and will become effective on the date immediately preceding the date on which the registration statement of which this prospectus is part is declared effective by the SEC. The ESPP has two components: a component intended to qualify as an “employee stock purchase plan” within the meaning of Section 423 of the Code, or the 423 Component, and a component that is not intended to so qualify, or the Non-423 Component. Except as otherwise provided, the Non-423 Component will be operated and administered in the same manner as the 423 Component, except where prohibited by law. The following summary describes the material terms of the ESPP. This summary is not a complete description of all provisions of the ESPP and is qualified in its entirety by reference to the ESPP, which will be filed as an exhibit to the registration statement of which this prospectus is a part.

Authorized Shares. The ESPP initially reserves and authorizes the issuance of up to a total of _____ shares of our common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2027 and each January 1 thereafter through

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January 1, 2036, by the least of (i) _____ % of the outstanding number of shares of our common stock on the immediately preceding December 31, (ii) _____ shares of common stock, or (iii) such number of shares of common stock as determined by the administrator of the ESPP. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend, or other change in our capitalization.

Eligibility. All individuals classified as employees on the payroll records of the Company or a “designated company” (as defined in the ESPP) as of the first day of the applicable offering period are eligible to participate in the ESPP, provided that the ESPP administrator may determine in advance of an offering that employees are eligible only if, as of the first day of the offering, they (a) are customarily employed by us or a designated company for more than 20 hours a week (or such lesser amount determined by the ESPP administrator), (b) are customarily employed by us or a designated company for more than five months per calendar year, (c) have completed a minimum period of employment as determined by the ESPP administrator, provided such service requirement does not exceed two years of employment, and/or (d) they are not highly compensated employees. However, any employee who owns, or as a result of participation in the ESPP would own or hold, 5% or more of the total combined voting power or value of all classes of our stock will not be eligible to purchase shares of common stock under the ESPP.

Offerings. We may make one or more offerings each year to our employees to purchase shares of our common stock under the ESPP, each of which may consist of one or more purchase periods. Offerings will begin and end on the dates determined by the ESPP administrator, except that no offering will exceed 27 months in duration. Each eligible employee may elect to participate in any offering by submitting an enrollment form by the deadline established by the ESPP administrator.

Each employee who is a participant in the ESPP may purchase shares by authorizing payroll deductions at a minimum of _____ % and up to a maximum of _____ % of such participant’s eligible compensation during an offering period (or such other minimum and maximum as determined by the administrator in advance of an offering). Unless the participating employee has previously withdrawn from the offering, such participant’s accumulated payroll deductions will be used to purchase shares of our common stock on the last day of each purchase period at a price equal to 85% of the fair market value of the shares on the first day or the last day of the purchase period, whichever is lower, provided that no more than the number of shares of common stock determined by dividing \$25,000 by the fair market value of our common stock on the first day of such offering period (or such other maximum number of shares as may be established by the administrator) may be purchased by any one employee during any purchase period. Under applicable tax rules, an employee may purchase no more than \$25,000 worth of shares of our common stock, valued at the start of the offering period, under the ESPP for each calendar year during which any option granted to the employee is outstanding at any time.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee’s rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

Sale Event. In the case of and subject to the consummation of a “sale event” (as defined in the ESPP), the administrator of the ESPP, in its discretion, and on such terms and conditions as it deems appropriate, is authorized to take any one or more of the following actions under the ESPP or with respect to any right under the ESPP to facilitate such transactions or events: (i) provide for either (A) termination of any outstanding option in exchange for an amount of cash, if any, equal to the amount that would have been obtained upon the exercise of such option had such option been currently exercisable or (B) the replacement of such outstanding option with other options or property selected by the administrator of the ESPP in its sole discretion; (ii) provide that the outstanding options under the ESPP shall be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for similar options covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices; (iii) make adjustments in the number and type of shares of common stock (or other securities or property) subject to outstanding options under the ESPP and/or in terms and conditions of outstanding options and options that may be granted in the future; (iv) provide that the offering with respect to which an option

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relates will be shortened by setting a new exercise date on which such offering period will end; and (v) provide that all outstanding options shall terminate without being exercised and all amounts in the accounts of participants shall be promptly refunded.

Amendment. The ESPP may be terminated or amended by our board of directors at any time. An amendment that increases the number of shares of our common stock authorized under the ESPP and certain other amendments require the approval of our stockholders.

IPO Grants

On the effective date of the registration statement of which this prospectus forms a part, assuming we issue _____ shares in connection with this offering at an assumed price of \$ _____ per share, we will grant certain executive officers and directors an aggregate of _____ shares under the 2026 Plan, subject to continued service through such grant date. Based on an assumed fair value of \$ _____ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, we estimate that the aggregate grant-date fair value of the shares to be granted in connection with this offering is \$ _____ million, which is expected to be recognized as stock-based compensation expense over a period of _____ years.

DIRECTOR COMPENSATION

2025 Director Compensation Table

The following table presents the compensation awarded to, earned by, or paid to each person who served as a non-employee member of our board of directors for their services to us during Fiscal Year 2025. During Fiscal Year 2025, Ms. Zohar served as a member of our board of directors and received no additional compensation for her service as a member of our board of directors. The compensation for Fiscal Year 2025 received by Ms. Zohar as our Founder, Chief Executive Officer, President & Board Member is presented in the “2025 Summary Compensation Table” above.

<u>Name</u> ⁽¹⁾	<u>Fees Earned or Paid in Cash (\$)</u> ⁽²⁾	<u>Option Awards (\$)</u> ⁽³⁾⁽⁴⁾	<u>All Other Compensation (\$)</u> ⁽⁵⁾	<u>Total (\$)</u>
Eric Elenko, Ph.D.	—	—	—	—
James I. Healy, M.D., Ph.D.	—	—	—	—
Robert Nelsen	—	—	—	—
Sandra E. Peterson	35,000	—	—	35,000
Jason Pitts, Ph.D.	—	—	—	—
Denice Torres, J.D.	35,000	—	—	35,000
David Wheadon, M.D.	35,000	—	—	35,000
Steven M. Paul, M.D. ⁽⁵⁾	—	—	500,000	500,000
Robert J. Hombach ⁽⁶⁾	29,069	433,175	—	462,245
Robert Lyne, LLB	—	—	—	—
Bharatt Chowrira, Ph.D., J.D. ⁽⁷⁾	—	—	—	—

- (1) Each of Ms. Peterson, Ms. Torres, Dr. Wheadon, and Mr. Hombach has entered into a letter agreement with our board pursuant to which he or she is entitled to receive an initial option grant and an annual cash retainer of \$35,000.
- (2) The amounts reported represent the cash fees each director earned for their services to our board of directors during Fiscal Year 2025.
- (3) The amounts reported represent the aggregate grant date fair value of stock option awards granted to our directors in Fiscal Year 2025, computed in accordance with FASB ASC Topic 718. Such grant date fair values do not take into account any estimated forfeitures related to service-based vesting. The assumptions used in calculating the grant date fair values of the option awards reported in this column are set forth in Note 10 of our consolidated financial statements for Fiscal Year 2025, included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for these option awards and do not correspond to the actual economic value that may be received by our directors upon the exercise of the option awards or any sale of the underlying securities.
- (4) The aggregate number of unvested restricted stock and the aggregate number of stock option awards for each non-employee director that were outstanding as of December 31, 2025 are, as follows:

<u>Name</u>	<u>Unvested Restricted Stock(#)</u>	<u>Unexercised Stock Options (#)</u>
Eric Elenko, Ph.D.	—	—
James I. Healy, M.D., Ph.D.	—	—
Robert Nelsen	—	—
Sandra E. Peterson	—	241,966
Jason Pitts, Ph.D.	—	—
Denice Torres, J.D.	—	241,966
David Wheadon, M.D.	—	241,966
Steven M. Paul, M.D.	486,114	5,221,402
Robert J. Hombach	—	241,966
Robert Lyne, LLB	—	—
Bharatt Chowrira, Ph.D., J.D.	—	—

- (5) Dr. Paul has entered into a Senior Advisor Agreement with us, pursuant to which Dr. Paul spends approximately 2.5 days per week at the company and shall be entitled to an annual fee of \$500,000 and received an initial equity grant intended to represent 5.0% of the Company's fully-diluted capitalization as of the effective date. In addition, Dr. Paul shall receive additional equity grants to maintain Dr. Paul's ownership at 5.0% of the fully diluted capitalization of the Company through our initial public offering (but excluding any shares issued pursuant to any over-allotment option). 100% of the unvested restricted stock will accelerate and become fully vested upon the closing of this offering, subject to Dr. Paul's continued service relationship through such closing.
- (6) Mr. Hombach was appointed as a director on March 3, 2025.
- (7) Dr. Chowrira resigned from the Board on July 16, 2025 in connection with his departure from PureTech.

Non-Employee Director Compensation Policy

In connection with this offering, we intend to adopt a new non-employee director compensation policy that will become effective upon the completion of this offering and is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee will be paid cash compensation from and after the completion of this offering, as set forth below, which amounts will be payable quarterly in arrears and prorated for partial years of service:

	Annual Retainer
Board of Directors:	
Members	\$
Additional retainer for non-executive chair	\$
Additional retainer for lead independent director	\$
Audit Committee:	
Members (other than chair)	\$
Retainer for chair	\$
Compensation Committee:	
Members (other than chair)	\$
Retainer for chair	\$
Nominating and Corporate Governance Committee:	
Members (other than chair)	\$
Retainer for chair	\$

In addition, the non-employee director compensation policy will provide that, upon initial election to our board of directors, each non-employee director will be granted an equity award with a fair market value of \$ or an option to purchase shares of our common stock, or the Initial Grant. The Initial Grant will vest on, subject to continued service as a director through the applicable vesting date.

Furthermore, on the date of each annual meeting of stockholders following the completion of this offering, each non-employee director who continues as a non-employee director following such meeting will be granted an annual equity award with fair market value of \$ or option to purchase shares of our common stock, or the Annual Grant. The Annual Grant will vest. These awards are subject to full accelerated vesting upon the sale of the company.

The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any non-employee director for service as a non-employee director in a calendar year period will not exceed \$ (or \$ for the calendar year in which the applicable non-employee director is initially elected or appointed to our board of directors).

We will reimburse all reasonable out-of-pocket expenses incurred by non-employee directors in attending meetings of the board of directors and committees thereof.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

In addition to the compensation arrangements, including employment, termination of employment and change in control arrangements, and indemnification arrangements discussed, when required, in the sections titled “Management,” “Executive Compensation” and “Director Compensation” and the registration rights described in the section titled “Description of Capital Stock—Registration Rights,” the following is a description of all transactions since our date of incorporation in April 2024 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amounts involved exceeded or will exceed the lesser of \$120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years; and
- any of our directors, executive officers or holders of more than 5% or more of our outstanding capital stock, or any immediate family member of, or person sharing the household with, any of these individuals or entities or affiliated entities, had or will have a direct or indirect material interest.

Asset Transfer Agreement with PureTech and Convertible Preferred Stock Financing

In April 2024, we entered into an Asset Transfer Agreement, as amended in December 2025, or the Asset Transfer Agreement, with PureTech Health LLC, or PureTech Health, and PureTech LYT, Inc., or PureTech LYT, pursuant to which PureTech Health and PureTech LYT agreed to contribute, convey, assign, transfer, and deliver to us all of PureTech Health and PureTech LYT’s right, title and interest in, to, and under the assets related to its Glyph technology or products, including the Monash License Agreement, subject to the terms set forth in the Asset Transfer Agreement. In exchange, we issued 40,000,000 shares of our Series A-1 convertible preferred stock and 949,000 shares of our common stock to PureTech LYT.

In connection with the Asset Transfer Agreement, we have agreed to make milestone payments of up to an aggregate of \$10.0 million for the first product covered by assets transferred through the Asset Transfer Agreement, or the Seaport Glyph Product, and up to an aggregate of \$5.0 million for each subsequent Seaport Glyph Product that achieves certain developmental and commercial milestones. In addition, we are obligated to pay royalties between 3% and 5% on the annual net sales of each Seaport Glyph Product as follows: less than \$500 million: 3%; \$500 million to \$1 billion: 3.5%; \$1 billion to \$2.5 billion: 4%; \$2.5 billion to \$3.5 billion: 4.5%; \$3.5 billion or greater: 5%. The royalty term will expire on a country-by-country basis as to each Seaport Glyph Product on the later of the ten year anniversary of the first commercial sale of such Seaport Glyph Product in such country or the date on which the last valid claim of patent rights of such Seaport Glyph Product expires in such country. For additional information, see “*Business Agreements—Asset Transfer Agreement with PureTech.*”

Concurrently, upon entry into the Asset Transfer Agreement, we entered into a stock purchase agreement with PureTech LYT and other third-party investors, in which we issued 26,342,102 shares of our Series A-2 convertible preferred stock, or the Series A Financing, of which 8,421,052 shares were issued and sold to PureTech LYT. PureTech LYT remained a majority investor of Seaport, until the completion of our Series B convertible preferred stock financing, or the Series B Financing, in October 2024, upon which we issued and sold an aggregate amount of 47,578,934 shares of its Series B convertible preferred stock, of which 3,031,578 shares were issued to PureTech LYT, and an aggregate of 494,734 shares issued to certain of our management and board of directors.

Transition Services Agreement with PureTech

In connection with entry into the Asset Transfer Agreement, we also entered into a Transition Services Agreement with PureTech pursuant to which PureTech agreed to provide us certain services relating to the orderly transition and continued operation on a transitional basis for one year following the entry into the Transition Services Agreement (unless extended by mutual agreement of the parties or the earlier termination of

all services provided under the Transition Services Agreement) in consideration of our payment of all fees associated with the transitioned services. Pursuant to the Transition Services Agreement, we made an upfront payment of \$0.5 million to reimburse PureTech for work performed by certain third-parties prior to the closing and have paid an aggregate of \$14.2 million of expenses since entering into the Asset Transfer Agreement to advance our programs and activities. In 2025, the TSA was amended to extend through July 2026 to provide ad hoc support as needed; however, the services to be provided under the amended TSA are expected to be de minimis.

Series A-2 Convertible Preferred Stock Financing

In April 2024, we issued and sold to certain investors an aggregate of 26,342,102 of Series A-2 convertible preferred stock at a price per share of \$3.80, for an aggregate purchase price of approximately \$100.1 million. Each outstanding share of Series A-2 convertible preferred stock will convert into one share of common stock immediately prior to the completion of this offering. The following table summarizes the shares of our Series A-2 convertible preferred stock issued to our related parties:

Purchasers ⁽¹⁾	Series A Convertible Preferred Stock	Total Purchase Price
PureTech LYT, Inc. ⁽²⁾	8,421,052	\$ 31,999,998
ARCH Venture Fund XII, L.P. ⁽³⁾	7,894,736	\$ 29,999,997
Sofinnova Venture Partners XI, L.P. ⁽⁴⁾	6,052,631	\$ 22,999,998
Third Rock Ventures VI, L.P. ⁽⁵⁾	3,947,368	\$ 14,999,998

- (1) Additional details regarding these stockholders and their equity holdings are included in the section titled “Principal Stockholders.”
- (2) PureTech LYT beneficially owns more than 5% of our outstanding capital stock. Dr. Elenko and Mr. Lyne, members of our board of directors, were designated to our board of directors by PureTech LYT and are executive officers at PureTech.
- (3) ARCH Venture Fund XII, L.P. beneficially owns more than 5% of our outstanding capital stock. Mr. Nelsen, a member of our board of directors, was designated to our board of directors by ARCH Venture Fund XII, L.P. and is a Managing Director of ARCH Venture Partners.
- (4) Sofinnova beneficially owns more than 5% of our outstanding capital stock. Dr. Healy, a member of our board of directors, was designated to our board of directors by Sofinnova and is a Managing Director of Sofinnova.
- (5) Third Rock Ventures beneficially own more than 5% of our outstanding capital stock.

Series B Convertible Preferred Stock Financing

In October 2024 and November 2024, we issued and sold to certain investors an aggregate of 47,578,934 shares of Series B convertible preferred stock at a price per share of \$4.75, for an aggregate purchase price of approximately \$226.0 million. Each outstanding share of Series B convertible preferred stock will convert into one share of common stock immediately prior to the completion of this offering. The following table summarizes the shares of our Series B convertible preferred stock issued to our related parties:

Purchasers ⁽¹⁾	Series B Convertible Preferred Stock	Total Purchase Price
General Atlantic (SP), L.P. ⁽²⁾	10,526,315	\$ 49,999,996
ARCH Venture Fund XII, L.P. ⁽³⁾	8,421,052	\$ 39,999,997
PureTech LYT, Inc. ⁽⁴⁾	3,031,578	\$ 14,399,996
Sofinnova Venture Partners XI, L.P. ⁽⁵⁾	2,526,315	\$ 11,999,996
Third Rock Ventures VI, L.P. ⁽⁶⁾	2,526,315	\$ 11,999,996
Steven M. Paul ⁽⁷⁾	210,526	\$ 999,999
Lana Gladstein ⁽⁸⁾	105,263	\$ 499,999
Antony Loebel ⁽⁹⁾	63,157	\$ 299,998
Eric D. Green and Jessica Santiago-Green, Trustees, or their Successors in interest, of the Eric D. Green Living Trust dated November 12, 2010 ⁽¹⁰⁾	42,105	\$ 199,999
Denice M. Torres Revocable Trust ⁽¹¹⁾	42,105	\$ 199,999

- (1) Additional details regarding these stockholders and their equity holdings are included in the section titled “Principal Stockholders.”
- (2) General Atlantic beneficially owns more than 5% of our outstanding capital stock. Dr. Pitts, a member of our board of directors, was designated to our board of directors by General Atlantic and is a Vice President of General Atlantic.
- (3) ARCH Venture Fund XII, L.P. beneficially owns more than 5% of our outstanding capital stock. Mr. Nelsen, a member of our board of directors, was designated to our board of directors by ARCH Venture Fund XII, L.P. and is a Managing Director of ARCH Venture Partners.
- (4) PureTech LYT beneficially owns more than 5% of our outstanding capital stock. Dr. Elenko and Mr. Lyne, members of our board of directors, were designated to our board of directors by PureTech LYT and are executive officers at PureTech.
- (5) Sofinnova beneficially owns more than 5% of our outstanding capital stock. Dr. Healy, a member of our board of directors, was designated to our board of directors by Sofinnova and is a Managing Director of Sofinnova.
- (6) Third Rock Ventures beneficially own more than 5% of our outstanding capital stock.
- (7) Steven M. Paul is Chairman and a member of our board of directors and a senior advisor to the Company.
- (8) Lana Gladstein is our General Counsel.
- (9) Antony Loebel is our Chief Medical Officer.
- (10) Eric Green is our Chief Operating Officer.
- (11) Denice Torres is a member of our board of directors.

