UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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, 2025

OR

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

For the transition period from _____ to _____s

Commission File Number 001-39538

CalciMedica, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**45-2120079**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

505 Coast Boulevard South, Suite 307
La Jolla, CA 92037
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (858) 952-5500

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 $0.0001 per share	CALC	The Nasdaq Capital 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 ☒

The number of shares of the Registrant's common stock outstanding as of November 6, 2025 was 14,409,431.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements about us and our industry that involve substantial risks and uncertainties. All statements, other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases you can identify these statements by forward-looking words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "would," "project," "plan," "expect" or the negative or plural of these words or similar expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- our expectations regarding the success, cost and timing of our development activities, non-clinical studies and clinical trials;
- our expectations regarding the timing and outcome of our current and future clinical trials, and the reporting of data from those trials;
- our research and development plans;
- the potential of our technologies and our ability to execute on our corporate strategy;
- our ability to attract and retain key scientific, medical, commercial and management personnel;
- our ability to fund our working capital needs;
- the strength and breadth of our patent portfolio;
- the therapeutic potential of Auxora and our other product candidates and the expected patient populations, market opportunities, commercial potential and commercialization strategy thereof;
- our expectations regarding our cash runway and expected use of cash, cash equivalents and short-term investments;
- our need to obtain additional funding and the ability to obtain such funding for our operations, including funding necessary to develop and commercialize our product candidates, subject to regulatory approvals:
- our ability and plans to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our expected competitive position;
- our ability to develop and maintain our corporate infrastructure, including our ability to design and maintain an effective system of internal controls;
- legislative and regulatory developments in the United States and other foreign countries;
- potential claims relating to our intellectual property or other legal proceedings;
- our expectations regarding future economic conditions or our financial performance;
- our expectations regarding the impact of global health pandemics, geopolitical conflicts and economic uncertainty, including tariffs and other trade measures, rising interest rates and inflation on our business and operations, including clinical trials, collaborators, contract research organizations ("CROs") and employees;
- our ability to obtain and adequately protect intellectual property rights for our product candidates;
- our ability to obtain regulatory approval for our product candidates and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our ability to extend our operating capital;
- estimates of the market size of our product candidates, addressable patient populations, and future revenue;
- our ability to service and comply with the terms of our outstanding indebtedness;
- our ability to continue to satisfy the Nasdaq listing requirements and have our stock continue to trade on Nasdaq; and
- statements of belief and any statement of assumptions underlying any of the foregoing.

These statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q. You should not rely upon forward-looking statements as predictions of future events.

New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, after the date of this report, we are under no duty to update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise.

We obtained industry, market and competitive position data in this report from our own internal estimates and research as well as from industry and general publications and research surveys and studies conducted by third parties. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information or estimates.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

An investment in our common stock involves a high degree of risk. Below is a list of the more significant risks associated with our business. This summary does not address all of the risks that we face. Additional discussion of the risks listed in this summary, as well as other risks that we face, are set forth under Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q. These risks include, but are not limited to, the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history. We have a history of net losses and anticipate that we will incur significant losses in the future. We have never generated any revenue from product sales and may never be profitable.
- Our need for additional capital raises substantial doubt about our ability to continue as a going concern. We will need to obtain substantial additional funding to complete the development and any commercialization of our product candidates. If we are unable to raise this capital when needed, on acceptable terms, or at all, we may be forced to delay, reduce or eliminate the development of our product candidates or other operations.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our proprietary platform or product candidates.
- Any acquisitions or strategic collaborations may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities or subject us to other risks.
- Our proprietary CRAC channel inhibition science 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 use and expand our science to build a pipeline of product candidates.
- Our business is highly dependent on the success of our product candidates, in particular Auxora, and we may fail to develop Auxora successfully or be unable to obtain regulatory approval.
- Clinical development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.
- We have conducted a significant portion of our CARPO trial in India, and regulatory authorities may not accept data from such trial or any future clinical trials we conduct outside the United States or the applicable foreign jurisdiction.
- We depend on enrollment of patients in our clinical trials for our product candidates. If we experience delays or difficulties enrolling patients in our clinical trials, our research and development efforts and business, financial condition, results of operations and prospects could be adversely affected.
- We rely on third parties to conduct and perform most of our research, preclinical studies and clinical trials. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements, fail to meet projected clinical trial enrollment schedules or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.
- We contract with third parties for the manufacturing and supply of certain goods and services for our product candidates for use in preclinical studies and clinical trials, which supply may become limited or interrupted or may not be of satisfactory quality and quantity.
- Any approved product candidates may fail to achieve the degree of market acceptance by physicians, patients, hospitals, healthcare payors and others in the medical community necessary for commercial success.
- We may not be able to successfully commercialize our product candidates due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell our product candidates profitably.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.
- If we are unable to obtain and maintain sufficient intellectual property protection for Auxora, any future product candidates, and other proprietary technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize Auxora, any future product candidates, and other proprietary technologies if approved, may be adversely affected.

