

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 September 30, 2024

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: 001-42382

Septerna, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

84-3891440
(I.R.S. Employer
Identification No.)

250 East Grand Avenue
South San Francisco, CA
(Address of principal executive offices)

94080
(Zip Code)

Registrant's telephone number, including area code: (650) 338-3533

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	SEPN	The Nasdaq Global Market

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

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

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

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

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

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

As of November 11, 2024, the registrant had 44,402,742 shares of common stock, \$0.001 par value per share, outstanding.

TABLE OF CONTENTS

	<u>Page</u>	
PART I.	FINANCIAL INFORMATION	1
Item 1.	Financial Statements (unaudited)	1
	Condensed Balance Sheets	1
	Condensed Statements of Operations and Comprehensive Loss	2
	Condensed Statements of Convertible Preferred Stock and Stockholders' Deficit	3
	Condensed Statements of Cash Flows	5
	Notes to Condensed Financial Statements (unaudited)	6
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	18
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	30
Item 4.	Controls and Procedures	30
PART II.	OTHER INFORMATION	31
Item 1.	Legal Proceedings	31
Item 1A.	Risk Factors	31
Item 2.	Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities	94
Item 3.	Defaults Upon Senior Securities	94
Item 4.	Mine Safety Disclosures	94
Item 5.	Other Information	94
Item 6.	Exhibits	95
	Signatures	96

We own various U.S. federal trademark applications and unregistered trademarks, including our company name and logo, that we use in connection with the operation of our business. This Quarterly Report on Form 10-Q (this "Quarterly Report") includes our trademarks and trade names which are protected under applicable intellectual property laws and are our property. This Quarterly Report also contains trademarks, trade names and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names and service marks referred to in this Quarterly Report may appear without the ®, ™ or SM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent permitted under applicable law, our rights or the right of the applicable licensor to these trademarks, trade names and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

From time to time, we may use our website, our X (formerly known as Twitter) account at [Septerna_Inc](#) and our LinkedIn account at <https://www.linkedin.com/company/septernainc/> to distribute material information about us and for complying with our disclosure obligations under Regulation FD. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at www.Septerna.com. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website or our social media are not incorporated into, and does not form a part of, this Quarterly Report.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report contains express or implied forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These statements are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Quarterly Report include, but are not limited to, statements about:

- the initiation, timing, progress, results and costs of conducting our research and development programs and our current and future preclinical studies and anticipated clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our current and future programs;
- our ability to demonstrate, and the timing of, preclinical proof-of-concept *in vivo* and *ex vivo* for multiple programs;
- our ability to advance any product candidates that we may identify and successfully complete any clinical studies, including the manufacture of any such product candidates;
- the timing, scope and likelihood of regulatory filings and approvals, including timing of Investigational New Drug (“IND”) applications or comparable foreign applications, and final U.S. Food and Drug Administration (the “FDA”) approval of our current product candidates or any future product candidates;
- the timing, scope or likelihood of foreign regulatory filings and approvals;
- the implementation of our business model, and strategic plans for our business, product candidates, and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and other product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- developments relating to our competitors and our industry;
- our ability to leverage programs within our initial target indications and to progress additional programs to further develop our pipeline;
- our ability of our preclinical studies and clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- our ability to identify and enter into future license agreements and collaborations and the potential benefits of such agreements and collaborations;
- our ability to rely on third-party manufacturers and successfully manufacture product candidates for preclinical use, clinical trials and on a larger scale for commercial use, if approved;
- our ability to realize the benefits of collaborations for the development and commercialization of current and future product candidates;
- our ability to commercialize any current and future product candidates;
- developments related to our proprietary Native Complex Platform™;
- regulatory developments in the United States and foreign countries;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates;
- the size and growth potential of the markets for our current and future product candidates and our ability to serve those markets;
- our need for and ability to attract and retain key scientific, management and other personnel and to identify, hire, and retain additional qualified professionals;
- our expectations regarding the period during which we will remain an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (“JOBS Act”);

- our anticipated use of our existing resources;
- our financial performance and estimates of our future expenses, capital requirements, and our needs for additional financing;
- the impact of global economic and political developments on our business, including rising inflation and capital market disruptions, economic sanctions and economic slowdowns or recessions that may result from such developments which could harm our research and development efforts as well as the value of our common stock and our ability to access capital markets;
- the ultimate impact of health epidemics, pandemics, and other widespread outbreaks of contagious disease, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our clinical trials, our research programs, healthcare systems or the global economy as a whole; and
- other risks and uncertainties, including those listed under the section titled “Risk Factors” in Part II, Item 1A.

In some cases, you can identify forward-looking statements by terminology such as “may,” “might,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “seek,” “predict,” “future,” “project,” “potential,” “continue,” “target,” “contemplate,” “possible,” “can,” or the negative of these terms or other comparable terminology, and similar expressions, although not all forward-looking statements contain these identifying words. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled “Risk Factors” and elsewhere in this Quarterly Report. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report and the documents that we reference in this Quarterly Report and have filed with the Securities and Exchange Commission (the “SEC”) thereto completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this Quarterly Report represent our views as of the date of this Quarterly Report. We do not undertake any obligation to publicly update any forward-looking statement except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report.

This Quarterly Report also contains estimates, projections and other information concerning our industry, our business and the markets for our product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. All of the market data used in this Quarterly Report involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research, and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

This Quarterly Report contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed as exhibits to this Quarterly Report. Unless the context otherwise requires, reference in this Quarterly Report to the terms “Septerna,” “the Company,” “we,” “us,” “our,” and similar designations refer to Septerna, Inc.

SUMMARY OF MATERIAL AND OTHER RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties and are subject to change based on various factors, including those highlighted in the section entitled “Risk Factors” and elsewhere in this Quarterly Report. These risks include, but are not limited to, the following:

- We have a limited operating history and have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.
- We will require substantial additional funding in order to finance our operations. If we are unable to raise additional capital when needed on acceptable terms, or at all, we may be forced to delay, reduce, or terminate certain of our research and product development programs, future commercialization efforts or other operations.
- We are early in our development efforts. We have only recently initiated early clinical studies, and as a result it will be years before we commercialize a product candidate, if ever. If we are unable to identify and advance product candidates through preclinical studies and clinical trials, obtain marketing approval and ultimately commercialize them, or experience significant delays in doing so, our business will be materially harmed.
- Preclinical and clinical drug development is a lengthy and expensive process, with uncertain timelines and outcomes. If preclinical studies or clinical trials of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our therapeutic candidates or any of our future therapeutic candidates on a timely basis or at all.
- We may encounter substantial delays in the commencement, enrollment or completion of our planned clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, which could prevent us from commercializing any product candidates we determine to develop on a timely basis, if at all.
- Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates, any of which would limit the commercial potential of such product candidate.
- Our product candidates are subject to extensive regulation and compliance obligations, which is costly and time-consuming and which may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.
- Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, which could adversely affect our business, operating results and prospects.
- Our proprietary Native Complex Platform™ is based on novel technologies that are unproven and 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, and we may not be successful in our efforts to expand our development portfolio of product candidates.
- We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may invest significant resources to develop these capabilities. If we are unable to establish marketing, sales or distribution capabilities or enter into agreements with third parties to market and sell our products, we may not be able to generate product revenue.
- Even if any of our current or future product candidates receive marketing approval, such product candidate may fail to achieve market acceptance by physicians, patients, third-party payors or others in the medical community necessary for commercial success, in which case we may not generate significant revenues or become profitable.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.
- We rely on third-party manufacturers, clinical research organizations (“CROs”), contract manufacturing organizations (“CMOs”), and suppliers to supply, develop and test components of our product candidates. The loss of our third-party manufacturers, CROs, CMOs, or suppliers, their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, or changes in methods of product candidate manufacturing, development or formulation would materially and adversely affect our business.

The material and other risks summarized above should be read together with the text of the full risk factors and in the other information set forth in this Quarterly Report, including our condensed financial statements and the related notes, as well as in other documents that we file with the SEC. If any such material and other risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above or described in full are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

SEPTERNA, INC.
Condensed Balance Sheets
(In thousands, except for share and per share data)
(Unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 88,242	\$ 88,483
Marketable securities	42,291	—
Accounts receivable	210	151
Other receivable related to sale of non-financial asset	—	22,625
Prepaid expenses and other current assets	2,668	1,419
Total current assets	133,411	112,678
Marketable securities, non-current	6,979	—
Property and equipment, net	5,412	4,665
Operating lease right-of-use asset	24,095	12,522
Restricted cash	905	905
Other non-current assets	3,479	97
Total assets	<u>\$ 174,281</u>	<u>\$ 130,867</u>
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 6,128	\$ 2,637
Accrued expenses and other current liabilities	5,987	4,277
Operating lease liability, current	1,116	—
Total current liabilities	13,231	6,914
Operating lease liability, non-current	24,110	12,566
Other non-current liabilities	191	546
Total liabilities	37,532	20,026
Commitments and contingencies (Note 5)		
Convertible preferred stock	224,157	149,215
Stockholders' deficit:		
Common stock	3	3
Additional paid-in capital	10,119	8,199
Accumulated other comprehensive income	176	—
Accumulated deficit	(97,706)	(46,576)
Total stockholders' deficit	(87,408)	(38,374)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 174,281</u>	<u>\$ 130,867</u>

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

SEPTERNA, INC.

Condensed Statements of Operations and Comprehensive Loss

(In thousands, except for share and per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue	\$ 176	\$ 33	\$ 863	\$ 33
Operating expenses:				
Research and development	17,832	9,281	46,020	25,653
General and administrative	4,894	2,792	10,948	6,622
Total operating expenses	<u>22,726</u>	<u>12,073</u>	<u>56,968</u>	<u>32,275</u>
Loss from operations	<u>(22,550)</u>	<u>(12,040)</u>	<u>(56,105)</u>	<u>(32,242)</u>
Other income, net:				
Interest income	1,900	1,096	4,709	1,531
Other expense, net	(9)	(1)	(72)	(3)
Total other income, net	<u>1,891</u>	<u>1,095</u>	<u>4,637</u>	<u>1,528</u>
Loss before benefit for income taxes	<u>(20,659)</u>	<u>(10,945)</u>	<u>(51,468)</u>	<u>(30,714)</u>
Benefit for income taxes	136	—	338	—
Net loss attributable to common stockholders	<u>\$ (20,523)</u>	<u>\$ (10,945)</u>	<u>\$ (51,130)</u>	<u>\$ (30,714)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (8.40)</u>	<u>\$ (5.45)</u>	<u>\$ (21.87)</u>	<u>\$ (16.49)</u>
Weighted-average shares outstanding, basic and diluted	<u>2,443,678</u>	<u>2,007,620</u>	<u>2,337,891</u>	<u>1,862,036</u>
Comprehensive loss:				
Net loss	\$ (20,523)	\$ (10,945)	\$ (51,130)	\$ (30,714)
Net unrealized gain on available-for-sale marketable securities	184	—	176	—
Total other comprehensive income	<u>184</u>	<u>—</u>	<u>176</u>	<u>—</u>
Comprehensive loss	<u>\$ (20,339)</u>	<u>\$ (10,945)</u>	<u>\$ (50,954)</u>	<u>\$ (30,714)</u>

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

SEPTERNA, INC.

Condensed Statements of Convertible Preferred Stock and Stockholders' Deficit
(In thousands, except for share and per share data)
(Unaudited)

	Convertible Preferred Stock				Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Deficit
	Series A		Series B		Shares	Amount				
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2023	75,000,000	\$ 74,694	60,828,720	\$ 74,521	3,168,134	\$ 3	\$ 8,199	\$ —	\$ (46,576)	\$ (38,374)
Issuance of common stock upon exercise of stock options	—	—	—	—	217	—	1	—	—	1
Vesting of restricted common stock	—	—	—	—	—	—	6	—	—	6
Repurchase of unvested restricted common stock	—	—	—	—	(11,517)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	577	—	—	577
Net unrealized loss on available-for-sale marketable securities	—	—	—	—	—	—	—	(7)	—	(7)
Net loss	—	—	—	—	—	—	—	—	(14,097)	(14,097)
Balance at March 31, 2024	75,000,000	\$ 74,694	60,828,720	\$ 74,521	3,156,834	\$ 3	\$ 8,783	\$ (7)	\$ (60,673)	\$ (51,894)
Issuance of Series B Convertible Preferred Stock, net of issuance costs of \$58	—	—	60,828,732	74,942	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	—	—	6,186	—	10	—	—	10
Vesting of restricted common stock	—	—	—	—	—	—	4	—	—	4
Stock-based compensation expense	—	—	—	—	—	—	628	—	—	628
Net unrealized loss on available-for-sale marketable securities	—	—	—	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	—	—	—	(16,510)	(16,510)
Balance at June 30, 2024	75,000,000	\$ 74,694	121,657,452	\$ 149,463	3,163,020	\$ 3	\$ 9,425	\$ (8)	\$ (77,183)	\$ (67,763)
Issuance of common stock upon exercise of stock options	—	—	—	—	2,730	—	5	—	—	5
Vesting of restricted common stock	—	—	—	—	—	—	6	—	—	6
Repurchase of unvested restricted common stock	—	—	—	—	(2,782)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	683	—	—	683
Net unrealized gain on available-for-sale marketable securities	—	—	—	—	—	—	—	184	—	184
Net loss	—	—	—	—	—	—	—	—	(20,523)	(20,523)
Balance at September 30, 2024	75,000,000	\$ 74,694	121,657,452	\$ 149,463	3,162,968	\$ 3	\$ 10,119	\$ 176	\$ (97,706)	\$ (87,408)

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

SEPTERNA, INC.

Condensed Statements of Convertible Preferred Stock and Stockholders' Deficit
(In thousands, except for share and per share data)
(Unaudited)

	Convertible Preferred Stock				Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Deficit
	Series A		Series B		Shares	Amount				
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2022	75,000,000	\$ 74,694	—	\$ —	3,181,829	\$ 3	\$ 6,552	\$ —	\$ (50,756)	\$ (44,201)
Vesting of restricted common stock	—	—	—	—	—	—	6	—	—	6
Stock-based compensation expense	—	—	—	—	—	—	343	—	—	343
Net loss	—	—	—	—	—	—	—	—	(9,171)	(9,171)
Balance at March 31, 2023	75,000,000	74,694	—	—	3,181,829	3	6,901	—	(59,927)	(53,023)
Issuance of Series B Convertible Preferred Stock, net of issuance costs of \$479	—	—	58,801,098	72,021	—	—	—	—	—	—
Vesting of restricted common stock	—	—	—	—	—	—	9	—	—	9
Repurchase of unvested restricted common stock	—	—	—	—	(2,807)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	355	—	—	355
Net loss	—	—	—	—	—	—	—	—	(10,598)	(10,598)
Balance at June 30, 2023	75,000,000	74,694	58,801,098	72,021	3,179,022	3	7,265	—	(70,525)	(63,257)
Issuance of Series B Convertible Preferred Stock, net of issuance costs of \$0	—	—	2,027,622	2,500	—	—	—	—	—	—
Vesting of restricted common stock	—	—	—	—	—	—	6	—	—	6
Repurchase of unvested restricted common stock	—	—	—	—	(10,888)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	347	—	—	347
Net loss	—	—	—	—	—	—	—	—	(10,945)	(10,945)
Balance at September 30, 2023	75,000,000	\$ 74,694	60,828,720	\$ 74,521	3,168,134	\$ 3	\$ 7,618	\$ —	\$ (81,470)	\$ (73,849)

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

SEPTERNA, INC.

Condensed Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine Months Ended September 30.	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (51,130)	\$ (30,714)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,013	605
Non-cash operating lease expense	890	515
Stock-based compensation	1,888	1,045
Amortization of premiums (discounts), net	(601)	—
Deferred income tax	(338)	—
Other	52	5
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,249)	(34)
Accounts receivable	(60)	(33)
Other non-current assets	(173)	(215)
Accounts payable	2,419	(1,131)
Accrued expenses and other current liabilities	579	559
Operating lease, net	198	(528)
Net cash used in operating activities	<u>(46,512)</u>	<u>(29,926)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(1,491)	(1,639)
Proceeds from sale of non-financial asset	22,625	25,000
Purchases of available-for-sale marketable securities	(65,828)	—
Maturities of available-for-sale marketable securities	17,335	—
Net cash (used in) provided by investing activities	<u>(27,359)</u>	<u>23,361</u>
Cash flows from financing activities:		
Proceeds from issuance of Series B Convertible Preferred Stock, net of issuance costs	74,942	74,521
Repurchases of unvested restricted common stock	(1)	(1)
Proceeds from exercise of stock options	16	—
Payments of deferred offering costs	(1,327)	—
Net cash provided by financing activities	<u>73,630</u>	<u>74,520</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	(241)	67,955
Cash, cash equivalents and restricted cash, beginning of period	89,388	31,469
Cash, cash equivalents and restricted cash, end of period	<u>\$ 89,147</u>	<u>\$ 99,424</u>
Reconciliation of cash, cash equivalents and restricted cash reported within the unaudited condensed balance sheets to the total amounts reported on the unaudited condensed statements of cash flows:		
Cash and cash equivalents	\$ 88,242	\$ 98,519
Restricted cash	905	905
Total cash, cash equivalents and restricted cash at end of period	<u>\$ 89,147</u>	<u>\$ 99,424</u>
Supplemental cash flow information:		
Cash paid for income taxes	\$ 232	\$ —
Supplemental disclosure for noncash investing and financing activities:		
Right-of-use asset recognized in exchange for operating lease liability	\$ (12,462)	\$ —
Unpaid deferred offering costs included in accounts payable and accrued expenses and other current liabilities	\$ 1,882	\$ —
Property and equipment included in accounts payable and accrued expenses and other current liabilities	<u>\$ 321</u>	<u>\$ 355</u>

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

SEPTERNA, INC.
NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

Note 1. Organization and Basis of Presentation

Description of the Business

Septerna, Inc. (“Septerna” or the “Company”) is a clinical-stage biotechnology company pioneering a new era of G protein-coupled receptor (“GPCR”) oral small molecule drug discovery powered by its proprietary Native Complex Platform™. The Company’s industrial-scale platform aims to unlock the full potential of GPCR therapies and has led to the discovery and development of its deep pipeline of product candidates focused on treating patients in three therapeutic areas: endocrinology, immunology and inflammation, and metabolic diseases.

The Company was incorporated in Delaware in December 2019, under the name GPCR NewCo, Inc. In June 2021, the Company changed its name to Septerna, Inc. The Company is headquartered in South San Francisco, California.

Reverse Stock Split

On October 18, 2024, the Company effected a 1-for-8.6103 reverse stock split of its issued and outstanding shares of common stock. Upon the effectiveness of the reverse stock split, (i) all shares of outstanding common stock were adjusted; (ii) the conversion ratio of the convertible preferred stock was adjusted; (iii) the number of shares of common stock for which each outstanding option to purchase common stock is exercisable were adjusted; and (iv) the exercise price of each outstanding option to purchase common stock was adjusted. All of the outstanding common stock (including shares of common stock subject to the Company’s options and as converted for the outstanding convertible preferred stock), share prices, exercise prices and per share amounts contained in the condensed financial statements have been retroactively adjusted to reflect this reverse stock split for all periods presented. The par value per share and the authorized number of shares of common stock and preferred stock were not adjusted as a result of the reverse stock split. The number of authorized shares did not change.

Initial Public Offering

In October 2024, the Company completed its initial public offering (“IPO”), pursuant to which it issued and sold an aggregate of 18.4 million shares of its common stock at the IPO price of \$18.00 per share, including 2.4 million shares that were issued to the underwriters pursuant to the full exercise of their option to purchase additional shares, resulting in net proceeds of approximately \$302.6 million, after deducting underwriting discounts, commissions and other offering expenses payable by the Company of approximately \$28.6 million. Immediately prior to the closing of the IPO, the Company’s outstanding convertible preferred stock automatically converted into 22,839,774 shares of common stock.

Following the closing of the IPO, no shares of convertible preferred stock were authorized or outstanding. In connection with the completion of the IPO, on October 28, 2024, the Company’s certificate of incorporation was amended and restated to (i) authorize 500.0 million shares of common stock, par value \$0.001 per share, which eliminates all references to the previously existing series of convertible preferred stock; and (ii) authorize 10.0 million shares of undesignated preferred stock, par value \$0.001 per share, that may be issued from time to time by the Company’s board of directors in one or more series.

The Company’s unaudited condensed financial statements as of September 30, 2024, including share and per share amounts, do not give effect to the IPO and related actions as it closed subsequent to September 30, 2024.

Liquidity and Capital Resources

The accompanying unaudited condensed financial statements have been prepared assuming the Company will continue as a going concern, which assumes that the Company will realize its assets and satisfies its liabilities in the normal course of business. The Company is subject to risks inherent in operating an early-stage biotechnology business. These risks include, but are not limited to, dependence on the development of marketable products, the ability to attract, retain, and motivate qualified personnel, rapid technological changes and the rapidly evolving nature of the biotechnology industry.

The Company has incurred significant losses and negative cash flows from operations since its inception and expects to incur losses as a result of its continued research and development activities. To date, none of the Company’s product candidates have been approved by the U.S. Food and Drug Administration (the “FDA”) for commercial sale and, therefore, the Company has not generated any revenue from product sales.

