UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2026

OR

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

For the transition period from _____ to _____

Commission File Number: 001-43254

Seaport Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware (State or other jurisdiction of incorporation or organization)	**99-2235719** (I.R.S. Employer Identification No.)
101 Seaport Blvd., Floor 12 **Boston, Massachusetts** (Address of principal executive offices)	**02210** (Zip Code)

Registrant's telephone number, including area code: (617) 807-4062

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Voting Common Stock, $0.0001 par value per share	SPTX	The Nasdaq Global Select Market

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

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

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

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

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

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

As of July 27, 2026, the registrant had 53,530,550 shares of voting common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q 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;

• 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, 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 Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in "*Risk Factor Summary,*" "*Risk Factors*" and elsewhere in this Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

You should read this Quarterly Report on Form 10-Q and the documents that we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

This Quarterly Report on Form 10-Q may include industry and market data, which we may obtain from our own internal estimates and research, as well as from industry and general publications and research, surveys, and studies conducted by third parties. Industry publications, studies, and surveys generally state that they have been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that such studies and publications are reliable, we have not independently verified market and industry data from third-party sources.

Website and Social Media Disclosure

From time to time, we may use our website (www.seaporttx.com), investor and media relations website (investors.seaporttx.com), LinkedIn page (http://www.linkedin.com/company/seaport-therapeutics), Bluesky (https://bsky.app/profile/seaporttx.bsky.social), and X feed (https://x.com/SeaportTx) as channels for the distribution of information. The information we post through these channels may be deemed material. Accordingly, investors should monitor these channels, in addition to following our press releases and subscribing to our email alerts, Securities and Exchange Commission filings and public conference calls and webcasts. The contents of our website and social media channels are not, however, a part of this report.

Risk Factor Summary

Investment in our securities involves risk. You should carefully consider the following summary of what we believe to be the principal risks facing our business, in addition to the risks described more fully in Part II. Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q and other information included in this report. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations.

If any of the following risks occurs, our business, financial condition and results of operations and future growth prospects could be materially and adversely affected, and the actual outcomes of matters as to which forward-looking statements are made in this report could be materially different from those anticipated in such forward-looking statements.

- We are a clinical-stage therapeutics company, have no history of generating commercial revenue, have a history of operating losses and may never achieve or maintain profitability.
- Company management has obtained and continues to pursue additional financing to support future operations, however such funding may not be available on acceptable terms or at all.
- We are substantially dependent on the success of our drug product candidates, and significant additional research and development and clinical testing will be required before we can potentially seek regulatory approval for or commercialize any of our drug product candidates.

- 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.
- Success in pre-clinical studies or early clinical trials may not be indicative of results obtained in later trials.
- 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 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 may not be successful in our efforts to identify additional drug product candidates. We must prioritize the development of certain drug product candidates, and these decisions may prove to be wrong and may adversely affect our business.
- We expect to expand our organization, and as a result, we may encounter difficulties in managing our growth, 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, manufacture our product candidates and seek to establish collaborations on product development and commercialization plans.
- Our commercial success depends on our ability to obtain, maintain, enforce, and otherwise protect our intellectual property and proprietary technology.
- We are an “emerging growth company” and a “smaller reporting company” and have elected to take advantage of the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies, and we will continue to incur significant costs associated with operating as a public company.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Seaport Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts) ***(Unaudited)***

	June 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 64,223	$ 46,042
Short-term investments	209,086	169,941
Prepaid expenses and other current assets	8,866	7,247
Total current assets	282,175	223,230
Property and equipment, net	360	412
Right-of-use assets - operating leases	4,741	4,813
Long-term investments	153,951	17,670
Other non-current assets	454	2,884
Total assets	$ 441,681	$ 249,009
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 5,705	$ 2,007
Related party payable	—	7
Accrued expenses and other current liabilities	8,358	9,131
Operating lease liability	1,611	1,637
Total current liabilities	15,674	12,782
Operating lease liability, net of current portion	3,405	3,444
Total liabilities	19,079	16,226
Series A-1 convertible preferred stock, par value $0.0001; zero and 40,000,000 shares authorized as of June 30, 2026 and December 31, 2025, respectively; zero and 40,000,000 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively; liquidation preference of zero and $4,000 as of June 30, 2026 and December 31, 2025, respectively	—	—
Series A-2 convertible preferred stock, par value $0.0001; zero and 26,342,102 shares authorized as of June 30, 2026 and December 31, 2025, respectively; zero and 26,342,102 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively; liquidation preference of zero and $100,100 as of June 30, 2026 and December 31, 2025, respectively	—	99,757
Series B convertible preferred stock, par value $0.0001; zero and 47,578,938 shares authorized as of June 30, 2026 and December 31, 2025, respectively; zero and 47,578,934 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively; liquidation preference of zero and $226,000 as of June 30, 2026 and December 31, 2025, respectively	—	225,571
Commitments and contingencies (Note 14)		
Stockholders' deficit		
Undesignated preferred stock, $0.0001 par value; 10,000,000 and zero shares authorized at June 30, 2026 and December 31, 2025, respectively; zero shares issued and outstanding at June 30, 2026 and December 31, 2025	—	—
Common stock, par value $0.0001; 700,000,000 and 159,070,000 shares authorized as of June 30, 2026 and December 31, 2025, respectively; 53,530,550 and 2,595,342 shares issued and outstanding as of June 30, 2026 and December 31, 2025, respectively	5	1
Additional paid-in capital	625,189	21,262
Accumulated other comprehensive income	(475)	301
Accumulated deficit	(202,117)	(114,109)
Total stockholders' equity (deficit)	422,602	(92,545)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 441,681	$ 249,009

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

Seaport Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts) ***(Unaudited)***

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development (including non-cash stock-based compensation expense of $0.9 million and $0.6 million for three months ended June 30, 2026 and 2025, respectively and $1.8 million and $1.1 million for six months ended June 30, 2026 and 2025, respectively)	$ 24,619	$ 13,409	$ 46,049	$ 23,944
General and administrative (including non-cash stock-based compensation expense of $36.0 million and $1.2 million for three months ended June 30, 2026 and 2025, respectively and $37.6 million and $2.3 million for six months ended June 30, 2026 and 2025, respectively)	41,189	5,061	47,302	10,711
Total operating expenses	65,808	18,470	93,351	34,655
Loss from operations	(65,808)	(18,470)	(93,351)	(34,655)
Other income (expense), net				
Interest income, net	3,257	2,976	5,390	6,076
Research and development tax credit	236	610	803	610
Other expense, net	(34)	(59)	(80)	(68)
Total other income, net	3,459	3,527	6,113	6,618
Loss before income taxes	(62,349)	(14,943)	(87,238)	(28,037)
Income tax provision	251	134	770	165
Net loss	$ (62,600)	$ (15,077)	$ (88,008)	$ (28,202)
Other comprehensive income (loss), net of tax:				
Foreign currency translation adjustment	18	(3)	33	(3)
Unrealized (loss) gain on available-for-sale securities	(557)	(59)	(809)	133
Comprehensive loss	$ (63,139)	$ (15,139)	$ (88,784)	$ (28,072)
Net loss per share, basic and diluted	$ (1.78)	$ (6.40)	$ (4.60)	$ (12.05)
Weighted-average common shares outstanding, basic and diluted	35,236,214	2,356,777	19,118,049	2,340,431