- Our business operations subject us to disputes, claims and lawsuits, which may be costly and time-consuming and could materially and adversely impact our financial position and results of operations.
- International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.
- The terms of the Loan Agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

CALCIMEDICA, INC.
Condensed Consolidated Balance Sheets
(in thousands, except par value and share amounts)
(Unaudited)

	September 30, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 5,470	$ 7,935
Short-term investments	8,614	10,734
Prepaid clinical trial expenses	230	748
Other prepaid expenses and current assets	539	248
Total current assets	14,853	19,665
Property and equipment, net	49	119
Other assets	11	10
Total assets	$ 14,913	$ 19,794
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	$ 1,133	$ 1,998
Accrued clinical trial costs	1,523	820
Accrued expenses	1,025	866
Total current liabilities	3,681	3,684
Long-term liabilities		
Promissory note	8,900	—
Warrant liability	2,600	1,700
Total liabilities	15,181	5,384
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit)		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at September 30, 2025 and December 31, 2024, respectively; no shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized at September 30, 2025 and December 31, 2024, respectively; 14,257,234 and 13,481,917, issued and outstanding at September 30, 2025 and December 31, 2024, respectively	4	4
Additional paid-in capital	178,293	174,166
Accumulated deficit	(178,566)	(159,764)
Accumulated other comprehensive income	1	4
Total stockholders' equity (deficit)	(268)	14,410
Total liabilities and stockholders' equity	$ 14,913	$ 19,794

See accompanying notes to unaudited condensed consolidated financial statements.

CALCIMEDICA, INC.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 3,851	$ 3,546	$ 12,127	$ 10,647
General and administrative	1,767	2,190	6,609	7,385
Total operating expenses	5,618	5,736	18,736	18,032
Loss from operations	(5,618)	(5,736)	(18,736)	(18,032)
Other income (expense):				
Change in fair value of financial instruments	(2,000)	(100)	200	7,790
Interest expense	(326)	—	(1,097)	—
Interest income	140	218	562	800
Other income	—	—	269	—
Total other income (expense)	(2,186)	118	(66)	8,590
Net loss	$ (7,804)	$ (5,618)	$ (18,802)	$ (9,442)
Net loss per share - basic and diluted	$ (0.52)	$ (0.50)	$ (1.28)	$ (0.88)
Weighted-average number of shares outstanding used in computing net loss per share—basic and diluted	15,076,456	11,134,964	14,734,641	10,674,531

See accompanying notes to unaudited condensed consolidated financial statements.

CALCIMEDICA, INC.
Condensed Consolidated Statements of Comprehensive Loss (in thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net loss	$ (7,804)	$ (5,618)	$ (18,802)	$ (9,442)
Unrealized (loss) gain on available-for-sale securities, net of tax	5	13	(3)	2
Comprehensive loss	$ (7,799)	$ (5,605)	$ (18,805)	$ (9,440)

See accompanying notes to unaudited condensed consolidated financial statements.