The Company historically financed its operations primarily through the issuances of convertible promissory notes and convertible preferred stock, and most recently, through sale of its common stock in an IPO.

The Company will need additional financing to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through equity offerings, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may not be able to obtain funding on acceptable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders.

For the nine months ended September 30, 2024 and 2023, the Company incurred net losses of \$51.1 million and \$30.7 million, respectively. The Company had an accumulated deficit of \$97.7 million as of September 30, 2024. The Company expects to continue to generate operating losses for the foreseeable future. The Company believes its cash, cash equivalents, marketable securities, and marketable securities, non-current of \$137.5 million as of September 30, 2024, together with the net proceeds of approximately \$302.6 million from its IPO, will be sufficient to fund its operations for, at least, 12 months from the date of issuance of the unaudited condensed financial statements.

Basis of Presentation

The accompanying unaudited interim condensed financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP") for interim financial information and pursuant to Article 10 of Regulation S-X of the Securities Act of 1933, as amended (the "Securities Act"), and reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for the fair presentation of the Company's unaudited interim condensed financial statements as of September 30, 2024 and December 31, 2023, and for the three and nine months ended September 30, 2024 and 2023. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification and Accounting Standards Updates ("ASUs"), of the Financial Accounting Standards Board ("FASB"). The interim condensed financial statements are unaudited. The operating results presented in these unaudited interim condensed financial statements are not necessarily indicative of the results that may be expected for the full year or for any other future annual or interim period. Actual results could differ materially from estimates and assumptions. As appropriate, the Company assesses estimates each period and updates them to reflect current information, and generally reflect any changes in estimates in the period first identified.

These unaudited interim condensed financial statements should be read in conjunction with the Company's audited financial statements for the year ended December 31, 2023 and notes thereto, included in the Company's final IPO prospectus filed with the Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b)(4) under the Securities Act on October 25, 2024.

Significant Accounting Policies

During the nine months ended September 30, 2024, there were no changes to the Company's significant accounting policies as described in Note 2 of the audited financial statements for the year ended December 31, 2023 as referenced above, other than the policies outlined below.

Cash Equivalents and Marketable Securities

The Company holds marketable securities that consist of highly liquid, investment grade debt securities. The Company's cash and marketable securities are held or issued by financial institutions that management believes are of high credit quality. Marketable securities are classified and accounted for as available-for-sale. Available-for-sale marketable securities with original maturities of 90 days or less are classified as cash equivalents. Available-for-sale marketable securities with original maturities over 90 days and remaining maturities of less than 12 months are classified as current. Available-for-sale marketable securities with remaining maturities of more than 12 months for which the Company has the intent and ability to hold the security for more than 12 months are classified as non-current. The Company's marketable securities are carried at estimated fair value, which is derived from independent pricing sources based on quoted prices in active markets for similar securities. Unrealized gains and losses are reported in stockholders' deficit as accumulated other comprehensive income (loss). The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income on the condensed statements of operations and comprehensive loss.

The Company has the ability, if necessary, to liquidate any of its cash equivalents and available-for-sale marketable securities to meet its liquidity needs in the next 12 months. After consideration of the Company's objectives to preserve capital, as well as its liquidity requirements, it may sell these available-for-sale marketable securities prior to their stated maturities.

The Company reviews its portfolio of available-for-sale marketable securities, using both quantitative and qualitative factors, to determine if declines in fair value below amortized cost have resulted from a credit-related loss or other factors. If the decline in fair

value is due to credit-related factors, the Company recognizes a loss in its condensed statement of operations, whereas if the decline in fair value is not due to credit-related factors, the Company recognizes the loss in other comprehensive loss.

The Company excludes the applicable accrued interest from both the fair value and amortized cost basis of available-for-sale marketable securities for purposes of identifying and measuring an impairment. Accrued interest receivable on available-for-sale marketable securities is recorded within prepaid expenses and other current assets on the interim condensed balance sheets. The Company's accounting policy is to not measure an allowance for credit loss for accrued interest receivable and to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which is considered to be in the period in which it is determined the accrued interest will not be collected.

Deferred Offering Costs

The Company's deferred offering costs consist of legal, accounting and other general and administrative costs directly attributable to the Company's IPO. As of September 30, 2024, \$3.2 million of deferred offering costs were included within other non-current assets in the Company's condensed balance sheet. As of December 31, 2023, there were no deferred offering costs. Upon the consummation of the Company's IPO in October 2024, these costs will be reclassified to additional paid-in capital in stockholders' equity in the Company's condensed balance sheets.

Accounting Pronouncements Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB, under its Accounting Standards Codification ("ASC") or other standard setting bodies, and adopted by the Company as of the specified date.

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. ASU 2023-07 will improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses on an interim and annual basis. The ASU is effective for fiscal years beginning after December 15, 2023, and interim periods after December 5, 2024, with early adoption permitted. The Company is currently evaluating the impact of ASU 2023-07 on its financial statements and related disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which enhances the transparency and decision usefulness of income tax disclosures. The standard is intended to improve income tax disclosures primarily related to the rate reconciliation and income taxes paid information. This update also includes certain other amendments to improve the effectiveness of income tax disclosures. The ASU is effective for fiscal years beginning after December 15, 2024, on a prospective basis with early adoption and retrospective reporting permitted. The Company is currently evaluating the impact of ASU 2023-09 on its financial statements and related disclosures.

Note 2. Balance Sheet Components

Restricted Cash

Restricted cash is comprised of cash that is restricted as to withdrawal or use under the terms of certain contractual agreements. In connection with the Company's lease agreement, the Company is required to maintain a collateral account to secure a letter of credit issued to its landlord. The collateral account is classified as restricted cash on the Company's condensed balance sheets.

Accounts Receivable and Other Receivables

The Company assessed if an allowance for expected credit losses over the life of its receivables should be reserved for based on a combination of historical experience, aging analysis, current economic trends and information on specific accounts, with related amounts recorded as a reserve against revenue recognized. The reserve is re-evaluated on a regular basis and adjusted as needed. Once a receivable is deemed to be uncollectible, such balance is charged against the reserve. Based on its assessment, as of September 30, 2024 and December 31, 2023, the Company determined that an allowance for credit loss was not required.

As of September 30, 2024, the Company's accounts receivable was entirely attributed to Vertex Pharmaceuticals Incorporated ("Vertex"). As of December 31, 2023, the Company's accounts receivable and other receivable related to sale of non-financial asset balances were entirely attributed to Vertex.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	<u>As of September 30,</u> <u>2024</u>	<u>As of December 31,</u> <u>2023</u>
Prepaid expenses	\$ 1,152	\$ 874
Prepaid clinical trial costs	679	—
Prepaid bonus	241	378
Prepaid taxes	232	75
Interest receivable	123	—
Other current assets	241	92
Prepaid expenses and other current assets	<u>\$ 2,668</u>	<u>\$ 1,419</u>

Property and Equipment, Net

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

	<u>As of September 30,</u> <u>2024</u>	<u>As of December 31,</u> <u>2023</u>
Lab equipment	\$ 5,613	\$ 4,967
Furniture, fixtures, and office equipment	1,222	713
Leasehold improvements	717	389
Computer equipment	401	218
Total property and equipment	<u>7,953</u>	<u>6,287</u>
Less: Accumulated depreciation and amortization	<u>(2,541)</u>	<u>(1,622)</u>
Property and equipment, net	<u>\$ 5,412</u>	<u>\$ 4,665</u>

Depreciation and amortization expense was \$0.4 million and \$1.0 million for the three and nine months ended September 30, 2024, respectively. Depreciation and amortization expense was \$0.2 million and \$0.6 million for the three and nine months ended September 30, 2023, respectively.

Accrued Expenses and Other Current Liabilities

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

	<u>As of September 30,</u> <u>2024</u>	<u>As of December 31,</u> <u>2023</u>
Accrued compensation expense	\$ 2,109	\$ 2,954
Accrued general and administrative expense	1,845	209
Accrued research and development expense	1,699	829
Accrued income taxes payable	200	200
Other current liabilities	134	85
Accrued expenses and other current liabilities	<u>\$ 5,987</u>	<u>\$ 4,277</u>

Note 3. Revenue

The Company recognizes service revenue associated with the Vertex Research Service Agreement (the “Vertex Research Service Agreement”) over the performance period of the research services as the services are provided in accordance with ASC Topic 606, Revenue from Contracts with Customers (“ASC Topic 606”).

During the three and nine months ended September 30, 2024, the Company recorded service revenue of \$0.2 million and \$0.9 million related to research activities performed in connection with the Vertex Research Service Agreement, respectively. During the three and nine months ended September 30, 2023, service revenue related to research activities performed in connection with the Vertex Research Service Agreement was not material.

Note 4. Available-for-Sale Marketable Securities and Fair Value Measurements

The Company records marketable securities and cash equivalents at their estimated fair values, which are based on market prices from a variety of industry standard data providers and generally represent quoted prices for similar assets in active markets or have been derived from observable market data.

Fair value is determined based on a three-tier hierarchy under the authoritative guidance for fair value measurements and disclosures that prioritizes the inputs used in measuring fair value as follows:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurements and unobservable (i.e., supported by little or no market activity).

The fair value measurements of the Company's cash equivalents and marketable securities are identified at the following levels within the fair value hierarchy (in thousands):

	September 30, 2024			
	Total	Fair Value Measurement		
		Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	\$ 60,991	\$ 60,991	\$ —	\$ —
Commercial paper	20,027	—	20,027	—
U.S. treasury securities	1,689	—	1,689	—
U.S. government agency securities	694	—	694	—
Marketable securities, current:				
U.S. treasury securities	21,722	—	21,722	—
U.S. government agency securities	9,741	—	9,741	—
Commercial paper	9,838	—	9,838	—
Corporate debt securities	990	—	990	—
Marketable securities, non-current:				
U.S. government agency securities	6,022	—	6,022	—
Corporate debt securities	957	—	957	—
Total measured at fair value	\$ 132,671	\$ 60,991	\$ 71,680	\$ —

	December 31, 2023			
	Total	Fair Value Measurement		
		Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	\$ 86,574	\$ 86,574	\$ —	\$ —
Total measured at fair value	\$ 86,574	\$ 86,574	\$ —	\$ —

Available-for-Sale Marketable Securities

As of September 30, 2024, the Company's available-for-sale marketable securities consist of debt securities, including U.S. Treasury and agency securities, corporate debt securities and commercial paper. These available-for-sale marketable securities are carried at fair value and are included in the tables above. The Company records an allowance for credit losses when unrealized losses are due to credit-related factors. At each reporting date, the Company evaluates securities with unrealized losses to determine whether such losses, if any, are due to credit-related factors. The Company evaluates, among others, whether the Company has the intention to sell any of these available-for-sale marketable securities and whether it is not more likely than not that the Company will be required to sell any of them before recovery of the amortized cost basis. Neither of these criteria were met at September 30, 2024. The credit ratings of the securities held remain of the highest quality. Moreover, the Company continues to receive payments of interest and principal as they become due, and the Company's expectation is that those payments will continue to be received timely. Based on this evaluation, as of September 30, 2024, the Company determined that unrealized losses of its available-for-sale marketable securities were primarily attributable to changes in interest rates and non-credit related factors. As such, no allowances for credit losses were recorded at September 30, 2024. The Company did not hold available-for-sale marketable securities at December 31, 2023.

Interest receivable as of September 30, 2024 was \$0.1 million and is recorded as a component of prepaid expenses and other current assets on the Company's condensed balance sheet. The Company did not have interest receivable at December 31, 2023.

As of September 30, 2024, all available-for-sale marketable securities in an unrealized loss position had been in an unrealized loss position for less than 12 months. As of September 30, 2024, the Company held 13 available-for-sale marketable securities which have been in an unrealized loss position for a period of less than 12 months.

As of September 30, 2024, the following table summarizes the amortized cost and the unrealized gains (losses) of the available-for-sale marketable securities presented within marketable securities, marketable securities, non-current and cash equivalents (in thousands):

	Remaining Contractual Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Estimated Fair Value
Corporate securities	Less than 1	\$ 987	\$ 3	\$ —	\$ 990
Commercial paper	Less than 1	29,851	16	(2)	29,865
U.S. treasury securities	Less than 1	23,397	14	—	23,411
U.S. government agency securities	Less than 1	10,406	30	(1)	10,435
Total maturity less than 1 year		64,641	63	(3)	64,701
Corporate debt securities	1 to 2	942	15	—	957
U.S. government agency securities	1 to 2	5,921	101	—	6,022
Total		\$ 71,504	\$ 179	\$ (3)	\$ 71,680

As of September 30, 2024, the following table summarizes available-for-sale marketable securities in an unrealized loss position (in thousands):

	Less than 12 Months	
	Fair Value	Gross Unrealized Loss
Commercial paper	\$ 16,100	\$ (2)
U.S. treasury securities	5,023	—
U.S. government agency securities	1,592	(1)
Total	\$ 22,715	\$ (3)

Note 5. Commitments and Contingencies

Leases

During the three months ended September 30, 2024, the Company recorded a \$12.5 million operating lease right-of-use asset and operating lease liability upon completion of the renovations of the 21,908 square foot office and research and development space (the "Original Leased Space") and as the Company occupied the property.

As of September 30, 2024, the remaining lease term of the Original Leased Space was approximately 7.8 years. The incremental borrowing rate used for the calculation of the present value of lease payments over the lease term at the lease commencement date was approximately 10.44%.

As of September 30, 2024, future minimum rental payments for operating leases, including for the Original Leased Space, were as follows (in thousands):

As of September 30,	Future Payments
2024 (remaining three months)	\$ 437
2025	4,469
2026	4,612
2027	4,760
2028	4,912
Thereafter	18,921
Total lease payments	38,111
Less: imputed interest	(12,885)
Total present value of operating lease liability	\$ 25,226
Operating lease liability, current	\$ 1,116
Operating lease liability, non-current	24,110
Total operating lease liability	\$ 25,226

Legal Proceedings

In the ordinary course of business, the Company may be subject to legal proceedings, claims and litigation, as the Company operates in an industry susceptible to patent or other legal claims. The Company accounts for estimated losses with respect to legal proceedings and claims when such losses are probable and estimable. Legal costs associated with these matters are expensed when incurred. The Company was not subject to any material legal proceedings as of September 30, 2024 and December 31, 2023, and the Company is not currently a party to any legal proceeding that, if determined adversely to the Company, in management's opinion, is currently expected to individually or in the aggregate have a material adverse effect on the Company's business, financial condition or results of operations taken as a whole.

Indemnifications

In the ordinary course of business, the Company enters into agreements that may include indemnification provisions. As permitted under Delaware law and in accordance with its bylaws, the Company indemnifies its officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. The Company is also party to indemnification agreements with its officers and directors.

The maximum potential amount of future payments that the Company could be required to make under these provisions is not determinable; however, the Company currently holds director and officer liability insurance. This insurance limits the Company's exposure and may enable it to recover a portion of any future amounts paid. The Company believes that the fair value of these indemnification obligations is minimal. In addition, the Company is not currently aware of any indemnification claims. Accordingly, the Company did not record any liabilities associated with these indemnification rights and agreements as of September 30, 2024 and December 31, 2023.

Note 6. Convertible Preferred Stock

Immediately prior to the closing of the Company's IPO in October 2024, the Company's outstanding convertible preferred stock automatically converted into 22,839,774 shares of common stock. Converted preferred stock outstanding as of the date of the IPO consisted of 196,657,452 shares. Each share of outstanding convertible preferred stock was converted into 8.6103 shares of common stock.

As of September 30, 2024, the Company's convertible preferred stock consisted of the following (in thousands, except for share and per share amounts):

Series	Authorized Shares	Issued and Outstanding	Carrying Value	Liquidation Preference	Conversion Price Per Share
Series A	75,000,000	75,000,000	\$ 74,694	\$ 75,000	\$ 1.00000
Series B	121,657,452	121,657,452	149,463	150,000	1.23297

As of December 31, 2023, the Company's convertible preferred stock consisted of the following (in thousands, except for share and per share amounts):

Series	Authorized Shares	Issued and Outstanding	Carrying Value	Liquidation Preference	Conversion Price Per Share
Series A	75,000,000	75,000,000	\$ 74,694	\$ 75,000	\$ 1.00000
Series B	121,657,452	60,828,720	74,521	75,000	1.23297

In June 2023 and July 2023, the Company issued 58.8 million and 2.0 million, respectively, shares of Series B Convertible Preferred Stock at an issuance price of \$1.23297 per share for total net proceeds of \$74.5 million under the first tranche.

In May 2024, the Company executed the second tranche of the Series B Convertible Preferred Stock financing arrangement and issued the remaining 60.8 million shares of Series B Convertible Preferred Stock for net proceeds of \$74.9 million.

Note 7. Common Stock

As of September 30, 2024, the Company was authorized to issue 260,590,689 shares of common stock, par value \$0.001 per share. As of December 31, 2023, the Company was authorized to issue 260,590,689 shares of common stock, par value \$0.001 per share.

In September 2024, the Company amended the 2021 Stock Option and Grant Plan, as amended ("2021 Plan") to, among other things, increase the shares reserved for issuance under the 2021 Plan to 5,403,314 shares.

On October 28, 2024, the Company amended and restated its certificate of incorporation, which was filed immediately prior to the closing of its IPO and among other things, increased the number of shares of common stock authorized for issuance to 500.0 million shares of common stock.

In October 2024, the Company completed its IPO of its common stock. In connection with the Company's IPO, the Company issued and sold 18.4 million shares of its common stock, which included an additional 2.4 million shares of common stock that were issued to the underwriters pursuant to the full exercise of their option to purchase additional shares of common stock, at the public offering price of \$18.00 per share. As a result, the Company received approximately \$302.6 million in net proceeds, after deducting underwriting discounts and commissions and other offering costs payable by the Company of approximately \$28.6 million.

The Company reserved the following shares of common stock, on an as-converted basis, for future issuance:

	As of September 30, 2024	As of December 31, 2023
Series A Convertible Preferred Stock	8,710,490	8,710,490
Series B Convertible Preferred Stock	14,129,284	14,129,284
Restricted stock outstanding under 2021 Plan	508,433	774,225
Restricted stock outstanding outside of 2021 Plan	170,803	227,819
Options issued and outstanding under 2021 Plan	3,018,073	1,123,296
Shares reserved for future grants under 2021 Plan	906,277	1,634,488
	<u>27,443,360</u>	<u>26,599,602</u>

Note 8. Stock-Based Compensation

Executive Officer and Director Equity Awards Modification

In May 2024, the Company's board of directors modified the terms of stock option awards for 1.3 million shares of the Company's common stock and restricted stock awards for 0.9 million shares of the Company's common stock to certain executive officers and members of the Company's board of directors. Under the modified terms, accelerated vesting provisions were added associated with certain change of control events. No incremental stock-based compensation expense was recognized as a result of the modification.

Restricted Stock Awards

The following summarizes restricted stock award activity under the 2021 Plan:

	Number of Shares Outstanding	Weighted- Average Grant Date Fair Value Per Share
Balance at December 31, 2023	774,225	\$ 2.32
Restricted stock awards vested	(251,493)	2.54
Restricted stock awards repurchased	(14,299)	2.31
Balance at September 30, 2024	<u>508,433</u>	2.27

The following summarizes restricted stock award activity outside of the 2021 Plan:

	Number of Shares Outstanding	Weighted- Average Grant Date Fair Value Per Share
Balance at December 31, 2023	227,819	\$ 3.79
Restricted stock awards vested	(57,016)	3.77
Balance at September 30, 2024	<u>170,803</u>	3.75

Restricted stock awards of 679,236 and 1,002,044 shares were subject to repurchase as of September 30, 2024 and December 31, 2023, respectively. The total fair value of shares vested during the three and nine months ended September 30, 2024 was \$0.3 million and \$0.9 million, respectively.

Stock Options

The following summarizes stock option activity under the 2021 Plan:

	Options Outstanding			
	Total Options Outstanding	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2023	1,123,296	\$ 2.62	9.78	\$ 2,287
Granted	1,925,905	5.35		
Exercised	(9,133)	1.76		
Forfeited	(21,850)	2.02		
Expired	(145)	2.76		
Outstanding as of September 30, 2024	<u>3,018,073</u>	4.37	9.52	19,840
Exercisable as of September 30, 2024	<u>385,048</u>	2.60	9.09	3,212
Vested and expected to vest as of September 30, 2024	<u>3,018,073</u>	4.37	9.52	19,840

The aggregate fair value of stock options that vested for the three and nine months ended September 30, 2024 was \$0.4 million and \$0.9 million. The stock options granted in the three months ended September 30, 2024 had a weighted-average grant-date fair value per share of \$8.54 and a total grant-date fair value of \$10.5 million. The options granted in the nine months ended September 30, 2024 had a weighted-average grant-date fair value per share of \$6.46 and a total grant date fair value of \$12.4 million.