Agreements with Stockholders

In connection with our Series A-2 and Series B convertible preferred stock financings, we entered into investors’ rights, voting, and right of first refusal and co-sale agreements containing registration rights and information rights, among other things, with certain holders of our preferred stock and certain holders of our common stock, including holders of more than 5% of our capital stock and entities with which certain of our directors or officers are affiliated. These agreements will terminate upon the closing of this offering, except for the registration rights granted under our amended and restated investors’ rights agreement, as more fully described in “Description of Capital Stock—Registration Rights.”

During the year-ended December 31, 2024, we made payments of \$0.2 million to Third Rock Ventures for professional fees. During the year ended December 31, 2025, amounts paid to Third Rock Ventures were not material.

Management Rights and Side Letters

In connection with the initial issuance and sale of our convertible preferred stock, we entered into management rights and side letters with certain purchasers of our convertible preferred stock, including holders of more than 5% of our capital stock and entities with which certain of our directors or officers are affiliated, pursuant to which such entities were granted certain management rights, among other things, including the right to consult with and advise our management on significant business issues, review our operating plans, examine our books, and records and inspect our facilities. These management rights letters will terminate upon completion of this offering.

Steven M. Paul Advisor Agreement

In February 2024, we entered into a senior advisor agreement with Steven M. Paul, the chair of our board of directors, whereby we pay Dr. Paul an annual fee of \$500,000 and agreed that if at any time while Dr. Paul is providing services to us up to and including the closing of an initial public offering, Dr. Paul’s ownership reduces to below 5% of our total outstanding capital on a fully diluted basis including all outstanding options and restricted common stock, we will grant him an additional equity award to maintain his ownership at the 5% threshold.

Employment and Benefit Arrangements

We have entered into offer letter or employment agreements with certain of our executive officers, and granted restricted stock and stock options to our executive officers, including an agreement with our Chief Executive Officer pursuant to which we have agreed to maintain our Chief Executive Officer's ownership at a certain percentage of our shares on a fully diluted basis and an agreement pursuant to which we've extended additional benefits to our Chief Executive Officer, as more fully described in the section titled "Executive Compensation."

Equity Grants

We have granted restricted stock and options to purchase shares of our common stock to certain of our executive officers and directors. For more information regarding the options granted to our executive officers and directors, see the sections titled "Executive Compensation" and "Director Compensation."

Indemnification Agreements

Our amended and restated certificate of incorporation will contain provisions limiting the liability of directors and officers, and our amended and restated bylaws will provide that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by our board of directors. In addition, we have entered into or intend to enter into an indemnification agreement with each of our directors and executive officers, which will require us to indemnify them. For more information regarding these agreements, see the section titled "Management—Limitations on Liability and Indemnification Agreements."

Directed Share Program

At our request, the underwriters have reserved for sale, at the initial public offering price, up to approximately _____ shares of our common stock being offered hereby (approximately _____ %) for directors, executive officers, employees and business associates. The directed share program will not limit the ability of our directors, officers, and their family members, or holders of more than 5% of our capital stock, to purchase more than \$120,000 in value of our common stock. We do not currently know the extent to which these related persons will participate in our directed share program, if at all, or the extent to which they will purchase more than \$120,000 in value of our common stock.

Policies and Procedures for Transactions with Related Persons

Prior to completion of this offering, we intend to adopt a written policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any series of our common stock, and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the approval or ratification of our board of directors or our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any series of our common stock, or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds \$120,000 (or, if less, 1% of the average of our total assets in a fiscal year) and such person would have a direct or indirect interest, must be presented to our board of directors or our audit committee for review, consideration, and approval. In approving or rejecting any such proposal, our board of directors or our audit committee is to consider the material facts of the transaction, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock as of February 15, 2026 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC. Under these rules, beneficial ownership includes any shares of common stock as to which the individual or entity has sole or shared voting power or investment power. Unless otherwise indicated below, to our knowledge the persons and entities named in the table have sole voting and sole investment power with respect to all shares that they beneficially owned, subject to community property laws where applicable. We have deemed shares of common stock subject to options that are currently exercisable or exercisable within 60 days of February 15, 2026 to be outstanding and to be beneficially owned by the person holding the option for the purpose of computing the percentage ownership of that person but have not treated them as outstanding for the purpose of computing the percentage ownership of any other person.

Applicable percentage ownership before the offering is based on an aggregate of 122,072,236 shares of common stock (which includes 486,114 shares of restricted common stock) deemed to be outstanding as of February 15, 2026 after giving effect to the Preferred Stock Conversion.

Applicable percentage ownership after the offering is based on _____ shares of common stock assumed to be outstanding immediately after the completion of this offering (assuming the sale of _____ shares of common stock in this offering based on an initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and no exercise of the underwriters' option to purchase additional shares).

The following table does not reflect any shares of common stock that may be purchased pursuant to our directed share program described under "Underwriting—Directed Share Program." If any shares are purchased by our existing principal stockholders, directors or their affiliated entities, the number and percentage of shares of our common stock beneficially owned by them after this offering will differ from those set forth in the following table.

Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o Seaport Therapeutics, Inc., 101 Seaport Blvd., Floor 12, Boston, Massachusetts 02210.

<u>Name of Beneficial Owner</u>	<u>Number of Shares Beneficially Owned</u>	<u>Percentage of Shares Beneficially Owned</u>	
		<u>Before Offering</u>	<u>After Offering</u>
Greater than 5% Holders			
PureTech LYT, Inc. ⁽¹⁾	52,402,630	42.93%	
ARCH Venture Fund XII, L.P. ⁽²⁾	16,315,788	13.37%	
General Atlantic (SP), L.P. ⁽³⁾	10,526,315	8.62%	
Sofinnova Venture Partners XI, L.P. ⁽⁴⁾	8,578,946	7.03%	
Third Rock Ventures VI, L.P. ⁽⁵⁾	6,473,683	5.30%	

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Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
Named Executive Officers and Directors			
Daphne Zohar, <i>Chief Executive Officer and Director</i> ⁽⁶⁾	10,494,307	8.15%	
Michael C. Chen ⁽⁷⁾	775,327	*%	
Antony Loebel, M.D. ⁽⁸⁾	785,556	*%	
Steven M. Paul, M.D. ⁽⁹⁾	7,206,725	5.69%	
Eric Elenko, Ph.D.	950,000	*%	
James I. Healy, M.D., Ph.D. ⁽¹⁰⁾	8,578,946	7.03%	
Robert J. Hombach ⁽¹¹⁾	87,376	*%	
Robert Nelsen	—	*%	
Sandra E. Peterson ⁽¹²⁾	107,540	*%	
Jason Pitts, Ph.D.	—	*%	
Denice Torres, J.D. ⁽¹³⁾	196,694	*%	
David Wheadon, M.D. ⁽¹⁴⁾	134,425	*%	
Robert Lyne, LLB	—	*%	
All executive officers and directors as a group (16 persons) ⁽¹⁵⁾	31,087,712	22.71%	

* Represents beneficial ownership of less than 1%.

- (1) Consists of (i) 950,000 shares of common stock, (ii) 40,000,000 shares of common stock issuable upon conversion of Series A-1 preferred stock, (iii) 8,421,052 shares of common stock issuable upon conversion of Series A-2 preferred stock and (iv) 3,031,578 of common stock issuable upon conversion of Series B preferred stock held by PureTech LYT, Inc. Voting and investment power over the shares held by PureTech LYT, Inc. is exercised by its parent entity, PureTech Health plc. The board of directors of PureTech Health plc consists of Ms. Sharon Barber-Lui, Dr. Michele Holcomb, Dr. John LaMattina, Dr. Robert Langer and Ms. Kiran Mazumdar-Shaw. None of the members of the board of directors of PureTech Health plc or PureTech Health LLC has individual voting or investment power with respect to such shares. The address for PureTech Health LLC and the individuals listed above is c/o PureTech Health LLC, 6 Tide Street, Boston, MA 02210.
- (2) Consists of (i) 7,894,736 shares of common stock issuable upon conversion of Series A-2 preferred stock and (ii) 8,421,052 shares of common stock issuable upon conversion of Series B preferred stock held by ARCH Venture Fund XII, L.P. (“ARCH XII”). ARCH Venture Partners XII, L.P. (AVP XII LP) is the general partner of ARCH XII. ARCH Venture Partners XII, LLC (AVP XII LLC) is the general partner of AVP XII LP. Keith Crandell, Kristina Burow, Steven Gillis and Robert Nelsen comprise the investment committee of AVP XII LLC (the AVP XII LLC Committee Members). Each of AVP XII LP and AVP XII LLC may be deemed to beneficially own the shares held by ARCH XII, and each of the AVP XII LLC Committee Members may be deemed to share the power to direct the disposition and vote of the shares held by ARCH XII. Each of AVP XII LP, AVP XII LLC and the AVP XII LLC Committee Members disclaims beneficial ownership except to the extent of their pecuniary interest therein, if any. The address for Arch Ventures Partners, L.P. and the individuals listed above is c/o Arch Ventures Partners L.P., 8755 W. Higgins Rd., Suite 1025, Chicago, IL 60631.
- (3) Consists of 10,526,315 shares of common stock issuable upon conversion of Series B preferred stock held by General Atlantic (SP), L.P., or General Atlantic SP. The limited partners that share beneficial ownership of the shares held by General Atlantic SP, or the GA Funds, are General Atlantic Partners 100, L.P., or GAP 100, General Atlantic Partners (Lux), SCSp, or GAP Lux, GAP Coinvestments III, LLC, or GAPCO III, GAP Coinvestments IV, LLC, or GAPCO IV, GAP Coinvestments V, LLC, or GAPCO V, and GAP Coinvestments CDA, L.P., or GAPCO CDA.

The general partner of GAP 100 is General Atlantic GenPar, L.P., or GA GenPar. General Atlantic, L.P., or GA LP, which is controlled by the Partnership Committee of GASC MGP, LLC (the “Partnership Committee”), is the managing member of GAPCO III, GAPCO IV and GAPCO V, the general partner of GAPCO CDA and GA GenPar, and the sole member of General Atlantic (SPV) GP, LLC, or GA SPV. The general partner of GAP Lux is General Atlantic GenPar, (Lux) SCSp, or GA GenPar Lux, and the general partner of GA GenPar Lux is General Atlantic (Lux) S.à r.l., or GA Lux. The sole shareholder of GA Lux is General Atlantic GenPar (Bermuda), L.P., or GenPar Bermuda. GAP (Bermuda) L.P., or GAP Bermuda, which is ultimately controlled by the Partnership Committee, is the general partner of GenPar Bermuda. There are six members of the Partnership Committee. The Partnership Committee is comprised of senior Managing Directors of General Atlantic: Mr. William E. Ford (CEO and Chairman), Martin Escobari, Gabriel Caillaux, David Hodgson, Torbjorn Caesar, and Christopher G. Lanning. By virtue of the foregoing, the Reporting Persons may be deemed to share voting power and the power to direct the disposition of the shares that each owns of record. Each of the members of the Partnership Committee disclaims ownership of the shares of common stock reported herein except to the extent he or she has a pecuniary interest therein. GA LP, GAP Bermuda, GA Lux, GA GenPar Lux, GA SPV, and the GA Funds are a “group” within the meaning of Rule 13d-5 of the Securities Exchange Act of 1934, as amended. The mailing address of each of the foregoing entities (other than GAP Lux, GA Lux, GA GenPar Lux, GAP Bermuda and GenPar Bermuda) is c/o General Atlantic Service Company, L.P., 55 East 52nd Street, 33rd Floor, New York, NY 10055. The mailing address of GenPar Bermuda and GAP Bermuda is Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda. The mailing address of GAP Lux, GA GenPar Lux, and GA Lux is 412F, Route d’Esch, L-1471 Luxembourg.

- (4) Consists of (i) 6,052,631 shares of common stock issuable upon conversion of Series A-2 preferred stock and (ii) 2,526,315 shares of common stock issuable upon conversion of Series B preferred stock held by Sofinnova Venture Partners XI, L.P. (“SVP XI”), except that Sofinnova Management XI, L.P. (“SM XI LP”), the general partner of SVP XI, may be deemed to have sole voting power, Sofinnova Management XI, L.L.C. (“SM XI LLC”), the general partner of SM XI LP, may be deemed to have sole voting power, and James I. Healy, M.D., Ph.D. and Maha Katabi, Ph.D., the managing members of SM XI LLC, may be deemed to have shared power to vote these shares. Each of SM XI LP, SM XI LLC, Dr. Healy and Dr. Katabi disclaim beneficial ownership of the shares held by SVP XI, except to the extent of their respective pecuniary interest therein. The principal address for the entities and individuals named in this paragraph is 3000 Sand Hill Road, Building 3-Suite 150, Menlo Park, CA 94025.
- (5) Consists of (i) 3,947,368 shares of common stock issuable upon conversion of Series A-2 preferred stock and (ii) 2,526,315 shares of common stock issuable upon conversion of Series B preferred stock held by Third Rock Ventures VI, L.P., or TRV VI. The sole general partner of TRV VI is Third Rock Ventures GP VI, L.P., or TRV GP VI. The sole general partner of TRV GP VI is TRV GP VI, LLC, or TRV GP VI LLC. Abbie Celniker, Ph.D.; Robert Tepper, M.D.; Reid Huber, Ph.D.; Jeffrey Tong, Ph.D.; Kevin Gillis; and David Kaufman, M.D., Ph.D. are the managing members of TRV GP VI LLC and collectively make voting and investment decisions with respect to shares held by TRV VI. The principal address for the entities and individuals named in this paragraph is 201 Brookline Avenue, Suite 1401, Boston, MA 02215.
- (6) Consists of (i) 3,750,000 shares of common stock and (ii) 6,744,307 shares of common stock underlying outstanding stock options that are immediately exercisable within 60 days of February 15, 2026.
- (7) Consists of (i) 10,526 shares of common stock issuable upon conversion of Series B preferred stock and (ii) 764,801 shares of common stock underlying outstanding stock options that are immediately exercisable within 60 days of February 15, 2026.
- (8) Consists of (i) 63,157 shares of common stock issuable upon conversion of Series B preferred stock and (ii) 722,399 shares of common stock underlying outstanding stock options that are immediately exercisable within 60 days of February 15, 2026.
- (9) Consists of (i) 2,500,000 shares of common stock, (ii) 210,526 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 4,496,199 shares of common stock underlying outstanding stock options that are immediately exercisable within 60 days of February 15, 2026.
- (10) Consists of the shares described in footnote (4) above.

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- (11) Consists of 87,376 shares of common stock underlying outstanding stock options that are immediately exercisable within 60 days of February 15, 2026.
- (12) Consists of 107,540 shares of common stock underlying outstanding stock options that are immediately exercisable within 60 days of February 15, 2026.
- (13) Consists of (i) 42,105 shares of common stock issuable upon conversion of Series B preferred stock held by the Denice M. Torres Revocable Trust and (ii) 154,589 shares of common stock underlying outstanding stock options that are immediately exercisable within 60 days of February 15, 2026. Ms. Torres exercises voting and dispositive power over the shares beneficially owned by the Denice M. Torres Revocable Trust.
- (14) Consists of 134,425 shares of common stock underlying outstanding stock options that are immediately exercisable within 60 days of February 15, 2026.
- (15) Consists of (i) 7,200,000 shares of common stock, (ii) 6,052,631 shares of common stock issuable upon conversion of Series A-2 preferred stock, (iii) 3,021,049 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 14,814,032 shares of common stock underlying outstanding stock options that are immediately exercisable within 60 days of April 11, 2025 held by all of our directors and executive officers as a group.

DESCRIPTION OF CAPITAL STOCK

General

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, and the amended and restated bylaws, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part. Copies of these documents have been filed with the SEC as exhibits to our registration statement of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will be in effect on the completion of this offering.

Upon filing of our amended and restated certificate of incorporation and the completion of this offering, our authorized capital stock will consist of _____ shares of common stock, par value \$0.0001 per share, and shares of preferred stock, par value \$0.0001 per share, all of which shares of preferred stock will be undesignated.

As of December 31, 2025, there were 8,151,200 shares of common stock outstanding (which includes 486,114 shares of unvested restricted common stock), held of record by 5 stockholders, 40,000,000 shares of Series A-1 preferred stock, 26,342,102 shares of Series A-2 preferred stock and 47,578,934 shares of Series B preferred stock outstanding and held of record by 34 stockholders.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid, and non-assessable.

Preferred Stock

Immediately prior to the completion of this offering, all outstanding shares of our convertible preferred stock will be converted into shares of our common stock. Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to _____ shares of preferred stock in one or more series and to fix the rights, preferences, privileges, and restrictions thereof. These rights, preferences, and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms, and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our Company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Stock Options

As of December 31, 2025, 27,633,144 shares of common stock were issuable upon the exercise of outstanding stock options under the 2024 Plan, at a weighted-average exercise price of \$1.52 per share; no shares of common stock were issuable upon exercise of outstanding stock options outside of our 2024 Plan; and _____ shares of our common stock that will become available for future issuance under our 2026 Plan, including shares reserved for the IPO Grants, which will become effective on the date immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2026 Plan and any shares underlying outstanding stock awards granted under the 2024 Plan that expire or are repurchased, forfeited, cancelled, or withheld; and For additional information regarding terms of our equity incentive plans, see the section titled “Executive Compensation—Employee Benefit and Equity Compensation Plans.”

Registration Rights

Upon the completion of this offering and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, certain holders of shares of our common stock, including those shares of our common stock that will be issued upon the Preferred Stock Conversion in connection with this offering, will initially be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities will possess these registration rights pursuant to the terms of our second amended and restated investors’ rights agreement and are described in additional detail below. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay all registration expenses, other than underwriting discounts, selling commissions, and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will expire no later than four years after the completion of this offering.