CALCIMEDICA, INC.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders' Equity
	Shares	Amount	Capital	Deficit	Gain (Loss)	(deficit)
Balance—December 31, 2024	13,481,917	$ 4	$ 174,166	$ (159,764)	$ 4	$ 14,410
Stock-based compensation expense	—	—	549	—	—	549
Issuance of common shares from underwritten public offering (net of issuance costs)	—	—	8	—	—	8
Issuance of common stock from at-the-market offering (net of issuance costs)	490,073	—	968	—	—	968
Unrealized loss on investments	—	—	—	—	(5)	(5)
Net loss	—	—	—	(5,042)	—	(5,042)
Balance—March 31, 2025	13,971,990	4	175,691	(164,806)	(1)	10,888
Stock-based compensation expense	—	—	1,174	—	—	1,174
Unrealized loss on investments	—	—	—	—	(3)	(3)
Net loss	—	—	—	(5,956)	—	(5,956)
Balance—June 30, 2025	13,971,990	4	176,865	(170,762)	(4)	6,103
Stock-based compensation expense	—	—	626	—	—	626
Issuance of common stock from at-the-market offering (net of issuance costs)	270,057	—	777	—	—	777
Issuance of common stock from exercise of stock options	15,187	—	25	—	—	25
Unrealized gain on investments	—	—	—	—	5	5
Net loss	—	—	—	(7,804)	—	(7,804)
Balance—September 30, 2025	14,257,234	$ 4	$ 178,293	$ (178,566)	$ 1	$ (268)

See accompanying notes to unaudited condensed consolidated financial statements.

CALCIMEDICA, INC.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2023	5,754,505	$ 1	$ 154,218	$ (146,064)	$ 2	$ 8,157
Stock-based compensation expense	—	—	414	—	—	414
Issuance of common shares from private placement (net of issuance costs)	4,985,610	2	7,903	—	—	7,905
Issuance of warrants in connection with the private placement	—	—	660	—	—	660
Unrealized loss on investments	—	—	—	—	(19)	(19)
Net income	—	—	—	130	—	130
Balance—March 31, 2024	10,740,115	$ 3	$ 163,195	$ (145,934)	$ (17)	$ 17,247
Stock-based compensation expense	—	—	486	—	—	486
Issuance of common stock from at-the-market offering (net of issuance costs)	8,950	—	47	—	—	47
Issuance of common stock from exercise of stock options	1,091	—	4	—	—	4
Unrealized gain on investments	—	—	—	—	8	8
Net loss	—	—	—	(3,954)	—	(3,954)
Balance—June 30, 2024	10,750,156	$ 3	$ 163,732	$ (149,888)	$ (9)	$ 13,838
Stock-based compensation expense	—	—	781	—	—	781
Issuance of common stock from exercise of stock options	11,761	—	16	—	—	16
Unrealized gain on investments	—	—	—	—	13	13
Net loss	—	—	—	(5,618)	—	(5,618)
Balance—September 30, 2024	10,761,917	$ 3	$ 164,529	$ (155,506)	$ 4	$ 9,030

See accompanying notes to unaudited condensed consolidated financial statements.

CALCIMEDICA, INC.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2025	2024
Operating activities:		
Net loss	$ (18,802)	$ (9,442)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,349	1,681
Depreciation	41	44
Change in the fair value of warrant liability	(177)	(7,790)
Change in the fair value of promissory note	(23)	—
Promissory note issuance costs	336	—
Transaction costs associated with warrants	—	776
Accretion of discount on short-term investments	(307)	(492)
Changes in operating assets and liabilities:		
Prepaid expenses, other current and non-current assets	281	(705)
Accounts payable	(884)	117
Accrued expenses and other liabilities	860	(363)
Net cash used in operating activities	(16,326)	(16,174)
Investing activities:		
Purchase of investments	(15,420)	(18,837)
Maturity of investments	17,845	19,587
Purchase of property and equipment	(22)	(6)
Net cash provided by investing activities	2,403	744
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	8	18,983
Proceeds from exercise of stock options	25	20
Proceeds from issuance of promissory note, net	9,664	—
Proceeds from issuance of common stock from ATM Facility, net of issuance costs	1,761	49
Net cash provided by financing activities	11,458	19,052
Net (decrease) increase in cash and cash equivalents	(2,465)	3,622
Cash and cash equivalents at beginning of period	7,935	5,530
Cash and cash equivalents at end of period	$ 5,470	$ 9,152
Supplemental cash flow information:		
Stock issuance costs in accounts payable	$ 28	$ —
Equipment purchases included in accounts payable	$ 4	$ —

See accompanying notes to unaudited condensed consolidated financial statements.