During the three and nine months ended September 30, 2024, the Company granted a total of 1.2 million and 1.9 million shares of stock options to its employees, respectively. A total of 0.6 million of the stock options granted in the three and nine months ended September 30, 2024 include vesting criteria subject to both service conditions and the achievement of performance-based conditions, related to the consummation of the Company's IPO or a Sale Event, while the remainder include vesting criteria subject to service conditions only. A total of 0.7 million of the stock options granted in the three and nine months ended September 30, 2024 also include accelerated vesting provisions associated with certain change of control events.

Stock Option Valuation

The weighted-average assumptions used to value employee and non-employee stock option awards granted under the 2021 Plan using the Black Scholes option pricing model, were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Fair value of common stock	\$ 8.54	—	\$ 6.46	\$ 2.74
Risk-free interest rate	3.59%	—	3.83%	3.58%
Expected volatility	90.7%	—	91.2%	80.6%
Expected term (years)	6.05	—	6.03	6.00
Expected dividend yield	—%	—	—%	—%

There were no stock options granted during the three months ended September 30, 2023.

Stock-based Compensation Expense

Stock-based compensation expense for restricted stock awards and stock options recognized in the Company's condensed statements of operations and comprehensive loss is presented as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development expense	\$ 356	\$ 203	\$ 968	\$ 612
General and administrative expense	327	144	920	433
Total stock-based compensation expense	\$ 683	\$ 347	\$ 1,888	\$ 1,045

As of September 30, 2024, total unrecognized stock-based compensation expense related to unvested restricted stock awards and unvested stock options was \$10.2 million, which is expected to be recognized over a weighted-average period of 3.0 years.

As of September 30, 2024, total unrecognized stock-based compensation expense related to unvested restricted stock awards and unvested stock options subject to performance conditions, which were improbable of achievement, was \$0.3 million and \$5.5 million, respectively.

Note 9. Related Parties

Third Rock Ventures

During the nine months ended September 30, 2024, the Company issued a total of 12.4 million shares of its Series B Convertible Preferred Stock to Third Rock Ventures VI, L.P., a holder of more than 5% of the Company's outstanding capital stock, during the second tranche closing in May 2024, for cash proceeds of \$15.3 million.

During the nine months ended September 30, 2023, the Company issued a total of 12.4 million shares of its Series B Convertible Preferred Stock to Third Rock Ventures V, L.P., a holder of more than 5% of the Company's outstanding capital stock, during the first tranche closing in June 2023, for cash proceeds of \$15.2 million.

In August 2021, the Company entered into a service agreement with Third Rock Ventures, LLC ("TRV"), a holder of more than 5% of the Company's outstanding capital stock, (the "TRV service agreement") under which TRV provides consulting services to the Company. For the three and nine months ended September 30, 2024, under the TRV service agreement, the Company incurred fees of \$0.1 million and \$0.2 million, respectively, which were recorded within general and administrative expenses in the Company's condensed statements of operations and comprehensive loss. For the three and nine months ended September 30, 2023, under the TRV service agreement, the Company incurred fees of \$0.1 million and \$0.2 million, respectively, which were recorded within general and administrative expenses in the Company's condensed statements of operations and comprehensive loss. As of December 31, 2023 and September 30, 2024, outstanding accounts payable to TRV was \$0.1 million.

For the three and nine months ended September 30, 2024, of the total fees under the TRV service agreement, \$0.1 million and \$0.2 million, respectively, were attributed to the Company's interim Chief Medical Officer. For the three and nine months ended September 30, 2023, of the total fees under the TRV service agreement, \$0.1 million and \$0.2 million, respectively, were attributed to the Company's interim Chief Medical Officer. Additionally, the Company granted its interim Chief Medical Officer options to purchase 23,227 shares during the nine months ended September 30, 2024, at exercise prices of \$2.76 per share.

RA Capital

During the nine months ended September 30, 2024, the Company issued a total of 12.2 million shares of its Series B Convertible Preferred Stock to entities affiliated with RA Capital Management, L.P. (collectively, "RA Capital"), which held more than 5% of the Company's outstanding capital stock, during the second tranche closing in May 2024, for total cash proceeds of \$15.0 million. During the nine months ended September 30, 2023, the Company issued a total of 12.2 million shares of its Series B Convertible Preferred Stock to RA Capital during the first tranche closing in June 2023, for total cash proceeds of \$15.0 million.

Samsara BioCapital

During the nine months ended September 30, 2024, the Company issued a total of 4.3 million shares of its Series B Convertible Preferred Stock to Samsara BioCapital, L.P. ("Samsara BioCapital"), a holder of more than 5% of the Company's outstanding capital stock, during the second tranche closing in May 2024, for cash proceeds of \$5.2 million. During the nine months ended September 30, 2023, the Company issued a total of 4.3 million shares of its Series B Convertible Preferred Stock to Samsara BioCapital during the first tranche closing in June 2023, for cash proceeds of \$5.2 million.

Note 10. Net Loss Per Share

For all periods presented, diluted net loss per share is the same as basic net loss per share since the effect of including potential common shares is anti-dilutive. Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive were as follows (in common stock equivalent shares):

	<u>As of September 30,</u> <u>2024</u>	<u>As of September 30,</u> <u>2023</u>
Outstanding stock options	2,380,470	131,812
Unvested restricted stock subject to repurchase	605,879	1,039,033
Total antidilutive securities	<u>2,986,349</u>	<u>1,170,845</u>

Note 11. Subsequent Events

2024 Plan

In October 2024, the Company's board of directors adopted, and its stockholders approved, the 2024 Option and Incentive Plan (the "2024 Plan"), which became effective upon the date immediately preceding the date on which the IPO registration statement was declared effective by the SEC. The 2024 Plan allows for the issuance of equity-based and cash-based incentive awards to the Company's officers, employees, directors and consultants. The 2024 Plan is administered by the Company's compensation committee. The exercise prices, vesting and other restrictions are determined at the discretion of the compensation committee, subject to the provisions of the 2024 Plan.

The Company initially reserved for issuance under the 2024 Plan 3,690,000 shares of its common stock. The 2024 Plan provides that the number of shares reserved and available for issuance under the 2024 Plan will automatically increase on January 1, 2025 and each January 1 thereafter through January 1, 2034, by 5% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Company's compensation committee.

The number of shares reserved under the 2024 Plan is subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization. The 2024 Plan replaced the 2021 Plan as the Company's board of directors determined not to make additional awards under the 2021 Plan following the completion of the IPO. However, the 2021 Plan will continue to govern outstanding equity awards granted thereunder. The shares of common stock underlying any awards under the 2024 Plan and the 2021 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by the Company prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) will be added to the shares of the Company's common stock available for issuance under the 2024 Plan.

2024 ESPP

In October 2024, the Company's board of directors adopted, and its stockholders approved, the 2024 Employee Stock Purchase Plan (the "2024 ESPP"), which became effective upon the date immediately preceding the date on which the IPO registration statement was declared effective by the SEC. The 2024 ESPP initially reserved and authorized the issuance of up to a total of 369,402 shares of the Company's common stock to participating employees. The 2024 ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1, 2026 and each January 1 thereafter through January 1, 2034, by the lesser of (i) 369,402 shares of common stock, (ii) 1% of the outstanding number of shares of common stock on the immediately preceding December

31, or (iii) such lesser number of shares of common stock as determined by the administrator of the 2024 ESPP. The number of shares reserved under the 2024 ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in the Company's capitalization.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited interim condensed financial statements and related notes included elsewhere in this Quarterly Report and with our audited financial statements and the notes thereto for the year ended December 31, 2023 included in our final prospectus (the "IPO Prospectus") filed with the SEC pursuant to Rule 424(b) under the Securities Act on October 25, 2024. This discussion and other parts of this Quarterly Report contain forward-looking statements based upon current beliefs, plans, and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements of our plans, objectives, expectations, intentions, forecasts and projections. Our actual results and the timing of selected events could differ materially from those discussed in these forward-looking statements as a result of several factors including, but not limited to, those set forth under the section titled "Risk Factors" and elsewhere in this Quarterly Report. Our historical results are not necessarily indicative of the results that may be expected for any period in the future, and you should carefully read the section titled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biotechnology company pioneering a new era of G protein-coupled receptor ("GPCR") oral small molecule drug discovery powered by our proprietary Native Complex Platform™. Our industrial-scale platform aims to unlock the full potential of GPCR therapies and has led to the discovery and development of our deep pipeline of product candidates focused initially on treating patients in three therapeutic areas: endocrinology, immunology and inflammation, and metabolic diseases. We intend to evaluate opportunities in other major therapeutic areas, such as neurology, women’s health, cardiovascular, and respiratory disease.

Our proprietary Native Complex Platform™ replicates the natural structure, function, and dynamics of GPCRs outside of cells at an industrial scale for, as we believe it, the first time. Our foundational technologies enable us to isolate, purify, and reconstitute full-length, properly folded GPCR proteins within ternary complexes with ligands and transducer proteins in a lipid bilayer that mimics the cell membrane. We then apply state-of-the-art discovery tools and technologies to these defined and tunable protein complexes to structurally design, screen for, and optimize potential product candidates. Leveraging our platform, we conduct GPCR oral small molecule drug discovery using an industrialized and iterative structure-based drug design approach for a diverse collection of GPCR targets. Our Native Complex Platform™ is designed to enable us to target specific GPCRs, uncover novel binding pockets for validated receptors, and pursue a wide spectrum of pharmacologies, including agonists (which activate GPCR signaling), antagonists (which inhibit GPCR signaling), and allosteric modulators (which either increase or decrease the degree of GPCR activation by endogenous ligands), to affect GPCR signaling in different ways to achieve desired therapeutic effects.

We are advancing a deep portfolio of oral small molecule GPCR-targeted programs with novel mechanistic approaches to treat diseases across multiple therapeutic areas for patients with significant unmet needs. Our wholly-owned pipeline is summarized in the figure below.

Program		Development Status				
Program / Target Mode of Action	Therapeutic Area Indications	Discovery	IND-enabling	Phase 1	Phase 2	Phase 3
SEP-786 (PTH1R) Agonist	Endocrinology Hypoparathyroidism	→				
SEP-631 (MRGPRX2) Negative Allosteric Modulator	Immunology and Inflammation CSU and other mast cell diseases	→				
TSHR Negative Allosteric Modulator	Endocrinology Graves' Disease and Thyroid Eye Disease	→				
GLP-1R, GIPR, GCGR Single- and Multi-Agonists	Metabolic Diseases Obesity, T2D and other metabolic diseases	→				

PTH1R = Parathyroid Hormone 1 Receptor MRGPRX2 = MAS-Related G Protein-Coupled Receptor X2 GIPR = Gastric Inhibitory Polypeptide Receptor
 TSHR = Thyroid-Stimulating Hormone Receptor GLP-1R = Glucagon-Like Peptide 1 Receptor GCGR = Glucagon Receptor

We are developing our lead product candidate, SEP-786, an oral small molecule agonist targeting the Parathyroid Hormone 1 Receptor ("PTH1R") for the treatment of hypoparathyroidism. Leveraging our team, scientific and technical advisors, and our

proprietary Native Complex Platform™, we aim to be a leader in the development of oral GPCR-targeted medicines for patients with significant unmet needs.

We were incorporated in Delaware in December 2019 under the name GPCR NewCo, Inc. In June 2021, we changed our name to Septerna, Inc. We are headquartered in South San Francisco, California.

We have incurred significant operating losses since our inception, except for the year ended December 31, 2023, when we recorded net income of \$4.2 million. Our revenue to date has been generated solely from research services. Since our founding, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, developing our proprietary and structure-based drug discovery platform, identifying and discovering our product candidates, establishing our intellectual property portfolio, conducting research and preclinical studies, including IND-enabling studies, initiating and conducting clinical trials, establishing arrangements with third parties for the manufacture of our product candidates and related raw materials, and providing general and administrative support for these operations. We have not had any products approved for sale and have not generated any revenue from product sales. Further, we do not expect to generate revenue from commercial product sales until such time, if ever, that we are able to successfully complete the development and obtain marketing approval for one or more of our product candidates. Our ability to generate product revenue will depend on the successful development and eventual commercialization of one or more of our product candidates.

We have incurred net losses in each year since inception, except for the year ended December 31, 2023. During the year ended December 31, 2023, we recorded a gain on sale of non-financial asset of \$47.6 million for the sale of an in-progress research and development (“IPR&D”) asset related to a GPCR program and \$0.2 million in revenue related to research services resulting in net income of \$4.2 million for the year then-ended. Of the \$47.6 million gain on sale of non-financial asset, \$25.0 million was received in cash in September 2023 and the remaining \$22.6 million during the nine months ended September 30, 2024. Our net losses were \$20.5 million and \$51.1 million for the three and nine months ended September 30, 2024, respectively. Our net losses were \$10.9 million and \$30.7 million for the three and nine months ended September 30, 2023, respectively. As of September 30, 2024, we had an accumulated deficit of \$97.7 million. We expect to continue to incur net losses for the foreseeable future. Our net losses may fluctuate significantly from period to period, depending on the timing and expenditures of our operational activities.

We expect to continue to incur significant and increasing net operating losses for the next several years as we:

- continue to advance our product candidates through preclinical studies and into clinical trials;
- attract, hire and retain additional personnel;
- operate as a public company, including expenses related to compliance with the rules and regulations of the SEC and those of any national securities exchange on which our securities are traded, legal, auditing, additional insurance expenses, investor relations activities, and other administrative and professional services;
- continue our research and development efforts and expand our pipeline of product candidates;
- acquire, discover, validate, and develop additional product candidates;
- require the manufacture of supplies for our preclinical studies and clinical trials;
- obtain, maintain, expand, and protect our intellectual property portfolio;
- implement operational, financial and information management systems;
- make royalty, milestone or other payments under any future, license or collaboration agreements;
- potentially seek to identify, assess, acquire, or in-license or develop new technologies or additional product candidates;
- potentially experience any delays, challenges, or other issues associated with the clinical development of our product candidates, including with respect to our regulatory strategies;
- pursue regulatory approval of product candidates that successfully complete clinical trials; and
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval and related commercial manufacturing build-out.

Our net losses may fluctuate significantly from period to period, depending upon the timing of our expenditures on research and development activities. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses and other current liabilities, which includes accrued research and development, in the statements of cash flows in our audited and unaudited interim condensed financial statements included elsewhere in this Quarterly Report.

As a result, we will require substantial additional funding to further develop our product candidates and support our continuing operations. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect existing stockholders' rights as common stockholders. Debt 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 collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate 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.

We historically financed our operations primarily through the issuances of convertible promissory notes and convertible preferred stock, and, most recently, through an initial public offering ("IPO"). In October 2024, we completed our IPO, pursuant to which we issued and sold an aggregate of 18.4 million shares of our common stock (inclusive of and additional 2.4 million shares of our common stock issued and sold pursuant to the underwriters' exercise of their option to purchase additional shares in full). The aggregate net proceeds received by us from the IPO was approximately \$302.6 million, after deducting underwriting discounts and commissions, and other offering costs payable by us of approximately \$28.6 million.

Since our inception, we have devoted substantially all of our resources to raising capital, organizing and staffing our company, business and scientific planning, conducting discovery and research and development activities, establishing and protecting our intellectual property portfolio, developing and progressing our product candidates and preparing for clinical trials, establishing arrangements with third parties for the manufacture of our product candidates and component materials, engaging in collaboration activities, and providing general and administrative support for these operations.

We believe our cash, cash equivalents, and marketable securities of \$137.5 million, together with approximately \$302.6 million of net proceeds from our IPO, will be sufficient to fund our operations and capital expenditure requirements into the second half of 2027. See the subsection titled "—Liquidity and Capital Resources" below.

We use contract research and development organizations to conduct our preclinical works and clinical trials. Additionally, we utilize third-party CMOs, to manufacture and supply our preclinical and clinical materials during the development of our product candidates. We expect to use similar contract resources for the commercialization of our products, at least until our resources and operations are at a scale that justifies investment in internal manufacturing capabilities.

Vertex Asset Purchase and Service Agreements

Asset Purchase Agreement

In September 2023, we entered into an asset purchase agreement with Vertex Pharmaceuticals Incorporated ("Vertex") for a total of \$47.6 million under which Vertex acquired all of our IPR&D asset related to a GPCR program, including all intellectual property, materials, and compounds associated with the program ("Vertex purchase agreement"). Of the \$47.6 million, \$25.0 million was received in cash in September 2023 and \$22.6 million was received during the nine months ended September 30, 2024. Additionally, as part of the agreement, Vertex assumed all claims, counterclaims and credits associated with the program, and we gave up all rights to the intellectual property. The transfer of the IPR&D asset to Vertex was completed in November 2023.

At the same time in September 2023, we entered into a research service agreement with Vertex under which we agreed to perform certain exploratory research activities for Vertex. See the subsection titled "—Service Agreement" below.

The Vertex purchase agreement also provides for a potential milestone payment payable to us contingent upon achievement of a certain research milestone. The milestone payment amount is determined based on the timing of achievement of the research milestone. The variable consideration related to this milestone payment was determined to be improbable of receipt at this time. As a result, the

milestone payment was excluded from the transaction price. After the potential milestone payment, we will not receive any other payments or future royalties related to this IPR&D asset.

Service Agreement

In addition to the Vertex purchase agreement, we also entered into a research service agreement with Vertex (“Vertex service agreement”) under which we agreed to perform certain exploratory research activities for Vertex. The Vertex service agreement is for a two-year term, however, Vertex has the ability to terminate the agreement with a 30-day notice at any time. As a result, we concluded that the contract duration is 30 days, representing a month-to-month service contract. We recognize revenue associated with the Vertex service agreement over the performance period of the research services as the services are provided.

Components of Results of Operations

Revenue

We have not generated any revenue from product sales and do not expect to do so in the foreseeable future. Our ability to generate product revenue, if ever, will depend on the successful development and eventual commercialization of any product candidates that we identify. If we fail to complete the development of any future product candidates in a timely manner or to obtain regulatory approval for such product candidates, our ability to generate future revenue and our results of operations and financial position would be materially adversely affected. Our revenues to date have been exclusively related to research services. We recognize revenue as specified research services are performed and the results of the research and development services are provided to the customer.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development

Research and development expenses account for the largest component of our total operating expenses. Research and development expenses consist primarily of direct and unallocated costs incurred for the research and development of our product candidates.

Our research and development expenses consist of:

- direct costs, including:
 - external research and development costs related to (i) the production of preclinical materials, including fees and milestones paid to contract manufacturers and (ii) agreements with contract development organizations, consultants and other third-party contract organizations to conduct our preclinical studies and other research and development activities on our behalf;
 - external costs to conduct clinical trials, including costs paid to CROs, the production of clinical materials and fees paid to contract manufacturers; and
 - costs incurred in connection with laboratory operations, materials and supplies, and other preclinical studies.
- unallocated costs, including:
 - employee-related costs, including salaries, benefits and stock-based compensation for employees engaged in research and development activities;
 - external research and development costs, including contract research and development and professional service fees for consulting and related services;
 - facility-related and office costs, including lease/rent, building-related expenses, facility-related overhead, and depreciation expense; and
 - other costs, including expenses related to our funded, sponsored research activities and technology licenses, laboratory operations, information technology (“IT”)-related expenses.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

A significant portion of our research and development costs have been external costs, which we track by stage of development. However, we do not track our unallocated costs on a program specific basis because these costs are deployed across multiple projects and, as such, are not separately classified.

At this time, we cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. We expect that our research and development expenses will increase substantially in absolute dollars for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, as our product candidates advance into later stages of development, as we begin to conduct clinical trials, as we seek regulatory approvals for any product candidates that successfully complete clinical trials, and as we incur expenses associated with hiring additional personnel to support our research and development efforts. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. This is due to the numerous risks and uncertainties associated with developing product candidates, many of which are outside of our control, including the uncertainty of:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- establishing an appropriate safety profile with IND-enabling studies;
- the number of sites and patients included in the clinical trials;
- the countries in which the clinical trials are conducted;
- per patient trial costs;
- successful patient enrollment in, and the initiation of, clinical trials, as well as drop out or discontinuation rates;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the U.S. Food and Drug Administration (the "FDA"), European Medicines Agency ("EMA"), or any other comparable foreign regulatory authorities;
- the number of trials required for regulatory approval;
- the timing, receipt and terms of any regulatory approvals from applicable regulatory authorities;
- our ability to establish collaboration arrangements;
- the performance of any future collaborators;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- significant and changing government regulation and regulatory guidance;
- the impact of any business interruptions to our operations or to those of the third parties with whom we work;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- launching commercial sales of our product candidates, if approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of the product candidates following approval.

Any changes in the outcome of any of these variables could mean a significant change in the costs and timing associated with the development of our product candidates. For example, if the FDA, EMA or any other comparable foreign regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development. We may never obtain regulatory approval for any of our product candidates.

General and Administrative

General and administrative expenses consist primarily of personnel-related costs, costs related to maintenance and filing of intellectual property, legal fees related to corporate matters, professional fees paid for accounting, auditing, consulting, tax and investor relations services, insurance costs, general corporate expenses, and IT-related and facility-related costs not otherwise included in research and development expenses. Personnel-related costs include salaries, benefits, and stock-based compensation for our personnel in executive, legal, finance and accounting, human resources, and other administrative functions.