Demand Registration Rights

Upon the completion of this offering, holders of _____ shares of our common stock, including those issuable upon the Preferred Stock Conversion, will be entitled to certain demand registration rights pursuant to that certain Investors’ Rights Agreement, by and between us and the investors party thereto, dated as of October 18, 2024, or the investors’ rights agreement. At any time beginning 180 days after the completion of this offering, the holders of at least 9% of these registrable securities may request that we register all or a portion of their shares. We are not required to effect more than two registration statements which are declared or ordered effective pursuant to these demand registration rights. Such request for registration must cover shares with an anticipated aggregate offering price of at least \$15 million, net of any underwriting discounts, selling commissions, and other related expenses. With certain exceptions, we are not required to effect the filing of a registration statement during the period starting with the date of the filing of, and ending on a date 60 days following the effective date of the registration statement for this offering.

Piggyback Registration Rights

In connection with this offering, holders of 113,921,036 shares of our common stock, including those issuable upon the Preferred Stock Conversion, were entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their shares of registrable securities in this offering pursuant to the investors’ rights agreement. After this offering, in the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the

holders of these registrable securities will be entitled to certain piggyback registration rights allowing such holders to include their shares in such registration, subject to certain marketing and other limitations.

Form S-3 Registration Rights

Upon the completion of this offering, holders of _____ shares of our common stock, including those issuable upon the Preferred Stock Conversion, will be entitled to certain Form S-3 registration rights pursuant to the investors' rights agreement. Holders of at least 9% of these registrable securities can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3 (which qualification may occur no sooner than twelve calendar months after the date of this offering) and if the reasonably anticipated aggregate net proceeds of the shares offered would equal or exceed \$5 million, net of any underwriting discounts, selling commissions and other related expenses. We will not be required to effect more than two registrations on Form S-3 within any twelve-month period. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Expiration of Registration Rights

The demand registration rights and Form S-3 registration rights granted under our Investor Rights Agreement will terminate upon the earliest of (i) the closing of a "Deemed Liquidation Event," as such term is defined in our amended and restated certificate of incorporation (as currently in effect), (ii) such date after the completion of this offering when each holder (A) together with its affiliates (as determined under Rule 144 of the Securities Act) holds less than 1% of our outstanding capital stock and (B) may immediately sell all registrable securities held by such holder pursuant to Rule 144 of the Securities Act without any volume limitations, or another similar exemption, during any three month period without registration, and (iii) the third anniversary of the completion of this offering.

Anti-Takeover Effects of Our Certificate of Incorporation and Bylaws and Delaware Law

Our amended and restated certificate of incorporation and amended and restated bylaws will include a number of provisions that may have the effect of delaying, deferring, or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies

Our amended and restated certificate of incorporation will provide for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our amended and restated certificate of incorporation also will provide that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our amended and restated certificate of incorporation will provide that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our amended and restated bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our amended and restated certificate of incorporation and amended and restated bylaws will provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our amended and restated bylaws will limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our amended and restated bylaws will establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures will provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our amended and restated bylaws will specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws

Any amendment to our amended and restated certificate of incorporation must first be approved by a majority of our board of directors and, if required by law or our amended and restated certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, and limitation of liability must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our amended and restated bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the amended and restated bylaws; and may also be amended by the affirmative vote of a majority of the outstanding shares entitled to vote on the amendment, voting together as a single class, except that the amendment of the provisions relating to notice of stockholder business and nominations and special meetings must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our amended and restated certificate of incorporation will provide for _____ authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest, or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our amended and restated certificate of incorporation will grant our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring, or preventing a change in control of us.

Section 203 of the Delaware General Corporation Law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge, or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges, or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Choice of Forum

Our amended and restated bylaws will provide that the Court of Chancery of the State of Delaware is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of, or a claim based on, a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees or stockholders to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws (including the interpretation, validity, or enforceability thereof) or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (iv) any action asserting a claim governed by the internal affairs doctrine.

However, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Consequently,

this choice of forum provision would not apply to claims or causes of action brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction or the Securities Act. Moreover, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

In addition, our amended and restated bylaws will provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Additionally, our amended and restated bylaws will provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

Limitations on Liability and Indemnification

See the section titled “Management—Limitations on Liability and Indemnification Agreements.”

Exchange Listing

Our common stock is currently not listed on any securities exchange. We have applied to have our common stock approved for listing on the Nasdaq Global Market under the symbol “SPTX.”

Transfer Agent and Registrar

The Transfer Agent and Registrar for our common stock will be Computershare Trust Company, N.A. The transfer agent’s address is 150 Royall Street, Suite 101, Canton, MA 02021.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock, including shares issued on the exercise of outstanding options, in the public market after this offering, or the possibility of these sales or issuances occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital. Although we have applied to list our common stock on the Nasdaq Global Market, we cannot assure you that there will be an active public market for our common stock.

Following the completion of this offering, based on our shares outstanding as of December 31, 2025, a total of _____ shares of common stock will be outstanding, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described below.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements described below. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately _____ shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares of common stock from us; or
- the average weekly trading volume of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 under the Securities Act, or Rule 701, generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule

to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below.

Form S-8 Registration Statements

We intend to file one or more registration statements on Form S-8 under the Securities Act with the SEC to register the offer and sale of shares of our common stock that are issuable under the 2024 Plan, the 2026 Plan, and the ESPP. These registration statements will become effective immediately upon filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below, and Rule 144 limitations applicable to affiliates.

Lock-up Arrangements

We, all of our directors and executive officers, and the holders of substantially all of our capital stock and securities convertible into or exchangeable for our capital stock have entered into lock-up agreements with the underwriters and/or are subject to market standoff agreements or other agreements with us, which prevents them from selling any of our common stock or any securities convertible into or exercisable or exchangeable for common stock for a period of not less than 180 days from the date of this prospectus without the prior written consent of _____, subject to certain exceptions. For more information, see the section titled “Underwriting.”

Registration Rights

Upon completion of this offering, certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. For more information, see the section titled “Description of Capital Stock—Registration Rights.”

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES FOR NON-U.S. HOLDERS

The following discussion is a summary of material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership, and disposition of our common stock issued pursuant to this offering. This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, Treasury Regulations promulgated thereunder, published rulings, and administrative pronouncements of the U.S. Internal Revenue Service, or IRS, and judicial decisions, all as in effect on the date hereof. These authorities are subject to differing interpretations and may change, possibly with retroactive effect, 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.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, the alternative minimum tax, or the special tax accounting rules under Section 451(b) of the Code, and also does not address any U.S. federal non-income tax consequences, such as estate or gift tax consequences, or any tax consequences arising under any state, local, or non-U.S. tax laws. This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a non-U.S. holder in light of such non-U.S. holder’s particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to non-U.S. 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 entities or arrangements treated as pass-through or disregarded entities for U.S. federal income tax purposes (and investors therein);
- “controlled foreign corporations”;
- “passive foreign investment companies”;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, mutual funds, financial institutions, investment funds, insurance companies, brokers, dealers, or traders in stock, securities, commodities or currencies;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons who acquire our common stock through the exercise of an option or otherwise as compensation;
- qualified foreign pension funds as defined in Section 897(1)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or synthetic security or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership generally will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Partnerships holding our common stock 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 owning and disposing of our common stock.

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 COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, OR NON-U.S. TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of Non-U.S. Holder

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a corporation or any organization taxable as a corporation for U.S. federal income taxes that is not created or organized under the laws of the United States, any state thereof, or the District of Columbia; or
- a foreign trust or estate, the income of which is not subject to U.S. federal income tax on a net income basis.

Distributions on Our Common Stock

As described under “*Dividend Policy*,” we do not currently anticipate declaring or paying, for the foreseeable future, any distributions on our capital stock. However, if we were to distribute cash or other property on our common stock, 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 then constitute a return of capital and will first be applied against and reduce a holder’s tax basis in our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under “—Gain on sale or other taxable disposition of our common stock” below.

Subject to the discussions below regarding effectively connected income, backup withholding and FATCA (as defined below), dividends paid to a non-U.S. holder of our common stock 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 to us or our withholding agent with a timely and valid IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying such holder’s qualification for the reduced rate. This certification must be provided to us or our withholding agent before the payment of the dividends and must be updated periodically. If the non-U.S. holder holds our common 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 withholding agent, either directly or through other intermediaries.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder’s U.S. trade or business (and, if required by an applicable tax treaty, are attributable to such holder’s permanent establishment or fixed base in the United States), such non-U.S. holder generally will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder generally must furnish a valid IRS Form W-8ECI (or applicable successor form), certifying that the dividends are effectively connected with the non-U.S. Holder’s conduct of a trade or business within the United States to the applicable withholding agent.

However, any such effectively connected dividends paid on our common stock 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 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 dividends, as adjusted for certain items.

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 or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Gain on Disposition of Our Common Stock

Subject to the discussions below regarding backup withholding and FATCA (as defined below), 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 taxable disposition of our common stock, 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 or fixed base maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for a period or periods aggregating 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a "United States real property interest" by reason of our status as a United States real property holding corporation, or USRPHC, 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 period for our common stock, and our common stock is not "regularly traded" on an "established securities market" within the meaning of applicable Treasury Regulations, 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 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.

Gain 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 of the non-U.S. holder (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.

Determining whether we are a USRPHC depends on the fair market value of our United States real property interests relative to the fair market value of our worldwide real property interests and our other trade or business assets. We believe that we are not currently and we do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we have not been, are not currently or will not in the future become a USRPHC. Even if we are treated as a USRPHC, gain realized by a non-U.S. holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the non-U.S. holder owned, directly, indirectly and constructively, no more than 5% of our common stock at all times within the shorter of (a) the five-year period preceding the disposition or (b) the holder's holding period and (2) our common stock is "regularly traded" on an "established securities market," within the meaning of applicable Treasury Regulations. There can be no assurance that our common stock qualifies as regularly traded on an established securities market for purposes of the rules described above. Prospective investors are encouraged to consult their own tax advisors regarding the possible consequences to them if we have been, are or were to become a USRPHC.

Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

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 distributions on our common stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply even if no withholding was required because the distributions 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, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of distributions on or the gross proceeds of a disposition of our common stock 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 otherwise establishes an exemption, and if the payor does not have 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.

Withholding on Foreign Entities

Sections 1471 through 1474 of the Code, which are commonly referred to as FATCA, impose 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 imposes a U.S. federal withholding tax of 30% on certain payments made to a "non-financial foreign entity" (as specially defined under these rules) unless such entity provides the withholding agent a certification that it does not have any "substantial United States owners" or provides information 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 currently applies to dividends paid on our common stock and would have applied also to payments of gross proceeds from the sale or other disposition of our common stock. However, proposed regulations under FATCA provide for the elimination of the federal withholding tax of 30% applicable to gross proceeds of a sale or other disposition of from property of a type that can produce U.S.-source dividends or interest. Under these proposed Treasury Regulations (which may be relied upon by taxpayers prior to finalization), FATCA withholding does not apply to gross proceeds from sales or other dispositions of our common stock.

Prospective investors are encouraged to consult with their tax advisors regarding the possible implications of FATCA on their investment in our common stock.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF ACQUIRING, OWNING, AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY RECENT AND PROPOSED CHANGE IN APPLICABLE LAW, AS WELL AS TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, NON-U.S., OR U.S. FEDERAL NON-INCOME TAX LAWS.

UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC, J.P. Morgan Securities LLC, and Leerink Partners LLC are the representatives of the underwriters.

<u>Underwriters</u>	<u>Number of Shares</u>
Goldman Sachs & Co. LLC	
J.P. Morgan Securities LLC	
Leerink Partners LLC	
Citigroup Global Markets Inc.	
Stifel, Nicolaus & Company, Incorporated	
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional _____ shares of our common stock from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total estimated underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase _____ additional shares of our common stock from us.

	<u>No Exercise</u>	<u>Full Exercise</u>
Per Share	\$	\$
Total	\$	\$

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to \$ _____ per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors, and holders of substantially all of our common stock and securities convertible into or exchangeable for our common stock have agreed or will agree with the underwriters, subject to certain exceptions, not to dispose of or hedge any of our or their common stock or securities convertible into or exchangeable for shares of common stock, or collectively, the Lock-Up Securities, during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of _____. This agreement does not apply to any existing employee benefit plans. See the section titled "Shares Available for Future Sale" for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the shares of our common stock. The initial public offering price has been negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of the business potential and earnings prospects of us, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We have applied to list our common stock on the Nasdaq Global Market under the symbol “SPTX.”

In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A “covered short position” is a short position that is not greater than the amount of additional shares for which the underwriters’ option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. “Naked” short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common stock, and together with the imposition of the penalty bid, may stabilize, maintain, or otherwise affect the market price of our common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the Nasdaq Global Market, in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, excluding the estimated underwriting discounts and commissions, will be approximately \$. We have agreed to reimburse the underwriters for certain of their expenses in an amount up to \$.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial, and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage, and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters, and their respective affiliates, officers, directors, and employees may purchase, sell, or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps, and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of ours (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates

may also communicate independent investment recommendations, market color, or trading ideas and/or publish or express independent research views in respect of such assets, securities, or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities, and instruments.

Directed Share Program

At our request, the underwriters have reserved up to % of the common stock offered by this prospectus for sale at the initial public offering price for sale at the initial public offering price to our directors, officers, certain employees and certain other persons associated with us. The sales will be made by through a directed share program. We do not know if these persons will choose to purchase all or any portion of these reserved shares, but any purchases they do make will reduce the number of shares of common stock available to the general public. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of common stock. Except for reserved shares purchased by our executive officers and directors, these reserved shares will not be subject to the lock-up restrictions described elsewhere in this prospectus.

Selling Restrictions

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the EEA, or, each, a Relevant Member State, an offer to the public of any shares may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares may be made at any time under the following exemptions under the EU Prospectus Regulation:

- a) to any legal entity which is a “qualified investor” as defined under the EU Prospectus Regulation;
- b) to fewer than 150 natural or legal persons (other than “qualified investors” as defined under the EU Prospectus Regulation), subject to obtaining the prior consent of the underwriters for any such offer; or
- c) in any other circumstances falling within Article 1(4) of the EU Prospectus Regulation,

provided that no such offer of shares shall result in a requirement for the Company or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or a supplemental prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, warranted and agreed to and with each of the underwriters and the Company that it is a qualified investor within the meaning of Article 2 of the EU Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 1(4) of the EU Prospectus Regulation, each financial intermediary will also be deemed to have represented, warranted, and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public, other than their offer or resale in a Relevant Member State to qualified investors as so defined or in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

The Company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, warranties, and agreements. Notwithstanding the above, a person who is not a “qualified investor” and who has notified the underwriters of such fact in writing may, with the prior consent of the Notwithstanding the above, a person who is not a “qualified investor” and who has notified the underwriters of such fact in writing may, with the prior consent of the underwriters, be permitted to acquire shares in the offer.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the

terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “EU Prospectus Regulation” means Regulation (EU) 2017/1129.

Notice to Prospective Investors in the United Kingdom

An offer to the public of any shares may not be made in the UK, except that an offer to the public in the UK of any shares may be made at any time under the following exemptions under the UK Prospectus Regulation:

- a) to any legal entity which is a “qualified investor” as defined under the UK Prospectus Regulation;
- b) to fewer than 150 natural or legal persons (other than “qualified investors” as defined under the UK Prospectus Regulation), subject to obtaining the prior consent of the underwriters for any such offer; or
- c) in any other circumstances falling within section 86 of the Financial Services and Markets Act 2000, as amended, or the FSMA,

provided that no such offer of shares shall result in a requirement for the Company or any Bookrunner to publish a prospectus pursuant to section 85 of the FSMA or a supplemental prospectus pursuant to Article 23 of the UK Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, warranted and agreed to and with each of the underwriters and the Company that it is a qualified investor within the meaning of Article 2 of the UK Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 1(4) of the UK Prospectus Regulation, each financial intermediary will also be deemed to have represented, warranted, and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public, other than their offer or resale in the UK to qualified investors as so defined or in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

The Company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, warranties, and agreements. Notwithstanding the above, a person who is not a “qualified investor” and who has notified the underwriters of such fact in writing may, with the prior consent of underwriters, be permitted to acquire shares in the offer.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in the UK means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares.

This Prospectus is only being distributed to and is only directed at: (A) persons who are outside the UK; or (B) qualified investors who are also (i) investment professionals falling within Article 19(5) of the FSMA (Financial Promotion) Order 2005, or the Order, or (ii) high net worth companies, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order, or, all such persons falling within (1)-(3) together being referred to as, relevant persons. The shares are only available to, and any invitation, offer, or agreement to subscribe, purchase, or otherwise acquire the shares will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this Prospectus or any of its contents.

Notice to Prospective Investors in Canada

The shares may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this offering memorandum (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong), or the Companies (Winding Up and Miscellaneous Provisions) Ordinance, or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the Securities and Futures Ordinance, or (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation, or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore, or Regulation 32.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The shares may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority, or the DFSA. This prospectus is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares of common stock to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares of common stock offered should conduct their own due diligence on the shares of common stock. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement, or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement, or other disclosure document under the Corporations Act.

Any offer in Australia of the shares of common stock may only be made to persons, the Exempt Investors, who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares of common stock without disclosure to investors under Chapter 6D of the Corporations Act.

The shares of common stock applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares of common stock must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation, or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Israeli Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares of common stock is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and “qualified individuals,” each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Notice to Prospective Investors in Brazil

The offer and sale of the shares have not been and will not be registered with the Brazilian securities commission (Comissão de Valores Mobiliários, or CVM) and, therefore, will not be carried out by any means that would constitute a public offering in Brazil under CVM Resolution No. 160, dated 13 July 2022, as amended, or CVM Resolution 160, or unauthorized distribution under Brazilian laws and regulations. The shares may only be offered to Brazilian professional investors (as defined by applicable CVM regulation), who may only acquire the shares through a non-Brazilian account, with settlement outside Brazil in non-Brazilian currency. The trading of these shares on regulated securities markets in Brazil is prohibited.

LEGAL MATTERS

The validity of the shares of our common stock being offered in this prospectus will be passed upon for us by Goodwin Procter LLP. Certain legal matters in connection with this offering will be passed upon for the underwriters by Latham & Watkins LLP, New York, New York.