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

Seaport Therapeutics, Inc.
Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share amounts) ***(Unaudited)***

	Series A-1 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2025	40,000,000	$ —	26,342,102	$ 99,757	47,578,934	$ 225,571	2,595,342	$ 1	$ 21,262	$ (114,109)	$ 301	$ (92,545)
Stock-based compensation expense	—	—	—	—	—	—	—	—	2,569	—	—	2,569
Unrealized loss on investments, net of tax	—	—	—	—	—	—	—	—	—	—	(252)	(252)
Cumulative translation adjustment	—	—	—	—	—	—	—	—	—	—	15	15
Net loss	—	—	—	—	—	—	—	—	—	(25,408)	—	(25,408)
Balance as of March 31, 2026	40,000,000	$ —	26,342,102	$ 99,757	47,578,934	$ 225,571	2,595,342	$ 1	$ 23,831	$ (139,517)	$ 64	$ (115,621)
Conversion of convertible preferred stock to common stock upon closing of the initial public offering	(40,000,000)	—	(26,342,102)	(99,757)	(47,578,934)	(225,571)	36,272,475	3	325,325	—	—	325,328
Issuance of common stock from initial public offering, net of issuance costs of $21.7 million	—	—	—	—	—	—	14,446,658	1	238,363	—	—	238,364
Stock option exercises	—	—	—	—	—	—	216,075	—	807	—	—	807
Stock-based compensation expense	—	—	—	—	—	—	—	—	36,863	—	—	36,863
Unrealized loss on investments, net of tax	—	—	—	—	—	—	—	—	—	—	(557)	(557)
Cumulative translation adjustment	—	—	—	—	—	—	—	—	-	—	18	18
Net loss	—	—	—	—	—	—	—	—	—	(62,600)	—	(62,600)
Balance as of June 30, 2026	—	$ —	—	$ —	—	$ —	53,530,550	$ 5	$ 625,189	$ (202,117)	$ (475)	$ 422,602

	Series A-1 Convertible Preferred Stock		Series A-2 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		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, 2024	40,000,000	$ —	26,342,102	$ 99,757	47,578,934	$ 225,571	2,594,960	$ 1	$ 14,378	$ (39,228)	$ —	$ (24,849)
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,619	—	—	1,619
Unrealized gain on investments, net of tax	—	—	—	—	—	—	—	—	—	—	192	192
Net loss	—	—	—	—	—	—	—	—	—	(13,125)	—	(13,125)
Balance as of March 31, 2025	40,000,000	$ —	26,342,102	$ 99,757	47,578,934	$ 225,571	2,594,960	$ 1	$ 15,997	$ (52,353)	$ 192	$ (36,163)
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,756	—	—	1,756
Unrealized loss on investments, net of tax	—	—	—	—	—	—	—	—	—	—	(59)	(59)
Cumulative translation adjustment	—	—	—	—	—	—	—	—	-	—	(3)	(3)
Net loss	—	—	—	—	—	—	—	—	—	(15,077)	—	(15,077)
Balance as of June 30, 2025	40,000,000	$ —	26,342,102	$ 99,757	47,578,934	$ 225,571	2,594,960	$ 1	$ 17,753	$ (67,430)	$ 130	$ (49,546)

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

Seaport Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands) ***(Unaudited)***

	Six Months Ended June 30, 2026	Six Months Ended June 30, 2025
Operating activities		
Net loss	$ (88,008)	$ (28,202)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	39,432	3,375
Depreciation expense	52	77
Amortization of operating lease right-of-use assets	656	592
Net amortization of premiums and discounts on investments	(582)	(2,019)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(433)	(5,494)
Other non-current assets	-	(1,191)
Accounts payable	3,690	(2,604)
Related party payable	(7)	(283)
Accrued expenses and other current liabilities	(461)	709
Operating lease liability	(652)	(490)
Net cash used in operating activities	(46,313)	(35,530)
Investing activities		
Purchases of investments	(300,652)	(304,171)
Proceeds from maturities of investments	125,000	77,500
Purchases of property and equipment	—	(323)
Net cash used in investing activities	(175,652)	(226,994)
Financing activities		
Proceeds from initial public offering, net of underwriting discounts and commissions and deferred offering costs	239,338	—
Proceeds from exercise of stock options	807	—
Net cash provided by financing activities	240,145	—
Effect of exchange rates on cash and cash equivalents	1	—
Net increase (decrease) in cash and cash equivalents	18,181	(262,524)
Cash, cash equivalents, and restricted cash, beginning of period	46,496	309,553
Cash, cash equivalents, and restricted cash, end of period	$ 64,677	$ 47,029
Supplemental disclosure of non-cash operating, financing, and investing information:		
Operating lease right-of-use assets obtained in exchange for lease liabilities	$ 584	$ 1,114
Deferred offering costs included in accounts payable and accrued expenses	$ 97	$ —

The accompanying notes are an integral part of these condensed 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 Company's lead product candidate, GlyphAllo ("Glyph Allopregnanolone"), is a 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.

The Company's second product candidate, GlyphAgo ("Glyph Agomelatine"), is a 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.

The Company is also advancing Glyph2BLSD (Glyph 2-bromo-LSD), a Glyphed oral prodrug of the non-hallucinogenic LSD analog 2-bromo-LSD, in preclinical studies for neuropsychiatric and headache disorders with significant unmet need.

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.

Reverse stock split

On April 24, 2026, in anticipation of the Company's initial public offering ("IPO"), the Company effected a 1-for-3.1407 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company’s convertible preferred stock. The par value and authorized number of shares of common stock and convertible preferred stock were not adjusted as a result. All share and per share amounts for all periods presented in these condensed consolidated financial statements and notes have been adjusted retroactively, where applicable, to reflect the effect of the reverse stock split.

Initial public offering

During the second quarter of 2026, the Company completed its IPO, in which the Company sold an aggregate of 14,446,658 shares of its common stock at a public offering price of $18.00 per share resulting in aggregate net proceeds of approximately $238.4 million, after deducting underwriting discounts, commissions and other offering expenses.

Immediately prior to the closing of the IPO, the Company's outstanding convertible preferred stock automatically converted into 36,272,475 shares of common stock. Following the closing of the IPO, no shares of convertible preferred stock were outstanding. In connection with the closing of the IPO, the Company's certificate of incorporation was amended and restated to authorize 700,000,000 shares of common stock, including 500,000,000 shares of voting common stock and 200,000,000 shares of non-voting common stock, par value $0.0001 per share and 10,000,000 shares of undesignated preferred stock, par value $0.0001 per share.

Liquidity

In accordance with Accounting Standards Update (“ASU”) 2014-15, Disclosure of Uncertainties About an Entity’s Ability to Continue as a Going Concern (Subtopic 205-40), the Company has evaluated whether there are conditions and events that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date the condensed consolidated financial statements are issued. The accompanying condensed consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

Since inception, the Company has incurred significant operating losses. During the six months ended June 30, 2026 and 2025, the Company had a net loss of $88.0 million and $28.2 million, respectively. As of June 30, 2026, the Company had an accumulated deficit of $202.1 million. The Company has not generated any revenue from product sales and does not expect to generate revenue from sales

of products in the near term, if at all. The Company expects to incur significant expenses and operating losses for the foreseeable future as it advances its product candidates into and through clinical development and continues to develop additional product candidates. As such, the Company expects research and development and general and administrative costs to continue to increase significantly, including the costs associated with operating as a public company. The Company's ability to access capital when needed is not assured and, if capital is not available to the Company when, and in the amounts needed, the Company may be required to significantly curtail, delay, or discontinue one or more of its research or development programs or the commercialization of any product candidate, or be unable to expand its operations, or otherwise capitalize on the Company's business opportunities, as desired, which could materially harm the Company's business, financial condition, and results of operations.