We expect that our general and administrative expenses will increase substantially in absolute dollars for the foreseeable future as we continue to increase our headcount to support our business growth. We also anticipate that we will incur increased expenses as a result of our operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and expenses related to audit, legal, regulatory services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs.

Other Income, Net

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and marketable securities during the period.

Other Expense, Net

Other expense, net consists primarily of changes in the fair value of our cash equivalents held in money market funds and loss on disposal of our fixed assets.

Benefit for Income Taxes

We are subject to corporate United States federal and state income taxation. Our provision (benefit) for income taxes are recorded in accordance with Accounting Standard Codification (“ASC”) 740, *Accounting for Income Taxes*, which provides for deferred taxes using an asset and liability approach. We establish a valuation allowance against all of our net deferred tax assets. We consider all available evidence, both positive and negative, including but not limited to our historical operating results, income or loss in recent periods, cumulative losses in recent years, forecasted earnings (losses), future taxable income (loss), and significant risk and uncertainty related to forecasts, and concluded the deferred tax assets are not more likely than not to be realized.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

Our results of operations for each of the periods indicated are summarized in the table below (in thousands):

	Three Months Ended September 30,		Change
	2024	2023	
Revenue	\$ 176	\$ 33	\$ 143
Operating expenses:			
Research and development	17,832	9,281	8,551
General and administrative	4,894	2,792	2,102
Total operating expenses	22,726	12,073	10,653
Loss from operations	(22,550)	(12,040)	(10,510)
Other income, net:			
Interest income	1,900	1,096	804
Other expense, net	(9)	(1)	(8)
Total other income, net	1,891	1,095	796
Loss before benefit for income taxes	(20,659)	(10,945)	(9,714)
Benefit for income taxes	136	—	136
Net loss	\$ (20,523)	\$ (10,945)	\$ (9,578)

Revenue

Our service revenue of \$0.2 million for the three months ended September 30, 2024 was generated from research activities performed for Vertex in connection with the Vertex service agreement. Our service revenue related to research activities for Vertex in connection with the Vertex service agreement for the three months ended September 30, 2023 was not material.

Operating Expenses

Research and Development

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

	Three Months Ended September 30,		Change
	2024	2023	
Direct costs:			
SEP-786 (PTH1R)	\$ 3,560	\$ 1,043	\$ 2,517
SEP-631 (MRGPRX2)	550	651	(101)
TSHR	381	368	13
Other programs	1,140	587	553
Unallocated costs:			
Employee-related costs	4,227	3,289	938
External research and development costs	4,763	1,335	3,428
Facility-related and office costs	1,841	784	1,057
Other costs	1,370	1,224	146
Total research and development expense	\$ 17,832	\$ 9,281	\$ 8,551

Research and development expenses were \$17.8 million and \$9.3 million for the three months ended September 30, 2024 and 2023, respectively. The increase of \$8.6 million was primarily due to (i) \$3.4 million of higher expenses attributable to external research and development costs, including \$0.8 million of expenses associated with our clinical trial, (ii) \$3.0 million of higher direct costs attributable to our preclinical programs, (iii) \$1.1 million of higher facility-related and office costs as we expanded our office space to accommodate higher occupancy and larger operational activities, and (iv) \$0.9 million of higher employee-related costs as a result of increased headcount.

General and Administrative

General and administrative expenses were \$4.9 million and \$2.8 million for the three months ended September 30, 2024 and 2023, respectively. The increase of \$2.1 million was primarily due to (i) \$1.1 million of higher consulting, audit and accounting-related fees mainly attributable to costs associated with our preparation of becoming a public company, (ii) \$0.6 million of higher employee-related costs as a result of increased headcount, (iii) \$0.2 million increase in corporate development expenses primarily attributable to increased public and investor relations costs for our preparation of becoming a public company and (iv) \$0.2 million of higher facility-related and office costs as we expanded our office space to accommodate higher occupancy and larger operational activities.

Other Income, Net

Interest Income

Interest income was \$1.9 million and \$1.1 million for the three months ended September 30, 2024 and 2023, respectively. The increase was due to higher interest rates and higher balances of invested cash in cash equivalents and marketable securities.

Benefit for Income Taxes

We recognized \$0.1 million of benefit for income taxes for the three months ended September 30, 2024. We did not record any benefit or provision for income taxes for the three months ended September 30, 2023.

Nine Months Ended September 30, 2024 and 2023

Our results of operations for each of the periods indicated are summarized in the table below (in thousands):

	Nine Months Ended September 30,		Change
	2024	2023	
Revenue	\$ 863	\$ 33	\$ 830
Operating expenses:			
Research and development	46,020	25,653	20,367
General and administrative	10,948	6,622	4,326
Total operating expenses	56,968	32,275	24,693
Loss from operations	(56,105)	(32,242)	(23,863)
Other income, net:			
Interest income	4,709	1,531	3,178
Other expense, net	(72)	(3)	(69)
Total other income, net	4,637	1,528	3,109
Loss before benefit for income taxes	(51,468)	(30,714)	(20,754)
Benefit for income taxes	338	—	338
Net loss	\$ (51,130)	\$ (30,714)	\$ (20,416)

Revenue

Our service revenue of \$0.9 million for the nine months ended September 30, 2024 was generated from research activities performed for Vertex in connection with the Vertex service agreement. Our service revenue related to research activities for Vertex in connection with the Vertex service agreement for the nine months ended September 30, 2023 was not material.

Operating Expenses

Research and Development

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

	Nine Months Ended September 30,		Change
	2024	2023	
Direct costs:			
SEP-786 (PTH1R)	\$ 8,306	\$ 3,169	\$ 5,137
SEP-631 (MRGPRX2)	1,424	1,652	(228)
TSHR	1,175	1,482	(307)
Other programs	2,499	1,503	996
Unallocated costs:			
Employee-related costs	12,203	8,860	3,343
External research and development costs	11,222	2,713	8,509
Facility-related and office costs	4,276	2,302	1,974
Other costs	4,915	3,972	943
Total research and development expense	<u>\$ 46,020</u>	<u>\$ 25,653</u>	<u>\$ 20,367</u>

Research and development expense was \$46.0 million and \$25.7 million for the nine months ended September 30, 2024 and 2023, respectively. The increase of \$20.4 million was primarily due to (i) \$8.5 million of higher expenses attributable to external research and development costs, including \$1.0 million of expenses associated with our clinical trial, (ii) \$5.6 million of higher direct costs mainly attributable to our preclinical programs, (iii) \$3.3 million of higher employee-related costs as a result of increased headcount, and (iv) \$2.0 million of higher facility-related and office costs as we expanded our office space to accommodate higher occupancy and larger operational activities.

General and Administrative

General and administrative expenses were \$10.9 million and \$6.6 million for the nine months ended September 30, 2024 and 2023, respectively. The increase of \$4.3 million was primarily due to (i) \$1.6 million of higher consulting, audit and accounting-related fees, and \$0.5 million higher legal fees, mainly attributable to costs associated with our preparation of becoming a public company, (ii) \$1.4 million of higher employee-related costs as a result of increased headcount, (iii) \$0.4 million increase in corporate development expenses primarily attributable to increased public and investor relations costs for our preparation of becoming a public company and (iv) \$0.4 million of higher facility-related and office costs as we expanded our office space to accommodate higher occupancy and larger operational activities.

Other Income, Net

Interest Income

Interest income was \$4.7 million and \$1.5 million for the nine months ended September 30, 2024 and 2023, respectively. The increase was due to higher interest rates and higher balances of invested cash in cash equivalents and marketable securities.

Benefit for Income Taxes

We recognized \$0.3 million of benefit for income taxes for the nine months ended September 30, 2024. We did not record any benefit or provision for income taxes for the nine months ended September 30, 2023.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred net losses in each year since inception, except for the year ended December 31, 2023. During the year ended December 31, 2023, we recorded a gain on sale of non-financial asset of \$47.6 million for the sale of an IPR&D asset related to a GPCR program and \$0.2 million in revenue related to research services resulting in net income of \$4.2 million for the year then-ended. Of the \$47.6 million gain on sale of non-financial asset, \$25.0 million was received in cash in September 2023 and the remaining \$22.6 million during the nine months ended September 30, 2024. Our net losses were \$20.5 million and \$51.1 million for the three and nine months

ended September 30, 2024, respectively. Our net losses were \$10.9 million and \$30.7 million for the three and nine months ended September 30, 2023, respectively. As of September 30, 2024, we had an accumulated deficit of \$97.7 million. We expect to continue to incur net losses for the foreseeable future. Our net losses may fluctuate significantly from period to period, depending on the timing and expenditures of our operational activities.

We historically financed our operations primarily through the issuances of convertible promissory notes and convertible preferred stock, and most recently, through an IPO. Additionally, during the year ended December 31, 2023, we recorded a gain on sale of non-financial asset of \$47.6 million for the sale of an IPR&D asset related to a GPCR program and \$0.2 million in revenue related to research services resulting in net income of \$4.2 million. Of the \$47.6 million gain on sale of non-financial asset, \$25.0 million was received in cash at the closing of the Vertex purchase agreement in September 2023 and \$22.6 million was received during the nine months ended September 30, 2024. In October 2024, we completed our IPO, pursuant to which we issued and sold an aggregate of 18.4 million shares of common stock (inclusive of 2.4 million shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares). The aggregate net proceeds received by us from the IPO was approximately \$302.6 million, after deducting underwriting discounts and commissions, and other offering costs payable by us of approximately \$28.6 million.

As of September 30, 2024, we had \$137.5 million in cash, cash equivalents, and marketable securities.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Net cash used in operating activities	\$ (46,512)	\$ (29,926)
Net cash (used in) provided by investing activities	(27,359)	23,361
Net cash provided by financing activities	73,630	74,520
Net increase in cash, cash equivalents and restricted cash	<u>\$ (241)</u>	<u>\$ 67,955</u>

Net Cash Used in Operating Activities

Net cash used in operating activities was \$46.5 million and \$29.9 million for the nine months ended September 30, 2024 and 2023, respectively. The net cash used in operating activities for the nine months ended September 30, 2024 was due to our net loss of \$51.1 million, partially offset by a \$1.7 million of net change in operating assets and liabilities and \$2.9 million of non-cash charges for depreciation and amortization, stock-based compensation, non-cash operating lease expense, deferred income tax and accretion of discounts on available-for-sale marketable securities. The net cash used in operating activities for the nine months ended September 30, 2023 was due to our net loss of \$30.7 million, and \$1.4 million of net change in operating assets and liabilities, partially offset by \$2.2 million of non-cash charges for depreciation and amortization, stock-based compensation and non-cash operating lease expense.

Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities of \$27.4 million for the nine months ended September 30, 2024 was due to \$65.8 million of purchases of available-for-sale marketable securities and \$1.5 million of purchases of property and equipment, partially offset by the receipt of the remaining \$22.6 million from the sale of non-financial asset in 2023 and the maturity of \$17.3 million of available-for-sale marketable securities.

Net cash provided by investing activities of \$23.4 million for the nine months ended September 30, 2023 was due to \$25.0 million proceeds from the sale of non-financial asset, partially offset by \$1.6 million of purchases of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$73.6 million and \$74.5 million for the nine months ended September 30, 2024 and 2023, respectively. Net cash provided by financing activities for the nine months ended September 30, 2024 and 2023 was primarily due to net proceeds from the sale and issuance of our Series B Convertible Preferred Stock.

Future Funding Requirements

Our primary use of cash is to fund our operations, primarily research and development expenditures. Cash used for operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, timing, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the expenses of manufacturing our product candidates for clinical trials and in preparation for marketing approval and commercialization;
- the extent to which we enter into collaborations or other arrangements with additional third parties in order to further develop our product candidates;
- the expenses of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the expenses and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;
- our ability to establish additional collaborations on favorable terms, if at all;
- the expenses required to scale up our clinical, regulatory and manufacturing capabilities;
- the expenses of future commercialization activities, if any, including establishing sales, marketing, manufacturing and distribution capabilities, for any of our product candidates for which we receive marketing approval; and
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval.

We will need additional funds to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and business development activities. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect existing stockholders' rights as common stockholders. Debt 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 collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate 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.

We historically financed our operations primarily through the issuances of convertible promissory notes and convertible preferred stock, and most recently, through an IPO. In June 2023, we entered into a total of \$150.0 million of Series B Convertible Preferred Stock financing, which was divided into two tranches of equal amounts. The first tranche, which was the issuance of \$75.0 million of Series B Convertible Preferred Stock, was completed in June and July 2023 for total net proceeds of \$74.5 million. The second tranche, which was the issuance of the remaining \$75.0 million, was completed in May 2024 for net proceeds of \$74.9 million. In October 2024, we completed our IPO which resulted in net proceeds of approximately \$302.6 million, after deducting underwriting discounts, commissions and offering expenses payable by us of approximately \$28.6 million. Since our inception, we have devoted substantially all of our resources to raising capital, organizing and staffing our company, business and scientific planning, conducting discovery and

research and development activities, establishing, maintaining, and protecting our intellectual property portfolio, developing and progressing our product candidates and preparing for clinical trials, establishing arrangements with third parties for the manufacture of our product candidates and component materials, engaging in collaboration activities, and providing general and administrative support for these operations.

We believe our existing cash, cash equivalents, and marketable securities of \$137.5 million as of September 30, 2024, together with approximately \$302.6 million of net proceeds from our IPO, will be sufficient to fund our operations and capital expenditure requirements into the second half of 2027.

Contractual Obligations and Other Commitments

The following table summarizes our future cash outflows for contractual obligations as of September 30, 2024 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease obligations, including interest	\$ 38,111	\$ 3,780	\$ 9,298	\$ 9,904	\$ 15,129

We lease certain office space in South San Francisco under a lease that expires in July 2032. See Note 6 to our audited financial statements for the year ended December 31, 2023 and notes thereto, included in the IPO Prospectus for more information on our lease obligations.

We enter into contracts in the normal course of business for contract research services, contract manufacturing services, professional services and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not included in the table above.

In the ordinary course of business, we enter into agreements that may include indemnification provisions. As permitted under Delaware law and in accordance with our bylaws, we indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving in such capacity. We are also party to indemnification agreements with our officers and directors.

The maximum potential amount of future payments that we could be required to make under these provisions is not determinable; however, we currently hold director and officer liability insurance. This insurance limits our exposure and may enable us to recover a portion of any future amounts paid. We believe that the fair value of these indemnification obligations is minimal. In addition, we are not currently aware of any indemnification claims.

Critical Accounting Estimates, Significant Judgments and Use of Estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

During the nine months ended September 30, 2024, 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 the IPO Prospectus.

Recent Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 1 to our condensed financial statements included elsewhere in this Quarterly Report.

Emerging Growth Company and Smaller Reporting Company Status

We qualify as “emerging growth company” under the JOBS Act, which permits us to take advantage of an extended transition period to comply with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to use this extended transition period under the JOBS Act until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We could be an emerging growth company until the earliest to occur: (i) the last day of the fiscal year in which we have more than \$1.235 billion in annual gross revenue; (ii) the date we qualify as a “large accelerated filers” as defined in Rule 12b-2 under the Exchange Act, with at least \$700.0 million of equity securities held by non-affiliates; (iii) the issuance, in any three-year period, by us of more than \$1.0 billion in non-convertible debt securities; or (iv) the last day of the fiscal year ending after the fifth anniversary of our IPO. Even after we no longer qualify as an emerging growth company, we may continue to qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, if either (i) the market value of our stock held by non-affiliates is less than \$250.0 million or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700.0 million.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Principal Executive Officer and Principal Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report.

Based on such evaluation, our Principal Executive Officer and Principal Financial Officer have concluded that these disclosures controls were effective at a reasonable assurance level as of September 30, 2024.

Changes in Internal Control Over Financial Reporting

Other than the implementation of NetSuite as our enterprise resource planning system during the three months ended September 30, 2024, there were no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act during the period covered by this Quarterly Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

Our management, including our Principal Executive Officer and Principal Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, the effectiveness of any internal control over financial reporting is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

The information required with respect to this item can be found under “Legal Proceedings” in Note 5 to our condensed financial statements included elsewhere in this Quarterly Report and is incorporated by reference into this Item 1. From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Quarterly Report on Form 10-Q (this “Quarterly Report”), including our condensed financial statements and the related notes appearing at the end of this Quarterly Report and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” before deciding to invest in our common stock. If any of the events or developments described below were to occur, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. This Quarterly Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. See the section titled “Special Note Regarding Forward-Looking Statements.”

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

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

Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biotechnology company with a limited operating history, which may make it difficult to evaluate the success of our business to date and assess our future viability. Since our inception in December 2019, we have focused primarily on organizing and staffing our company, business planning, establishing our intellectual property portfolio, raising capital, developing our proprietary and structure-based drug discovery platform, identifying and developing our product candidates, conducting research and preclinical studies, including Investigational New Drug (“IND”)-enabling studies, initiating and conducting clinical trials, and providing general and administrative support for these operations. Our approach to the discovery and development of product candidates based on our Native Complex Platform™ is unproven, and we do not know whether we will be able to develop any product candidates that succeed in clinical development or commercially. Further, our lead product candidate, SEP-786, is in early clinical development and our other product candidates and development programs are in preclinical development or in the drug discovery stages. Accordingly, we have not yet completed any clinical trials, demonstrated an ability to successfully obtain regulatory approvals, manufactured a clinical- or commercial-scale product, or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we 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 significant losses since our inception, with the exception of the year ended December 31, 2023, and negative cash flows from operating activities and capital expenditures and expect to continue to incur significant and increasing operating losses for at least the next several years. If our product candidates are not successfully developed and approved, we may never generate any significant revenue. For the nine months ended September 30, 2024 and 2023, our net loss was \$51.1 million and \$30.7 million, respectively. As of September 30, 2024, we had an accumulated deficit of \$97.7 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. All of our product candidates will require substantial additional development time and resources before we would be able to apply for or receive marketing approvals and begin generating revenue from product sales. We expect to continue to incur significant losses for the foreseeable future, and we expect that our expenses will increase substantially as we continue our development of, seek marketing approval for and potentially commercialize any of our product candidates, recruit and maintain key personnel and seek to identify, assess, acquire, in-license or develop additional product candidates.

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

We will require substantial additional funding in order to finance our operations. If we are unable to raise additional capital when needed on acceptable terms, or at all, we may be forced to delay, reduce, or terminate certain of our research and product development programs, future commercialization efforts or other operations.

The development of pharmaceutical product candidates, including conducting preclinical studies and clinical trials, is a very time-consuming, capital-intensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we identify, continue the research and development of, initiate and conduct clinical trials of, and seek regulatory approval for, SEP-786 and any additional product candidates we may identify. In addition, if we obtain regulatory approval for any product candidates we may identify, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution to the extent that such sales, marketing, manufacturing, and distribution are not the responsibility of a collaborator. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reasonably estimate the actual amount of capital necessary to successfully complete the development and commercialization of our product candidates. Other unanticipated costs may also arise. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce, or eliminate our research and product development programs, future commercialization efforts or other operations.

As of September 30, 2024, we had \$137.5 million in cash, cash equivalents and marketable securities. We expect that the net proceeds of approximately \$302.6 million from our initial public offering ("IPO"), together with our existing cash, cash equivalents, and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2027. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of factors currently unknown to us, and we may need to seek funding sooner than planned. Our future capital requirements will depend on many factors, including:

- the timing and progress of research and development, preclinical and clinical development activities;
- the number, scope and duration 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 in any jurisdictions in which we or our current or any future collaborators may seek approval for our current or future product candidates;
- the costs of manufacturing clinical and commercial supplies of our current or future product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our current or future product candidates for which we receive regulatory approval;
- the costs of preparing, filing and prosecuting our patent applications, maintaining and enforcing our patents and other intellectual property rights and defending intellectual property-related claims;
- our ability to maintain existing, and establish new, strategic collaborations, licensing 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 of manufacturing clinical and commercial supplies of our current or future product candidates;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our current or future product candidates for which we receive regulatory approval;
- the costs of preparing, filing and prosecuting our patent applications, maintaining and enforcing our patents and other intellectual property rights and defending intellectual property-related claims;

- our ability to maintain existing, and establish new, strategic collaborations, licensing 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;
- our ability to establish and maintain collaboration and license agreements on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies;
- any product liability or other lawsuits related to our current or future product candidates;
- our implementation of various computerized informational systems and efforts to enhance operational systems;
- expenses incurred 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 extent to which we acquire or invest in businesses, products, and technologies;
- the effect of competing technological and market developments; and
- the impact of global economic uncertainty and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we identify, continue the research and development of, initiate preclinical studies and clinical trials of, and seek marketing approval for, product candidates, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our current or future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, 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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, 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 common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, and possibly other restrictions.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. We have no committed sources of additional capital and, if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our current or future product candidates or other research and development initiatives. Without sufficient funding, our license agreements and any future collaboration agreements may also be terminated if we are unable to meet the payment or other obligations under such agreements.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Additionally, if we raise 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, or product candidates we develop, or we may have to grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock.