CALCIMEDICA, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Nature of Business

Description of Business

CalciMedica, Inc. ("CalciMedica" or the "Company") (f/k/a Graybug Vision, Inc.) was incorporated in the state of Delaware in February 2015, following the conversion of Graybug, LLC, which was organized in May 2011, and has its principal operations in La Jolla, California. The Company is a clinical-stage biopharmaceutical company focused on developing therapeutics that treat serious illnesses driven by inflammatory processes and direct cellular damage. The Company had a wholly owned subsidiary, CalciMedica Subsidiary, Inc., incorporated in Delaware in October 2006, which survived the Merger as more fully described below. The CalciMedica Subsidiary entity was dissolved and combined with the Company as of December 31, 2024.

Reverse Merger Transaction

On March 20, 2023, Graybug Vision, Inc. ("Graybug") completed a reverse merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger and Reorganization, dated as of November 21, 2022, as amended on February 10, 2023 (the "Merger Agreement"), by and among Graybug, Camaro Merger Sub, Inc., a wholly owned subsidiary of Graybug ("Merger Sub"), and CalciMedica, Inc. ("Private CalciMedica"), pursuant to which Merger Sub merged with and into Private CalciMedica, with Private CalciMedica surviving as a wholly owned subsidiary of Graybug (the "Merger"). Additionally, on March 20, 2023, Graybug changed its name from "Graybug Vision, Inc." to "CalciMedica, Inc." and Private CalciMedica changed its name from "CalciMedica, Inc." to "CalciMedica Subsidiary, Inc." At the completion of the Merger, the prior Private CalciMedica equity holders and the prior Graybug equity holders owned 72% and 28%, respectively, of the combined company, in each case, on a fully diluted basis using the treasury stock method and excluding out-of-the-money options and warrants.

The Merger was accounted for as a reverse recapitalization, with Private CalciMedica being treated as the acquirer for accounting purposes.

Liquidity and Need for Additional Capital

The Company has experienced net losses and negative cash flows from operating activities since its inception. The Company has an accumulated deficit of $178.6 million as of September 30, 2025 and a net loss of $7.8 million and $18.8 for the three and nine months ended September 30, 2025, respectively. Substantially all of the Company's operating losses resulted from expenses incurred in connection with its research and development programs and from general and administrative costs associated with its operations.

The Company expects to incur significant expenses and increasing operating losses for the foreseeable future as the Company initiates and continues the preclinical and clinical development of its product candidates and adds personnel necessary to operate as a company with an advanced clinical pipeline of product candidates. The Company expects that its operating losses will fluctuate significantly from quarter-to-quarter and year-to-year due to timing of clinical development programs.

From inception to September 30, 2025, the Company has completed financings from the sale of preferred and common stock for total net proceeds of $142.5 million and has issued convertible promissory notes and promissory notes for net proceeds of $18.3 million. In connection with the Merger, the Company received approximately $29.4 million of cash, cash equivalents and short-term investments. On February 28, 2025, the Company entered into the ("Loan Agreement") with Avenue Venture Opportunities Fund II, L.P. and Avenue Capital Management II, L.P. for an initial $10.0 million of gross proceeds. At September 30, 2025, the Company had cash, cash equivalents and short-term investments of approximately $14.1 million.

The Company intends to seek additional funding through public and private financings, debt financings, collaboration agreements, strategic alliances and licensing agreements. Although the Company has been successful in raising capital in the past, there is no assurance of success in obtaining such additional financing on terms acceptable to us, if at all, and there is no assurance that the Company will be able to enter into collaborations or other arrangements. In addition, the terms of the Loan Agreement contain certain restrictions on incurring additional indebtedness. If the Company is unable to obtain funding when required or on acceptable terms, the Company may be required to scale back or discontinue the advancement of the product candidates, reduce headcount, file for bankruptcy, reorganize, merge with another entity or cease operations.

Based on the Company's current operating plans, management believes its cash, cash equivalents and short-term investments may not be sufficient to fund its operations for a period of one year following the issuance of these financial statements. As a result, there is substantial doubt about the Company's ability to continue as a going concern. The unaudited condensed consolidated financial statements have been prepared on a basis which assumes we are a going concern and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from any uncertainty related to our ability to continue as a going concern.

If the Company becomes unable to continue as a going concern, it may have to liquidate its assets, and might realize significantly less than the values at which they are carried on its financial statements, and stockholders may lose all or part of their investment in the Company's common stock.