Prior to the Company's initial public offering, the Company funded its operations with the aggregate gross proceeds of $326.1 million from the Series A and Series B Financings. The Company believes that its existing cash, cash equivalents and investments of $427.3 million as of June 30, 2026, will be sufficient to allow the Company to fund operations at least twelve months from the date these condensed consolidated financial statements are issued.

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or GAAP. These condensed 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.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

There have been no significant changes from the significant accounting policies and estimates disclosed in Note 2 of the "Notes to Consolidated Financial Statements" in the audited consolidated financial statements for the year ended December 31, 2025 and notes thereto, included in the Company's IPO final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on May 1, 2026.

Unaudited interim financial information

The accompanying condensed consolidated balance sheet as of June 30, 2026, the condensed consolidated statements of operations and comprehensive loss, and condensed consolidated statements of convertible preferred stock and stockholders' deficit and condensed for the three and six months ended June 30, 2026 and 2025, and the condensed consolidated statements of cash flows for the six months ended June 30, 2026 and 2025 are unaudited. The condensed consolidated interim financial statements have been prepared on the same basis as the December 31, 2025 and 2024 audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the Company's condensed consolidated financial statements as of June 30, 2026. The results for the six months ended June 30, 2026 are not necessarily indicative of results to be expected for the year ending December 31, 2026, or for any other subsequent period.

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 condensed 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):

	June 30, 2026	December 31, 2025
Cash and cash equivalents	$ 64,223	$ 46,042
Restricted cash within other non-current assets	454	454
Total cash, cash equivalents, and restricted cash per the condensed consolidated statements of cash flows	$ 64,677	$ 46,496

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 condensed consolidated statements of operations and comprehensive loss. Upon closing of the Company's IPO in May 2026, capitalized deferred offering costs of $3.5 million were reclassified within stockholders' equity (deficit) and recorded against the proceeds from the offering. The Company recorded deferred offering costs of zero and $1.2 million within other non-current assets as of June 30, 2026 and December 31, 2025.

Government Grants

The Company accounts for government awards under ASC 832, Government Assistance. For awards related to income, the Company recognizes grant income when it is probable that the conditions attached to the grant will be satisfied and the grant will be received. The Company elects an accounting policy for the presentation of grant income based on the nature of the underlying government assistance, which it applies consistently to grants of a similar nature.

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, prior to conversion upon the Company's IPO, to be participating securities as, in the event a dividend was paid on common stock, the holders of convertible preferred stock would have been 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.

Recently Adopted Accounting Pronouncements

In December 2025, the FASB issued ASU 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities*, which adds guidance to ASC 832 on the recognition, measurement, and presentation of government grants. In developing the ASU's recognition and measurement framework, the FASB largely leveraged the guidance in IAS 20, to which many for-profit entities that apply U.S. GAAP have historically analogized when accounting for government grants. The ASU is effective for fiscal years beginning after December 15, 2028, including interim periods within those fiscal years. Early adoption is permitted. The Company early adopted ASU 2025-10 prospectively on January 1, 2026. There was not a material impact on the Company's condensed consolidated financial statements as a result of this adoption.

Recently Issued Accounting Standards Updates Not Yet Adopted

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 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):

	June 30, 2026	December 31, 2025
Prepaid research and development	$ 1,755	$ 3,026
Interest receivable	2,723	1,733
Australia research and development tax credit receivable	2,136	1,296
Prepaid other	2,252	1,192
Prepaid expenses and other current assets	$ 8,866	$ 7,247

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):

	June 30, 2026			
	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	$ 48,843	$ 48,843	$ —	$ —
U.S. treasuries with original maturities less than 90 days	14,969	—	14,969	—
Investments:				
United States treasuries	363,037	—	363,037	—
Total financial assets	$ 426,849	$ 48,843	$ 378,006	$ —

	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:				
United States treasuries	187,611	—	187,611	—
Total financial assets	$ 233,321	$ 45,710	$ 187,611	$ —

As of June 30, 2026 and December 31, 2025, 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 and United States treasuries with original maturities less than 90 days, which are classified as Level 2 financial assets.

As of June 30, 2026 and December 31, 2025, the Company's investments consisted of 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 June 30, 2026 and December 31, 2025, the Company had no financial liabilities that required fair value measurement. As of June 30, 2026, there were no securities in an unrealized loss position for more than twelve months.

During the three and six months ended June 30, 2026 and 2025, there were no transfers or reclassifications between fair value measurement levels of assets. The carrying amounts reflected in the condensed consolidated balance sheets for prepaid expenses and other current assets, accounts payable, 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 (in thousands):

	June 30, 2026			
	Amortized Cost	Unrealized Holding Gains	Unrealized Holding Losses	Fair Value
Cash equivalents:				
United States treasuries	$ 14,970	$ —	$ (1)	$ 14,969
Short-term investments:				
United States treasuries	209,557	—	(471)	209,086
Long-term investments:				
United States treasuries	154,289	—	(338)	153,951
Total financial assets	$ 378,816	$ —	$ (810)	$ 378,006

	December 31, 2025			
	Amortized Cost	Unrealized Holding Gains	Unrealized Holding Losses	Fair Value
Short-term investments:				
United States treasuries	$ 169,662	$ 279	$ —	$ 169,941
Long-term investments:				
United States treasuries	17,639	31	—	17,670
Total financial assets	$ 187,301	$ 310	$ —	$ 187,611

As of June 30, 2026, the Company's investments were in net unrealized loss position of $0.8 million. These amounts are included in other comprehensive income (loss) in the condensed consolidated statements of operations and comprehensive loss. The Company determined that there was no material credit risk associated with its investments as of June 30, 2026. As of June 30, 2026, the Company's investments had remaining maturities of two years or less.

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 condensed 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.

6. PROPERTY AND EQUIPMENT, NET

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

	June 30, 2026	December 31, 2025
Lab equipment	$ 944	$ 943
Leasehold improvements	432	432
Furniture and fixtures	25	26
Total	1,401	1,401
Less: Accumulated depreciation	(1,041)	(989)
Property and equipment, net	$ 360	$ 412

Depreciation expense was $52 thousand and $77 thousand for the six months ended June 30, 2026 and 2025, respectively.

7. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	June 30, 2026	December 31, 2025
Accrued research and development expense	$ 2,980	$ 2,639
Accrued personnel and bonus expense	3,072	5,192
Accrued professional and legal fees	555	260
Accrued other	1,751	1,040
Accrued expenses and other current liabilities	$ 8,358	$ 9,131

8. LICENSE AND COLLABORATION AGREEMENTS

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 between PureTech Health and Monash University entered into in August 2017, 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 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. Since the formation of the Company, 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 three and six months ended June 30, 2026 and 2025.