We have never generated revenue from product sales and may never be profitable.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, obtain the regulatory approvals necessary to commercialize and eventually commercialize, product candidates we may identify for development. We may not generate revenues from product sales for many years, if ever. Our ability to generate future revenues from product sales depends heavily on our or our collaborators' ability to successfully:

- identify product candidates and successfully complete research and development of any product candidates we may identify;
- advance our product candidates through preclinical and clinical development, including as we advance SEP-786 into later-stage clinical trials;
- seek and obtain regulatory approvals for any product candidates for which we successfully complete clinical trials;
- launch and commercialize any product candidates for which we may obtain regulatory approval by establishing a sales force, marketing and distribution infrastructure, or alternatively, collaborating with a commercialization partner;
- qualify for adequate coverage and reimbursement by government and third-party payors for any product candidates for which we may obtain regulatory approval;
- establish and maintain supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for any product candidates for which we obtain regulatory approval;
- develop, maintain and enhance a sustainable, scalable, reproducible and transferable manufacturing process for the product candidates we may develop;
- address competing technological and market developments;
- negotiate favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations;
- receive market acceptance by physicians, patients, healthcare payors, and others in the medical community;
- receive coverage and adequate reimbursement by healthcare payors;
- maintain, protect, enforce, defend and expand our portfolio of intellectual property and other proprietary rights, including patents, trade secrets and know-how;
- defend against third-party intellectual property claims of infringement, misappropriation or other violation; and
- attract, hire and retain qualified personnel.

Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration (the “FDA”), European Medicines Agency (“EMA”), the competent authorities of individual European Union (the “EU”) Member States, or other comparable foreign regulatory authorities to perform preclinical studies or clinical trials in addition to those that we currently anticipate. Even if one or more of the product candidates we may develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Additionally, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives. Even if we are able to generate revenues from the sale of any approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations. Our failure to become and remain profitable may have an adverse effect on the value of our company and depress the market price of our common stock and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidate pipeline, achieve our strategic objectives or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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

We are early in our development efforts. We have only recently initiated early clinical studies, and as a result it will be years before we commercialize a product candidate, if ever. If we are unable to identify and advance product candidates through preclinical studies and clinical trials, obtain marketing approval and ultimately commercialize them, or experience significant delays in doing so, our business will be materially harmed.

The success of our business depends primarily upon our ability to identify, develop and commercialize product candidates. We are early in our development efforts and our lead product candidate, SEP-786, is in early clinical development and our other product candidates and development programs are in preclinical development or in the drug discovery stages. We have invested substantially all of our research efforts to date in developing our Native Complex Platform™, identifying potential product candidates and conducting preclinical and clinical studies. As an organization, we have limited experience in conducting and managing clinical trials necessary to obtain regulatory approvals, and we may be unable to do so for our product candidates. While we have successfully completed IND-enabling studies for SEP-786, our lead product candidate from our PTH1R program, and have initiated a Phase 1 clinical trial to assess preliminary safety, tolerability, pharmacokinetics (“PK”), and pharmacodynamics (“PD”) of SEP-786, we have not yet completed any clinical trials for SEP-786 or any of our product candidates to date. Additionally, we have a portfolio of targets and programs that are in earlier stages of discovery or preclinical development and may never advance to clinical-stage development. If we are able to advance these other targets and programs into clinical development, we do not have experience managing multiple clinical trials simultaneously, working with global clinical trials, or working in multiple different disease indications. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing our product candidates, either alone or with third parties, and we cannot guarantee you that we will ever obtain regulatory approval for any of our product candidates. Before obtaining regulatory approval for the commercial distribution of our product candidates, we must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates.

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

- preclinical study results may show the product candidate to be less effective than desired or to have harmful or problematic side effects;
- negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by patients in our clinical trials or by individuals using product similar to our product candidates;
- our third-party manufacturers’ inability to successfully manufacture our products;
- inability of any third-party contract manufacturer to scale up manufacturing of our product candidates and those of our collaborators to supply the needs of clinical trials or commercial sales;
- delays in submitting INDs or other comparable foreign applications or delays or failures in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- preclinical studies conducted outside of the United States may be affected by tariffs or import/export restrictions imposed by the United States or other foreign governments;
- conditions imposed by the FDA, EMA or other comparable foreign regulatory authorities regarding the scope or design of our clinical trials;
- delays in enrolling patients in our clinical trials;
- high drop-out rates of our clinical trial patients;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;

- inability to obtain alternative sources of supply for which we have a single source for product candidate components or materials;
- greater than anticipated costs of our clinical trials;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that no longer make a product candidate economically feasible;
- harmful side effects or inability of our product candidates to meet efficacy endpoints during clinical trials;
- failure to demonstrate a benefit-risk profile acceptable to the FDA, EMA, or other comparable foreign regulatory authorities;
- unfavorable FDA, EMA, or other comparable foreign regulatory authority inspection and review of any of the clinical trial sites or manufacturing facilities used in the testing and manufacture of any of our product candidates;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our technology in particular; or
- varying interpretations of our data by the FDA, EMA, and similar foreign regulatory authorities.

Our inability to complete development of, or commercialize our product candidates, or significant delays in doing so due to one or more of these factors, could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Preclinical and clinical drug development is a lengthy and expensive process, with uncertain timelines and outcomes. If preclinical studies or clinical trials of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our therapeutic candidates or any of our future therapeutic candidates on a timely basis or at all.

Successful development of pharmaceutical products involves a lengthy and expensive process, is highly uncertain, and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- clinical trial results may show the product candidates to be less effective than expected (for example, a clinical trial could fail to meet its primary or key secondary endpoint(s)) or have an unacceptable safety or tolerability profile;
- failure to receive the necessary regulatory approvals or a delay in receiving such approvals, which, among other things, may be caused by patients who fail the trial screening process, slow enrollment in clinical trials, patients dropping out of trials, patients lost to follow-up, length of time to achieve trial endpoints, additional time requirements for data analysis or New Drug Application (“NDA”) or similar foreign application preparation, discussions with the FDA, EMA or other comparable foreign regulatory authorities, including FDA, EMA or other comparable foreign regulatory authorities requesting additional preclinical or clinical data (such as long-term toxicology studies), or encountering unexpected safety or manufacturing issues;
- preclinical study results may show the product candidate to be less effective than desired or to have harmful on-target or off-target side effects;
- imposition of extensive post-marketing approval requirements; or
- the proprietary rights of others and their competing products and technologies that may prevent our product candidates from being commercialized.

Furthermore, the length of time necessary to complete clinical trials and submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one product candidate to the next and from one country or jurisdiction to the next and may be difficult to predict. Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including

government payors such as the Medicare and Medicaid programs and managed care organizations in the United States or country-specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced. Even if we are able to obtain coverage and adequate reimbursement for our products once approved, there may be features or characteristics of our products, such as dose preparation requirements, that prevent our products from achieving market acceptance by the healthcare or patient communities.

In addition, if any of our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports and registration, and will need to continue to comply (or ensure that our third-party providers comply) with current Good Manufacturing Practice (“cGMPs”) and Good Clinical Practice (“GCPs”) for any clinical trials that we conduct post-approval. In addition, there is always the risk that we, a regulatory authority or a third party might identify previously unknown problems with a product post-approval, such as adverse events (“AEs”) of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post-approval could adversely affect our business, financial condition and results of operations.

We may encounter substantial delays in the commencement, enrollment or completion of our planned clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, which could prevent us from commercializing any product candidates we determine to develop on a timely basis, if at all.

The risk of failure in developing product candidates is high. It is impossible to predict when or if any product candidate would prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development, submit an IND or comparable foreign application to permit initiation of clinical studies, and then conduct extensive clinical trials to demonstrate the safety and efficacy of product candidates in humans. We have not yet completed a clinical trial of any product candidate.

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our INDs and other regulatory filings. We cannot be certain of the timely identification of a product candidate or the completion or outcome of our preclinical testing and studies and cannot predict whether the FDA, EMA or other comparable foreign regulatory authorities will accept our proposed clinical programs or whether the outcome of our preclinical testing and studies will ultimately support the further development of any product candidates. Conducting preclinical testing is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. As a result, we cannot be sure that we will be able to submit INDs or other comparable foreign regulatory submissions for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs will result in the FDA, EMA, or other comparable foreign regulatory authority allowing clinical trials to begin.

Furthermore, product candidates are subject to continued preclinical safety studies, which may be conducted concurrently with our clinical testing. The outcomes of these safety studies may delay the launch of or enrollment in future clinical trials and could impact our ability to continue to conduct our clinical trials.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, or at all. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, but not limited to, flaws in trial design, dose selection issues, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits.

Other events that may prevent successful enrollment, initiation or timely completion of clinical development include:

- we may be unable to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in reaching a consensus with applicable regulatory authorities on trial design or implementation;
- delays in obtaining regulatory authorization to commence a clinical trial;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations (“CROs”), other vendors, or clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different vendors and trial sites;

- delays in obtaining approval from one or more institutional review boards (“IRB”) refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional participants, or withdrawing their approval of the trial;
- delays in recruiting suitable patients to participate in our ongoing and planned clinical trials;
- changes to the clinical trial protocol;
- clinical sites deviating from trial protocol such as the data collection omission we experienced at a clinical site as discussed above or dropping out of a trial;
- delays in manufacturing sufficient quantities of our product candidates for use in clinical trials, or delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- delays in having our product candidates being shipped on time, clearing customs and arriving at clinical trial sites intact;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- participants choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue a clinical trial;
- occurrence of AEs or serious adverse events (“SAEs”) associated with the product candidate that are viewed to outweigh its potential benefits;
- occurrence of SAEs in clinical trials of the same class of agents conducted by other companies;
- imposition of a temporary or permanent clinical hold by regulatory authorities;
- selection of clinical trial end points that require prolonged periods of clinical observation or analysis of the resulting data;
- clinical trials producing negative or inconclusive results;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign authorities to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or contamination or cross-contaminations of product candidates in the manufacturing process;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol or other regulatory requirements or committing fraud; or
- changes in regulatory requirements, guidance, or feedback from regulatory agencies that require amending or submitting new clinical protocols or otherwise modifying the design of our clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs overseeing the conduct of such trials, by a Data Safety Monitoring Board for such trial or by the FDA, EMA, or other comparable foreign regulatory authorities. Such regulatory authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA, or other comparable regulatory foreign authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination and approval, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated

with foreign regulatory requirements, as well as political, currency exchange and other economic risks relevant to such foreign countries. Investigators and patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff which in turn could adversely impact our clinical trial operations. Additionally, we may experience interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers and others in connection with public health concerns. We may face delays in meeting our anticipated timelines for our ongoing and planned clinical trials, which could adversely affect our business, financial condition, results of operations and growth prospects.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future product sales and regulatory and commercialization milestones. In addition, if we make manufacturing or formulation changes to our product candidates, we may need to conduct additional testing to bridge our modified product candidate to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring comparable products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

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

To date, we have not completed the evaluation of any product candidates in human clinical trials. It is impossible to predict when or if any product candidates we may develop will ultimately prove safe in humans. As is the case with pharmaceuticals generally, it is likely that there may be side effects and AEs associated with our product candidates' use. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Regulatory authorities may draw different conclusions or require additional testing to confirm these determinations, if they occur. In addition, it is possible that as we test our product candidates in larger, longer and more extensive clinical trials with a broader group of patients, or as use of these product candidates becomes more widespread if they receive marketing approval, illnesses, injuries, discomforts and other AEs that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by participants. Many times, side effects are only detectable after investigational product candidates are tested in large-scale, Phase 3 trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our current or future product candidates has serious or life-threatening side effects or other side effects that outweigh the potential therapeutic benefit, the development of the product candidate may fail or be delayed, or, if the product candidate has received marketing approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition. In particular, because we are developing our product candidates for chronic indications, the FDA, EMA, and other comparable foreign regulatory authorities will likely require that our product candidates demonstrate a higher level of safety over a longer period of time than would be the case for product candidates intended for short-term use. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed and our ability to generate revenue through their sale may be delayed or eliminated. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, if our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial value for the product candidate if approved. We may also be required to modify our trial plans based on findings after we commence our clinical trials. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound.

In addition, if any of our product candidates receive marketing approval, the FDA could require us to include a boxed warning in our label or adopt a risk evaluation and mitigation strategy ("REMS"), to ensure that the benefits outweigh its risks, which may include, among other things, a medication guide outlining the risks of the drug for distribution to patients and a communication plan to health care practitioners. For example, the FDA required that the product label for NATPARA, an approved, injectable parathyroid hormone product targeting PTH1R for the management of hypoparathyroidism include a boxed warning related to the risk of osteosarcoma based on rodent carcinogenicity studies and also implemented a REMS program to ensure patients and prescribers were appropriately counseled on the benefits and risks of the drug. Similarly, the FDA initially included boxed warnings for FORTEO and TYMLOS, injectable parathyroid hormone ("PTH") peptides approved for osteoporosis due to the risk of osteosarcoma. While we have not yet conducted carcinogenicity studies for SEP-786, because it also targets PTH1R, it is possible that absent compelling data to the contrary, the FDA, EMA, and other comparable foreign regulatory authorities will similarly require a boxed warning for SEP-786 if it is approved for marketing. Furthermore, if we or others later identify undesirable side effects caused by our product candidates, several other potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such product candidate;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties;
- we may need to conduct a recall;
- we may be forced to suspend marketing of that product, or decide to remove the product from the marketplace; and
- the product may become less competitive, and our reputation may suffer.

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

Our product candidates are subject to extensive regulation and compliance obligations, which is costly and time-consuming and which may cause unanticipated delays or prevent the receipt of the required approvals to commercialize our product candidates.

The research, clinical development, testing, quality control, safety, effectiveness, manufacturing, labeling, packaging, storage, record-keeping, advertising, promotion, marketing, import, export, distribution, post-approval monitoring, and post-approval reporting of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, neither we nor any future collaborators are permitted to market our product candidates until we receive regulatory approval from the FDA. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, new relevant statutes or regulations may be enacted, and the FDA, EMA and other comparable foreign regulatory authorities have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our potential future collaborators must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA, EMA and other comparable foreign regulatory authorities, which could require us to delay or abandon clinical development plans. In addition, regulatory authorities may require us to conduct further preclinical studies before evaluating our product candidate in a clinical trial. Once we initiate clinical trials, the FDA, EMA, or other comparable foreign regulatory authorities may require additional clinical trials or suggest changes to our planned clinical trials, prior to and in support of the approval of a NDA or equivalent foreign marketing application. Changes to data requirements by the FDA, EMA, or other comparable foreign regulatory authorities during the development of our product candidates may cause the applicable regulatory authorities to require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or regulatory authorities may object to elements of our clinical development program.

The FDA, EMA or other comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA, EMA or other comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;

- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we may be unable to demonstrate that a product candidate is safe and effective, and that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation or analysis of data from preclinical studies or clinical trials; such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes, approval policies or facilities of our third-party manufacturers with which we or any of our current or future collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA, EMA, and other comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing our product candidates.

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

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

Patient enrollment and retention in clinical trials is a significant factor in the timing of clinical trials and depends on many factors, including the size and nature of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number, nature and duration of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical trial sites and the eligibility criteria for the clinical trial. As we progress our programs we may not be able to initiate or continue clinical trials for any product candidates we identify or develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, EMA, or other comparable foreign authorities, or as needed to provide appropriate statistical power for a given trial. For certain of our product candidates, the conditions which we may evaluate include rare diseases with limited patient pools from which to draw. In some cases, patient populations for rare diseases are located at specific academic sites focused on such indications, often with multiple competing clinical trials. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for such trials. We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for our planned clinical trials and monitoring such patients adequately during and after treatment. As noted above, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. In addition, the process of finding and diagnosing patients may prove costly.

The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If the actual number of patients with these diseases is smaller than we anticipate, we may encounter difficulties in enrolling patients in our clinical

trials, thereby delaying or preventing development and approval of our product candidates. Even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment or retention in our clinical trials for a variety of reasons. Patient enrollment and retention in clinical trials depends on many factors, including:

- the size and nature of the patient population, in particular for rare diseases such as the diseases on which we are focused initially, and process for identifying patients;
- the severity of the disease under investigation;
- the design of the trial protocol;
- the existing body of safety and efficacy data for the product candidate;
- the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication;
- the proximity and availability of clinical trial sites for patients;
- the eligibility criteria for the trial;
- the complexity of the trial, including number of office visits, lab tests, patient evaluations, and dosing regimens;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the ability to adequately monitor patients during a trial, clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied;
- the risk that enrolled patients will drop out of a trial before completing all site visits; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

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

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, advertising, promotion, sampling, 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 GCP requirements for any clinical trials that we conduct post-approval.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, EMA and other comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. As such, we and our contract manufacturers will be subject to continual review

and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

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, EMA or other comparable foreign 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.

Additionally, under the Food and Drug Omnibus Reform Act (“FDORA”) sponsors of approved drugs and biologics must provide six months’ notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product’s ability to be marketed. The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The policies of the FDA, EMA and other comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. In addition, the U.S. Supreme Court’s July 2024 decision to overturn established case law giving deference to regulatory agencies’ interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA’s regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. As a result of the U.S. Supreme Court’s decision, the FDA and other agencies may be less inclined to engage in formal regulation and may rely to a greater degree on informal guidance, which may not always be susceptible to immediate challenge. We cannot predict the likelihood, nature or extent of government regulation or guidance that may arise from future court decisions, 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 guidance or the adoption of new requirements, guidance, 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.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our therapeutics may be delayed and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. 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 or the initiation of other clinical programs. All of these milestones are and will be based on numerous assumptions, 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, EMA, and other comparable foreign 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.
- Securing product reimbursement

The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our product candidates may be delayed or never achieved and, as a result, our stock price may decline.

Results of preclinical studies and early clinical trials on any of our product candidates may not be predictive of results of future clinical trials.

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later 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. In addition, while the animal models used in preclinical studies are designed to be representative of disease states in humans, these preclinical models may not be able to accurately predict the way a product candidate will affect patients in clinical trials. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support regulatory approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen, product formulation and other clinical trial protocols and the rate of dropout among clinical trial patients. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our most advanced product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

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

We have limited financial and managerial resources, and to date, we have focused on research programs and product candidates within the endocrinology, immunology and inflammation, neurology and metabolic therapeutic areas, with a particular focus on our lead product candidate, SEP-786. Correctly prioritizing our research and development activities is particularly important for us due to the breadth of potential product candidates and indications that we believe could be pursued by leveraging our Native Complex Platform™. As a result, we may forgo or delay pursuit of opportunities with other product candidates or in other therapeutic areas that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We must continually assess the potential commercial viability of our research programs and product candidates, and we may decide to pause or discontinue development of any of our product candidates based upon such assessments, even if we obtain positive data from our product candidates in preclinical studies and clinical trials.

Our proprietary Native Complex Platform™ is based on novel technologies that are unproven and 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, and we may not be successful in our efforts to expand our development portfolio of product candidates.

A key element of our strategy is to use our proprietary Native Complex Platform™ to overcome the historical limitations of GPCR drug development, including the isolation, purification and stabilization of GPCRs in their native forms, in order to build a robust and diverse portfolio of potentially first-in-class and best-in-class oral small molecule therapies that address both well-validated and novel GPCR targets.

We have only recently commenced our first clinical trial of the first candidate developed with our platform. The scientific research that forms the basis of our efforts to develop product candidates with our platform is still ongoing. We are not aware of any FDA approved therapeutics utilizing the technology underlying our platform. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our platform is both preliminary and limited. As a result, we are exposed to a number of unforeseen risks and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates. For example, we have not yet generated any meaningful clinical data on any of the product candidates being developed using our platform, and our current data is limited to animal models and preclinical cell lines, the results of which may not translate into humans. Further, relevant animal models and assays may not accurately predict the safety and efficacy of our product candidates in humans, and we may encounter significant challenges creating appropriate models and assays for demonstrating the safety and purity of our product candidates.

Given the novelty of our technology, we intend to work closely with the FDA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates; however, due to a lack of comparable experiences, the regulatory pathway with the FDA and comparable regulatory authorities may be more complex and time-consuming relative to other more well-known therapeutics. Even if we obtain human data to support our product candidates, the FDA or comparable foreign regulatory authorities may lack experience in evaluating the safety and efficacy of product candidates like those developed using our platform, which could result in a longer than expected regulatory review process, increase our expected development costs, and delay or prevent commercialization of our product candidates. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies.

Although our research and development efforts to date have resulted in a development portfolio of potential programs and product candidates, we may not be able to discover or identify novel chemical matter to new GPCR targets and thus not be able to develop product candidates to expand our development portfolio. We may also pursue opportunities to acquire or in-license additional businesses, technologies or products, form strategic alliances or create joint ventures with third parties to complement or augment our existing business. However, we may not be able to identify any product candidates through such acquisition or in-license.

Even if we are successful in continuing to build and expand our development portfolio, the potential product candidates that we identify may not be suitable for clinical development. For example, they may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will be successful in clinical trials 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.

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

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

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

We may develop our current or future product candidates in combination with other therapies, which would expose us to additional risks.

We may develop our current or potential future product candidates in combination with one or more currently approved therapies or therapies in development. Even if any of our current or future product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

We may also evaluate our current or future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA, EMA or other comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved therapies that do not ultimately obtain marketing approval.