EXPERTS

The financial statements as of December 31, 2025 and 2024 and for the years then ended included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-) under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC also maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov/edgar.

We currently do not file periodic reports with the SEC. On the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements, and other information with the SEC. These reports, proxy statements and other information will be available for review at the website of the SEC referred to above.

We also maintain a website at www.seaporttx.com. Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference. Upon completion of this offering, you may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

Seaport Therapeutics, Inc.
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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Seaport Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Seaport Therapeutics, Inc. and its subsidiaries (the “Company”) as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock and stockholders’ deficit and of cash flows for the years then ended, 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, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended 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 audits. 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 of these consolidated financial statements in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits 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 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 a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
February 27, 2026

We have served as the Company’s auditor since 2024.

Seaport Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31,	
	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 46,042	\$309,099
Short-term investments	169,941	—
Prepaid expenses and other current assets	7,247	1,053
Total current assets	223,230	310,152
Property and equipment, net	412	240
Right-of-use assets—operating leases	4,813	4,931
Long-term investments	17,670	—
Other non-current assets	2,884	454
Total assets	\$ 249,009	\$ 315,777
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 2,007	\$ 4,733
Related party payable	7	351
Accrued expenses and other current liabilities	9,131	5,208
Operating lease liability	1,637	857
Total current liabilities	12,782	11,149
Operating lease liability, net of current portion	3,444	4,149
Total liabilities	16,226	15,298
Commitments and contingencies (Note 14)		
Series A-1 convertible preferred stock, par value \$0.0001; 40,000,000 shares authorized, issued, and outstanding; liquidation preference of \$4,000 as of December 31, 2025 and 2024	—	—
Series A-2 convertible preferred stock, par value \$0.0001; 26,342,102 shares authorized, issued and outstanding; liquidation preference of \$100,100 as of December 31, 2025 and 2024	99,757	99,757
Series B convertible preferred stock, par value \$0.0001; 47,578,938 shares authorized; 47,578,934 shares issued and outstanding; liquidation preference of \$226,000 as of December 31, 2025 and 2024	225,571	225,571
Stockholders' deficit		
Common stock, par value \$0.0001; 159,070,000 shares authorized; 8,151,200 and 8,150,000 shares issued and outstanding as of December 31, 2025 and 2024, respectively	1	1
Additional paid-in capital	21,262	14,378
Accumulated other comprehensive income	301	—
Accumulated deficit	(114,109)	(39,228)
Total stockholders' deficit	(92,545)	(24,849)
Total liabilities, convertible preferred stock and stockholders' deficit	\$ 249,009	\$ 315,777

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

Seaport Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development ⁽¹⁾ (including stock-based compensation expense of \$2.3 million and \$0.7 million for 2025 and 2024, respectively)	\$ 66,313	\$ 25,070
General and administrative ⁽²⁾ (including stock-based compensation expense of \$4.6 million and \$15.2 million for 2025 and 2024, respectively)	20,981	27,346
Total operating expenses	87,294	52,416
Loss from operations	(87,294)	(52,416)
Other income (expense), net		
Interest income, net	11,403	5,537
Research and development tax credit	1,898	—
Other (expense), net	(115)	—
Total other income, net	13,186	5,537
Loss before income taxes	(74,108)	(46,879)
Income tax provision	773	—
Net loss	<u>\$ (74,881)</u>	<u>\$ (46,879)</u>
Other comprehensive income (loss), net of tax:		
Foreign currency translation adjustment	(9)	—
Unrealized gain on available-for-sale securities	310	—
Comprehensive loss	<u>\$ (74,580)</u>	<u>\$ (46,879)</u>
Net loss per share, basic and diluted	<u>\$ (10.04)</u>	<u>\$ (15.83)</u>
Weighted-average common shares outstanding, basic and diluted	<u>7,456,011</u>	<u>2,961,543</u>

- (1) Includes related-party amounts of \$0.3 million and \$14.2 million for research and development expenses for the years ended December 31, 2025 and 2024, respectively. See Note 17—Related Parties.
- (2) Includes related-party amounts of \$0.1 million and \$5.8 million for general and administrative expenses for the years ended December 31, 2025 and 2024, respectively. See Note 17—Related Parties.

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

Seaport Therapeutics, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit
(In thousands, except share amounts)

	Series A-1 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Net Parent Investment	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balance as of December 31, 2023	—	\$ —	—	\$ —	—	\$ —	—	\$ —	\$ (6,462)	\$ —	\$ —	\$ —	\$ (6,462)
Net loss attributable to Seaport	—	—	—	—	—	—	—	—	(9,714)	—	—	—	(9,714)
Net transfers from PureTech Health plc prior to formation	—	—	—	—	—	—	—	—	13,967	—	—	—	13,967
Stock-based compensation expense allocated from PureTech Health plc	—	—	—	—	—	—	—	—	146	—	—	—	146
Issuance of common stock to PureTech Health plc upon formation	—	—	—	—	—	—	1,000	—	—	—	—	—	—
Issuance of common stock and Series A-1 convertible preferred stock to PureTech Health plc upon Asset Transfer	40,000,000	—	—	—	—	—	949,000	—	—	—	—	—	—
Reclassification of net investments from PureTech Health plc	—	—	—	—	—	—	—	—	2,063	—	(2,063)	—	—
Issuance of Series A-2 convertible preferred stock, net of issuance costs of \$343	—	—	26,342,102	99,757	—	—	—	—	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of \$429	—	—	—	—	47,578,934	225,571	—	—	—	—	—	—	—
Issuance of common stock	—	—	—	—	—	—	950,000	—	—	—	—	—	—
Issuance of restricted stock	—	—	—	—	—	—	6,250,000	1	—	—	—	—	1
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	14,378	—	—	14,378
Net loss	—	—	—	—	—	—	—	—	—	—	(37,165)	—	(37,165)
Balance as of December 31, 2024	<u>40,000,000</u>	<u>\$ —</u>	<u>26,342,102</u>	<u>\$ 99,757</u>	<u>47,578,934</u>	<u>\$ 225,571</u>	<u>8,150,000</u>	<u>\$ 1</u>	<u>\$ —</u>	<u>\$ 14,378</u>	<u>\$ (39,228)</u>	<u>\$ —</u>	<u>\$ (24,849)</u>
Exercise of stock options	—	—	—	—	—	—	1,200	—	—	1	—	—	1
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	6,883	—	—	6,883
Unrealized gain on investments	—	—	—	—	—	—	—	—	—	—	—	310	310
Cumulative translation adjustment	—	—	—	—	—	—	—	—	—	—	—	(9)	(9)
Net loss	—	—	—	—	—	—	—	—	—	—	(74,881)	—	(74,881)
Balance as of December 31, 2025	<u>40,000,000</u>	<u>\$ —</u>	<u>26,342,102</u>	<u>\$ 99,757</u>	<u>47,578,934</u>	<u>\$ 225,571</u>	<u>8,151,200</u>	<u>\$ 1</u>	<u>\$ —</u>	<u>\$ 21,262</u>	<u>\$ (114,109)</u>	<u>\$ 301</u>	<u>\$ (92,545)</u>

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

Seaport Therapeutics, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2025	2024
Operating activities		
Net loss	\$ (74,881)	\$ (46,879)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	6,883	14,524
Depreciation expense	173	166
Loss on disposal of property, plant and equipment	11	—
Amortization of operating lease right-of-use assets	1,232	48
Net amortization of premiums and discounts on investments	(3,430)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(6,212)	(508)
Other non-current assets	(1,556)	—
Accounts payable	(2,726)	1,723
Related party payable	(344)	351
Accrued expenses and other current liabilities	3,947	919
Operating lease liability	(1,039)	27
Net cash used in operating activities	(77,942)	(29,629)
Investing activities		
Purchases of investments	(396,389)	—
Proceeds from maturities of investments	212,500	—
Purchases of property and equipment	(356)	(113)
Net cash used in investing activities	(184,245)	(113)
Financing activities		
Payment of deferred offering costs	(874)	—
Proceeds from exercise of stock options	1	—
Net transfers from PureTech Health plc	—	13,967
Proceeds from the issuance of Series A-2 convertible preferred stock ⁽¹⁾	—	100,100
Payment of issuance costs associated with issuance of Series A-2 convertible preferred stock	—	(343)
Proceeds from the issuance of Series B convertible preferred stock ⁽²⁾	—	226,000
Payment of issuance costs associated with issuance of Series B convertible preferred stock	—	(429)
Net cash (used in) provided by financing activities	(873)	339,295
Effect of exchange rates on cash and cash equivalents	3	—
Net increase (decrease) in cash and cash equivalents	(263,057)	309,553
Cash, cash equivalents, and restricted cash, beginning of period	309,553	—
Cash, cash equivalents, and restricted cash, end of period	<u>\$ 46,496</u>	<u>\$309,553</u>
Supplemental disclosure of non-cash operating, financing, and investing information:		
Operating lease right-of-use assets obtained in exchange for lease liabilities	\$ 1,114	\$ 4,979
Cash paid for income taxes	\$ 258	\$ —
Deferred offering costs included in accounts payable and accrued expenses	\$ 365	\$ —
Fixed assets recorded in accounts payable	\$ 12	\$ —

(1) Includes proceeds from certain related parties of \$32.0 million. See Note 17—Related Parties.

(2) Includes proceeds from certain related parties of \$16.7 million. See Note 17—Related Parties.

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

Seaport Therapeutics, Inc.
Notes to Consolidated Financial Statements

1. NATURE OF BUSINESS AND BASIS OF PRESENTATION

Background

Seaport Therapeutics, Inc., and its consolidated subsidiaries, Seaport or the Company, is a clinical-stage therapeutics company focused on inventing and developing medicines for patients with depression, anxiety, and other debilitating neuropsychiatric disorders using the Company's proprietary Glyph Platform.

The accompanying financial statements include the historical financial position, results of operations, and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows of the Glyph platform business, or the Seaport Business, which was a business of PureTech Health plc and its consolidated subsidiaries, or PureTech, a public company incorporated, domiciled and registered in the United Kingdom. The Seaport Business was historically managed as part of PureTech prior to the completion of the spin-off of the Seaport Business from PureTech in April 2024, pursuant to the Asset Transfer Agreement (as defined below). The Company, which holds the assets, liabilities, and operations associated with the Seaport Business, was incorporated under the laws of the State of Delaware as SP Therapeutics, Inc. on April 1, 2024, and changed its name to Seaport Therapeutics, Inc. on April 2, 2024. Its wholly owned subsidiary, SPTX, Inc., or SPTX, was a previously created entity in February 2024 under the laws of the State of Delaware under the name Seaport Therapeutics, Inc. and changed its name to SPTX, Inc. in April 2024. In April 2024, the Company entered into a share exchange agreement with SPTX, which resulted in SPTX becoming the Company's wholly owned subsidiary. See Note 10—Common Stock, for further disclosure regarding the share exchange with SPTX.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, completion of preclinical studies and clinical trials, obtaining regulatory approvals for product candidates, dependence on key personnel, protection of intellectual property, compliance with government regulations, and ability to secure capital necessary to fund operations. Product candidates currently under development by the Company will require significant additional research and development efforts, including preclinical and clinical development, and regulatory approval prior to commercialization. There can be no assurance that the Company's research and development efforts will be successfully completed, that any product candidates developed will obtain necessary government regulatory approval, or that any products, if approved, will be commercially viable. The Company operates in an environment of rapid technological innovation and substantial competition from pharmaceutical and biotechnology companies. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant product revenue from product sales.

The Asset Transfer and Series A Financing

The Company was incorporated in April 2024 by PureTech LYT Inc., or PureTech LYT, a wholly owned subsidiary of PureTech, as the sole stockholder, and the Company issued 1,000 shares of its common stock to PureTech LYT. On April 8, 2024, or the Asset Transfer Date, the Company entered into an asset transfer agreement, as amended in December 2025, or the Asset Transfer Agreement with PureTech Health LLC, or PureTech Health, and PureTech LYT, pursuant to which PureTech Health and PureTech LYT, agreed to contribute, convey, assign, transfer, and deliver to the Company all of its right, title, and interest in, to and under the assets related to its Glyph technology and products, or the Asset Transfer. As consideration, the Company issued to PureTech LYT 40,000,000 shares of its Series A-1 convertible preferred stock and 949,000 shares of its common stock on the Asset Transfer Date, and also agreed to contingent payments to PureTech upon successful development and commercialization of products developed using the Glyph platform, each of which is referred to as a Seaport Glyph Product, including; milestone payments of up to an aggregate of \$10.0 million for the first product covered by assets transferred through the Asset Transfer Agreement, or the Seaport Glyph Product, of \$2.0 million for the first patient dosed in the first phase 3 clinical trial, \$4.0 million for the first commercial sale

Seaport Therapeutics, Inc.
Notes to Consolidated Financial Statements

in the United States, \$2.0 million for the first commercial sale in a major European market, and \$2.0 million for the first commercial sale in Japan, and for each subsequent Seaport Glyph Product, the Company has agreed to make milestone payments of \$1.0 million for the first patient dosed in the first phase 3 clinical trial, \$2.0 million for the first commercial sale in the United States, \$1.0 million for the first commercial sale in a major European market, and \$1.0 million for the first commercial sale in Japan. In addition, the Company is obligated to pay royalties between 3% and 5% on the annual net sales of each Seaport Glyph Product and a percentage of net income generated by the Company from third parties on any products licensed under the Glyph intellectual property which was transferred as part of the Asset Transfer Agreement.

The Company determined that the Asset Transfer and related spin-off transaction represented the transfer of a business between entities under common control. As a result, the net liabilities were transferred from PureTech to the Company at PureTech's carrying amounts on the Asset Transfer Date, and the Company ascribed a nil value to the Series A-1 convertible preferred stock and common stock issued to PureTech Health and PureTech LYT. The consolidated financial statements for the period prior to the Asset Transfer Date, were prepared on a "carve-out" basis from the consolidated financial statements of PureTech to represent Seaport Business' financial position, results of operations, changes in net parent investment and cash flows as if the Seaport Business existed on a standalone basis. Effective April 8, 2024, the Company's financial statements are presented on a consolidated basis, as PureTech Health and PureTech LYT completed the transfer of the Seaport Business on such date. The audited financial statements for the year presented, including the historical results of the Company prior to April 8, 2024, are referred to as the consolidated financial statements.

Concurrently, upon entry into the Asset Transfer Agreement, the Company entered into a stock purchase agreement with PureTech LYT and other third-party investors, pursuant to which the Company issued and sold shares of its Series A-2 convertible preferred stock, or the Series A Financing, and together with the Asset Transfer, the Transaction. Subsequent to the Transaction, PureTech LYT remained the controlling investor of the Company, until the completion of the Company's Series B convertible preferred stock financing, or the Series B Financing (as further discussed herein), in October 2024. The Series B Financing resulted in a decrease to PureTech LYT's fully diluted ownership, resulting in PureTech LYT no longer maintaining a controlling interest in the Company. See Note 9—Convertible Preferred Stock, for further disclosure regarding issuances of the Company's convertible preferred stock.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP. These consolidated financial statements include the accounts of Seaport Therapeutics, Inc. and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

For the period prior to the Transaction, the accompanying consolidated financial statements of the Company have been prepared on a standalone basis and are derived from PureTech's consolidated financial statements and accounting records. The consolidated financial statements reflect PureTech's historical accounting policies, adjusting for differences between International Financial Reporting Standards and GAAP as appropriate. These consolidated financial statements do not purport to reflect what the Company's results of operations, financial position, or cash flows would have been had the Company operated as a standalone company during the period prior to the Transaction, nor are they indicative of the Company's future results of operations, financial position, or cash flows.

As the Company's operations were not historically conducted by a single legal entity, net parent investment is shown in lieu of stockholders' equity in the historical consolidated financial statements for the period prior to

Seaport Therapeutics, Inc.
Notes to Consolidated Financial Statements

the Transaction. Net parent investment represents the cumulative investment by PureTech in the Seaport Business through the Transaction date, inclusive of operating results. All transactions between the Seaport Business and PureTech were effectively settled in the consolidated financial statements at the time the Transaction was recorded. The effects of the settlement of such transactions between the Seaport Business and PureTech are reflected in the consolidated statements of cash flows as “Net transfers from PureTech Health plc” within financing activities and in the statement of convertible preferred stock and stockholders’ deficit as “Net parent investment” for the year ended December 31, 2024.

The Company was dependent upon PureTech for all of its working capital and financing requirements through the date of the Transaction. PureTech used a centralized approach for cash management and the financing of its operations. There were no cash amounts specifically attributable to the Seaport Business prior to the Transaction; therefore, cash and cash equivalents were excluded in the consolidated financial statements prior to the Transaction.

The consolidated financial statements of the Company include, for the period prior to the Transaction, the assets, liabilities, and expenses of PureTech that Seaport management determined were specifically identifiable to the Seaport Business and its related programs, as well as indirect costs that are not specifically identifiable to the Seaport Business or its related programs but are deemed necessary to operate as a standalone entity. The assets and liabilities in the consolidated financial statements for the period prior to the Transaction were recorded based on their legal title or related to the exclusive use of the Seaport Business. Shared assets were not included on the consolidated balance sheet, but costs reflecting the use of such assets by the Seaport Business were reflected in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2024. Indirect costs are the costs of support functions that are provided on a centralized basis by PureTech prior to the Transaction, which include, but are not limited to, facilities, information technology, insurance, quality, compliance, finance, human resources, legal, corporate strategy, corporate governance, and other general and administrative type functions.

The consolidated financial statements of the Company also include, for the period prior to the Transaction, indirect costs that have been allocated to the Seaport Business for the purposes of preparing the consolidated financial statements based on proportional cost allocation methods using headcount, proportional time spent, and other organizational activities, as applicable, which were considered to be reasonable reflections of the utilization of services provided to or benefit received by the Seaport Business for the period prior to the Transaction. Seaport management considers that such allocations were made on a reasonable basis; however, these allocations may not necessarily be indicative of the costs that would have been incurred if the Seaport Business had operated on a standalone basis for the full year ended December 31, 2024 and, therefore, may not be indicative of the Company’s results of operations, financial position, and cash flows had the Company operated as a standalone entity prior to the Transaction. See Note 17—Related Parties, for additional information regarding related-party transactions with PureTech.