Monash Collaboration Agreement and ARPA-H Award

In March 2026, the Advanced Research Projects Agency for Health ("ARPA-H") granted the Company and Monash University an award for research under the Groundbreaking Lymphatic Interventions and Drug Exploration ("GLIDE") program (the "Award Agreement"). The Award Agreement provides for total funding of up to $15.2 million, which includes committed funding of $3.5 million for the first phase of research under the award and uncommitted funding of up to $11.7 million for the second phase of the research plan under the award. The funding for the second phase is not currently committed and is subject to mutual agreement by the parties; if exercised, the parties will execute a contract modification at that time. The initial term of the Agreement is 48 months. The Agreement may be terminated by either party upon 60 days' written notice, in which case the parties are required to negotiate in good faith to resolve any outstanding matters.

Payments under the Award Agreement are fixed and are earned upon the achievement of defined milestones. As of June 30, 2026, the Company earned $22 thousand on milestone achievement. During the three and six months ended June 30, 2026, the Company recognized $0.1 million under the Award Agreement as a reduction of research and development expense and recorded an unbilled receivable of $0.1 million in prepaid expenses and other current assets on the Company's condensed consolidated balance sheets.

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.

Immediately prior to the closing of the Company's IPO on May 1, 2026, pursuant to the reverse stock split and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock as discussed further below, all of the Company's outstanding shares of convertible preferred stock were converted into an aggregate of 36,272,475 shares of common stock.

In connection with the closing of the IPO, the Company's certificate of incorporation was amended and restated to authorize 10,000,000 undesignated shares of preferred stock, par value $0.0001 per share. There are no shares of undesignated preferred stock outstanding.

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.

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.

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, 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	$ 0.32	12,736,014
Series A-2 Preferred Stock	26,342,102	26,342,102	99,757	100,100	$ 11.94	8,387,331
Series B Preferred Stock	47,578,938	47,578,934	225,571	226,000	$ 14.92	15,149,130
Total Preferred Stock	113,921,040	113,921,036	$ 325,328	$ 330,100		36,272,475

As of December 31, 2025 the holders of the Preferred Stock had 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.

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. In July 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. All outstanding convertible preferred stock was converted into common stock immediately prior to the closing of the Company's IPO.

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.

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 were, prior to the conversion of all outstanding preferred shares into common stock upon the Company's IPO, 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 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 (the "Board"). As of June 30, 2026, no dividends have been declared or paid.

As of June 30, 2026, the Company had authorized 500,000,000 shares of voting common stock and 200,000,000 shares of non-voting common stock, par value $0.0001 per share, of which 53,530,550 voting common stock were issued and outstanding. There are no shares of non-voting common stock outstanding.

11. STOCK-BASED COMPENSATION

2024 Equity Incentive Plan

The Company's 2024 Equity Incentive Plan, as amended (the "2024 Plan"), provided for the Company to sell or issue common stock or restricted common stock, and other awards as determined by the Board could be granted to employees, non-employees and directors of the Company. As of the effective date of the 2026 Equity Incentive Plan (the "2026 Plan"), and as of June 30, 2026, there were no shares remaining available for future issuance under the 2024 Plan. Any options or other awards outstanding under the 2024 Plan remain outstanding and effective. The remaining shares reserved for issuance under the 2024 Plan ceased to be available for issuance at the time that the 2026 Plan became effective.

Subsequent to the effectiveness of the 2026 Plan, the shares of common stock underlying any awards under the 2024 Plan that are forfeited, canceled, reacquired by the Company prior to vesting, satisfied without the issuance of stock or otherwise terminated (other than by exercise) and shares withheld upon exercise of an option or settlement of an award to cover the exercise price or tax withholding will be added to the shares of common stock available for issuance under the 2026 Plan.

2026 Equity Incentive Plans

In January 2026, the Board and the Company's stockholders adopted and approved the 2026 Plan, which became effective on the date that the registration statement on Form S-1 for the Company's IPO was declared effective by the SEC. The 2026 Plan initially reserved 6,020,000 shares of common stock for future issuances and is subject to automatic increases in the number of shares of common stock reserved for future issuances in accordance with the evergreen provisions in the 2026 Plan. The shares reserved for future issuance under the 2024 Plan ceased to be available for issuance at the time the 2026 Plan became effective. Any shares underlying outstanding stock awards granted under the 2024 Plan that subsequently expire or are repurchased, forfeited, cancelled, or withheld will return to the 2026 Plan and be reserved and available for issuance. On the effective date of the Company's registration statement, as previously disclosed, the Company granted 2,477,978 fully vested equity awards under the 2026 Plan to an executive officer and a director pursuant to provisions designed to maintain their aggregate ownership at 12.5%, and recognized $32.2 million of non-cash stock-based compensation expense related to these awards. These ownership maintenance provisions expired upon effectiveness of the registration statement, and no additional awards will be granted pursuant to them. In addition, the Company's IPO triggered the accelerated vesting of 687,816 equity awards held by an executive officer and a director that were originally granted under the 2024 Plan, resulting in the recognition of $2.1 million of non-cash stock-based compensation expense.

In April 2026, the Board and the Company's stockholders adopted and approved the 2026 Employee Stock Purchase Plan (the "2026 ESPP"), which became effective the date that the registration statement on Form S-1 for the Company's IPO was declared effective by the SEC. The 2026 ESPP initially reserved 510,000 shares of common stock for future issuance and is subject to automatic increases in the number of shares of common stock reserved for future issuances in accordance with the evergreen provisions in the 2026 ESPP. As of June 30, 2026, the Company has issued no shares under the 2026 ESPP.

The vesting periods for stock options issued under the plans 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.

Stock Option Activity

The following is a summary of the Company’s stock option award activity under the 2024 Plan and 2026 Plan during the six months ended June 30, 2026:

	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	8,569,619	$ 4.60	8.67	$ 28,669
Granted	4,211,692	16.05	—	—
Exercised	(216,075)	3.74	—	1,421
Forfeited	(331,437)	5.10	—	—
Expired		—	—	—
Outstanding at June 30, 2026	12,233,799	$ 8.55	8.60	$ 161,146
Vested and expected to vest at June 30, 2026	12,233,799	$ 8.55	8.60	$ 161,146
Exercisable at June 30, 2026	8,576,419	$ 8.44	8.47	$ 113,853

The table above excludes 152,514 of the 228,770 performance-based options which have an exercise price of $7.39 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 June 30, 2026. During the six months ended June 30, 2026, 76,256 of these performance-based options were determined to be granted from an accounting perspective and the company recorded stock compensation expense of $0.6 million.

The Company utilized the Black-Scholes option-pricing model for estimating the fair value of the stock options issued under the plans 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 six months ended June 30, 2026 and 2025:

	June 30,	
	2026	2025
Expected term (in years)	5.00 - 6.11 years	5.19 - 6.08 years
Risk-free interest rate	3.59% - 4.08%	3.93% - 4.39%
Volatility	90.36% - 94.23%	89.40% - 91.63%
Dividend yield	0.00%	0.00%

The weighted-average grant date fair value of options granted during the six months ended June 30, 2026 and 2025 was $11.88 and $5.66 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.

As of June 30, 2026, there was $24.6 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 2.6 years.