2. Summary of Significant Accounting Policies

Basis of Presentation

The unaudited condensed consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC"), and Accounting Standards Update ("ASU"), of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of the Company's unaudited condensed consolidated financial statements requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's unaudited condensed consolidated financial statements and accompanying notes. The most significant estimates in the Company's unaudited condensed consolidated financial statements relate to accruals for research and development expenses, valuation of promissory notes, valuation of warrants and valuation of equity awards. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Concentration of Credit Risk and other Risks and Uncertainties

Financial instruments, which potentially subject the Company to concentration of risk, consist principally of cash, cash equivalents and short-term investments. The Company's cash is deposited with major federally insured U.S. financial institutions. The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

The Company is dependent on contract manufacturing organizations ("CMO") to supply products for research and development of its product candidates, including preclinical and clinical studies, and for commercialization of its product candidates, if approved. The Company's development programs could be adversely affected by any significant interruption in CMO operations or by a significant interruption in the supply of active pharmaceutical ingredients and other components.

Products developed by the Company require approval from the U.S. Food and Drug Administration ("FDA") or other international regulatory agencies prior to commercial sales. There can be no assurance the Company's product candidates will receive the necessary approvals. If the Company is denied approvals, approvals are delayed, or the Company is unable to maintain approvals received, such events could have a materially adverse impact on the Company.

Cash and Cash Equivalents

Cash and cash equivalents consist of readily available cash in checking accounts, money market funds, U.S. treasury bills and commercial paper. The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents.

Short-term Investments

The Company invests excess cash in commercial paper, U.S. treasury bills and U.S. government sponsored entities, such as mortgage-backed securities. These investments are included in short-term investments on the balance sheet, classified as available-for-sale and reported at fair value with unrealized gains and losses included in accumulated other comprehensive loss. Realized gains and losses on the sale of these securities are recognized in net gain (loss) in other income (expense) in the unaudited condensed consolidated statements of operations.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The financial information is regularly reviewed by the chief operating decision maker ("CODM"), in deciding how to allocate resources. The Company's CODM is its chief executive officer. The Company's singular focus is on developing highly selective calcium release-activated calcium channel inhibitors to improve outcomes for patients with acute inflammatory indications. No revenue has been generated since inception, and all tangible assets are held in the United States.

The Company operates as one operating segment focused on developing and commercializing innovative therapeutics primarily in the U.S. The accounting policies of the segment are the same as those described in the summary of significant accounting policies.

The determination of a single business segment is consistent with the consolidated financial information regularly reviewed by the chief executive officer, who is the Company's CODM, in assessing segment performance and deciding how to allocate resources on a consolidated basis.

The CODM makes decisions on resource allocation, assesses performance of the business, and monitors budget versus actual results using income from operations. Net loss is also a measure that is considered in monitoring budget versus actual results. The measure of segment assets is reported on the unaudited condensed consolidated balance sheets as total assets.

The following table presents information about reported segment loss and significant segment expenses for the three and nine months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Segment research and development *(a) (b)*	$ (3,627)	$ (3,265)	$ (11,330)	$ (9,988)
Segment general and administrative *(a) (b)*	(1,354)	(1,676)	(5,016)	(6,319)
Stock-based compensation (see Note 7)	(626)	(781)	(2,349)	(1,681)
Depreciation expense	(11)	(14)	(41)	(44)
Operating loss	$ (5,618)	$ (5,736)	$ (18,736)	$ (18,032)
Reconciliation of profit or loss				
Adjustments and reconciling items	—	—	—	—
Consolidated operating loss	$ (5,618)	$ (5,736)	$ (18,736)	$ (18,032)

a) Stock-based compensation expense of $219,000 and $273,000 related to research and development and $407,000 and $508,000 related to general and administrative have been excluded for the three months ended September 30, 2025 and 2024. Stock-based compensation expense of $777,000 and $634,000 related to research and development and $1,572,000 and $1,047,000 related to general and administrative have been excluded for the nine months ended September 30, 2025 and 2024. All amounts are included within stock-based compensation expense.

b) Depreciation expense of $5,000 and $8,000 related to research and development and $6,000 and $7,000 related to general and administrative have been excluded for the three months ended September 30, 2025 and 2024. Depreciation expense of $19,000 and $24,000 related to research and development and $22,000 and $20,000 related to general and administrative have been excluded for the nine months ended September 30, 2025 and 2024. All amounts are included within depreciation expense.