Furthermore, we cannot be certain that we will be able to obtain a steady supply of such therapies for use in developing combinations with our product candidates on commercially reasonable terms or at all. Any failure to obtain such therapies for use in clinical development and the expense of purchasing therapies in the market may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If the FDA, EMA or other comparable foreign regulatory authorities do not approve or withdraw their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with any of our current or future product candidates, we may be unable to obtain approval of or successfully market any one or all of the current or future product candidates we develop. Additionally, if the third-party providers of therapies or therapies in development used in combination with our current or future product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our current or future product candidates, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Risks Related to Commercialization, Marketing and Competition

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

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

resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

Even if any of our current or future product candidates receive marketing approval, such product candidate may fail to achieve market acceptance by physicians, patients, third-party payors or 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 current or future product candidates are approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Historically, several injectable PTH peptides have been approved by the FDA and other regulatory authorities for treatment of hypoparathyroidism and osteoporosis. However, our lead product candidate is an oral small molecule agonist; to date, no such oral small molecule in this indication has been approved by the FDA or any other regulatory agency. Market participants with significant influence over acceptance of new treatments, such as clinicians and third-party payors, may not adopt new oral treatments for hypoparathyroidism or osteoporosis, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our existing or future collaborators. If our current or future product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our current or future product candidates, if approved for commercial sale, will depend on a number of factors, including but not limited to:

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

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

Even if we are able to commercialize any product candidate, the third-party payor coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors in the United States are essential for most patients to be able to afford treatments such as our products or product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for drug treatments by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our products, and potentially attract additional collaboration partners to invest in the development of our product candidates. We cannot be sure that adequate coverage and reimbursement in the United States, the EU, Australia or elsewhere will be available for our products or any products that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. For more information, see the section titled “Business–Government Regulation–Coverage and Reimbursement.”

Third-party payors increasingly are challenging prices charged for pharmaceutical products, medical devices and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug is available. It is possible that a third-party payor may consider our products or product candidates, if approved, and the generic or biosimilar parent drug as substitutable and only offer to reimburse patients for the generic drug. Even if we show improved efficacy or safety or improved convenience of administration with our products or product candidates, if approved, pricing of the existing parent drug may limit the amount we will be able to charge for such product. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products or product candidates, and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs, biologics and medical devices will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs, biologics and medical devices. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products or product candidates.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our products and product candidates, if approved, and on related parent drugs. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Many countries, including the EU Member States, established complex and lengthy procedures to obtain price approvals, coverage and reimbursement. These procedures vary from country to country but are commonly initiated after grant of the related marketing authorization. More particularly, in the EU, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing systems. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced countries. Reductions in the pricing of our medicinal products in one EU Member State could affect the price in other EU Member States and, thus, have a negative impact on our financial results. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products or product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. As an example, many EU Member States review periodically their decisions concerning the pricing and reimbursement of medicinal products. The outcome of these reviews cannot be predicted and could have adverse effects on the pricing and reimbursement of our medicinal products in the EU Member States.

Moreover, increasing efforts by governmental and 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 new products approved and, as a result, they may not cover or provide adequate payment for our products or product candidates. We expect to experience pricing pressures in connection with the sale of our products and product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

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

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary and novel products and product candidates. While we believe our product candidates, platform,

knowledge, experience and scientific personnel provide us with several key competitive advantages, we face competition from major pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions, among others. Our future success will depend in part on our ability to maintain a competitive position with our structure-based drug discovery platform. If we fail to stay at the forefront of technological change in utilizing our platform to create and develop product candidates, we may be unable to compete effectively. Our competitors may render our approach obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and platform. Several other companies also focus on GPCRs and have platform technologies that are distinct from the Native Complex Platform™, including Nxera Pharma (formerly Sosei Heptares), Structure Therapeutics, Tectonic Therapeutics, and Confo Therapeutics.

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

We are aware of several pharmaceutical companies that have commenced clinical trials of product candidates or have successfully commercialized products addressing areas that we are targeting. Takeda owns the rights to parathyroid hormone product (brand name NATPARA) for the treatment of hypoparathyroidism. NATPARA was voluntarily recalled due to manufacturing issues in September 2019 in the United States and is now only available to a limited number of patients through a Special Use Program offered by its manufacturer. In October 2022, Takeda announced manufacturing of all strengths of NATPARA will be discontinued globally by the end of 2024. Ascendis Pharma received regulatory approval for a proprietary once-daily injectable PTH peptide, palopegteriparatide (brand name YORVIPATH), in Europe and the United States. In March 2024, AstraZeneca acquired Amolyt Pharma, who was developing eneboparatide, a proprietary, once-daily injectable PTH peptide, for hypoparathyroidism, currently in Phase 3 studies. In addition, we are aware of several academic groups and companies working on making longer-acting agonists of the PTH1R. Other companies and groups are developing or commercializing therapies for hypoparathyroidism, including Calcilytix (a BridgeBio company), Entera Bio, Extend Biosciences, and MBX Biosciences. Several companies are developing clinical-stage small molecule MRGPRX2 inhibitors, including Escient Pharmaceuticals (acquired by Incyte Pharmaceuticals in April 2024), Evommune, and BioArdis. Further there are several other companies pursuing therapies for Chronic spontaneous urticaria addressing other receptors of interest, such as Genentech, Sanofi, Celldex Therapeutics, Jasper Therapeutics, Acelyrin, Allakos, Novartis, Third Harmonic Bio, and Blueprint Medicines. For TSHR, we are aware that Byondis and Crinetics are also working on research stage compounds, but they have not yet entered clinical development. In addition several companies are working on other mechanisms to address Graves' disease, such as Immunovant, and thyroid eye disease ("TED"), including Amgen, Viridian, Argenx, Roche, Lassen Therapeutics, Tourmaline Bio, Sling Therapeutics, and Acelyrin. There are also several currently approved injectable products targeting incretin receptors for the treatment of obesity or type 2 diabetes ("T2D"). These include, but are not limited to, products such as Ozempic and Wegovy (semaglutide, each marketed by Novo Nordisk) for T2D and obesity, respectively, Trulicity (dulaglutide, marketed by Eli Lilly and Company) for T2D, and Mounjaro and Zepbound (tirzepatide, each marketed by Eli Lilly and Company) for T2D and obesity, respectively. There are also several injectable peptide products in development pursuing similar indications with similar mechanism of actions along with combination products, including those being developed by Amgen, AstraZeneca, Boehringer Ingelheim, Eli Lilly and Company, Novo Nordisk, Roche, and Viking, among others. In addition, there are oral products such as Rybelsus (semaglutide, marketed by Novo Nordisk) approved for patients with T2D and other oral products in development for treating obesity or T2D, including those being developed by AstraZeneca, Eli Lilly and Company, Pfizer, Roche, Structure Therapeutics, and Terns. Based on our continuing evaluations of the competitive landscape, we may decide to reallocate resources and reprioritize our development programs if we determine that a particular product candidate or target indication is no longer commercially viable or advantageous.

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

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting

and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Any failure to compete effectively could harm our business, financial condition and operating results.

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 in selected foreign jurisdictions, including the EU. 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 EU, 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 EU. The provision of benefits or advantages to reward improper performance 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 EU.

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 EU, 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 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. 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.

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

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, it does not mean that comparable foreign regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining marketing approval in one jurisdiction may negatively impact the marketing approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, 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.

Obtaining foreign marketing approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed, which would adversely affect our business, prospects, financial condition, and results of operations.

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

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, manufacturing, commercial sales, pricing and distribution of our product candidates. If we obtain regulatory approval of our product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

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

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

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new information may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere

may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Risks Related to Business Operation and Industry

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

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

- the timing, degree of success and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to our product candidates, which may change from time to time;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products;
- the cost of manufacturing our current and future product candidates, which may vary depending on FDA, EMA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with third-party manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies or other assets;
- the level of demand for any of our product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies or clinical trials or regulatory approval for our product candidates or any competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- potential unforeseen business disruptions that increase our costs or expenses;
- effects of macro events, such as inflation, geopolitical conflicts, pandemics, natural disasters and supply chain issues, on our business and operations; and
- the changing and volatile global economic and political environment.

In addition, from time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the

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

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

As of September 30, 2024, we had 73 full-time employees. As we advance our research and development programs, we may need to further increase the number of our employees and the scope of our operations, particularly in the areas of clinical development, biology, chemistry, manufacturing, general and administrative matters related to being a public company, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must:

- expand our general and administrative functions;
- identify, recruit, integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our product candidates;
- establish and build a marketing and commercial organization; and
- improve our operational, financial and management controls, reporting systems and procedures.

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

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

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

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

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

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. For example, employment of our key employees is at-will, which means that any of our employees could leave our employment at any time, with or without notice. In addition, we rely on consultants and advisors, including scientific

and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product candidates, harming future marketing approvals, sales of our product candidates and our results of operations.

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

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaboration partners may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (i) FDA, the national competent authorities of individual EU Member States, or comparable foreign regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, EMA, or other comparable foreign regulatory authorities; (ii) manufacturing standards; (iii) U.S. federal and state fraud and abuse and other healthcare laws and regulations, including foreign requirements; or (iv) laws that require the reporting of true and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These activities also include the improper use of information obtained in the course of clinical trials or falsification of clinical trial data, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third-parties, 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 be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other U.S. federal or non U.S. healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Changes in U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.

The U.S. government has recently made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs and export control and sanctions restrictions affecting certain products manufactured in China. Both China and the United States have each imposed tariffs indicating the potential for further trade barriers, including the U.S. Commerce Department adding numerous Chinese entities to its Unverified List, which requires U.S. exporters to go through more procedures before exporting goods to such entities. It is unknown whether and to what extent new tariffs, export controls, or other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry. Most recently, legislation pending in Congress called the BIOSECURE Act would, among other things, prohibit U.S. federal government contracts, grants, and loans in connection with biotechnology equipment or services provided or produced by certain named Chinese “biotechnology companies of concern,” which include WuXi AppTec and WuXi Biologics, or collectively WuXi. See the risk factor titled “Risks Related to Government Regulatory and Legal Requirements—We rely on third-party manufacturers, CROs, contract manufacturing organizations (“CMOs”), and suppliers to supply, develop and test components of our product candidates. The loss of our third-party manufacturers, CROs, CMOs, or suppliers, their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, or changes in methods of product candidate manufacturing, development or formulation would materially and adversely affect our business.”

Any unfavorable government policies on international trade, such as export controls, economic, sanctions, capital controls or tariffs, may increase the cost of manufacturing our product candidates and platform materials, affect our ability to commercialize our product candidates if approved, the competitive position of our product candidates, and import or export of raw materials and finished product candidate used in our preclinical studies and clinical trials, particularly with respect to any product candidates and materials that we import from China, including pursuant to our service arrangements with WuXi. If any new tariffs, export controls, sanctions, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if either the U.S. or Chinese government takes retaliatory trade actions due to the recent trade tensions, such changes could have an adverse effect on our business, financial condition and results of operations.

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

We will face an inherent risk of clinical trial and product liability exposure related to the testing of any product candidates we may develop in clinical trials, and we will face an even greater risk if we commercially sell any products that we may develop. While we currently have not completed the evaluation of any product candidates in human clinical trials or that have been approved for commercial sale, the 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 that we may develop;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend any related litigation;
- a diversion of our management's time and our resources;
- exhaustion of any available insurance and our capital resources;
- initiation of investigations by regulators;
- the inability to commercialize any product candidates that we may develop;
- injury to our reputation and significant negative media attention; and
- a decline in price of our common stock.

We will need to increase our insurance coverage if we continue to commence clinical trials or if we commence commercialization of any product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If and when coverage is secured, our insurance policies may also have various exclusions and we may be subject to a product liability claim for which we have no coverage. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim 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.

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

We are subject to numerous foreign, federal, state and local 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, including any available insurance. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities.

We could incur significant costs and liabilities which may adversely affect our financial condition and operating results for failure to comply with such laws and regulations, including, among other things, civil or criminal fines and penalties, property damage and

personal injury claims, costs associated with upgrades to our facilities or changes to our operating procedures, or injunctions limiting or altering our operations.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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, which are becoming increasingly more stringent, may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

Since our inception, we have incurred losses and we may never achieve profitability. As of December 31, 2023, we had \$14.6 million of federal net operating loss ("NOL") carryforwards and \$28.9 million of state NOL carryforwards, available to reduce future taxable income. To the extent that we continue to generate taxable losses, under current law, our unused U.S. NOLs may be carried forward to offset a portion of future taxable income, if any. Additionally, we continue to generate business tax credits, including research and development tax credits, which generally may be carried forward to offset a portion of future taxable income, if any, subject to expiration of such credit carryforwards. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ("Code"), if a corporation undergoes an "ownership change," generally defined as one or more stockholders or groups of stockholders who own at least 5% of the corporation's equity increasing their equity ownership in the aggregate by more than 50 percentage points (by value) 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. Similar rules may apply under state tax laws. Our prior equity offerings and other changes in our stock ownership may have resulted in such ownership changes in the past. In addition, we may experience ownership changes in the future due to shifts in our stock ownership, some of which are outside of our control. As a result, if we earn net taxable income, our ability to use our pre-change NOLs or other pre-change tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us and could require us to pay U.S. federal income taxes earlier than would be required if such limitations were not in effect. Additional limitations on our ability to utilize our NOLs to offset future taxable income may arise as a result of our corporate structure whereby NOLs generated by our subsidiary may not be available to offset taxable income earned by our subsidiary. There is a risk that due to changes under the tax law, regulatory changes or other unforeseen reasons, our existing NOLs or business tax credits could expire or otherwise be unavailable to offset future income tax liabilities. At the state level, there may also be periods during which the use of NOLs or business tax credits is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, under Senate Bill 167 enacted by California in June 2024, generally, there is a suspension of the NOL deduction for tax years beginning on or after January 1, 2024, and before January 1, 2027 for individual and corporate taxpayers with net business income or modified adjusted gross income of \$1 million or more, and a limit of \$5 million of business credits on the aggregate use of otherwise allowable business tax credits that any individual or corporate taxpayer could claim for tax years beginning on or after January 1, 2024, and before January 1, 2027. For these reasons, we may not be able to realize a tax benefit from the use of our NOLs or tax credits, even if we attain profitability.

We have and may in the future engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

We have and in the future, we may consider strategic transactions, such as acquisitions of companies, asset purchases, and in-licensing or out-licensing of products, product candidates or technologies from time to time. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our senior management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- up-front, milestone and royalty payments, equity investments and financial support of new research and development candidates including increase of personnel, all of which may be substantial;

- exposure to unknown liabilities, including potential indemnification claims from a potential spin-off or out-license of certain of our intellectual property rights;
- disruption of our business and diversion of our management's time and attention to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected costs in risk-sharing collaborations;
- higher-than-expected acquisition and integration costs;
- lower-than-expected benefits, from out-licensing or selling our technology, intellectual property or any of our subsidiaries or, from in-licensing intellectual property or purchasing assets;
- write-downs of assets or goodwill or impairment charges;
- difficulty and cost in combining or separating the operations and personnel of any acquired or sold businesses with our existing operations and personnel;
- we may disagree with our strategic partners about decisions affecting the business, which could result in litigation or arbitration that increases our expenses, distracts our officers and directors and disrupts the day-to-day operations of the strategic venture, including by delaying important decisions until the dispute is resolved;
- our strategic partners may take actions that we oppose;
- our strategic partners might experience financial distress or become bankrupt;
- impairment of relationships with key suppliers or customers of any acquired or sold businesses due to changes in our senior management and ownership; and
- inability to retain key employees of any acquired businesses.

In addition, to the extent we enter into a strategic transaction that includes ongoing operations or shared ownership and management, our strategic partners may take actions that we oppose or we may disagree with our strategic partners about decisions affecting the business, which could result in litigation or arbitration, distract our officers and directors and otherwise disrupt the day-to-day operations of our business and the business of the strategic partner or entity. Furthermore, to the extent that our directors and officers serve on the boards of our strategic partners, such directors may be required to abstain from board decision-making in the event of a conflict of interest.

Accordingly, although we cannot be certain that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks, and could harm our business, results of operations, financial condition and prospects.

We are conducting, and will continue to conduct, clinical trials for our current product candidates outside of the United States, and we may do so for our other product candidates. However, conducting trials outside of the United States exposes us to additional risks, which could materially harm our business.

We are conducting, and may in the future conduct, certain of our clinical trials at centers outside of the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or another comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. For example, in cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar

approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. If the FDA, the EMA, the U.K. Medicines and Healthcare products Regulatory Agency, or other foreign regulatory authorities do not accept any data generated from other jurisdictions, we would likely be required to conduct additional clinical trials, which would be costly and time consuming, and delay aspects of our development plan, which could harm our business.

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

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

If our information systems or data, or those of third parties with whom we work, are or were compromised, we could experience adverse consequences from such compromises, such as damage our reputation, significant financial and legal exposure, or other adverse effects to our business.

We rely on information technology systems that we or third parties with whom we work, operate to process, transmit and store electronic information, including sensitive information, in our day-to-day operations. For example, in connection with our product development efforts, we may collect and process a variety of personal data, proprietary information, trade secrets, and clinical trial information. As a result, we and the third parties with whom we work, face a variety of evolving threats that could cause security incidents.

Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities could result in the theft or destruction of intellectual property, personal data, or other misappropriation of assets, or otherwise threaten to compromise our confidential or proprietary information and disrupt our operations. Such threats are increasing in their frequency, sophistication, and intensity, have become 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. Some actors now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities, wrongful conduct by hostile foreign governments and industrial espionage. During times of war and other major conflicts, we and the third parties upon which we work may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

We and the third parties with whom we work are subject to a variety of evolving threats, including but not limited to the deployment of harmful malware (including as a result of advanced persistent threat intrusions), ransomware, denial-of-service, credential stuffing, credential harvesting, social engineering fraud (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware 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.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, there can be no assurance that our efforts will prevent information cybersecurity incidents or breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past 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. Furthermore, we may discover security issues or other constraints not found during due diligence of such acquired or integrated entities, creating additional challenges to integrate said information systems into our information technology environment and security program.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate known vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, detect and remediate all such vulnerabilities on a timely basis for various reasons including but not limited to the impact on the functional operations of affected information systems or the availability of a solution for the impacted technology. While remedial measures and/or patches designed to address identified vulnerabilities are being developed and/or implemented, these vulnerabilities could be exploited and result in a security incident.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Additionally, laws in all 50 states require businesses to provide notice to customers whose personal data has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. We also may be contractually required to notify patients or other counterparties of a cybersecurity incident or breach. Although we may have contractual protections with our service providers, any actual or perceived cybersecurity incident or breach could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach. Any contractual protections we may have from our service providers may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply with such standards. Determining whether personal data has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation.

While we maintain insurance coverage, we cannot assure that such coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or material adverse effects arising out of our data protection, privacy, and security practices, or that such coverage will continue to be available on acceptable terms or at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Threat actors and their techniques change frequently, are often sophisticated in nature, and may not be detected until after a cybersecurity incident has occurred. Any failure to prevent or mitigate cybersecurity incidents, breaches or other improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., Health Insurance Portability and Accountability Act of 1996), and foreign (e.g., the GDPR) laws, and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

In addition, our reliance on the computer systems of various third parties with whom we work, including our CROs and other contractors, introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on our third-party partners to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. However, our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. While we may be entitled to damages if the third parties with whom we work 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. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

If we or our third-party partners fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party partners could have difficulty preventing, detecting and controlling such cyberattacks and any such attacks could result in disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects

and cash flows. Any failure by such third parties to prevent or mitigate cybersecurity incidents, breaches or other improper access to or disclosure of such information could have similarly adverse consequences for us.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive data of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative artificial intelligence technologies.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services.

Risks Related to Government Regulatory and Legal Requirements

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

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

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

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

We may not be able to obtain orphan drug designation or exclusivity for our product candidates, and even if we do, that designation may not provide an expedited development or regulatory review or approval process and any orphan drug exclusivity we may receive for approved products may not prevent the FDA or the EMA from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition. A similar regulatory scheme governs the designation of orphan product candidates by the EMA in the EU. Generally, if a product with an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA (as applicable) from approving another marketing authorization application for another similar product candidate for the same orphan therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the EU (which can be extended to 12 years if the sponsor complies with an agreed-upon pediatric investigation plan). The exclusivity period in the EU can be reduced to six years if at the end of the fifth year it is determined that a product no longer meets the criteria for orphan designation, including if the product is sufficiently profitable so that market exclusivity is no longer justified.