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 1,990,001 restricted stock awards granted: (i) 796,000 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) 1,194,001 have performance based vesting which vested in full upon the close of the Series B Financing. The company completed its IPO in May 2026, upon which all unvested restricted stock awards vested in full.

The following is a summary of the Company's restricted stock award activity during the six months ended June 30, 2026:

	Number of Units	Weighted-Average Fair Value
Unvested at December 31, 2025	154,778	$ 3.05
Vested	(154,778)	3.05
Unvested at June 30, 2026	—	$ —

No restricted stock awards were granted during the six months ended June 30, 2026 and 2025. The total fair value of the restricted stock awards that vested during the six months ended June 30, 2026 and 2025 was $0.5 million and $0.1 million, respectively. The total stock-based compensation associated with the restricted stock awards was $0.1 million and $0.5 million during the three and six months ended June 30, 2026, respectively, and $0.1 million and $0.1 million during the three and six months ended June 30, 2025, respectively. As of June 30, 2026, there was no unrecognized stock-based compensation expense associated with issued and outstanding restricted stock awards.

Stock-Based Compensation Expense

The following table represents stock-based compensation expense recorded in the Company's condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development	$ 898	$ 589	$ 1,789	$ 1,086
General and administrative	35,965	1,167	37,643	2,289
Stock-based compensation expense	$ 36,863	$ 1,756	$ 39,432	$ 3,375

12. INCOME TAXES

The Company's effective tax rates were (0.4)% and (0.9)% for the three and six months ended June 30, 2026, respectively; and

(0.9)% and (0.6)% for the three and six months ended June 30, 2025, respectively. The effective tax rate in 2026 differs from 2025 primarily due to tax expense recorded in Australia. The income tax provision and effective tax rate are driven primarily by a valuation allowance in the United States, partially offset by income tax expense recorded for Australian operations. The Australian subsidiary is profitable due to its research and development tax credit and transfer pricing agreement with Seaport Therapeutics, Inc. and is subject to income tax expense.

The Company maintains a valuation allowance on the majority of its deferred tax assets, and it has concluded that it is more likely than not that the deferred assets will not be utilized.

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 condensed consolidated balance sheets as of June 30, 2026 and December 31, 2025.

In December 2024, the Company entered into a laboratory lease agreement with a third party for lab space located in Boston, Massachusetts. The lease commenced in January 2025 and was for an initial term of 24 months from the commencement date. In March 2026, the Company exercised its option to extend the lease for an additional 12 months. The modification resulted in an increase to the operating lease right of use asset and lease liability of $0.6 million.

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 8—License and Collaboration Agreements, for further disclosure of the Monash license agreement.

The Asset Transfer and Series A Financing

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 302,161 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 sales 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 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% 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.

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 members of the 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 condensed consolidated financial statements as of June 30, 2026 and December 31, 2025 and for the six months ended June 30, 2026 and 2025.

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.

The chief operating decision-maker, or CODM, manages the Company's operations on a consolidated basis, and assesses performance based on consolidated net loss that is reported on the condensed 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 condensed consolidated balance sheet as total consolidated assets.

The following table presents certain significant segment expenses that are regularly provided to the CODM (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Research and development expenses:				
GlyphAllo direct research and development expenses	$ 12,796	$ 4,751	$ 21,093	$ 8,060
GlyphAgo direct research and development expenses	3,478	2,011	9,972	3,971
Glyph2BLSD direct research and development expenses	1,617	1,552	2,199	2,448
Preclinical and early discovery assets	1,411	967	2,354	1,790
Personnel-related (including non-cash stock-based compensation expense of $0.9 million and $0.6 million for three months ended June 30, 2026 and 2025, respectively and $1.8 million and $1.1 million for six months ended June 30, 2026 and 2025, respectively)	4,732	3,715	9,331	6,870
Other indirect research and development expenses	585	413	1,100	805
Total research and development expenses	24,619	13,409	46,049	23,944
General and administrative expenses:				
Personnel-related (including non-cash stock-based compensation expense of $36.0 million and $1.2 million for three months ended June 30, 2026 and 2025, respectively and $37.6 million and $2.3 million for six months ended June 30, 2026 and 2025, respectively)	38,168	3,239	42,292	6,262
Other general and administrative expenses[1]	3,021	1,822	5,010	4,449
Total general and administrative expenses	41,189	5,061	47,302	10,711
Other segment items[2]	(3,208)	(3,393)	(5,343)	(6,453)
Net loss	$ 62,600	$ 15,077	$ 88,008	$ 28,202

(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

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 three and six months ended June 30, 2026 and 2025, presented since the effects of any potentially dilutive securities, would be antidilutive given the net loss of the Company.

Basic and diluted net loss per share is calculated as follows (in thousands except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Net loss	$ (62,600)	$ (15,077)	$ (88,008)	$ (28,202)
Net loss per share, basic and diluted	$ (1.78)	$ (6.40)	$ (4.60)	$ (12.05)
Weighted-average shares outstanding, basic and diluted	35,236,214	2,356,777	19,118,049	2,340,431

For accounting purposes, the computation of basic and diluted weighted-average common shares outstanding for the three and six months ended June 30, 2026, 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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Stock options to purchase common stock [1]	12,233,799	8,566,646	12,233,799	8,566,646
Unvested restricted stock awards	-	221,111	-	221,111
Series A-1 Preferred Stock (as converted to common stock)	-	12,736,014	-	12,736,014
Series A-2 Preferred Stock (as converted to common stock)	-	8,387,331	-	8,387,331
Series B Preferred Stock (as converted to common stock)	-	15,149,130	-	15,149,130
Total	12,233,799	45,060,232	12,233,799	45,060,232

(1) The table above excludes the performance-based options that have not been deemed granted from an accounting perspective. See Note 11—Stock-Based Compensation, for more information.

17. RELATED PARTIES

During the six months ended June 30, 2026, the Company incurred immaterial expenses from PureTech under the transition services agreement, or the TSA, related to general and administrative expenses. During the six months ended June 30, 2025, the Company incurred $0.3 million of expenses from PureTech under the TSA, primarily related to research and development expenses.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes included in our final prospectus for our initial public offering ("IPO") filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Securities Act") on May 1, 2026 (the "IPO Prospectus"). References to the "Company," "Seaport," "Seaport Therapeutics," "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. This discussion and analysis and other parts of this Quarterly Report on Form 10-Q 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. 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 Quarterly Report on Form 10-Q. You should carefully read the sections entitled "Risk Factors" and "Special Note Regarding Forward-Looking Statements" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

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 ("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 the first half of 2027. We continue to advance a Phase 1 driving simulation trial of GlyphAllo, with topline data expected in the second half of 2026, in advance of the expected topline readout of the BUOY-1 trial.