Fair Value Promissory Note

As permitted under ASC 825, *Financial Instruments*, the Company has elected the fair value option to account for its promissory note due to certain embedded features within the notes. The Company recognizes the promissory note at fair value with changes in fair value recognized in the unaudited condensed consolidated statements of operations located on the change in fair value of financial instruments line item. Changes in fair value as a result of the Company's own credit risk is reflected in other income in the unaudited condensed consolidated statements of operations. As a result of applying the fair value option, direct costs and fees related to the promissory note were expensed as incurred and not deferred.

Leases

The Company leases office space with an original lease term of twelve months and does not have a right-of-use asset or lease liability recorded. The Company's policy is not to record leases with an original term of twelve months or less on the unaudited condensed consolidated balance sheets. The Company recognizes lease expense for this short-term lease on a straight-line basis over the term of the lease. The lease is accounted for under ASC 842, *Leases*, and has been classified as an operating lease. Rent expense recognized was $32,000 and $30,000 for the three months ended September 30, 2025 and 2024, respectively, and $95,000 and $90,000 for the nine months ended September 30, 2025 and 2024, respectively.

Research and Development Costs

Research and development costs consist primarily of salaries, payroll taxes, employee benefits and stock-based compensation for those individuals involved in ongoing research and development efforts, as well as fees paid to consultants, external research fees, license fees paid to third parties for use of their intellectual property, laboratory supplies and development of compound materials, associated overhead expenses and facilities and depreciation costs. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. All research and development costs are expensed as incurred.

The Company estimates preclinical studies and clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on the Company's behalf. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. These estimates are based on communications with the third-party service providers, and on information available at each balance sheet date. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. The estimates are trued up to reflect the best information available at the time of the financial statement issuance. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's estimate of the status and timing of services performed relative to the actual status and timing of services performed may vary.

General and Administrative Costs

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to executive, finance, business development, legal, human resources and support functions, including professional fees for auditing, tax, consulting and patent-related services, rent, utilities and insurance.

Patent Costs

Costs related to filing and pursuing patent applications are expensed as incurred since recoverability of such expenditures is uncertain.

Deferred Offering Costs

The Company capitalizes costs that are directly associated with equity financings until such financings are consummated, at which time such costs are recorded against the gross proceeds of the offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statements of operations and comprehensive loss. As of September 30, 2025, the Company had deferred costs associated with its ATM Facility (as defined in Note 6) and expensed these costs as of December 31, 2024 in the Company's unaudited condensed consolidated statements of operations and capitalized these costs net of proceeds as of September 30, 2025.

Warrant Liability

As a result of the 2024 Private Placement (described in Note 6), certain warrants to purchase common stock were deemed freestanding warrants and are reflected in the Company's unaudited condensed consolidated balance sheets as a liability as of and for the period ending September 30, 2025.

Stock-based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee stock options, restricted stock units ("RSU's") and Common Stock Warrants (as defined in Note 6) recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. The Company estimates the fair value of stock option grants, RSU's and Common Stock Warrants using the Black-Scholes option pricing model ("Black-Scholes"). Forfeitures are recognized as a reduction of stock-based compensation expense as they occur. Equity-based compensation expense is classified in the statements of operations in the same manner in which the award recipients' payroll costs are classified or in which the award recipients' service payments are classified. The fair value of each stock option grant, RSU and Common Stock Warrant is estimated on the date of grant using Black Scholes. The following summarizes the inputs used:

Fair Value of Common Stock

The Company uses the closing stock price the day of the grant date for the fair value.

Risk-Free Interest Rate

The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities similar to the expected term of the awards.

Expected Volatility

The Company uses an average volatility for comparable publicly-traded biopharmaceutical companies over a period equal to the expected term of the stock award grant as the Company does not yet have sufficient historical trading history for its own stock. The Company will continue to apply this method until a sufficient amount of historical information over a period equal to the expected term of the stock-based awards becomes available.

Expected Term

The Company used the simplified method to calculate the expected term for all grants during all periods, which is based on the midpoint between the vesting date and the end of the contractual term.