In order for the FDA to grant orphan drug exclusivity to one of our product candidates, the agency must find that the product candidate is indicated for the treatment of a condition or disease that affects fewer than 200,000 individuals in the United States or that affects 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product candidate available for the disease or condition will be recovered from sales of the product in the United States. Hypoparathyroidism is a disease that affects approximately 70,000 individuals in the United States, and accordingly, SEP-786, our small molecule agonist to PTH1R, in development for hypoparathyroidism, may qualify for orphan drug designation. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. In the EU, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) it is unlikely that the product, without the benefits derived from orphan status, would generate sufficient return in the EU to justify the

necessary investment in its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different product candidates can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA or the EMA can subsequently approve the same product candidate for the same condition if the FDA or EMA (as applicable) concludes that the later product candidate is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care compared with the product that has orphan exclusivity. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

While we may in the future seek designations for our product candidates with the FDA, EMA and other comparable foreign 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, EMA, and other comparable foreign 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 our lead product candidate, SEP-786, and one or more of our product candidates. 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.

In the EU, we may seek to participate in the PRiority Medicines (“PRIME”) scheme for our potential product candidates. The PRIME scheme is intended to encourage development of product candidates in areas of unmet medical need and provides accelerated assessment of product candidates representing substantial innovation, where the marketing authorization application will be made through the centralized procedure in the EU. Eligible products must target conditions for which there is an unmet medical need (i.e. no treatment option exists in the EU or, they can offer a major therapeutic advantage over existing treatments). Many benefits accrue to sponsors of product candidates with access to the PRIME scheme, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. There is no guarantee, however, that our potential product candidate would be deemed eligible for the PRIME scheme and even if we do participate in the PRIME scheme, where during the course of development a product no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval.

We may seek Breakthrough Therapy Designation for one or more of our product candidates. 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, EMA, or other comparable foreign regulatory authorities through the use of expedited approval pathways, such as accelerated approval. If we are unable to obtain such approvals, 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, EMA, or other comparable foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA, EMA, or other comparable foreign regulatory authorities may seek to withdraw the accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for our one or more of our product candidates from the FDA, EMA, or other comparable foreign 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 product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product 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, EMA, or other comparable foreign 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 or BLA 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, EMA, or other comparable foreign 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, EMA, or other comparable foreign 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 product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We are subject to stringent and evolving U.S. and foreign laws, rules, regulations, policies, industry standards, contractual requirements, and other obligations related to data protection, privacy, and security. Our actual or perceived failure to comply with such obligations could adversely affect our business.

We are subject to various data protection, privacy, and security laws, rules, regulations, policies, industry standards, contractual requirements, and other obligations that apply to our collection, transmission, storage, use, disclosure, transfer, maintenance and other

processing of sensitive information, including personal data. The legislative and regulatory landscape for data protection, privacy, and security continues to evolve across jurisdictions worldwide. For example, in the United States, federal, state, and local governments have enacted numerous data protection, privacy, and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws).

In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act, and implementing regulations, establish stringent privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information.

Data protection, privacy, and security obligations remain an evolving landscape at both the domestic and foreign level, with new laws, rules and regulations coming into effect, posing continued legal and compliance challenges. For example, in the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to conduct our operations. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, in California, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (collectively, “CCPA”), provides for fines of up to \$7,500 per intentional violation and allows privacy litigants affected by certain data breaches to recover significant statutory damages. The CCPA and other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties with whom we work.

Similar laws are being proposed in numerous other states and at the federal level. Proposed legislation, if enacted, may add additional complexity, variation in requirements, processing restrictions, potential legal risk, require additional investment of resources, impact business strategies, and could result in increased compliance costs and/or changes in business practices and policies.

There are also states that specifically regulate consumer health information. For example, Washington has enacted a consumer health privacy law, the My Health My Data Act (“MHMD”), that regulates the collection and sharing of consumer health information. MHMD places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data protection, privacy, and security. For example, if we conduct clinical trials in the European Economic Area (“EEA”) and/or the United Kingdom (“U.K.”), we may become subject to additional privacy laws in those jurisdictions, such as the EU General Data Protection Regulation (“EU GDPR”) and the EU GDPR as incorporated into U.K. domestic law post-Brexit (“U.K. GDPR” and, together with the EU GDPR, “GDPR”), both of which impose strict requirements for processing personal data.

For example, under the GDPR, data protection authorities may impose large penalties for violations of the GDPR, including potential fines of up to €20 million (£17.5 million GBP) or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Non-compliance could also result in the imposition of orders to stop data processing activities, which could have a material adverse effect on our business, financial position, and results of operations.

In addition, we may be unable to transfer personal data from the EEA, U.K., and other jurisdictions to the U.S. or other countries due to data localization requirements or limitations on cross-border data flows. Although there are various mechanisms that may be used in some cases to lawfully transfer personal data to the U.S. or other countries, these mechanisms are subject to legal challenges and may not always be available to us. For example, the GDPR requires certain adequate safeguards to enable the transfer of personal data outside of the EEA or the U.K., in particular to the U.S., such as the EU standard contractual clauses, U.K. International Data Transfer Addendum/Agreement, and the EU-U.S. Data Privacy Framework (“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). However, 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 U.S. If there is no lawful manner for us to transfer personal data from the EEA, the U.K. or other jurisdictions to the U.S., 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.

Furthermore, if we fail, or are perceived to have failed, to comply with applicable data protection, privacy, and security laws, including applicable HIPAA privacy and security standards, we could face significant administrative, civil and criminal penalties. For example, HHS has the discretion to impose significant penalties, and such enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the data protection, privacy, or security of the personal data of state residents. We cannot be sure how these laws, rules and regulations will be interpreted, enforced, or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws, rules and regulations at the international, federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

Additionally, we rely on certain third-party vendors to process certain confidential, sensitive, or personal data on our behalf. Failure by us or our third-party vendors to comply with any of these laws, rules, regulations, contractual requirements, industry standards, or other obligations could result in notification obligations, enforcement actions, regulatory investigations or inquiries, significant fines, imprisonment of company officials and public censure, litigation and claims for damages by affected individuals, customers or business partners, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

Our employees and personnel use generative artificial intelligence technologies to perform their work, and the disclosure and use of personal data in generative artificial intelligence technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative artificial intelligence. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative artificial intelligence, it could make our business less efficient and result in competitive disadvantages.

We also make public statements about our use, collection, disclosure, and other processing of personal data through our privacy policies and information provided on our website. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about data protection, privacy, and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices.

In addition to data protection, privacy, and 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 data protection, privacy, and security, and our efforts to comply with such obligations may not be successful.

Obligations related to data protection, privacy, and 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.

All of these compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. Our efforts to comply with the evolving data protection, privacy, and security laws, rules, regulations, and other obligations may be unsuccessful. It is possible that these various obligations may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection, privacy, and security obligations may be unsuccessful. We may need to devote significant resources to understanding and complying with this changing landscape. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Any actual or perceived failure by us or our third-party partners to comply with such laws, rules, regulations, and other obligations regarding data protection, privacy, and security could result in significant government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, rules or regulations, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity. Further, any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

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

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. For more information, see the section titled “Business–Government Regulation–Current and Future U.S. Healthcare Reform.”

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

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical and biologic products. In addition, 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.

In August 2022, the Inflation Reduction Act of 2022 (“IRA”) was signed into law. The IRA includes several provisions that may impact our business, depending on how various aspects of the IRA are implemented. Provisions that may impact our business include a \$2,000 out-of-pocket cap for Medicare Part D beneficiaries, the imposition of new manufacturer financial liability on most drugs in Medicare Part D, permitting the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, requiring companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA’s Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

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

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

Healthcare providers and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations. These laws will impact, among other things, our clinical research, as well as our proposed sales and marketing programs. In addition, we may be subject to health information privacy and security laws by the federal government, the states and other jurisdictions in which we may conduct our business. For more information, see the section titled “Business–Government Regulation–Other Healthcare Laws.”

Because of the breadth of these laws and the limited statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

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

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

Legislation or other changes in U.S. tax law may have a material adverse effect on our business, cash flow, financial condition, or results of operations.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the United States will be capitalized and amortized, which may have an adverse effect on our cash flow. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations.

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our stockholders’ tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. 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.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could hinder our ability to compete in certain markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

Our operations are subject to U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. Anti-corruption laws generally prohibit us and our employees, officers, CROs, consultants, contractors and other partners and agents from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies and clinical trials and/or to obtain necessary permits, licenses, patent registrations and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

We are also subject to U.S. and foreign export controls, trade sanctions, and import laws and regulations. Such laws may prevent or prohibit the export or provision of certain products and services to countries, governments, and persons targeted by sanctions. Violations of these above laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, breach of contract and fraud litigation, reputational harm and other consequences.

Risks Related to Third Party Relationships

We may depend on collaborations with third parties for the discovery, development and commercialization of our product candidates. If any of these collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates.

We may in the future seek third-party collaborators for research, development and commercialization of our product candidates. Pharmaceutical companies are our prior and likely future collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements. If we fail to enter into future collaborations on commercially reasonable terms, or at all, or such collaborations are not successful, we may not be able to execute our strategy to develop certain targets, product candidates or disease areas that we believe could benefit from the resources of either larger pharmaceutical companies or those specialized in a particular area of relevance.

With respect to any future collaboration agreements, we expect to have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our current or future product candidates. Moreover, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our current or future product candidates may pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- 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 preclinical studies or clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates 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 current or future product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators 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;
- 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 litigation or potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our current or future product candidates or that result in costly litigation or arbitration that diverts management attention and resources; 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.

As a result of the foregoing, any future collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. If a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our current or future product development or commercialization program could be delayed, diminished or terminated. Any failure to successfully develop or commercialize our product candidates pursuant to any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Moreover, to the extent that any of our future collaborators were to terminate a collaboration agreement, we may be forced to independently develop these product candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects.

We rely on third-party manufacturers, CROs, CMOs, and suppliers to supply, develop and test components of our product candidates. The loss of our third-party manufacturers, CROs, CMOs, or suppliers, their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, or changes in methods of product candidate manufacturing, development or formulation would materially and adversely affect our business.

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing. We currently rely, and may continue to rely, on third-party contract manufacturers, including in China, to manufacture and test bulk drug substances, drug products, raw materials, samples, components, or other materials and reports. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, terminated or of satisfactory quality or continue to be available at acceptable prices. In addition, any replacement of our manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements.

The manufacturing process for a product candidate is subject to FDA, EMA and foreign regulatory authority review. In some cases, we, and our suppliers and manufacturers, some of which may be our sole source of supply, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA, EMA, and other comparable foreign regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA, and other comparable foreign regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our product candidates. Moreover, we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party.

These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines; and we may be required to repeat some of the development program. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our products will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the FDA or foreign regulatory authorities could adversely affect our business in a number of ways, including:

- delay in the progress on certain research programs;
- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of existing or future collaborators;

- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our therapeutics.

Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our contract manufacturers were to encounter any of these difficulties, our ability to provide our product candidates to patients in preclinical and clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

In addition, we currently rely on foreign CROs and CMOs, including WuXi AppTec (HongKong) Limited, for manufacturing and development activities and will likely continue to rely on foreign CROs and CMOs in the future. Foreign 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, if enacted, legislation pending in Congress known as the BIOSECURE Act would prohibit U.S. federal agencies from entering into or renewing a contract with any company that uses biotechnology equipment or services produced or provided by a “biotechnology company of concern” in the performance of that contract. It would also prohibit loans or grant funding from U.S. federal agencies to entities that use any biotechnology equipment or services produced or provided by a “biotechnology company of concern” in the performance of the government grant or loan. The effects of this legislation, if enacted, is unknown; however, it could have the downstream effect of restricting the ability of pharmaceutical companies that enter into contracts with or receive funding from U.S. federal agencies from purchasing services or equipment from certain Chinese biotechnology companies, including those that are specifically named in the proposed BIOSECURE Act, as well as supply chain disruptions or delays. The current version of the BIOSECURE Act introduced in the House of Representatives names WuXi Biologics and WuXi AppTec as “biotechnology companies of concern” and includes a grandfathering provision allowing biotechnology equipment and services provided or produced by named “biotechnology companies of concern” under a contract or agreement entered into before the effective date until January 1, 2032. Depending on whether the BIOSECURE Act becomes law, what the final language of the BIOSECURE Act includes, and how the law is interpreted by U.S. federal agencies, we could be potentially restricted from pursuing U.S. federal government business or government reimbursement for our products in the future if we continue to use WuXi Biologics, WuXi AppTec or other suppliers or partners identified as “biotechnology companies of concern” beyond this grandfathering period. In addition to the BIOSECURE Act, any additional executive action, legislative action, or potential sanctions with China could materially impact our work with WuXi STA. U.S. executive agencies have the ability to designate entities and individuals on various governmental prohibited and restricted parties lists. Depending on the designation, potential consequences can range from a comprehensive prohibition on all transactions or dealings with designated parties, or a limited prohibition on certain types of activities, such as exports and financing activities, with designated parties.

For example, the pharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting pharmaceutical companies are unpredictable and may have a material adverse effect on our collaborators in China which could have an adverse effect on our business, financial condition, results of operations and prospects. Evolving changes in China’s public health, economic, political, and social conditions and the uncertainty around China’s relationship with other governments, such as the U.S. and the United Kingdom, or U.K., could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical development programs. Any of the foregoing factors could have a material adverse effect on our business, results of operations, or financial condition.

Furthermore, as product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality 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 current or future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

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

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

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

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

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

collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into additional agreements on certain terms or at all with other potential collaborators.

As a result of these risks, we may not be able to realize the benefit of any future collaborations or licensing agreements we may enter into. In addition, we may face regulatory obstacles in completing such transactions. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our structure-based drug discovery platform or product candidates or bring them to market and generate revenue.

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

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

The manufacturing of our product candidates is complex, and our third-party manufacturers may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our products for patients, if approved, could be delayed or stopped.

The process of manufacturing pharmaceuticals is complex, time-consuming, highly regulated and subject to multiple risks. Our contract manufacturers must comply with legal requirements, cGMPs and guidelines for the manufacturing of pharmaceuticals used in clinical trials and, if approved, marketed products. Our contract manufacturers may have limited experience in the manufacturing of cGMP batches.

Manufacturing pharmaceuticals is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at our third-party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. Even if we or our future collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

Scaling up a pharmaceutical manufacturing process is a difficult and uncertain task, and our third-party manufacturers may not have the necessary capabilities to complete the implementation, manufacturing and development process. If we are unable to adequately validate or scale-up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer

and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

We cannot assure that any stability or other issues relating to the manufacture of any of our current or future product candidates will not occur in the future. If our third-party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, prospects, financial condition and results of operations.

As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our current or future product candidates to perform differently and affect the results of our current or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

We intend to rely on third parties to conduct, supervise and monitor our preclinical studies and clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

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

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

While we will have agreements governing their activities, our CROs and other third parties we engage will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future nonclinical and clinical programs. These CROs and others may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs and others, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. In addition, certain of our agreements with CROs and other third parties currently or will provide for monetary and other limitations on their liability. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for any other reasons, our preclinical or clinical programs may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product

candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed, decreased or eliminated.

If our relationship with these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, financial condition and prospects.

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

We currently depend and in the future may continue to depend on single- or limited-source suppliers for some of the components and materials used in the product candidates we may develop.

We currently depend and in the future may continue to depend on single- or limited-source suppliers for some of the components and materials used in any product candidates we may develop. We cannot ensure that these suppliers or service providers will remain in business, have sufficient capacity or supply to meet our needs or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of raw materials, components, key processes and finished goods could expose us to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single-source supplier or service provider could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

If we have to switch to a replacement supplier, the manufacture and delivery of any product candidates we may develop could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers, if required, may not be accomplished quickly or at all. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single source components and materials used in our therapeutics, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our product candidates.

Risks Related to Intellectual Property

If we are unable to obtain, maintain, defend and enforce patent or other intellectual property protection for our current or any future product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We anticipate that we will file additional patent applications both in the United States and in other jurisdictions, as appropriate. However, we cannot predict:

- if and when any patents will issue;
- the degree and scope of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether others will apply for or obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to defend our patent rights, which may be costly whether we win or lose; or

- whether the patent applications that we own, or may in-license, will result in issued patents with claims that cover our current or future product candidates or uses thereof in the United States or in foreign jurisdictions.

We rely, and may in the future rely, upon a combination of patent, trade secret and trademark protection for our current and any future product candidates and proprietary technologies to prevent third parties from exploiting our achievements, thus eroding our competitive position in our market. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success depends in large part on our ability to obtain, maintain, expand, enforce, and defend the scope, ownership or control, validity and enforceability of our intellectual property protection in the United States and other countries with respect to our current and any future product candidates and other proprietary technologies we may develop. Our commercial success depends in large part on our ability to obtain and maintain patent protection in the United States and other jurisdictions with respect to our current and any future product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our current and future development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner, including as a result of factors impacting our, our licensors' or governmental patent offices' operations.

It is possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current or any future product candidates in the United States or in foreign jurisdictions. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been or will be found, which unknown prior art can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do issue and even if such patents cover our current or any future product candidates, third parties may challenge their scope, validity, or enforceability, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any current or future product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

If the patent applications we hold or have in-licensed with respect to our product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for current or any future product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future drug products. Any such outcome could have a negative effect on our business.

Composition of matter patents for pharmaceutical products provide intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain, however, that the claims in our pending patent applications covering the composition of matter of any of our current or future product candidates will be considered patentable by the U.S. Patent and Trademark Office ("USPTO"), or by patent offices in foreign jurisdictions, or that the claims in any of our patents that may issue will be considered valid and enforceable by courts in the United States or foreign jurisdictions. Method of use patents protect the use of a product for the specified method. We cannot be certain, however, that the claims in our pending patent applications covering methods of use of our current or future product candidates will be considered patentable by the USPTO, or by patent offices in foreign jurisdictions, or that the claims in any of our patents that may issue will be considered valid and enforceable by courts in the United States or foreign jurisdictions. Further, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, once approved for therapeutic use by FDA, or counterpart foreign regulatory authorities, physicians may prescribe these products "off-label" for those uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or enforce against.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign jurisdictions may not protect our rights to the same extent as the laws of the United States. Patent applications in the United States and certain other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to file for patent protection. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies or products.

Changes in either the patent laws or interpretation of the patent laws in the United States and other jurisdictions may diminish the value of our patents or narrow the scope of our patent protection. These changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a negative effect on our business.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or another patent office or become involved in opposition, derivation, reexamination, *inter partes* review (“IPR”), post-grant review (“PGR”) or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights or obtaining a costly license from a third party. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology, products or methods, or limit the duration of the patent protection of our technology, products or methods.

Moreover, patents have a limited lifespan. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years from the earliest filing date of a non-provisional patent application. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. For instance, a patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not necessarily extend to all claims, but instead only to claims that read on the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially. In addition, although upon issuance in the United States a patent’s term can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Without patent protection for our current or future product candidates, including once the patent life has expired even if patents covering our product candidates are obtained, we may be open to competition from generic versions of such drugs. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Even if patents covering our current or future product candidates are obtained, once the patent term has expired for a product, we may be open to competition from generic medications. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

Even if we have or obtain patents covering our products or methods, we may still be barred from making, using and selling such products or methods because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering compositions, products or methods that are similar or identical to ours, which could materially affect our ability to successfully develop our technology or to successfully commercialize any approved products alone or with collaborators.

Patent applications in the United States and elsewhere are generally published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our methods and current or future product candidates could have been filed by others without our knowledge. Additionally, pending claims in patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies or related products. These patent applications may have priority over patent applications filed by us.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor, co-inventor, owner or co-owner. For example, we or our licensors may have inventorship or ownership disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our current or future product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors’ ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, we may be required to pay monetary damages and we may also lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our current or future product candidates. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our current or future product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical 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. We cannot be certain that our product candidates and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. Third parties may assert infringement claims against us based on existing or future intellectual property rights. In the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe 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. 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. 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. A finding of infringement could prevent us from commercializing our investigational products or force us to cease some of our business operations, which could materially harm our business.

We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, might assert are infringed by our current or future product candidates, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates and other proprietary technologies we may develop, could be found to be infringed by one or more of our current or future product candidates. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our current or future product candidates may infringe. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our current or future product candidates. The pharmaceutical and biotechnology industries have produced a considerable 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 our current or future product candidates, products or methods 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 may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

We may choose to challenge the enforceability or validity of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an *ex parte* re-examination, IPR or PGR proceeding. These proceedings are expensive and may consume our

time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the European Patent Office ("EPO"), or other foreign patent office. The costs of these opposition proceedings could be substantial and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office, then we may be exposed to litigation by a third party alleging that the patent may be infringed by our current or future product candidates or proprietary technologies.

If we are found to infringe 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. 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. 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. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, and could divert the time and attention of our technical personnel and management, cause development delays, and/or require us to develop non-infringing technology, which may not be possible on a cost-effective basis, any of which could materially harm our business. In the event of a successful claim of infringement against us, we may have to pay substantial monetary damages, including treble damages and attorneys' fees for willful infringement, pay royalties and other fees, redesign our infringing drug or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

Our technology licensed from various third parties may be subject to retained rights.

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

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act ("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. We sometimes collaborate with academic institutions to accelerate our preclinical research or development, creating a risk that federal funds may be commingled. Therefore, we cannot be sure that any intellectual property co-developed from a collaboration with an academic institution 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.