Our second product candidate, GlyphAgo ("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. In April 2026, we reported topline data from the single-ascending dose, or SAD, and crossover portions of our Phase 1 proof-of-concept clinical trial for GlyphAgo. In the head-to-head crossover portion of the trial, GlyphAgo demonstrated a 6.8-fold increase in bioavailability of agomelatine compared to unmodified orally administered agomelatine, and showed significantly lower (10-fold) pharmacokinetic variability compared to unmodified agomelatine. In the SAD portion of the trial, GlyphAgo demonstrated a 9.6 to 14.5-fold increase in dose-normalized exposure compared to agomelatine. GlyphAgo was well-tolerated and no liver-related adverse events were observed. In June 2026, we reported topline data from the multiple-ascending dose, or MAD, portion of the trial, which showed that seven-day dosing of GlyphAgo achieved therapeutic exposures of agomelatine at doses projected to avoid liver enzyme elevations and reduce or eliminate the need for liver function testing, and demonstrated favorable safety and tolerability, with no liver-related adverse events observed. We plan to initiate a Phase 2a proof-of-pharmacology trial designed to evaluate the potential sleep benefit of GlyphAgo in patients with GAD and sleep disturbance in the second half of 2026, with topline data expected in early 2028 and, in parallel, initiate a Phase 2b trial designed to evaluate the efficacy and safety of GlyphAgo in patients with GAD in the first half of 2027, with topline data expected by the end of 2028.

We are also advancing Glyph2BLSD (Glyph 2-bromo-LSD), a novel, Glyphed oral prodrug of the non-hallucinogenic LSD analog 2-bromo-LSD, in preclinical studies for neuropsychiatric and headache disorders with significant unmet need.

We have devoted substantially all of our efforts to organizing and staffing our company, business planning, capital raising, research and development activities, building and strengthening our intellectual property portfolio, and providing general and administrative support for these operations. 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 and the $226.0 million gross proceeds we received in October 2024 from our Series B Financing. During the second quarter of 2026, we completed our IPO, in which we sold an aggregate 14,446,658 shares of our common stock at a public offering price of $18.00 per share, resulting in aggregate net proceeds of approximately $238.4 million, after deducting underwriting discounts, commissions and other offering expenses.

We have incurred significant operating losses since the inception of our business and expect to continue to generate operating losses for the foreseeable future, and expect that our expenses and operating losses will continue to increase substantially. Our ability to generate product revenue sufficient to achieve profitability, if ever, will depend on the successful development and eventual commercialization of any product candidates we may develop. During the six months ended June 30, 2026 and 2025, we had a net loss

of $88.0 million and $28.2 million, respectively. As of June 30, 2026, we had an accumulated deficit of $202.1 million. 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.

As of June 30, 2026, we had cash, cash equivalents and investments of $427.3 million. Based on our current operating plans, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our operating expenses and capital expenditure requirements into 2029.

Components of Results of Operations

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.

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 condensed 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 in 2023, and Glyph2BLSD in 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, costs to maintain compliance as a public company and legal costs consisting of general corporate legal fees and patent legal fees.

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.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on our investments 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 in Australia. 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 have no benefit (losses) recorded in the U.S. as we have recorded a full valuation allowance of our U.S. deferred tax asset position as of June 30, 2026 and 2025 as we believe it was more likely than not that we would not be able to utilize our deferred tax assets.

Results of Operations

Comparison of the three months ended June 30, 2026 and 2025

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

	Three Months Ended June 30,		
	2026	2025	$ Change
Operating expenses:			
Research and development (including non-cash stock-based compensation expense of $0.9 million and $0.6 million for three months ended June 30, 2026 and 2025, respectively)	$ 24,619	$ 13,409	$ 11,210
General and administrative (including non-cash stock-based compensation expense of $36.0 million and $1.2 million for three months ended June 30, 2026 and 2025, respectively)	41,189	5,061	36,128
Total operating expenses	65,808	18,470	47,338
Loss from operations	(65,808)	(18,470)	$ (47,338)
Other income (expense), net	3,257	2,976	$ 281
Other income, net	202	551	$ (349)
Total other income, net	3,459	3,527	(68)
Loss before income taxes	(62,349)	(14,943)	$ (47,406)
Income tax provision	251	134	$ 117
Net loss	$ (62,600)	$ (15,077)	$ (47,523)

Research and Development Expenses

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

	Three Months Ended June 30,		
	2026	2025	$ Change
Direct costs:			
GlyphAllo	$ 12,796	$ 4,751	$ 8,045
GlyphAgo	3,478	2,011	1,467
Glyph2BLSD	1,617	1,552	65
Preclinical and early discovery assets	1,411	967	444
Indirect costs:			
Employee compensation (excluding non-cash stock-based compensation)	3,834	3,126	708
Stock-based compensation (non-cash)	898	589	309
Other research and development	585	413	172
Total research and development expenses	$ 24,619	$ 13,409	$ 11,210

Research and development expenses increased by $11.2 million from $13.4 million for the three months ended June 30, 2025 to $24.6 million for the three months ended June 30, 2026. The increase in research and development expenses was primarily attributable to:

- $8.0 million of increased costs associated with our lead program GlyphAllo, which was primarily due to the advancement of our Phase 2b BUOY-1 trial which commenced in July 2025 and other supporting clinical studies;
- $1.5 million of increased costs associated with our GlyphAgo program, which was primarily due to our Phase 1 trial, for which we announced dosing of the first participant in September 2025 and completed the study in the second quarter of 2026, and other development activities as we advance the program;
- $0.1 million of increased costs associated with our Glyph2BLSD program due to timing of our development activities;
- $0.4 million of increased costs associated with advancing our preclinical and early discovery assets;
- $0.7 million of increased costs associated with employee compensation primarily due to increased headcount to support our research and development operations and salary adjustments; and

- $0.3 million of increased costs associated with non-cash stock-based compensation costs primarily due to additional equity grants issued under our 2024 and 2026 Equity Plan.

General and Administrative Expenses

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

	Three Months Ended June 30,		
	2026	2025	$ Change
Employee compensation (excluding non-cash stock-based compensation)	$ 2,203	$ 2,072	$ 131
Stock-based compensation (non-cash)	35,965	1,167	34,798
Professional fees	1,953	1,031	922
Facilities, depreciation, IT, and other	1,068	791	277
Total general and administrative expenses	$ 41,189	$ 5,061	$ 36,128

General and administrative expenses increased by $36.1 million from $5.1 million for the three months ended June 30, 2025 to $41.2 million for the three months ended June 30, 2026. The increase in general and administrative expenses was primarily attributable to:

- $34.8 million of increased costs associated with non-cash stock-based compensation primarily due to fully vested awards issued and awards accelerated upon the successful completion of the IPO, as described in previous SEC filings, and additional equity grants issued under our 2024 and 2026 Equity Plans;
- $0.9 million of increased professional fees primarily due to higher audit, legal, and consulting fees as a result of operating as a public company;
- $0.3 million of increased facilities, depreciation, IT, and other costs primarily due to increased public company directors and officers insurance costs; and
- $0.1 million of increased employee compensation due to salary adjustments.

Other Income, Net

Other income, net, decreased by $0.1 million from $3.5 million for the three months ended June 30, 2025 to $3.5 million for the three months ended June 30, 2026. The decrease in other income, net was primarily attributed to an increase in interest income on our investments and cash equivalents due to the investment of funds received from our IPO in May 2026, offset by a decrease in our research and development tax credit from our qualifying research and development spend in Australia.

Income tax provision

Income tax provision increased by $0.1 million from $0.1 million for the three months ended June 30, 2025 to $0.3 million for the three months ended June 30, 2026. The increase in the income tax provision was attributed to foreign income taxes related to our Australian subsidiary primarily as a result of our research and development tax credit and transfer pricing agreement with Seaport Therapeutics, Inc.