As of December 31, 2025, PureTech continued to provide various research and development and corporate services under the transition services agreement, or the TSA, which was initially set to terminate one year following the date of the Asset Transfer Agreement. In 2025, the TSA was amended to extend through July 2026 to provide ad-hoc support; however, the total value of the incremental services are not material.

Going Concern

Management has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the consolidated financial statements were available to be issued.

Seaport Therapeutics, Inc.
Notes to Consolidated Financial Statements

The Company has incurred losses and negative cash flows from operations since inception, including net losses of \$74.9 million and \$46.9 million for the years ended December 31, 2025 and 2024, respectively, and cash used in operations of \$77.9 million and \$29.6 million for the years ended December 31, 2025 and 2024, respectively. The Company expects to continue to generate operating losses and negative cash flows for the foreseeable future as the Company continues to develop its product candidates. The Company's future operations will be dependent on its ability to raise additional capital to finance such operations.

The Company's consolidated financial statements have been prepared assuming it will continue as a going concern, which presumes it will continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in the ordinary course of business. The Company believes its cash and cash equivalents and investments of \$233.7 million as of December 31, 2025 will be sufficient to fund its expected operating expenses and capital expenditure requirements for at least 12 months from the date these consolidated financial statements were available to be issued.

Until such time that the Company can generate significant product revenue, if ever, the Company expects to fund its operations through equity offerings or debt financings, credit or loan facilities, collaborations, out-license arrangements, other capital resources, or a combination of one or more of these funding sources. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. The Company's failure to raise or secure capital as and when needed could have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate funds are not available to the Company, the Company may be required to delay, reduce, or eliminate clinical programs, obtain funds through arrangements with collaborators on terms unfavorable to the Company, or pursue merger or acquisition strategies. There can be no assurances the Company will be successful in obtaining sufficient capital on acceptable terms to fund continuing operations, if at all.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of expenses during the reporting year presented. Management of the Company evaluates its estimates which include, but are not limited to, accrued research and development expenses and stock-based compensation expense for periods after the Transaction. For the period before the Transaction, Management included allocations of direct expenses and indirect expenses, such as personnel-related expenses, including stock-based compensation, facility, information technology, or IT, and other general overhead expenses from PureTech. The Company based its estimates on the historical experience of PureTech and on various other assumptions that are believed to be reasonable. Actual results may differ from these estimates under different assumptions or conditions.

Foreign Currency

The financial statements of the Company's foreign subsidiary are measured using the local currency as the functional currency. Assets and liabilities are translated from their functional currency to their U.S. dollar equivalents at balance sheet date exchange rates and revenue and expenses are translated from functional currency to U.S. dollar equivalents at average exchange rates in effect during the year. Any gain or loss from these translations are included in accumulated other comprehensive loss. Realized foreign currency transaction gains and losses are included in other expense, net in the consolidated statements of operations and comprehensive loss.

Seaport Therapeutics, Inc.
Notes to Consolidated Financial Statements

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments that are readily convertible into cash with original maturities of three months or less at the date of purchase to be cash equivalents. The Company invests excess cash primarily in overnight cash sweeps and money market funds which are highly liquid and have high credit ratings. Such investments are subject to minimal credit and market risks. The Company classifies all cash of which use is limited by contractual provisions as restricted cash. Restricted cash is recorded on the consolidated balance sheet within other non-current assets and includes amounts held as a security deposit for a letter of credit in connection with leased facilities and its corporate card program.

The following table summarizes the Company's cash, cash equivalents, and restricted cash (in thousands):

	December 31,	
	2025	2024
Cash and cash equivalents	\$ 46,042	\$ 309,099
Restricted cash within other non-current assets	454	454
Total cash, cash equivalents, and restricted cash per the consolidated statements of cash flows	<u>\$ 46,496</u>	<u>\$ 309,553</u>

Investments

Short-term investments consist of investments in United States treasuries with original maturities greater than ninety days and less than one year from the balance sheet date. Long-term investments consist of investments in United States treasuries with maturities of greater than one year from the balance sheet date and are not expected to be used to fund current operations. The Company classifies all of its investments as available-for-sale securities. Accordingly, these investments are recorded at fair value. Realized gains and losses, amortization and accretion of discounts and premiums are included in other income, net. Unrealized gains and losses on available-for-sale securities are included in other comprehensive income as a component of stockholders' equity until realized.

The Company assesses its available-for-sale securities under the available-for-sale debt security impairment model in ASC Topic 326, *Financial Instruments—Credit Losses*, as of each reporting date in order to determine if a portion of any decline in fair value below carrying value recognized on its available-for-sale debt securities is the result of a credit loss. For any available-for-sale debt securities that may be in an unrealized net loss position, the Company does not intend to sell, and it is not more likely than not that the Company will be required to sell, such securities before recovery of their amortized cost bases. The Company records credit losses in the consolidated statements of operations and comprehensive loss as a component of other income, net, which is limited to the difference between the fair value and the amortized cost of the security. To date, the Company has not recorded any credit losses on its available-for-sale debt securities.

Accrued interest receivable related to the Company's available-for-sale securities is presented within prepaid and other current assets on the Company's consolidated balance sheet. The Company has elected the practical expedient available to exclude accrued interest receivable from both the fair value and the amortized cost basis of available-for-sale debt securities for the purposes of identifying and measuring any impairment. The Company writes off accrued interest receivable once it has determined that the asset is not realizable. Any write offs of accrued interest receivable are recorded by reversing interest income, recognizing credit loss expense, or a combination of both. To date, the Company has not written off any accrued interest receivable associated with its investments.

Seaport Therapeutics, Inc.
Notes to Consolidated Financial Statements

Concentrations of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash, cash equivalents and investments. The Company invests its excess cash, in line with its investment policy. The Company maintains its cash and cash equivalent balances with high-quality financial institutions and, consequently, the Company believes that such funds are subject to minimal credit risk. At times, the Company's cash and cash equivalents may be uninsured or in deposit accounts that exceed Federal Deposit Insurance Corporation limits. The Company's cash equivalents and investments are comprised of money market funds and investments that are invested in U.S. Treasury obligations. The Company has no significant off-balance sheet risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the convertible preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned or delayed the deferred offering costs would be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. The Company recorded deferred offering costs of \$1.2 million within other non-current assets as of December 31, 2025. There were no deferred offering costs as of December 31, 2024.

Fair Value of Financial Instruments

Accounting Standards Codification, or ASC, Topic 820, Fair Value Measurement, or ASC 820, identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants, or in the absence of a principal market, the most advantageous market for the investment or liability. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy are as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
- Level 3 inputs are unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation, and consists of lab equipment, furniture and fixtures, and leasehold improvements. Depreciation of property and equipment are calculated using

Seaport Therapeutics, Inc.
Notes to Consolidated Financial Statements

the straight-line method over the estimated useful lives of the assets. Significant replacements and improvements are capitalized, while maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to expense as incurred. The estimated useful lives of the Company’s respective assets are as follows:

	Estimated Useful Life
Lab equipment	5 years
Furniture and fixtures	5 years
Leasehold improvements	The lesser of 5 years or the remaining term of the lease

Upon retirement or disposal of property and equipment, the cost, and related accumulated depreciation are removed from the consolidated balance sheet and any gain or loss is reflected in the consolidated statements of operations and comprehensive loss.

Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the recoverability of the asset group to be held and used is measured by a comparison of the carrying amount of an asset group to future undiscounted cash flows expected to be generated by the asset group. If the carrying amounts of the asset group is less than its future undiscounted cash flows, an impairment loss is then measured by comparing the fair value of the asset group to its respective carrying amount. There have been no impairments of long-lived assets recorded for the years ended December 31, 2025 or 2024.

Leases

The Company accounts for leases in accordance with ASC 842, Leases. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the relevant facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the consolidated balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable. The Company typically only includes an initial lease term in its assessment of a lease arrangement, and options to renew a lease are not included in the Company’s assessment unless there is reasonable certainty that the Company will renew. The Company has elected not to recognize leases with an original term of one year or less on the consolidated balance sheet.

Leases contain both lease and non-lease components. Non-lease components may include common area maintenance, utilities, and other operating costs. The Company combines the lease and non-lease components in its lease arrangements as a single lease component. Variable costs are not included in the measurement of right-of-use assets and lease liabilities and are expensed when incurred.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded at the lease commencement date based on the present value of lease payments measured over the expected remaining lease term. Certain adjustments to right-of-use assets may be required for items such as prepaid lease payments or any incentives received. The Company measures the net present value of lease payments using a discount rate based on the interest rate implicit in the lease or an incremental borrowing rate if the rate implicit in the lease is not readily determinable. The interest rate implicit in the lease contracts is typically not readily determinable, and as a result, the Company estimates an incremental borrowing rate, which reflects the fixed rate at which the

Seaport Therapeutics, Inc.
Notes to Consolidated Financial Statements

Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. To estimate the incremental borrowing rate, a credit rating applicable to the Company is estimated using a synthetic credit rating analysis since the Company does not currently have any outstanding third-party debt or a rating agency-based credit rating. Operating lease costs are expensed using the straight-line method over the lease term and are classified within research and development or general and administrative expense based on the use of the underlying facility or using a reasonable allocation method.

Assumptions that the Company made at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification.

Convertible Preferred Stock

The Company has classified its convertible preferred stock as temporary equity on the Company's consolidated balance sheets due to the terms that allow for redemption of the shares in cash upon certain deemed liquidation events that are not solely within the control of the Company. The Company initially recorded its Series A-2 and Series B convertible preferred stock at fair value, net of issuance costs. The occurrence of such deemed liquidation event is not currently probable and thus the carrying values of the convertible preferred stock are not being adjusted to their redemption values. Subsequent adjustments to the carrying values of the convertible preferred stock would be made only when a deemed liquidation event becomes probable.

Research and Development Costs

Research and development, or R&D, costs are expensed as incurred. Internal costs include personnel related expenses, stock-based compensation, facility and IT costs, and depreciation. External costs include fees for goods and services to conduct clinical and non-clinical activities, such as costs paid to contract research organizations, consulting fees, laboratory services and supplies, and costs incurred in connection with license agreements. Prior to the Transaction, these expenses included allocations from PureTech.

The Company is required to estimate its accrued R&D costs as of the end of the reporting period. In accruing R&D costs, the Company estimates the period over which services will be performed or goods will be provided and the level of effort to be performed in each period. The financial terms of the R&D contracts vary and may result in payments that do not match the periods over which the goods or services are provided. The Company accrues costs under its contracts based on analyzing the work performed and amounts paid. In circumstances where amounts have been paid in excess of costs incurred, the Company records the excess as prepaid expense and recognizes research and development expense as the goods are received or the related services are rendered.

General and Administrative Expenses

General and administrative expenses are primarily comprised of employee-related expenses, including stock-based compensation and occupancy costs, depreciation, and third-party expenses related to finance, legal and other general and administrative functions. Prior to the Transaction, these expenses included allocations from PureTech.

Intellectual Property Matters

The Company expenses costs associated with intellectual property-related matters as incurred and classifies such costs as general and administrative expenses within the consolidated statements of operations and comprehensive loss.

Seaport Therapeutics, Inc.
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Asset Acquisitions and Acquired In-Process Research and Development Expenses

The Company accounts for acquisitions of assets or a group of assets that do not meet the definition of a business as asset acquisitions based on the cost to acquire the asset or group of assets, which include certain transaction costs. In an asset acquisition, the cost to acquire is allocated to the identifiable assets acquired and liabilities assumed based on their relative fair values as of the acquisition date. No goodwill is recorded in an asset acquisition. Assets that are acquired in an asset acquisition for use in research and development activities that have an alternative future use are capitalized as in-process research and development, or IPR&D. Acquired IPR&D that has no alternative future use as of the acquisition date is recognized as research and development expense as of the acquisition date. The Company will recognize additional research and development expenses in the future or capitalize such amounts for completed technology if and when the Company becomes obligated to make contingent milestone payments under the terms of the agreements by which it acquired the IPR&D assets.

Contingent consideration in asset acquisitions is measured and recognized when payment becomes probable and reasonably estimable. Subsequent changes in the accrued amount of contingent consideration are measured and recognized at the end of each reporting period and upon settlement as an adjustment to the cost basis of the acquired asset or group of assets, or, if related to IPR&D with no alternative future use, charged to expense. The Company did not recognize any IPR&D expense during the years ended December 31, 2025 and 2024.

Stock-Based Compensation

Employees of the Company participate in the Company's stock-based compensation plans and prior to the Transaction, participated in PureTech's stock-based compensation plans.

Stock-based compensation expense allocated to the Company for the period prior to the Transaction relates to equity awards issued by PureTech, including stock options, service-based restricted stock unit awards and performance-based restricted stock unit awards with both market and performance conditions. Stock-based compensation expense recorded during the period prior to the Transaction was recognized through allocations, based on the proportion of time the employee spent on the Seaport Business during the year presented and PureTech's estimate of fair value. Stock-based compensation expense associated with service-based awards granted by PureTech was recognized over the requisite service period of the awards, which is generally the vesting period, on a straight-line basis. Service-based awards granted to employees under the PureTech plans generally vest in four equal annual installments, commencing on the first anniversary of the date of grant, provided the employee remains continuously employed during the applicable vesting period. Performance-based restricted stock unit awards granted under the PureTech plans to its executives included both performance and market conditions, and did not have a material impact on the consolidated financial statements for the years ended December 31, 2025 and 2024.

Stock-based compensation expense of the Company for periods subsequent to the Transaction relates to equity awards issued by the Company to its employees and non-employees under its 2024 Equity Incentive Plan, or the 2024 Plan, including stock options and restricted stock awards with both service and performance-based vesting conditions. Stock-based compensation expense is measured at estimated fair value on the grant date and is recognized as compensation expense over the requisite service period, which is the vesting period during which an employee provides service in exchange for the award. Compensation expense for awards to non-employees is recognized in the same manner as if the Company had paid cash in exchange for the goods or services, which is generally over the vesting period of the award. Forfeitures are accounted for as they occur. Stock-based compensation expense for service-only based awards is recognized on a straight-line basis. Stock-based compensation expense for awards with both performance and service-based vesting conditions is recognized over the requisite service period using an accelerated attribution method, commencing once the performance conditions are considered probable of being achieved, using management's best estimates.

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The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends. The fair value of each restricted stock award granted is measured on the date of grant at the estimated fair value of the common stock.

Because there has not historically been a public market for the Company's common stock, the estimated fair value of common stock was determined by the Company's Board of Directors as of the date of each option grant, with inputs from management, considering third-party valuations of its common stock as well as the Company's Board of Directors' assessment of additional objective and subjective factors that it believed were relevant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately Held Company Equity Securities Issued as Compensation*.

The Company estimates its expected stock price volatility based on the historical volatility of publicly traded peer companies. The expected term of the Company's stock options has been determined utilizing the "simplified" method. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant for time periods approximately equal to the expected term of the award. There is no expected dividend yield since the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

The Company classifies stock-based compensation expense in the consolidated statements of operations and comprehensive loss in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified. See Note 11—Stock-Based Compensation, for more information.

Australia Research and Development Tax Credit

The Company is eligible to obtain certain research and development tax credits, through its wholly owned Australian subsidiary, as part of a program administered by the Australian Tax Office. The Company recognizes the research and development incentive as income within other income (expense), net within the consolidated statements of operations and comprehensive loss as it incurs costs eligible for reimbursement under the Australia R&D credit program when it is reasonably assured that the cash incentive will be received, as evidenced through enrollment in the program and when the applicable conditions under the program have been met.

Income Taxes

Prior to the Transaction, the Company was included in PureTech's income tax returns, and all income taxes were paid by PureTech. Income tax expense and other income tax related information contained in these consolidated financial statements prior to the Transaction are presented on a separate return approach as if the Company filed its own tax return for those periods. Under this approach, the provision for income taxes represents income tax paid or payable (or received or receivable) for the current year plus the change in deferred taxes during the year calculated as if the Company were a standalone taxpayer filing hypothetical income tax returns. Current income tax liabilities were assumed to be immediately settled with PureTech and were relieved through the "Net parent investment" account and were reflected as "Net transfers from PureTech Health plc" within financing activities in the consolidated statements of cash flows.

The Company recognizes income taxes under the asset and liability method. Deferred income taxes are recognized for differences between the financial reporting and tax basis of assets and liabilities at enacted

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statutory tax rates in effect for the years in which the differences are expected to reverse. The effect on deferred taxes of a change in tax rates are recognized in income in the period that includes the enactment date. In evaluating the Company's ability to recover its deferred tax assets, the Company considers all available positive and negative evidence including its past operating results, the existence of cumulative losses in the most recent fiscal years, changes in the business in which the Company operates and its forecast of future taxable income. In determining future taxable income, the Company is responsible for assumptions utilized, including the amount of pre-tax operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that the Company is using to manage the underlying business.

The Company accounts for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity, and changes in facts or circumstances related to a tax position. The Company also accrues for potential interest and penalties related to unrecognized tax benefits in income tax expense. For the years ended December 31, 2025 and 2024, the Company had no tax reserves accrued for uncertain tax positions.

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) consists of unrealized gains on available-for-sale securities and foreign currency translation adjustments.

Net Loss per Share

The Company applies the two-class method when computing net loss per share attributable to common stockholders as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income (loss) available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in the undistributed earnings as if all income (loss) for the period had been distributed. The Company considers its convertible preferred stock to be participating securities as, in the event a dividend is paid on common stock, the holders of convertible preferred stock would be entitled to receive dividends on a basis consistent with the common stockholders. There is no allocation required under the two-class method during periods of loss since the participating securities do not have a contractual obligation to share in the losses.

Basic net loss per share is computed by dividing the net loss in each period by the weighted average number of shares of common stock outstanding during such period, excluding potentially dilutive common shares. Diluted net loss per share is computed similarly to basic net loss per share except that the denominator is increased to include the number of additional shares of common stock that would have been outstanding if the potential shares of common stock had been issued and if the additional shares of common stock were dilutive. The shares of common stock and convertible preferred stock distributed to PureTech upon the formation of the Company and on the effective date of the Asset Transfer were considered as outstanding in the calculation of basic and diluted earnings per share for the period prior to the formation of the Company and the Asset Transfer, as the formation and Asset Transfer were deemed to be common control transactions. Additionally, the SPTX March 2024 Shares were considered outstanding in the calculation of basic and diluted earnings per share as of

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their date of issuance and the SPTX February 2024 Shares were considered outstanding in the calculation of diluted earnings per share as of their date of issuance (See Note 10—Common Stock, for definitions and further disclosure regarding these SPTX shares). The Company had no additional shares of common stock outstanding or any potentially dilutive equity instruments other than described above prior to its formation and the Asset Transfer Date. See Note 16—Net Loss per Share for definitions and further disclosure.