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

We have reviewed certain third-party patents and patent filings that we believe may be relevant to our product candidates; and on August 1, 2024, we completed freedom-to-operate searches for the exact structures of SEP-786 and SEP-631, which did not identify any third-party patents and patent filings that we believe are relevant to our product candidates. Nevertheless, we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our product candidates. Thus, we cannot guarantee that our current or future product candidates, or our commercialization thereof, do not and will not infringe any third party's intellectual property.

We cannot guarantee that any patent searches or analyses that are performed, including the identification of relevant patents, the scope of patent claims or the expiration dates 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 current or future product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our future 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 determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our future products.

One aspect of the determination of patentability of our inventions depends on the scope and content of the “prior art,” information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim.

The landscape of intellectual property related to our current or future product candidates and future products is constantly changing. Therefore, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications in the United States and certain other jurisdictions are confidential for typically a period of at least 18 months after their priority date, or may not be published at all, we cannot be certain that we were the first to file any patent application related to our current or future product candidates. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U.S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the America Invents Act, which brought into effect significant changes to the U.S. patent laws, including new procedures for challenging pending patent applications and issued patents. Should we fail to win an interference challenge, a third party may obtain rights to intellectual property related to our current or future product candidates and future products.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our 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 or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights 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 successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our current or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology platform or product candidates in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce, and defend such patents or patent applications, or lose rights to those patents or patent applications, the rights we

have licensed may be reduced or eliminated, and our right to develop and commercialize any of our current or future product candidates that are subject of such licensed rights could be adversely affected.

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

It is possible that we may be unable to obtain necessary licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Disputes may arise between us and our 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;
- whether and the extent to which our technology and processes infringe on 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 future licensors and us and our partners; and
- the priority of invention of patented technology.

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

In spite of our best efforts, our 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 and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

From time to time, we may be required to license technologies relating to our programs from additional third parties to further develop or commercialize our current or future product candidates. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

We may be involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including but not limited to lack of novelty, obviousness, or insufficient written description or enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, PGR, IPR, derivation proceedings, interference proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in loss of rights to, the revocation of, cancellation of or amendment to our patents in such a way that they no longer cover our technology or platform, or any product candidates that we may develop. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. There is also no assurance that there is no prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a patent claim. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates or other intellectual property that we may develop. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened or questioned, it could dissuade companies from collaborating with us to license, develop or commercialize our current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

We may be subject to claims that we or our employees have misappropriated the intellectual property, including confidential information, know-how or trade secrets, of a third-party, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, consultants and contractors were previously employed at or engaged by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we have wrongfully hired an employee from a competitor or that we or these employees, consultants or contractors have used or disclosed such third-party intellectual property, including know-how, trade secrets or other proprietary information, to us. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, it may have negative impact on our business and our ability to develop product candidates or commercialize our technology. In addition to paying substantial monetary damages, we may lose valuable intellectual property rights or personnel, or access to consultants and contractors. Even if we are successful in defending against such claims, litigation could incur substantial costs and be a distraction to management and scientific personnel.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying

monetary damages, we may lose valuable intellectual property rights. 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.

We may license intellectual property rights from third parties. Such licenses may be subject to early termination if we fail to comply with our obligations in our licenses with third parties, which could result in the loss of rights or technology that are material to our business.

We may become a party to licenses that give us rights to third-party intellectual property or technology that is necessary or useful for our business, and we may enter into additional licenses in the future. Under these license agreements, we are or may become obligated to pay the licensor fees, which may include annual license fees, milestone payments, royalties, a percentage of revenues associated with the licensed technology and a percentage of sublicensing revenue. These fees may be significant, which could make it difficult for us to achieve or maintain profitability. In addition, under certain of such agreements, we are or may become required to diligently pursue the development of products using the licensed technology. If we fail to comply with these obligations, including due to our use of the intellectual property licensed to us in an unauthorized manner, and fail to cure our breach within a specified period of time, the licensor may have the right to terminate the applicable license, in which event we could lose valuable rights and technology that are material to our business, harming our ability to develop, manufacture and/or commercialize our platform, products or product candidates.

In addition, the agreements under which we license intellectual property or technology to or from third-parties can 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 our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. The failure to obtain or in-license any compositions, methods of use, processes or other third-party intellectual property rights at a reasonable cost or on reasonable terms, could harm our business. If we fail to obtain licenses to necessary third-party intellectual property rights, we may need to cease use of the compositions or methods covered by such third-party intellectual property rights. Furthermore, we may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

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

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

The USPTO and various non-U.S. government patent agencies require compliance with numerous procedural, documentary, and other similar provisions during the patent application process. For example, many jurisdictions, including the U.S. and China, require a foreign filing license before seeking patent protection in a jurisdiction outside of the jurisdiction of which the inventor is a citizen or in which the invention was made. Each jurisdiction's laws regarding foreign filing licenses vary and may even conflict. We employ reputable law firms in foreign jurisdictions and other professionals to help us comply and we are also dependent on any licensors to take the necessary action to comply with these requirements with respect to our intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Additional non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and

submit formal documents. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

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

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

Many companies have encountered significant problems protecting and defending intellectual property rights in jurisdictions outside the United States. The legal systems of certain jurisdictions do not favor the enforcement of patents, trade secrets and other intellectual property rights, particularly those relating to pharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, including the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patents and other intellectual property rights in jurisdictions outside the United States could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business.

Our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in intellectual property laws in the United States and around the world. For example, in Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (“UPC”). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes. Certain jurisdictions, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties under certain circumstances. In those jurisdictions, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. In addition, many jurisdictions limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop and our technology, one or more U.S. patents that we license or may own in the future may be eligible for limited patent term extension under the Hatch-Waxman Amendments. Under certain circumstances the Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought and within 60 days of FDA approval. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable patent term extension or the scope of patent protection afforded could be less than we request. 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. If we are unable to obtain patent term extension or the term of any such extension is less than we request, we may be open earlier than projected to competition from competitive products, including generics or biosimilars following our patent expiration, and our revenue could be reduced earlier than projected. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of our trade secrets and other proprietary information. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

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

Trade secrets, confidential know-how and proprietary information, however, may be difficult to protect. We seek to protect our trade secrets, confidential know-how and proprietary information, including our proprietary processes and drug discovery platform, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. Although we use reasonable efforts to protect our trade secrets, we cannot provide any assurances that all such agreements have been duly executed, and notwithstanding the existence of a confidentiality agreement our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information, including to competitors. In addition, competitors or other third parties may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, the laws of some foreign jurisdictions do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

Our intellectual property rights do not necessarily protect against all potential threats to our business.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business. These risks and uncertainties include the following:

- others may be able to make compounds or formulations that are similar to our current or future product candidates but that are not covered by the claims of any patents, should they issue, that we own or control;
- we or any strategic partners might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or control;
- we might not have been the first to file patent applications covering certain of our current or future product candidates or inventions we own or control;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- pending patent applications that we own or control may not lead to issued patents;

- issued patents that we own or control may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other jurisdictions that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in jurisdictions where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

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

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

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties 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. Furthermore, assertions of potential trademark infringement or possible market confusion may lead to coexistence agreements in order to avoid costly disputes related to our trademarks. As a consequence, we may be forced to amend the list of goods and services covered by our trademarks more narrowly than as originally filed and intended, which could adversely affect our ability to establish name recognition. 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. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Rights to improvements to our product candidates may be held by third parties.

In the course of testing our current or future product candidates, we may enter into agreements with third parties to conduct clinical testing, which may provide that improvements to our product candidates may be owned solely by a third party or jointly between the parties. If we determine that rights to such improvements owned solely by a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain a license from such third party in order to use the improvements and continue developing, manufacturing or marketing the product candidates. 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 such a license, it could be granted on non-exclusive terms, thereby giving our competitors and other third parties access to the same technologies licensed to us. Failure to obtain a license on commercially reasonable terms or at all, or to obtain an exclusive license, could prevent us from commercializing our current or future product candidates or force us to cease some of our business operations, which could materially harm our business. If we determine that rights to improvements jointly owned between us and a third party are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain an exclusive license from such third party. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such improvements, such co-owners may be able to license their rights to other parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our intellectual property in order to enforce such intellectual property against other parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

The use of new and evolving technologies, such as artificial intelligence, in our offerings may present risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate artificial intelligence tools into our processes for specific use cases reviewed by legal and information security. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. The use of certain artificial intelligence technology can give rise to intellectual property risks, including compromises to proprietary intellectual property and intellectual property infringement. Additionally, we expect to see increasing government and supranational regulation related to artificial intelligence use and ethics, which may also significantly increase the burden and cost of research, development and compliance in this area. For example, several jurisdictions around the globe, including Europe and certain U.S. states, have proposed enacted, or are considering laws governing the development and use of artificial intelligence, such as the EU's AI Act. We expect other jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use artificial intelligence. These obligations may make it harder for us to conduct our business using artificial intelligence, lead to regulatory fines or penalties, require us to change our business practices, retrain our artificial intelligence, or prevent or limit our use of artificial intelligence. For example, the FTC has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of artificial intelligence where they allege the company has violated privacy and consumer protection laws. If we cannot use artificial intelligence or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage. The rapid evolution of artificial intelligence will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that artificial intelligence is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate artificial intelligence tools into their own offerings, and the providers of these artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to data protection, privacy, and security. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal data, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Risks Related to Ownership of Our Common Stock

We do not know whether a market will be sustained for our common stock or what the market price of our common stock will be, and, as a result, it may be difficult for you to sell your shares of our common stock.

Although our common stock is listed on the Nasdaq Global Market ("Nasdaq"), an active trading market for our common stock may not be sustained. If a market for our common stock is not sustained or if trading volume in our common stock is low, it may be difficult for you to sell your shares of common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our common stock may fall.

The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares.

The market price for our common stock may be influenced by those factors discussed in this “Risk Factors” section and many others, some of which may include:

- the success of existing or new competitive product candidates or technologies;
- the commencement, enrollment, completion and results of preclinical studies and clinical trials for our current and future product candidates;
- adverse results or delays, suspensions or terminations in future preclinical studies or clinical trials;
- unanticipated serious safety concerns related to our current or future product candidates;
- 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 current or future product candidates or the failure of a regulatory authority to accept data from preclinical studies or clinical trials conducted in other countries;
- our failure to commercialize our current or future product candidates, if approved;
- failure or discontinuation of any of our development and research programs;
- results of any preclinical studies, clinical trials or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs, clinical development programs or product candidates that we may develop;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts, if any, that cover our stock;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreements;
- 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;
- trading volume of our common stock;
- variations in our financial results or those of companies that are perceived to be similar to us;

- changes in accounting practices;
- ineffectiveness of our internal controls;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, political, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In addition, the stock market in general, and the market for pharmaceutical 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. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company’s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management’s attention and resources.

Future sales, or the perception of future sales, of our common stock in the public market by existing stockholders could cause our stock price to fall.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and legal restrictions on resale lapse, the trading price of our common stock could decline. The possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

As of September 30, 2024, we had 3,162,968 shares of our common stock outstanding. Shares of unvested restricted stock that were issued and outstanding will become available for sale immediately upon the vesting of such shares, as applicable, and the expiration of any applicable market stand-off or lock-up agreements. Shares issued upon the exercise of stock options pursuant to future awards that may be granted 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, any applicable market stand-off and lock-up agreements and Rule 144 and Rule 701 under the Securities Act of 1933, as amended (the “Securities Act”).

Certain holders of our common stock have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans, and those shares are available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above. Once we register the offer and sale of shares for the holders of registration rights, they can be freely sold in the public market upon issuance, subject to the lock-up agreements.

In addition, we expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, in the future, we may issue additional shares of our common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

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

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012 (“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 not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (“Sarbanes-Oxley Act”), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements, in

addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in our periodic reports. 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 \$700.0 million as of the prior June 30, 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 following December 31, 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. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply 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.
- providing 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;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

Even after we no longer qualify as an emerging growth company, we could still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements and reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements. 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 share price may be more volatile.

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 will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a “smaller reporting company” as defined in the Exchange Act of 1934, as amended (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 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 new 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, and these expenses may increase even more after we are no longer an “emerging growth company.” We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the Securities and Exchange Commission (the “SEC”) annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial reporting controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (“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 the fifth anniversary 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.

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

Insiders have substantial influence over us, which could limit your ability to affect the outcome of key transactions, including a change of control.

Based on the beneficial ownership of our common stock as of September 30, 2024, our directors and executive officers, holders of 5% or more of our capital stock and their respective affiliates beneficially own a significant percentage of our outstanding common stock. These stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

We do not expect to pay any dividends for the foreseeable future. Investors may never obtain a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

If we fail to maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

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 re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). As a public company, we are required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, beginning with our second Annual Report on Form 10-K after we become a public company, we are required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we may be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We are engaged in the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy or consequent inability to produce accurate financial statements on a timely basis could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis cause investors to lose confidence in the accuracy and completeness of our financial reports and could cause the market price of our common stock to decline significantly.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably 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 or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. 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.

If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

We may in the future discover material weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls over financial reporting, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline, and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorized our board of directors to make, alter, amend or repeal our amended and restated bylaws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated bylaws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. 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 we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, 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.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

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 provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of, or a claim based on, fiduciary duty owed by any of our current or former directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, 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 ("Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act 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 ("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, 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.

General Risk Factors

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

The global credit and financial markets have experienced extreme volatility and disruptions (including as a result of actual or perceived changes in interest rates, inflation and macroeconomic uncertainties), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, global supply chain disruptions, and increases in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflicts between Russia and Ukraine, and Israel and Hamas, terrorism, or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for our product candidates and in our ability to raise additional capital when needed on acceptable terms, if at all. There are also current geopolitical tensions with China that may affect our operations. For example, there has been proposed United States legislation, such as the bill titled the BIOSECURE Act, that may restrict the ability of United States pharmaceutical companies 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 United States 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 or public health crises, could negatively impact the timely execution of our

ongoing and future clinical trials. In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and 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.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems.

Although we assess our banking and customer 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 affect our Company, the financial institutions with which we have 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.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- potential or actual breach of statutory, regulatory or contractual obligations, including obligations that require us to maintain letters of credit or other credit support arrangements;
- termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the United States or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity, our current and/or planned business operations, and our current or projected financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our suppliers, which in turn, could have a material adverse effect on our current and/or planned business operations and our current or projected results of operations and financial condition. For example, a customer may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a customer or supplier could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on the Company, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any customer, collaborator or supplier bankruptcy or insolvency, or the failure of any customer or collaborator to make payments when due, or any breach or default by a customer, collaborator or supplier, or the loss of any significant supplier or collaborator relationships, could result in material losses to the Company and may have a material adverse impact on our business.

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

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our

stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

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.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

While we maintain commercial insurance at a level we believe is appropriate against certain risks commonly insured in the industry in which we operate, there is no guarantee that our insurer will cover costs or that we will be able to obtain the desired level of coverage on acceptable terms in the future. Some of the policies we currently maintain include property, general liability, crime insurance, workers' compensation, and directors' and officers', employment practices and fiduciary liability insurance, clinical trial insurance, transportation insurance and umbrella insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Changes in the market conditions and our business operations may necessitate the addition of new insurance policies or change of our existing insurance policies. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

Our operations are vulnerable to interruption by disasters, terrorist activity, pandemics and other events beyond our control, which could harm our business.

Our facilities are located in California. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major flood, power loss, terrorist activity, pandemics or other regional or global disasters and generally do not have a recovery plan for such events. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Increased attention to, and evolving expectations for, environmental, climate change, social, and governance initiatives could increase our costs, harm our reputation, or otherwise adversely impact our business.

Companies across industries are facing increasing scrutiny from a variety of stakeholders related to their environmental, climate change, social, and governance ("ESG") and sustainability practices. Expectations regarding voluntary ESG initiatives and disclosures may result in increased costs (including but not limited to increased costs related to compliance, stakeholder engagement, contracting and insurance), enhanced compliance or disclosure obligations, or other adverse impacts to our business, financial condition, or results of operations.

While we may at times engage in voluntary initiatives (such as voluntary disclosures, certifications, or goals, among others) to improve the ESG profile of the Company, such initiatives may be costly and may not have the desired effect. Moreover, we may not be able to successfully complete such initiatives due to factors that are within or outside of our control. Even if this is not the case, our actions may subsequently be determined to be insufficient by various stakeholders, and we may be subject to investor or regulator engagement on our ESG efforts, even if such initiatives are currently voluntary.

Certain market participants, including major institutional investors and capital providers, use third-party benchmarks and scores to assess companies' ESG profiles in making investment or voting decisions. Unfavorable ESG ratings could lead to increased negative investor sentiment towards us, which could negatively impact our share price as well as our access to and cost of capital. To the extent ESG matters negatively impact our reputation, it may also impede our ability to compete as effectively to attract and retain employees, which may adversely impact our operations.

In addition, we expect there will likely be increasing levels of regulation, disclosure-related and otherwise, with respect to ESG matters. For example, the SEC has issued rules that require companies to provide significantly expanded climate-related disclosures in

their periodic reporting, which may require us to incur significant additional costs to comply, including the implementation of significant additional internal controls processes and procedures regarding matters that have not been subject to such controls in the past, and impose increased oversight obligations on our management and board of directors. These and other changes in stakeholder expectations will likely lead to increased costs as well as scrutiny that could heighten all of the risks identified in this risk factor. Additionally, our business partners may be subject to similar expectations, which may augment or create additional risks, including risks that may not be known to us.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

Set forth below is information regarding shares of equity securities sold, and options granted, by us during the three months ended September 30, 2024 that were not registered under the Securities Act.

(a) Unregistered Sales of Equity Securities

During the three months ended September 30, 2024, we granted stock options to purchase an aggregate of 1,230,166 shares of our common stock at a weighted-average exercise price of \$6.81 per share, to certain of our employees, directors and consultants, pursuant to our 2021 Stock Option and Grant Plan, as amended (“2021 Plan”).

The issuances of the securities under the 2021 Plan described above were deemed to be exempt from registration under Rule 701 promulgated under the Securities Act as transactions under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering. The recipients of such securities were our directors, employees or bona fide consultants and received the securities under our equity incentive plans. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

On October 25, 2024, we filed a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to our equity compensation plans.

(b) Use of Proceeds

On October 24, 2024, our Registration Statement on Form S-1 (File No. 333-282469), as amended, relating to our IPO was declared effective by the SEC (the “Registration Statement”). Pursuant to the Registration Statement, we registered the offer and sale of 18,400,000 shares of our common stock. On October 28, 2024, we closed our IPO, pursuant to which we issued and sold 18.4 million shares of common stock at the public offering price of \$18.00 per share and on October 30, 2024, we issued and sold an additional 2.4 million shares of our common stock to the underwriters pursuant to the full exercise of their option to purchase additional shares of our common stock, at the public offering price of \$18.00 per share and received gross proceeds of \$331.2 million, which resulted in net proceeds to us of approximately \$302.6 million, after deducting underwriting discounts and commissions and other offering costs payable by us of approximately \$28.6 million. J.P. Morgan Securities LLC, TD Securities (USA) LLC, Cantor Fitzgerald & Co. and Wells Fargo Securities, LLC acted as joint book-running managers for the IPO.

The net proceeds from our IPO have been invested according to our approved investment policy in a mix of money market funds and high-quality, fixed income securities. There has been no material change in our planned use of the net proceeds from the IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on October 25, 2024.

Issuer Repurchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Plans

None of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted or terminated a Rule 10b5-1 trading plan or arrangement or a non-Rule 10b5-1 trading plan or arrangement, as defined in Item 408(c) of Regulation S-K, during the fiscal quarter ended September 30, 2024 covered by this Quarterly Report.

Item 6. Exhibits.

(a) Exhibits.

Exhibit Number	Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-42382	3.1	October 28, 2024
3.2	Amended and Restated Bylaws of the Registrant.	8-K	001-42382	3.2	October 28, 2024
4.1†	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated as of June 28, 2023.	S-1	333-282469	4.1	October 24, 2024
4.2	Specimen Common Stock Certificate.	S-1	333-282469	4.2	October 24, 2024
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**	Certifications of Principal Executive Officer and 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 formatted as Inline XBRL and contained in Exhibit 101				

* Filed herewith.

+ The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report 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.

† Annexes, schedules and/or exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of any omitted attachment to the SEC on a confidential basis upon request.

(b) Financial Statement Schedules. None.

**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, Jeffrey Finer, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Septerna, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) (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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 20, 2024

By: _____ /s/ Jeffrey Finer, M.D., Ph.D.

Jeffrey Finer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

**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, Ran Xiao, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Septerna, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) (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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 20, 2024

By: _____
/s/ Ran Xiao, M.B.A., CFA
Ran Xiao, M.B.A., CFA
Interim Chief Financial Officer, Vice President of Finance and Business Operations
(Principal Financial Officer and Principal Accounting Officer)

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Septerna, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officers of the Company hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 20, 2024

By: _____
/s/ Jeffrey Finer, M.D., Ph.D.
Jeffrey Finer, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 20, 2024

By: _____
/s/ Ran Xiao, M.B.A., CFA
Ran Xiao, M.B.A., CFA
Interim Chief Financial Officer, Vice President of Finance and Business Operations
(Principal Financial Officer and Principal Accounting Officer)