Comparison of the six months ended June 30, 2026 and 2025

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

	Six Months Ended June 30,		
	2026	2025	$ Change
Operating expenses:			
Research and development (including non-cash stock-based compensation expense of $1.8 million and $1.1 million for six months ended June 30, 2026 and 2025, respectively)	$ 46,049	$ 23,944	$ 22,105
General and administrative (including non-cash stock-based compensation expense of $37.6 million and $2.3 million for six months ended June 30, 2026 and 2025, respectively)	47,302	10,711	36,591
Total operating expenses	93,351	34,655	58,696
Loss from operations	(93,351)	(34,655)	$ (58,696)
Other income (expense), net	5,390	6,076	$ (686)
Other income, net	723	542	$ 181
Total other income, net	6,113	6,618	(505)
Loss before income taxes	(87,238)	(28,037)	$ (59,201)
Income tax provision	770	165	$ 605
Net loss	$ (88,008)	$ (28,202)	$ (59,806)

Research and Development Expenses

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

	Six Months Ended June 30,		
	2026	2025	$ Change
Direct costs:			
GlyphAllo	$ 21,093	$ 8,060	$ 13,033
GlyphAgo	9,972	3,971	6,001
Glyph2BLSD	2,199	2,448	(249)
Preclinical and early discovery assets	2,354	1,790	564
Indirect costs:			
Employee compensation (excluding non-cash stock-based compensation)	7,542	5,784	1,758
Stock-based compensation (non-cash)	1,789	1,086	703
Other research and development	1,100	805	295
Total research and development expenses	$ 46,049	$ 23,944	$ 22,105

Research and development expenses increased by $22.1 million from $23.9 million for the six months ended June 30, 2025 to $46.0 million for the six months ended June 30, 2026. The increase in research and development expenses was primarily attributable to:

- $13.0 million of increased costs associated with our lead program GlyphAllo, which was primarily due to advancement of our Phase 2b BUOY-1 trial which commenced in July 2025 and other supporting clinical studies;
- $6.0 million of increased costs associated with our GlyphAgo program, which was primarily due to our Phase 1 trial, for which we announced dosing of the first participant in September 2025 and completed the study in the second quarter of 2026, and other development activities as we advance the program;
- $0.6 million of increased costs associated with advancing our preclinical and early discovery assets;
- $1.8 million of increased costs associated with employee compensation primarily due to increased headcount to support our research and development operations and salary adjustments; and
- $0.7 million of increased costs associated with non-cash stock-based compensation costs primarily due to additional equity grants issued under our 2024 and 2026 Equity Plans.

These increase were partially offset by:

- $0.2 million of decreased costs associated with our Glyph2BLSD program due to timing of our development activities.

General and Administrative Expenses

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

	Six Months Ended June 30,		
	2026	2025	$ Change
Employee compensation (excluding non-cash stock-based compensation)	$ 4,649	$ 3,973	$ 676
Stock-based compensation (non-cash)	37,643	2,289	35,354
Professional fees	3,155	2,915	240
Facilities, depreciation, IT, and other	1,855	1,534	321
Total general and administrative expenses	$ 47,302	$ 10,711	$ 36,591

General and administrative expenses increased by $36.6 million from $10.7 million for the six months ended June 30, 2025 to $47.3 million for the six months ended June 30, 2026. The increase in general and administrative expenses was primarily attributable to:

- $35.4 million of increased costs associated with non-cash stock-based compensation costs primarily due to fully vested awards issued and awards accelerated upon the successful completion of the IPO, as described in previous SEC filings, and additional equity grants issued under our 2024 and 2026 Equity Plans;
- $0.7 million of increased employee compensation due to salary adjustments;
- $0.3 million of increased facilities, depreciation, IT, and other costs primarily due to increased public company directors and officers insurance costs; and
- $0.2 million of increased professional fees primarily due to higher audit, consulting, and board of director fees as a result of operating as a public company.

Other Income, Net

Other income, net decreased by $0.5 million from $6.6 million for the six months ended June 30, 2025 to $6.1 million for the six months ended June 30, 2026. The decrease in other income, net was primarily attributed to decrease in interest income on our investments and cash equivalents due to the amount of funds invested in interest bearing accounts, offset by an increase in our research and development tax credit as a result of qualifying research and development spend in Australia.

Income tax provision

Income tax provision increased by $0.6 million from $0.2 million for the six months ended June 30, 2025 to $0.8 million for the six months ended June 30, 2026. The increase in the income tax provision was attributed to foreign income taxes related to our Australian subsidiary primarily as a result of our research and development tax credit and transfer pricing agreement with Seaport Therapeutics, Inc.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses. During the six months ended June 30, 2026 and 2025, we had a net loss of $88.0 million and $28.2 million, respectively. As of June 30, 2026, we had an accumulated deficit of $202.1 million. We have not generated any revenue from product sales and we do not expect to generate revenue from sales of products in the near term, if at all. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates into and through clinical development and as we continue to develop additional product candidates. As such, we expect our research and development and general and administrative costs to continue to increase significantly, including the costs associated with operating as a public company.

To date we have funded our operations with the aggregate gross proceeds of $326.1 million from the Series A and Series B Financings and aggregate net proceeds of $238.4 million from the sale of shares of common stock in our IPO, after deducting underwriting discounts, commissions and other offering expenses. As of June 30, 2026, we had cash, cash equivalents and investments of $427.3 million. Based on our current operating plans, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our operating expenses and capital expenditure requirements into 2029.

Cash Flows

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

	Six Months Ended June 30,		
	2026	2025	$ Change
Net cash used in operating activities	$ (46,313)	$ (35,530)	$ (10,783)
Net cash used in investing activities	(175,652)	(226,994)	51,342
Net cash provided by financing activities	240,145	—	240,145
Effect of exchange rate changes on cash and cash equivalents[1]	1	—	1
Net increase (decrease) in cash, cash equivalents, and restricted cash	$ 18,181	$ (262,524)	$ 280,705

(1) Our 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

Net cash used in operating activities was $46.3 million for the six months ended June 30, 2026 and $35.5 million for the six months ended June 30, 2025, respectively. Cash used in operating activities increased by $10.8 million due to an increase in our operating expenses for the six months ended June 30, 2026, offset by changes in operating assets and liabilities including an increase in our accounts payables balance due to timing of payments.

Net Cash Used in Investing Activities

Net cash used in investing activities was $175.7 million for the six months ended June 30, 2026, compared to $227.0 million for the six months ended June 30, 2025. Cash used in investing activities decreased by $51.3 million, driven by lower purchases of U.S. Treasury securities for the six months ended June 30, 2026, as the amount of IPO net proceeds invested was less than our initial investment purchases for the six months ended June 30, 2025. The decrease also reflects higher maturities of investments for the six months ended June 30, 2026, the proceeds of which were used to fund operations.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $240.1 million for the six months ended June 30, 2026, primarily consisting of net proceeds from our IPO. There were no cash flows from financing activities for the six months ended June 30, 2025.

Future Funding Requirements

As of June 30, 2026, we had cash, cash equivalents and investments of $427.3 million. Based upon our current operating plans, we believe our cash, cash equivalents and investments as of June 30, 2026, will be sufficient to fund our operations into 2029. 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 with PureTech

We were incorporated in April 2024 by PureTech LYT, as our sole stockholder, and upon formation issued 318 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 302,161 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 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% 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.