Segment Information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker, or CODM, in deciding how to allocate resources and assess performance. The Company has one operating and reportable segment, which is the business focused on advancing the development of neuropsychiatric medicines in areas of high unmet patient needs using the Company's proprietary Glyph™ Platform. The Company's CODM, its chief executive officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources. All of the Company's long-lived assets are held in the United States. See Note 15—Segments, for further disclosure regarding the Company's segment information.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, or ASU 2023-09. Additionally, the amendments in the ASU 2023-09 update require entities to disclose certain information about income taxes paid, income tax disaggregation, disclosures around unrecognized tax benefits, and the removal of disclosures related to temporary differences surrounding deferred tax liabilities to enhance the transparency and decision usefulness of income tax disclosures. For public entities, the amendments in this update are effective for fiscal years beginning after December 15, 2024 and for entities other than public entities, the amendments in this update are effective for fiscal years beginning after December 15, 2025. Early adoption is permitted for any annual periods for which financial statements have not been issued or made available for issuance. The Company elected to early adopt the standard in 2025 on a retrospective basis. See Note 12- Income Taxes, for further disclosure.

Recently Issued Accounting Standards Updates

From time to time, new accounting pronouncements are issued by the FASB, or other standard-setting bodies that are adopted by Seaport as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and non-public companies, the Company can adopt the new or revised standard at the time non-public companies adopt the new or revised standard and can do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for non-public companies. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, or ASU 2024-03, which is intended to provide more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation, and amortization) included in certain

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expense captions presented on the statement of operations. The guidance in ASU 2024-03 is effective for fiscal years beginning after December 15, 2026. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for periods after the effective date of ASU 2024-03 or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact that the adoption of ASU 2024-03 may have on its consolidated financial statements and disclosures for fiscal years beginning after December 15, 2026.

3. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets consisted of the following (in thousands):

	Year Ended December 31,	
	2025	2024
Prepaid research and development	\$ 3,026	\$ 389
Interest receivable	1,733	—
Australia research and development tax credit receivable	1,296	—
Prepaid other	1,175	393
Prepaid employee compensation and benefits	17	271
Prepaid expenses and other current assets	<u>\$ 7,247</u>	<u>\$ 1,053</u>

4. FAIR VALUE MEASUREMENTS

The following table sets forth by level, within the fair value hierarchy, the financial assets, and liabilities carried at fair value on a recurring basis (in thousands):

	December 31, 2025			
	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cash equivalents:				
Money market funds	\$ 45,710	\$ 45,710	\$ —	\$ —
Investments:				
U.S. treasuries	187,611	—	187,611	—
Total financial assets	<u>\$233,321</u>	<u>\$ 45,710</u>	<u>\$ 187,611</u>	<u>\$ —</u>

	December 31, 2024			
	Total	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Cash equivalents:				
Money market funds	\$308,849	\$ 308,849	\$ —	\$ —
Total financial assets	<u>\$308,849</u>	<u>\$ 308,849</u>	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2025 and 2024, the Company's cash equivalents consisted of money market funds which are classified as Level 1 financial assets, as these assets are valued using quoted market prices in active markets without any valuation adjustment. As of December 31, 2025, the Company's investments consisted of

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United States treasuries, which are classified as Level 2 financial assets. The Company estimates the fair value of the investments by taking into consideration valuations obtained from third-party pricing sources. As of December 31, 2025 and 2024, the Company had no financial liabilities that required fair value measurement.

During the years ended December 31, 2025 and 2024, there were no transfers or reclassifications between fair value measurement levels of assets. The carrying amounts reflected in the consolidated balance sheets for prepaid expenses and other current assets, accounts payable, related party payable and accrued expenses and other current liabilities approximate fair value due to their short-term nature.

5. INVESTMENTS

The following table summarizes the Company's investments held as of December 31, 2025.

	December 31, 2025			Fair Value
	Amortized Cost	Unrealized Holding Gains	Unrealized Holding Losses	
Short-term investments:				
U.S. Treasuries	\$169,662	\$ 279	\$ —	\$169,941
Long-term investments:				
U.S. Treasuries	17,639	31	—	17,670
Total financial assets	<u>\$187,301</u>	<u>\$ 310</u>	<u>\$ —</u>	<u>\$187,611</u>

As of December 31, 2025, the Company's investments were in net unrealized gain position of \$0.3 million. These amounts are included in other comprehensive income (loss) in the consolidated statements of operations and comprehensive loss. As of December 31, 2025, there were no investments in an unrealized loss position. The Company determined that there was no material credit risk associated with its investments as of December 31, 2025. As a result, the Company did not record any charges for credit-related impairments for its investments during the year ended December 31, 2025. As of December 31, 2025, the Company's investments had remaining maturities of two years or less. The Company did not have any investments as of December 31, 2024.

6. PROPERTY AND EQUIPMENT, NET

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

	December 31,	
	2025	2024
Lab equipment	\$ 943	\$ 976
Leasehold improvements	432	101
Furniture and fixtures	26	—
Total	1,401	1,077
Less: Accumulated depreciation	(989)	(837)
Property and equipment, net	<u>\$ 412</u>	<u>\$ 240</u>

Depreciation expense was \$0.2 million and \$0.3 million for the years ended December 31, 2025 and 2024, respectively. The depreciation expense recorded for the year ended December 31, 2024 consisted of \$0.2 million of depreciation expense on the Company's assets included on the consolidated balance sheet as of December 31, 2024 and \$0.1 million of allocated depreciation expense from PureTech associated with shared assets.

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7. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	December 31,	
	2025	2024
Accrued research and development expense	\$2,639	\$1,567
Accrued personnel and bonus expense	5,192	2,915
Accrued professional and legal fees	260	384
Accrued other	1,040	342
Accrued expenses and other current liabilities	<u>\$9,131</u>	<u>\$5,208</u>

8. MONASH LICENSE AGREEMENT

In April 2024, PureTech Health exclusively assigned to the Company, and the Company assumed all rights and obligations under a license agreement entered into in August 2017 between PureTech Health and Monash University, or the Original License Agreement. In March 2025, the Company entered into an amended and restated license agreement with Monash University, which amended and restated the Original License Agreement, or the Monash License Agreement.

Pursuant to the Monash License Agreement, Monash University grants the Company (i) a worldwide, exclusive, sublicensable license under certain Monash University intellectual property rights, including patent rights related to the Glyph platform, or the Licensed Patents, know-how, and intellectual property stemming from joint research and development activities, for the purpose of developing and commercializing products in all fields with one exception, (ii) a worldwide, non-exclusive, sublicensable license under certain background technology and certain other intellectual property strictly to the extent necessary to exercise the license described in subclause (i) above, and (iii) a first right and an exclusive option to obtain an exclusive license to any invention generated by Monash University outside of the Licensed Patents and pertaining to certain prodrug technology. Additionally, the Company and Monash University agreed to collaborate in conducting research and development activities.

Under the Monash License Agreement, the Company has agreed to use reasonable commercial endeavors to (i) develop at least one Licensed Product, (ii) seek regulatory approval for at least one Licensed Product, and (iii) after receipt of such regulatory approval in the United States or Europe, promote, and develop the sale of at least one Licensed Product in such territory. Monash University agrees to provide reasonable technical assistance and advice based on Monash University's know-how relating to the technology licensed under the Monash License Agreement. The Company granted Monash University a non-exclusive, perpetual, royalty-free license under the Licensed Patents, related know-how, and intellectual property stemming from joint research and development activities solely for academic, teaching, and non-commercial collaborative research uses, which includes the right to sublicense for non-commercial collaborative research to other academic institutions or non-commercial research entities.

As consideration for the licenses granted by Monash University, the Company is required to pay Monash University: (i) between 3% and 5% on net sales per calendar year (subject to certain reductions); (ii) a low-double digit percentage of any net income received under a sublicense (subject to a license payment stacking reduction) with the percentage varying based on the development stage of the Licensed Products at the time the sublicense is granted during the term of the Monash License Agreement; (iii) an agreed upon research funding amount to progress mutually agreed research and development or commercialization activities; (iv) a mid-five-figure annual maintenance fee during the term of the agreement commencing on the third anniversary of the

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execution date of the Original License Agreement until the first commercial sale of a Licensed Product creditable against net income sharing, royalties, and milestone payments; (v) milestone payments in the event of successful development milestones of up to \$1.075 million per Licensed Product for the first three Licensed Products; and (vi) milestone payments in the event of successful commercial milestones of up to \$7.25 million per Licensed Product for the first three Licensed Products. The Company is also obligated to (a) pay all costs incurred for the prosecution and maintenance of the Licensed Patents and patent filings stemming from collaboration activities and (b) reimburse Monash University for all patent prosecution costs of the Licensed Patents prior to the execution date of the Original License Agreement.

The Monash License Agreement commenced on the execution date of the Original License Agreement and will expire seven years after the last of the Licensed Patents expires, unless terminated earlier. Either party may terminate for due cause, including for material breach and bankruptcy. Monash University may terminate if the Company fails to meet its diligence requirements. Either party may terminate the Monash License Agreement if the Company determines that the activities are no longer commercially viable.

The Monash License Agreement was determined to represent an asset acquisition, as the acquired licenses and intellectual property did not meet the definition of a business. All upfront consideration paid in exchange for the Monash License Agreement was expensed as research and development upon execution of the agreement, as the Licensed Patents and intellectual property was determined to represent in-process research and development with no alternative future use.

Prior to the formation of the Company, PureTech paid \$0.2 million in development milestones under the Monash License Agreement. During the year ended December 31, 2025 the Company paid \$0.1 million in development milestones under the agreement. No milestones were paid by the Company under the Monash License Agreement during the year ended December 31, 2024.

9. CONVERTIBLE PREFERRED STOCK

The Company has issued Series A-1 convertible preferred stock, or the Series A-1 Preferred Stock, Series A-2 convertible preferred stock, or the Series A-2 Preferred Stock, and Series B convertible preferred stock, or the Series B Preferred Stock, and collectively with the Series A-1 Preferred Stock and Series A-2 Preferred Stock, the Preferred Stock.

Series A-1 and Series A-2 Preferred Stock

In April 2024, the Company issued to PureTech LYT, a wholly owned subsidiary of PureTech, 40,000,000 shares of its Series A-1 Preferred Stock, as part of the consideration for the assets contributed to the Company as part of the Asset Transfer Agreement. No value was assigned to the Series A-1 Preferred Stock as it represented consideration paid as part of a common control transaction. See Note 1—Nature of Business and Basis of Presentation, for further disclosure of the Asset Transfer Agreement.

Concurrently, upon the issuance of the Series A-1 Preferred Stock to PureTech LYT, the Company entered into a Series A-2 Preferred Stock Purchase Agreement, or the Series A-2 Financing, with PureTech LYT and other third-party investors pursuant to which the Company issued and sold 26,342,102 shares of its Series A-2 Preferred Stock at a price of \$3.80 per share for gross aggregate proceeds of \$100.1 million. See Note 17—Related Parties, for further disclosure of the issuances of the Company's Series A-2 Preferred Stock to related parties.

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Series B Preferred Stock

In October 2024, the Company entered into a stock purchase agreement with new and existing investors, or the Series B Financing, pursuant to which the Company issued and sold an aggregate amount of 47,578,934 shares of its Series B Preferred Stock at a purchase price of \$4.75 per share, for gross aggregate proceeds of \$226.0 million. See Note 17—Related Parties, for further disclosure around the issuances of the Company’s Series B Preferred Stock to related parties.

Upon issuance of the Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities and determined that such features did not require the Company to separately account for these features.

As of December 31, 2025 and 2024, Preferred Stock consisted of the following (in thousands, except share and per share amounts):

	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Conversion Price per Share	Common Stock Issuable Upon Conversion
Series A-1 Preferred Stock	40,000,000	40,000,000	\$ —	\$ 4,000	\$ 0.10	40,000,000
Series A-2 Preferred Stock	26,342,102	26,342,102	99,757	100,100	\$ 3.80	26,342,102
Series B Preferred Stock	47,578,938	47,578,934	225,571	226,000	\$ 4.75	47,578,934
Total Preferred Stock	<u>113,921,040</u>	<u>113,921,036</u>	<u>\$ 325,328</u>	<u>\$ 330,100</u>		<u>113,921,036</u>

As of December 31, 2025, the holders of the Preferred Stock have the following rights and preferences:

Voting

The holders of the Preferred Stock are entitled to vote, together with the holders of common stock, as a single class, on all matters submitted to the shareholders for a vote and are entitled to the number of votes equal to the number of shares of common stock into which the Preferred Stock would convert on the record date for determination of shareholders entitled to vote. The holders of the Preferred Stock generally vote together as a single class with holders of common stock except that, (i) the holders of Series A-1 Preferred Stock, exclusively and voting together as a separate class on an as converted basis, shall be entitled to elect two (2) directors of the Company, each, a Series A-1 Director, (ii) the holders of record of the shares of Series A-2 Preferred Stock, exclusively and voting together as a separate class on an as converted basis, shall be entitled to elect two (2) directors of the Company, each, a Series A-2 Director, (iii) the holders of record of the shares of Series B Preferred Stock, exclusively and voting together as a separate class on an as converted basis, shall be entitled to elect one (1) director of the Company, or the Series B Director and, together with the Series A-1 Directors and Series A-2 Directors, each, a Preferred Director.

Further, a majority vote of the holders of the Company’s Preferred Stock is required to, among others, liquidate or dissolve the Company, amend the certificate of incorporation or bylaws, reclassify common stock or establish another class of capital stock, create shares that would rank senior to or authorize additional shares of Preferred Stock, declare a dividend or make a distribution, or change the authorized number of directors constituting the board of directors.

Dividends

The holders of the Preferred Stock are entitled to participate in any dividends payable to common stockholders on an as converted basis and have priority over the payment of dividends to holders of common stock.

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In the case of a dividend on common stock or any class of stock that is convertible into common stock, the dividend per share of Preferred Stock would equal the product of (A) the dividend payable on each share of such class or series as if all shares of such class or series had been converted into common stock and (B) the number of shares of common stock issuable upon conversion of such share of Preferred Stock. In the case of a dividend on any class or series that is not convertible into common stock, the dividend per share of Preferred Stock would be determined by (A) dividing the amount of dividend payable on each share of such class or series of capital stock by the original issue price of such class or series and (B) multiplying such fraction by the original issue price of the applicable class or series of Preferred Stock.

Conversion

Each outstanding share of Preferred Stock is convertible, at any time, at its holder's discretion, and without the payment of additional consideration, into such whole number of fully paid, non-assessable shares of common stock, at the applicable conversion ratio then in effect. The conversion price for each share of Preferred Stock shall initially be equal to the original issuance price for such series of Preferred Stock and is subject to standard anti-dilutive adjustments for share splits and similar transactions. In the event certain conditions are not met prior to March 31, 2026, the conversion price of the Series B Preferred Stock will be reduced to \$3.80. During the year ended December 31, 2025, the Company satisfied the applicable condition, thereby eliminating the conversion price reduction contingency.

Each outstanding share of Preferred Stock shall automatically be converted into fully-paid, non-assessable shares of common stock upon the earliest to occur of (i) the consummation of a qualified initial public offering at a public offering price of at least \$5.70 per share, in a firm commitment resulting in at least \$100.0 million of gross proceeds or (ii) the date specified by vote or written consent of the holders of at least a majority of the outstanding shares of the Preferred Stock, voting together as a single class on an as-converted basis, and the holders of a majority of the outstanding shares of Series A-2 Preferred Stock and Series B Preferred Stock, which majority must include at least one new investor from the Series B Financing that holds at least 2,100,000 shares of Series B Preferred Stock, voting together as a single class on an as-converted basis, or the Requisite Holders, and the holders of at least 65% of the then-outstanding shares of Series B Preferred Stock, or the Series B Majority.

There shall be no adjustment in the conversion price of the Preferred Stock as a result of the issuance or deemed issuance of additional shares of the Company's common stock if the Company receives written notice from the holders of at least a majority of the then outstanding shares of Preferred Stock, voting together as a single class, and, solely in the respect of an adjustment in the conversion price of the Series B Preferred Stock, the Series B Majority, agreeing that no such adjustment shall be made as the result of the issuance or deemed issuance of additional shares of the Company's common stock.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, or upon the occurrence of a Deemed Liquidation Event (as defined below), the holders of shares of Preferred Stock then outstanding shall be entitled, on a pari passu basis among the series of Preferred Stock, to be paid out of the assets or funds of the Company available for distribution to stockholders before any payment is made to the holders of common stock. The holders of Preferred Stock are entitled to an amount per share equal to the greater of (i) the original issue price for such series, plus any dividends declared but unpaid thereon, or (ii) the amount that would have been payable had all shares of each series of Preferred Stock been converted into common stock immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event. After the payment in full of the Preferred Stock preference amount, the remaining assets of the Company available for distribution to stockholders shall be distributed among the holders of common stock on a pro rata basis.

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Each of the following events shall be considered a “Deemed Liquidation Event,” unless the Requisite Holders, elect otherwise; a merger, consolidation, statutory conversion, transfer, domestication, continuance involving the Company or a subsidiary, or a sale, lease, or transfer of substantially all of the assets of the Company.

Redemption

The Preferred Stock does not have any redemption rights, except for the contingent redemption upon the occurrence of a Deemed Liquidation Event.

10. COMMON STOCK

The voting, dividend, and liquidation rights of the holders of the Company’s common stock are subject to and qualified by the rights, powers, and preferences of the holders of the Preferred Stock set forth above. Each share of common stock entitles the holder to one vote, together with the holders of the Preferred Stock, on all matters submitted to the stockholders for a vote. The holders of common stock are entitled to receive dividends, if any, as declared by the Company’s board of directors, subject to the preferential dividend rights of Preferred Stock. As of December 31, 2025, no dividends have been declared or paid.

As of December 31, 2025, the Company had authorized 159,070,000 shares of common stock, of which 8,151,200 were issued and outstanding, including 486,114 unvested shares of restricted common stock that are subject to service-based vesting as of December 31, 2025.

Concurrent with the Transaction, the Company issued 2,500,000 shares of restricted common stock in exchange for shares of restricted common stock of SPTX. Such shares were originally issued upon the formation of SPTX in February 2024, or the SPTX February 2024 Shares. SPTX subsequently became a subsidiary of the Company upon the formation date. See Note 11—Stock-Based Compensation for further disclosure of restricted common stock issued by the Company.

Concurrent with the Transaction, the Company issued 950,000 shares of common stock to a board member in exchange for shares of common stock of SPTX issued in March 2024, or the SPTX March 2024 Shares, and together with the SPTX February 2024 Shares, or the Exchange Shares. SPTX had no other material activity beyond its previously issued shares.

In connection with the SPTX March 2024 Shares, the Company recognized \$0.9 million of stock-based compensation expense in its consolidated statements of operations and comprehensive loss for the year ended December 31, 2024.

The Company had no shares of common stock outstanding or any potentially dilutive equity instruments for any period prior to its formation and the Asset Transfer.

11. STOCK-BASED COMPENSATION

PureTech Stock-based Compensation Plan

PureTech has stock-based compensation plans which provide for granting equity awards, including non-qualified and incentive stock options, restricted stock, restricted stock units, cash-based awards, and performance shares to employees, officers, and directors of, and consultants to, PureTech. All stock-based compensation plans were managed on a consolidated basis by PureTech. Stock-based compensation expense was

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allocated to the Company based on the proportion of time each employee or non-employee spent on the Seaport Business in the period. Accordingly, the amounts presented are not necessarily indicative of future stock-based compensation of Seaport and do not necessarily reflect the amount that Seaport would have issued as an independent company for the year presented.

Under PureTech's stock-based compensation plan, the Company's employees transferred pursuant to the Asset Transfer were granted 22,500 stock options during the year ended December 31, 2024. During the year ended December 31, 2025, there were no stock options granted to the Company's employees under PureTech's stock-based compensation plan.

PureTech utilized the Black-Scholes option-pricing model for estimating the fair value of the stock options issued under PureTech's stock-based compensation plans on each grant date. The following table presents the assumptions used by PureTech in the Black-Scholes option-pricing model during the year ended December 31, 2024:

	December 31, 2024
Expected term (in years)	6.16
Risk-free interest rate	4.21%
Volatility	44.93%
Dividend yield	—

The weighted-average grant date fair value of options granted by PureTech during the year ended December 31, 2024 was \$1.02. The aggregate intrinsic value is calculated as the difference between the exercise price and the market price of PureTech's common stock at December 31, 2024. As of December 31, 2024, all outstanding stock options issued by PureTech to the Company's employees were fully vested.

Seaport employees continued to vest in their PureTech equity awards until the completion of the Company's Series B Financing (as discussed in Note 9) in October 2024 at which time PureTech no longer maintained a controlling interest in the Company. Accordingly, Seaport employees forfeited their unvested awards in October 2024 as the employees were no longer deemed to be continuing service providers under PureTech's plan, except for restricted stock units granted to an employee of Seaport for services performed to PureTech. As of December 31, 2024, Seaport employees held 873,617 of outstanding vested options that Seaport employees had 90 days to exercise from October 2024.

2024 Equity Incentive Plan

The 2024 Equity Incentive Plan, or the 2024 Plan, was approved by the Company's subsidiary's Board and Stockholders and became effective for the Company in April 2024 and was subsequently amended in April 2024 and October 2024.

Under the 2024 Plan, the Company can issue incentive stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based awards to employees, directors, and consultants of the Company. The 2024 Plan is administered by the Company's Board of Directors, or by a committee at the discretion of the Board of Directors. The exercise prices, vesting, and other restrictions are determined at the discretion of the Board of Directors, or its committee if so delegated, except that exercise prices of each stock option shall not be less than 100% of the fair market value of the Company's common stock and that each stock option term cannot exceed 10 years. The Company's Board of Directors determines the fair market value of the Company's common stock, taking into consideration its most recently available valuation of common stock performed by third parties as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

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A total of 10,000,000 shares of common stock were initially reserved for issuance under the 2024 Plan, and it was subsequently amended to allow for the issuance of up to 38,607,011 shares of common stock. As of December 31, 2025, there were 4,722,667 awards available for future grants under the 2024 Plan. Shares of common stock underlying any awards that are forfeited, canceled, or reacquired by the Company prior to vesting will again be available for the grant of awards under the 2024 Plan. Through the completion of an Initial Public Offering, the Company will continue to grant additional equity awards to certain individuals to maintain in total a 12.5% ownership on a fully diluted basis as specified by underlying agreements.

The vesting periods for stock options issued under the 2024 Plan generally vest over four years with a one-year cliff and equal monthly installments thereafter and may be subject to accelerated vesting. Performance-based options vest in three annual installments that are contingent upon the achievement of the Company's annual goals. For restricted stock awards, the vesting periods can vary and may contain accelerated vesting that would result in unvested shares becoming fully vested upon the occurrence of certain events.

2024 Plan Stock Option Activity

The following is a summary of the Company's stock option award activity under the 2024 Plan during the year ended December 31, 2025:

	Number of Stock Options	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	24,535,828	\$ 1.37	9.60	\$ 23,999
Granted	2,837,406	2.38	—	—
Exercised	(1,200)	0.97	—	—
Forfeited	(438,931)	2.18	—	—
Expired	(18,459)	0.97	—	—
Outstanding at December 31, 2025	26,914,644	\$ 1.46	8.67	\$ 28,669
Vested and expected to vest at December 31, 2025	26,914,644	\$ 1.46	8.67	\$ 28,669
Exercisable at December 31, 2025	15,728,318	\$ 1.31	8.58	\$ 19,208

The table above excludes the 718,500 performance-based options which have an exercise price of \$2.35 per share, that were approved to be issued by the Company's Board of Directors in December 2024, but have not yet been deemed granted from an accounting perspective as of December 31, 2025.

The Company utilized the Black-Scholes option-pricing model for estimating the fair value of the stock options issued under the 2024 Plan on each grant date. The following table presents the ranges of assumptions used by the Company in the Black-Scholes option-pricing model during the years ended:

	December 31,	
	2025	2024
Expected term (in years)	5.19 - 6.08	5.19 - 6.08
Risk-free interest rate	3.73% - 4.39%	3.70% - 4.39%
Volatility	89.40% - 91.67%	87.10% - 92.33%
Dividend yield	0.00%	0.00%

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The weighted-average grant date fair value of options granted during the years ended December 31, 2025 and 2024 was \$1.82 and \$1.02 per share, respectively. The aggregate intrinsic value is calculated as the difference between the exercise price and the fair value of the Company's common stock as of each period end or exercise date. The aggregate intrinsic value of options exercised during the year ended December 31, 2025 was not material. There were no stock options exercised during the year ended December 31, 2024.

As of December 31, 2025, there was \$14.0 million in unrecognized stock-based compensation expense associated with issued and outstanding service-based stock options, which is expected to be recognized over a weighted-average period of 1.3 years and is partially subject to future accelerated vesting upon the close of an initial public offering.

2024 Plan Restricted Stock Awards

The Company has granted restricted stock awards to certain members of the Company's Board of Directors and Chief Executive Officer. Of the total 6,250,000 restricted stock awards granted: (i) 2,500,000 have service-based vesting in equal monthly installments over a three-year period, of which 50% of the unvested amount was subject to accelerated vesting upon the close of the Series B Financing and 50% of any unvested amounts is subject to future acceleration upon the close of an initial public offering; and (ii) 3,750,000 have performance based vesting which vested in full upon the close of the Series B Financing.

The following is a summary of the Company's restricted stock award activity under the 2024 Plan during the year ended December 31, 2025:

	Number of Units	Weighted- Average Fair Value
Unvested at December 31, 2024	902,778	\$ 0.97
Vested	(416,664)	0.97
Unvested at December 31, 2025	<u>486,114</u>	<u>\$ 0.97</u>

The total fair value of restricted stock awards granted during the year ended December 31, 2024 was \$6.1 million. No restricted stock awards were granted during the year ended December 31, 2025. The total fair value of the restricted stock awards that vested during the year ended December 31, 2025 and 2024 was \$0.4 million and \$5.2 million, respectively, and the total stock-based compensation associated with the restricted stock awards during the years ended December 31, 2025 and 2024 was \$0.4 million and \$5.2 million, respectively. As of December 31, 2025, there was \$0.5 million in unrecognized stock-based compensation expense associated with issued and outstanding restricted stock awards, which is expected to be recognized over a weighted-average period of 0.6 years.

Stock-Based Compensation Expense

The following table represents stock-based compensation expense recorded in the Company's consolidated statements of operations and comprehensive loss (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	\$ 2,272	\$ 562
General and administrative	4,611	13,962
Stock-based compensation expense	<u>\$ 6,883</u>	<u>\$ 14,524</u>

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Total stock-based compensation expense for the year ended December 31, 2024 of \$14.5 million included \$14.4 million of stock-based compensation expense for Seaport employees, of which \$9.6 million was due to accelerated vesting of certain awards upon the close of the Series B Financing, and \$0.1 million of stock-based compensation expense associated with awards issued to Seaport employees prior to the Asset Transfer under PureTech's stock-based compensation plans. Seaport employees continued to vest in their PureTech equity awards until October 2024, at which time PureTech no longer maintained a controlling interest and the Seaport employees ceased to vest in their PureTech awards. No related tax benefits from stock-based compensation expense were recognized for the years ended 2025 or 2024.

During the year ended December 31, 2024, the Company allocated stock-based compensation of \$1.3 million, associated with PureTech employee's equity awards who spent a proportion of time providing services to the Company through the Asset Transfer, which is excluded from the table above.

12. INCOME TAXES

Prior to the Transaction, income taxes and related income tax accounts have been calculated using the separate return method as if the Company filed income tax returns on a standalone basis. Prior to the Transaction, the Company's operations were calculated on a carve-out basis and included certain hypothetical tax attributes. Following the Transaction, these hypothetical tax attributes are not available for future utilization by the Company and were removed from the tax provision. Furthermore, the Company operated as part of PureTech until the completion of the Asset Transfer on April 8, 2024, and therefore the Company will be included in PureTech's U.S. Federal consolidated income tax return until that date.

The following table presents the components of loss before income taxes (in thousands):

	Year Ended December 31,	
	2025	2024
U.S.	\$ (76,365)	\$ (46,879)
Foreign	2,257	—
Loss before the provision for income taxes	<u>\$ (74,108)</u>	<u>\$ (46,879)</u>

The components of the provision for income taxes are as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Current		
Federal	\$ —	\$ —
State	146	—
Foreign	627	—
Total Current	<u>773</u>	<u>—</u>
Deferred		
Federal	—	—
State	—	—
Foreign	—	—
Total Deferred	<u>—</u>	<u>—</u>
Total Provision	<u>\$ 773</u>	<u>\$ —</u>

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A reconciliation of the federal statutory income tax rate to the effective tax rate, in accordance with the guidance in ASU 2023-09 which the Company has elected to retrospectively adopt, is as follows:

	Year Ended December 31,			
	2025		2024	
U.S. Federal statutory tax rate	\$ (15,563)	21.0%	\$ (9,845)	21.0%
State and local income tax, net of federal income tax effect ⁽¹⁾	93	(0.1)%	3	— %
Tax credits				
Research and development tax credits	(2,149)	2.9%	(1,043)	2.4%
Effect of cross border transactions	458	(0.6)%	—	— %
Nontaxable or nondeductible item				
Stock compensation	571	(0.8)%	779	(1.7)%
Changes in valuation allowance	17,129	(23.1)%	10,106	(21.7)%
Other	234	(0.3)%	—	— %
Effective Tax Rate	<u>\$ 773</u>	<u>(1.0)%</u>	<u>\$ —</u>	<u>(0.0)%</u>

(1) The state that contributes to the majority (greater than 50%) of the tax effect in this category is Massachusetts.

The effective income tax rate differs from the U.S. federal statutory rate of 21.0% primarily as a result of the valuation allowance maintained against the Company's U.S. net deferred tax assets.

The amounts of cash taxes paid, net of refunds, by Seaport are as follows:

	Year Ended December 31,	
	2025	2024
US Federal	\$ —	\$ —
US State and local:		
Massachusetts	155	—
Foreign:		
Australia	103	—
Total	<u>\$ 258</u>	<u>\$ —</u>

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Deferred tax assets and liabilities reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities were as follows (in thousands):

	2025	2024
Deferred tax assets:		
Net operating losses	\$ 14,616	\$ 1,940
Tax credits	3,674	946
Lease liability	1,360	1,349
Accrued expenses	1,272	751
Research and development expenses	9,456	4,505
Stock-based compensation	3,397	2,293
Other temporary differences	19	—
Less: valuation allowance	(32,506)	(10,447)
Total deferred tax assets	\$ 1,288	\$ 1,337
Deferred tax liabilities:		
Right of use lease asset	(1,288)	(1,329)
Property and equipment	—	(8)
Total deferred tax liabilities	\$ (1,288)	\$ (1,337)
Net deferred tax assets	\$ —	\$ —

The Company's change in its valuation allowance account with respect to deferred tax assets is as follows (in thousands):

	Year Ended December 31, 2025	2024
Beginning Balance	\$10,447	\$ 15,850
Additions	22,059	13,039
Reductions	—	(18,442)
Ending Balance	\$32,506	\$ 10,447

The valuation allowance increased during the year ended December 31, 2025 primarily as a result of the increase to the Company's taxable loss. The valuation allowance decreased during the year ended December 31, 2024 primarily as a result of the hypothetical tax attributes which are not available for future utilization by the Company as a result of the Transaction, partially offset by U.S. operating losses incurred, research credits generated, and capitalized research and other expenses generated after the Transaction.

In determining the need for a valuation allowance, the Company considers the cumulative income or loss position. The Company has assessed, on a jurisdictional basis, the available means of recovering deferred tax assets, including the ability to carryback net operating losses, or NOLs, the existence of reversing taxable temporary differences, the availability of tax planning strategies, and forecasted future taxable income. At December 31, 2025, the Company maintained a full valuation allowance against its net deferred tax assets, as it has concluded that it is more likely than not that the deferred assets will not be utilized.

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As of December 31, 2025 and 2024, the Company had U.S. federal NOLs of \$53.4 million and \$7.2 million, respectively. The U.S. federal NOLs do not expire. As of December 31, 2025 and 2024, the Company had U.S. federal tax credit carryforwards of \$2.9 million and \$0.7 million, respectively, that begin to expire in 2044.

As of December 31, 2025 and 2024, the Company had \$53.7 million and \$6.9 million, of state NOLs, respectively. These NOLs were generated in Massachusetts and that begin to expire in 2044. As of December 31, 2025 and 2024, the Company had U.S. state tax credit carryforwards of \$1.0 million and \$0.3 million, respectively, that begin to expire in 2039.

Under Sections 382 and 383 of the U.S. Internal Revenue Code, if a corporation undergoes an ownership change, the corporation's ability to use its pre-ownership change NOLs and other pre-ownership change tax attributes, such as research tax credits, to offset its post-change income and taxes may be limited. In general, an ownership change will occur if there is a cumulative change in the Company's ownership by 5% shareholders that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under U.S. state tax laws. Under the Tax Cuts and Jobs Act of 2017, the use of federal NOLs arising in taxable years beginning after December 31, 2017 is limited to 80% of current year taxable income and NOLs arising in taxable years ending after December 31, 2017 may not be carried back (though any such NOLs may be carried forward indefinitely).

The Company may have experienced an ownership change in the current period and may experience ownership changes in the future as a result of future transactions in its share capital, some of which may be outside of the control of the Company. As a result, if the Company earns net taxable income, its ability to use its pre-ownership change NOLs, or other pre-ownership change tax attributes, to offset U.S. federal and state taxable income and taxes may be subject to significant limitations.

Undistributed earnings of Seaport's foreign subsidiary are indefinitely invested outside the U.S. The majority of Seaport's cash flow is generated from domestic operations, and the Company is not dependent on foreign cash or earnings to meet funding requirements, nor does the Company intend to repatriate these undistributed foreign earnings to fund U.S. operations. As a result, the Company has not provided U.S. deferred taxes on these undistributed earnings because it intends that it will remain indefinitely reinvested outside of the U.S. and, therefore unavailable for use in funding U.S. operations. The Company estimates the income taxes that would be payable on the repatriation of the unremitted earnings would not be material.

The Company is subject to taxation in the United States and Australia. At December 31, 2025, the Company is subject to examination by taxing authorities in the United States and Australia for the years ended December 31, 2025 and 2024.

For the years ended December 31, 2025, and 2024, the Company had no tax reserves accrued for uncertain tax positions.

On July 4, 2025, the One Big Beautiful Bill Act H.R. 1 was signed into law in the U.S. The legislation has multiple effective dates, with certain provisions effective in 2025 and others implemented through 2027. The bill did not have a material impact on the Company's consolidated financial statements.

13. LEASES

In October 2024, the Company entered into an operating lease for office space in Boston, Massachusetts, which commenced in December 2024 and has an initial lease term that continues through October 20, 2030, with no options to extend. In conjunction with entering into the lease, the Company paid a security deposit of \$0.2 million in the form of a letter of credit, which is recorded as restricted cash within other non-current assets on the Company's consolidated balance sheets as of December 31, 2025 and 2024.

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In December 2024, the Company entered into a laboratory license agreement with a third party for lab space located in Boston, Massachusetts. The license commenced in January 2025 and is for an initial term of 24 months from the commencement date, with no renewal option.

Prior to entering into the lease and laboratory license agreement, the Company did not have any leases as it shared office and lab space with PureTech and made payments to PureTech under the TSA. See Note 17—Related Parties for further disclosure of transactions with PureTech.