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 June 30, 2026, the first two development milestones under the Monash License Agreement, totaling $0.2 million, had been achieved and were paid by PureTech, as they occurred prior to our formation. We have since paid the third development milestone of $0.1 million, as well as annual maintenance fees. No other milestone payments have become due or been paid under the Monash License Agreement as of June 30, 2026.

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 was for an initial term of 24 months from the commencement date. The aggregate payments under the full license total approximately $1.2 million. In March 2026, we exercised our option to extend the lease for an additional 12 months. The modification resulted in an increase in the aggregate payments under the full license total approximately $0.6 million.

For additional information on our contractual obligation and commitments please see Note 8—License and Collaboration Agreements and Note 14—Commitments and Contingencies.

Critical Accounting Estimates and Significant Judgments

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed 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.

Our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included in our IPO prospectus. During the six months ended June 30, 2026, there were no material changes to our critical accounting policies and estimates described under Management's Discussion and Analysis of Critical Accounting Policies and Estimates which are included in our IPO Prospectus, except that our common stock is now publicly traded and we therefore no longer require common stock valuations.

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 *Quarterly Report on Form 10-Q*;
- 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 our 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a "smaller reporting company," as defined by Rule 12b-2 of the Exchange Act, and pursuant to Item 305 of Regulation S-K, we are not required to provide quantitative and qualitative disclosures about market risk.

Item 4. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Our disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. As required by Rule 13a-15(b) or Rule 15d-15(b) promulgated by the SEC under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Quarterly Report on Form 10-Q at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. 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.

Item 1A. 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 Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations," our condensed *consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes included in the IPO Prospectus, 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. This Quarterly Report on Form 10-Q 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.

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™ , certain preclinical development of GlyphAgo™ 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 $88.0 million and $28.2 million for the six months ended June 30, 2026 and 2025, respectively. As of June 30, 2026, we have not yet generated product or collaboration revenue and had an accumulated deficit of $202.1 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;
- 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.

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 and our IPO. 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.

As of June 30, 2026, we had $427.3 million of cash, cash equivalents and investments. Based upon our current operating plan, we believe that our existing cash, cash equivalents, and investments, will enable us to fund our operating expenses and capital expenditure requirements into 2029. 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, we expect to continue incurring 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, other financings, or any future proceeds received under any licenses or collaborations, if any. 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 an ongoing Phase 1 trial and we intend to advance GlyphAgo into parallel Phase 2a and Phase 2b clinical trials. 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 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, in development for the treatment of neuropsychiatric and headache disorders with significant unmet need, 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;
- 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.

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 June 30, 2026, we had 58 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, 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 in our IPO 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.

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.

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.

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 Cellect, 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 Ownership of Our Common Stock

An active trading market may not be sustained for our common stock.

Although our common stock is listed on The Nasdaq Global Select Market, an active or liquid market in our common stock may not be sustainable. 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 is 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 Quarterly Report on Form 10-Q, 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;
- 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.

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 depends 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.

Our executive officers, directors, principal stockholders, and their respective affiliates collectively own a significant percentage of our outstanding stock. As a result, any stockholders who own more than 5% or more of our capital stock, if acting together, 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.

All shares of common stock sold in our IPO are 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 38,029,523 shares, or 98% of our outstanding shares of common stock following our IPO, 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 the IPO. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning on the 18st day after the date of our IPO. 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.

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.

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.

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 and our amended and restated bylaws 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;
- 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 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 provides 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 maintain a listing of our common stock on Nasdaq.

Because 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.

The structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The structure of our common stock may also limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. We do not currently have any shares of non-voting common stock outstanding. Nonetheless, we may issue non-voting common stock in the future and each outstanding share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation.

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 recent military action in Iran and effects thereof, 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 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 an "emerging growth company" and a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make us 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 Quarterly Report on Form 10-Q;
- 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.

We could be an emerging growth company for up to five years following the completion of our IPO, 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 have incurred, and will continue to incur, significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives and corporate governance practices.

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

The rules and regulations applicable to public companies 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, these rules and regulations 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. We have begun 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 our IPO. 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.

We are 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 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 well as other factors that could adversely affect our reputation, as 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.

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

(a) Recent Sales of Unregistered Equity Securities

None.

(b) Use of Proceeds from our Initial Public Offering

On April 30, 2026, the SEC declared effective our registration statement on Form S-1 (File No. 333-294976), as amended, or the Registration Statement, filed in connection with our IPO. Pursuant to the Registration Statement, we registered the offer and sale of 14,160,000 shares of our common stock with a maximum aggregate offering price of approximately $237.0 million. Goldman Sachs & Co. LLC, J.P. Morgan, Leerink Partners, Citigroup, and Stifel acted as representatives of the underwriters for the IPO. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates.

There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b) of the Securities Act on May 1, 2026.

(c) Issuer Repurchases of Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

During the six months ended June 30, 2026, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as those terms are defined in Item 408 of Regulation S-K.

Item 6. Exhibits.

Furnish the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (as currently in effect) (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on May 4, 2026 (File No. 001-43254)).
3.2	Amended and Restated Bylaws of Seaport Therapeutics, Inc (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the SEC on May 4, 2026 (File No. 001-43254)).
4.1†+	Amended and Restated Investors' Rights Agreement, by and between the Registrant and certain of its stockholders, dated as of October 18, 2024 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-294976)).
4.2	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-294976)).
10.1#	2026 Equity Incentive Plan and form of award agreements thereunder (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-294976)).
10.2#	2026 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-294976)).
10.3#	Form of Officer Indemnification Agreement, by and between the Registrant and executive officers (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-294976)).
10.4#	Form of Director Indemnification Agreement, by and between the Registrant and its directors (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-294976)).
10.5#	Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-294976)).
10.6#	Executive Severance Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-294976)).
10.7#	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-294976)).
10.8#	Compensation Recovery Policy (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-294976)).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 and 32.2 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, except to the extent that the Registrant specifically incorporates it by reference.

\# 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.

SIGNATURES

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

Seaport Therapeutics, Inc.

Date: August 3, 2026

By: /s/ Daphne Zohar
Daphne Zohar
Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 3, 2026

By: /s/ Lauren White
Lauren A. White
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO

RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daphne Zohar, certify that:

1. I have reviewed this Form 10-Q for the Quarterly Period Ended June 30, 2026 of Seaport Therapeutics, Inc.;

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

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

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

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

    b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date: August 3, 2026

By: /s/ Daphne Zohar
Daphne Zohar
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO

RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lauren White, certify that:

1. I have reviewed this Form 10-Q for the Quarterly Period Ended June 30, 2026 of Seaport Therapeutics, Inc.;

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

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

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

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

    b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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

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

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

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

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

Date:August 3, 2026

By: /s/ Lauren White
Lauren White
Chief Financial Officer
(Principal Financial Officer and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Seaport Therapeutics, Inc. (the "Company") for the period ended June 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: August 3, 2026

By: /s/ Daphne Zohar
Daphne Zohar
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO

18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Seaport Therapeutics, Inc. (the "Company") for the period ended June 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: August 3, 2026

By: /s/ Lauren White
Lauren White
Chief Financial Officer
(Principal Financial Officer and Accounting Officer)