The following table contains a summary of the components of lease costs recognized pertaining to the Company's operating leases (in thousands):

	Year Ended December 31,	
	2025	2024
Operating lease cost	\$ 1,593	\$ 75
Total lease cost	<u>\$ 1,593</u>	<u>\$ 75</u>

The following table contains a summary of other supplemental lease information pertaining to the Company's operating lease for the year ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
Other Lease Information		
Cash paid for amounts included in the measurement of lease liability—operating leases (in thousands)	\$ 1,400	\$ —
Weighted-average remaining lease term—operating leases	4.3	5.8
Weighted-average discount rate—operating leases	6.53%	6.61%

The table below reconciles future minimum payments under non-cancellable operating leases as of December 31, 2025 (in thousands):

	Operating Leases
2026	\$ 1,635
2027	1,100
2028	1,079
2029	1,112
2030	918
Thereafter	—
Total lease payments	5,844
Less: interest	(763)
Total lease liabilities	<u>\$ 5,081</u>

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14. COMMITMENTS AND CONTINGENCIES

Legal Matters

The Company, from time to time, may be involved with lawsuits arising in the ordinary course of business. The Company is not involved in any pending legal proceedings that it believes could have a material adverse effect on its financial condition, results of operations, or cash flows.

Contracts

The Company enters into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, testing, manufacturing, and other services. These contracts generally provide for termination upon notice and are cancellable without significant penalty or payment, and do not contain any minimum purchase commitments.

License and Other Agreements

The Company is obligated to make fixed and contingent payments under the Asset Transfer Agreement and Monash License Agreement. See Note 1—Nature of Business and Basis of Presentation, for further disclosure of the Asset Transfer Agreement and see Note 8—Monash License Agreement, for further disclosure of the Monash license agreement.

Guarantees and Indemnification

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with all board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements that could have a material effect on its financial position, results of operations, or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2025 and 2024.

401(k) Plan

The Company has a defined-contribution savings plan under Section 401(k) of the IRC (the “401(k) Plan”). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. The Company will make a contribution of 3% of each employee’s annual compensation up to annual safe harbor limits. The Company has expensed \$0.4 million and \$0.1 million in 401(k) contributions for the years ended December 31, 2025 and 2024, respectively. The Company participated in the PureTech defined-contribution plan through July 2025. Beginning in August 2025, the Company implemented its own defined-contribution plan for eligible employees.

Leases

See Note 13—Leases, for information related to the Company’s lease obligations.

15. SEGMENTS

The Company has one operating and reportable segment focused on inventing and developing novel medicines for patients with depression, anxiety, and other debilitating neuropsychiatric disorders using the Company’s proprietary Glyph™ Platform.

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The CODM manages the Company's operations on a consolidated basis, and assesses performance based on consolidated net loss that is reported on the consolidated statements of operations and comprehensive loss. The CODM makes decisions about allocating resources and assessing performance for the entire company. The measure of segment assets is reported on the consolidated balance sheet as total consolidated assets.

The following table presents certain significant segment expenses that are regularly provided to the CODM (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development expenses:		
GlyphAllo direct research and development expenses	\$ 25,858	\$ 7,396
GlyphAgo direct research and development expenses	13,546	5,204
Glyph2BLSD direct research and development expenses	6,437	—
Preclinical and early discovery assets	3,856	5,903
Personnel-related (including stock-based compensation expense of \$2.3 million and \$0.7 million for 2025 and 2024, respectively)	14,829	5,699
Other indirect research and development expenses	1,787	868
Total research and development expenses	66,313	25,070
General and administrative expenses:		
Personnel-related (including stock-based compensation expense of \$4.6 million and \$15.2 million for 2025 and 2024, respectively)	12,800	20,661
Other general and administrative expenses	8,181	6,685
Total general and administrative expenses ⁽¹⁾	20,981	27,346
Other segment items ⁽²⁾	(12,413)	(5,537)
Net loss and comprehensive loss	\$ 74,881	\$ 46,879

⁽¹⁾ Other general and administrative expenses include professional fees, facilities, depreciation, IT, and other expenses.

⁽²⁾ Other segment items include interest income, net, research and development tax credit, income tax provision, and other (expense), net.

16. NET LOSS PER SHARE

Upon the Company's formation on April 1, 2024, the Company issued 1,000 shares of its common stock to PureTech and on April 8, 2024, the effective date of the Asset Transfer, an additional 949,000 shares of its common stock were issued to PureTech. The aggregate 950,000 shares were considered outstanding for the full year and the Exchange Shares were considered outstanding based on their issuance or vesting dates, as applicable, in the calculation of basic and diluted earnings per share for the year ended December 31, 2024, as the formation, Asset Transfer and Exchange Shares were deemed to be common control transactions. There were no shares of the Company outstanding prior to the Company's formation and the Asset Transfer Date.

Under the two-class method, basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration for potentially dilutive securities. The net loss available to common stockholders was not allocated to the Preferred Stock as the holders did not have a contractual obligation to share in losses. Diluted net loss per share is the same as basic net loss per share for the years presented since the effects of any potentially dilutive securities, would be antidilutive given the net loss of the Company.

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Basic and diluted net loss per share is calculated as follows (in thousands except share and per share amounts):

	Year Ended December 31,	
	2025	2024
Net loss	\$ (74,881)	\$ (46,879)
Net loss per share, basic and diluted	\$ (10.04)	\$ (15.83)
Weighted-average shares outstanding, basic and diluted	7,456,011	2,961,543

For accounting purposes, the computation of basic and diluted weighted-average common shares outstanding for the years ended December 31, 2025 and 2024, excludes all shares of unvested restricted common stock as such shares are not considered outstanding. See Note 11—Stock-Based Compensation, for more information.

The following outstanding potentially dilutive securities have been excluded from the calculation of diluted net loss per share attributable to common stockholders, as their effect is antidilutive:

	Year Ended December 31,	
	2025	2024
Stock options to purchase common stock ⁽¹⁾	26,914,644	24,535,828
Unvested restricted stock awards	486,114	902,778
Series A-1 Preferred Stock (as converted to common stock)	40,000,000	40,000,000
Series A-2 Preferred Stock (as converted to common stock)	26,342,102	26,342,102
Series B Preferred Stock (as converted to common stock)	47,578,934	47,578,934
Total	141,321,794	139,359,642

(1) The table above excludes the performance-based options, as they were not yet been deemed granted from an accounting perspective. See Note 11—Stock-Based Compensation, for more information.

17. RELATED PARTIES

During the year ended December 31, 2024, there was \$5.5 million of corporate expense allocations from PureTech Health plc prior to the Transaction and \$14.2 million of expenses incurred pursuant to the TSA after the Asset Transfer Date.

Prior to the Transaction, the Company historically operated as part of PureTech and not as a separate entity. Accordingly, for the period prior to the Transaction, certain corporate expenses represent shared costs of PureTech that were allocated to the Company based on a systematic and rational methodology and are reflected as expenses in these consolidated financial statements. These amounts include, but are not limited to, items such as payroll, general management and executive oversight, costs to support Seaport's information technology infrastructure, facilities, compliance, human resources, legal, and finance functions, risk management, and stock-based compensation, all of which supported the operations of PureTech as a whole. Corporate expense and shared cost allocations are generally allocated to the Company based on proportional cost allocation methods using headcount or proportional time worked supporting the Seaport Business and other organizational activities, as applicable, which were considered to be reasonable reflections of the utilization of services provided or benefit received by the Company during the periods presented prior to the Transaction. Total corporate expense allocations were \$1.7 million in research and development and \$3.8 million in general and administrative

Seaport Therapeutics, Inc.
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expenses during the year ended December 31, 2024. Net transfers from PureTech Health plc within financing activities in the consolidated statements of cash flows and the consolidated statements of convertible preferred stock and stockholders' deficit consist of the following (in thousands):

	Year Ended December 31, 2024
Corporate cost allocations from PureTech	\$ 5,459
General finance activities	8,508
Net transfers from PureTech	<u>\$ 13,967</u>

As disclosed in Note 1—Nature of Business and Basis of Presentation, the Company entered into the Asset Transfer Agreement with PureTech and issued 40,000,000 shares of its Series A-1 Preferred Stock to PureTech LYT. In connection with entering into the Asset Transfer Agreement, the Company entered into the TSA with PureTech, under which the Company made an up-front payment of \$0.5 million to reimburse PureTech for work performed by certain third-parties prior to the closing of the Asset Transfer Agreement to advance the Company's programs and activities. During the year ended December 31, 2025, the Company incurred \$0.4 million of expenses from PureTech under the TSA of which \$0.3 million related to research and development and \$0.1 million related to general and administrative expenses. During the year ended December 31, 2024, the Company incurred \$14.2 million of expenses from PureTech under the TSA of which \$12.4 million related to research and development and \$1.8 million related to general and administrative expenses.

In April 2024, as part of its Series A-2 Financing, the Company issued and sold 8,421,052 shares of its Series A-2 Preferred Stock to PureTech LYT, at a purchase price of \$3.80 per share for gross aggregate proceeds of \$32.0 million. Subsequent to the Series A-2 financing, PureTech LYT remained the controlling investor of the Company.

In October 2024, as part of its Series B Financing, the Company issued and sold an aggregate 3,031,578 and 494,734 shares of its Series B Preferred Stock to PureTech LYT and to certain of the Company's management and board of directors, respectively, at a purchase price of \$4.75 per share, for gross aggregate proceeds of \$14.4 million and \$2.3 million, respectively. Subsequent to the Series B Financing, PureTech LYT was no longer a controlling investor of the Company.

During the year ended December 31, 2024 the Company paid \$0.2 million, to Third Rock Ventures for professional fees. Such amounts were included in general and administrative expenses. During the year ended December 31, 2025, amounts paid to Third Rock Ventures were not material.

18. SUBSEQUENT EVENTS

The Company has evaluated subsequent events through February 27, 2026, the date these consolidated financial statements were available to be issued. In January and February 2026, the Company granted 3,023,510 stock options, under the 2024 Plan, at an exercise price of \$3.28 to the Company's board of directors and employees, which vest over a one year and four-year period, respectively. The aggregate grant date fair value of these stock options granted by the Company was determined to be approximately \$7.6 million. There were no other subsequent events that require adjustments to or disclosure in the financial statements.

Shares

Seaport Therapeutics, Inc.

Common Stock



Goldman Sachs & Co. LLC

J.P. Morgan

Leerink Partners

Citigroup

Stifel

Through and including _____, 2026 (the 25th day after the date of this prospectus), all dealers effecting transactions in our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Unless otherwise indicated, all references to “Seaport,” the “company,” “we,” “our,” “us”, or similar terms refer to Seaport Therapeutics, Inc. and its wholly owned, consolidated subsidiaries, or either or both of them as the context may require.

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all expenses to be paid by us, other than underwriting discounts and commissions, in connection with this offering. All amounts shown are estimates except for the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq Global Market, or Nasdaq, listing fee.

SEC registration fee	\$	*
FINRA filing fee		*
Nasdaq listing fee		*
Printing and mailing expenses		*
Legal fees and expenses		*
Accounting fees and expenses		*
Custodian transfer agent and registrar fees and expenses		*
Miscellaneous expenses		*
Total	<u>\$</u>	<u>*</u>

* To be provided by amendment.

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits, and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys’ fees) judgments, fines, and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit, or proceeding. Section 145 permits corporations to pay expenses (including attorneys’ fees) incurred by directors and officers in advance of the final disposition of such action, suit, or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We will adopt provisions in our amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering, and the amended and restated bylaws, which will become effective upon the effectiveness of the registration statement of which this prospectus forms a part, that will limit or eliminate the personal liability of our directors and officers to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, our directors and officers will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as directors or officers, except for liability for:

- any breach of their duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

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- for our directors, any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions;
- any transaction from which they derived an improper personal benefit; or
- for our officers, any derivative action by or in the right of the corporation.

These limitations of liability do not alter director and officer liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our amended and restated bylaws will provide that:

- we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and intend to enter into such agreements with our executive officers. These agreements provide that we will indemnify each of our directors, our executive officers, and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees (but excluding judgments, fines, and settlement amounts), to each indemnified director, executive officer, or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as a director or officer brought on behalf of us or in furtherance of our rights. Additionally, certain of our directors or officers may have certain rights to indemnification, advancement of expenses, or insurance provided by their affiliates or other third parties, which indemnification relates to and might apply to the same proceedings arising out of such director's or officer's services as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors or officers are primary and any obligation of such affiliates or other third parties to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act of 1933, as amended, or Securities Act.

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Securities Exchange Act of 1934.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding securities we have issued within the past three years that were not registered under the Securities Act.

(a) Preferred Stock Issuances

In April 2024, we issued an aggregate of 40,000,000 shares of Series A-1 convertible preferred stock in connection with entry into an asset transfer agreement, dated as of April 8, 2024, or the Asset Transfer Agreement, with PureTech LYT.

We also issued and sold to accredited investors an aggregate of 26,342,102 shares of Series A-2 convertible preferred stock at a price per share of \$3.80, for an aggregate purchase price of \$100.1 million.

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In October and November 2024, we issued and sold to accredited investors an aggregate of 47,578,934 shares of Series B convertible preferred stock at a price per share of \$4.75, for an aggregate purchase price of approximately \$226.0 million.

(b) Common Stock Issuances

In April 2024, we issued an aggregate of 1,000 shares of common stock to PureTech LYT in connection with our formation.

In April 2024, we issued an aggregate of 949,000 shares of common stock to PureTech LYT in connection with the Asset Transfer Agreement.

Since April 2024, we have sold or issued by exchange to our founders an aggregate of 7,200,000 shares of restricted common stock under our 2024 Plan or pursuant to agreement, at a purchase price of \$0.0 million.

(c) Grants and exercises of stock options

Since April 2024, we have granted certain employees, consultants, and directors options to purchase an aggregate of 31,144,262 shares of our common stock under our 2024 Plan, at exercise prices ranging from \$0.97 to \$3.28 per share.

Since April 2024, 1,200 stock options have been exercised under our 2024 plan at a weighted average purchase price of \$0.97 per share.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. Unless otherwise specified above, the Registrant believes these transactions were exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act (and Regulation D or Regulation S promulgated thereunder) or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or under benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed on the share certificates issued in these transactions. All recipients had adequate access, through their relationships with the Registrant, to information about the Registrant. The sales of these securities were made without any general solicitation or advertising.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Exhibit Number	Description
1.1*	Form of Underwriting Agreement.
3.1**	Amended and Restated Certificate of Incorporation, as amended, as currently in effect.
3.2*	Certificate of Amendment to Amended and Restated Certificate of Incorporation, as amended.
3.3*	Form of Amended and Restated Certificate of Incorporation, to be in effect immediately prior to the completion of this offering.
3.4**	Bylaws, as currently in effect.
3.5*	Form of Amended and Restated Bylaws, to be in effect as of the effectiveness of the registration statement of which this prospectus forms a part.

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Exhibit Number	Description
4.1*	Specimen Common Stock Certificate.
4.2+†**	Amended and Restated Investors' Rights Agreement, by and between the Registrant and certain of its stockholders, dated as of October 18, 2024.
5.1*	Opinion of Goodwin Procter LLP.
10.1#**	2024 Equity Incentive Plan, as amended, and form of award agreements thereunder.
10.2*#	2026 Equity Incentive Plan and form of award agreements thereunder.
10.3*#	2026 Employee Stock Purchase Plan.
10.4*#	Form of Indemnification Agreement, by and between the Registrant and its directors and executive officers.
10.5*#	Senior Executive Cash Incentive Bonus Plan.
10.6*#	Non-Employee Director Compensation Policy.
10.7*#	Employment Agreement, by and between the Registrant and Daphne Zohar, to be in effect upon the closing of this offering.
10.8*#	Employment Agreement, by and between the Registrant and Michael Chen, to be in effect upon the closing of this offering.
10.9*#	Employment Agreement, by and between the Registrant and Anthony Loebel, to be in effect upon the closing of this offering.
10.10†+**	Asset Transfer Agreement, by and between the Registrant, PureTech Health LLC and PureTech LYT, Inc., dated April 8, 2024, as amended by that certain amendment, dated December 16, 2025.
10.11†+**	Amended and Restated License Agreement between Monash University, ABN 12 377 614 012, a body politic and corporate constituted in accordance with the Monash University Act 2009 of Wellington Road, Clayton, Victoria, Australia 3800 and the Registrant, dated March 12, 2025.
21.1**	Subsidiaries of Registrant.
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Goodwin Procter LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (included on signature page).
107*	Filing Fee Table.
*	To be filed by amendment.
**	Previously filed.
#	Indicates a management contract or any compensatory plan, contract or arrangement.
†	Certain portions of this document that constitute confidential information have been redacted pursuant to Item 601(b)(10) of Regulation S-K.
+	Certain exhibits and schedules to these agreements have been omitted pursuant to Item 601(a)(5) and (6) of Regulation S-K. The registrant will furnish copies of any of the exhibits and schedules to the Securities and Exchange Commission upon request.

(b) Financial Statement Schedules.

All financial statement schedules are omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or the notes thereto.

Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit, or proceeding) is asserted by such director, officer, or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The registrant hereby undertakes that:

- (a) For purposes of determining any liability under the Securities Act of 1933, as amended, the information omitted from a form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933, as amended, shall be deemed to be part of this registration statement as of the time it was declared effective.
- (b) For the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Boston, Massachusetts, on the _____ of _____, 2026.

SEAPORT THERAPEUTICS, INC.

By: _____
Name: Daphne Zohar
Title: Chief Executive Officer and Director

POWER OF ATTORNEY AND SIGNATURES

Each individual whose signature appears below hereby constitutes and appoints Daphne Zohar and Lauren A. White as such person’s true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for such person in such person’s name, place, and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement (or any Registration Statement for the same offering that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933), and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission granting unto each said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that any said attorney-in-fact and agent, or any substitute or substitutes of any of them, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement and Power of Attorney has been signed by the following person in the capacities and on the date indicated.

Signature	Title	Date
_____ Daphne Zohar	Chief Executive Officer and Director (Principal Executive Officer)	_____, 2026
_____ Lauren A. White	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	_____, 2026
_____ Steven M. Paul, M.D.	Director and Chairman	_____, 2026
_____ Robert J. Hombach	Director	_____, 2026
_____ Eric Elenko, Ph.D.	Director	_____, 2026
_____ James I. Healy, M.D., Ph.D.	Director	_____, 2026

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Signature	Title	Date
Robert Nelsen	Director	, 2026
Jason Pitts, Ph.D.	Director	, 2026
Sandra E. Peterson	Director	, 2026
Denice Torres, J.D.	Director	, 2026
David Wheadon, M.D.	Director	, 2026
Robert Lyne, LLB	Director	, 2026