Expected Dividend Yield

The Company has never paid and has no present intention to pay cash dividends.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

The Company recognizes net deferred tax assets to the extent that the Company believes these assets are more likely than not to be realized. In making such a determination, management considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If management determines that the Company would be able to realize its deferred tax assets in the future in excess of

their net recorded amount, management would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions on the basis of a two-step process whereby (1) management determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, management recognizes the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits within income tax expense. Any accrued interest and penalties are included within the related tax liability.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources which are excluded from net loss. The Company's only element of other comprehensive loss is unrealized gains and losses on marketable securities and short-term investments.

Related Party Transactions

The Company's board of directors reviews and approves transactions with directors, officers and holders of 5% or more of its voting securities and their affiliates, each a related party. The material facts as to the related party's relationship or interest in the transaction are disclosed to its board of directors prior to their consideration of such transaction, and the transaction is not considered approved by its board of directors unless a majority of the directors who are not interested in the transaction approve the transaction.

Beginning in November 2020, Private CalciMedica has paid consulting fees monthly to a consulting firm affiliated with the Company's former interim chief financial officer in connection with its consulting agreement. In November 2024, the interim chief financial officer was replaced with a chief financial officer. The Company recorded expense of $57,000 and $243,000 during the three and nine months ended September 30, 2024, respectively, in general and administrative expense in the unaudited condensed consolidated statements of operations.

In May 2024, the Company granted a warrant to purchase 10,000 shares of common stock to a consulting firm affiliated with the Company's former interim chief financial officer. The warrant is classified as equity, and the Company recorded expense of zero and $5,000 for the three months ended September 30, 2025 and 2024, respectively, and $7,000 and $8,000 for the nine months ended September 30, 2025 and 2024, respectively, in general and administrative expense in the unaudited condensed consolidated statements of operations.

Net Loss Per Share

Basic net loss per share is computed using the weighted average number of shares of common stock outstanding during the period, including the Pre-Funded Warrants and Placement Agent Warrants (as defined in Note 6). The Company calculates diluted net loss per share using the more dilutive of the (i) treasury stock method, if-converted method, or contingently issuable share method, as applicable, or (ii) the two-class method. For warrants, the calculation of diluted net loss per share requires that, to the extent the average fair value of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of such securities are dilutive to net loss per share for the period, adjustments to net loss used in the calculation are required to remove the change in fair value of the warrants for the period.

In the periods presented, the Company's outstanding stock options, RSU's and warrants, other than the Pre-Funded Warrants and Placement Agent Warrants, were excluded from the calculation of net loss per share because the effect would be antidilutive.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40)* which requires public entities to disclose in the notes to financial statements, of additional specified information about certain costs and expenses. For public business entities, the guidance is effective for annual periods beginning after December 15, 2026 and interim periods after December 15, 2027, with early adoption permitted. The Company is currently assessing the impact that this guidance will have on the unaudited condensed consolidated financial statements.

3. Fair Value Measurements

The Company's assets and liabilities which are measured at fair value include short-term investments, the promissory note and warrants for common stock. All assets and liabilities recorded at fair value are revalued at each measurement period.

The Company elected the fair value option for the promissory note and estimated the fair value based on a discounted cash flow analysis, a form of the Income Approach. Several different settlement scenarios were considered, and probability weighted to arrive at the final valuation. Increases or decreases in the fair value of the promissory note can result from updates to assumptions such as the expected timing or probability of the different settlement scenarios, or changes in discount rates. Judgment is used in determining these assumptions as of the initial valuation date and at each subsequent reporting period. Updates to assumptions could have a significant impact on our results of operations in any given period.

The Common Warrants (as defined in Note 6) were valued using Black-Scholes utilizing the following inputs; (i) a risk-free interest rate; (ii) volatility based on the expected term of the Common Warrant; (iii) and an exercise price and stock price on the date of the transaction. Several different scenarios were considered, and probability weighted to arrive at the final valuation.

Increases or decreases in the fair value of the Common Warrants can result from updates to assumptions such as the expected timing or probability of the different settlement scenarios. Judgment is used in determining these assumptions as of the initial valuation date and at each subsequent reporting period. Updates to assumptions could have a significant impact on our results of operations in any given period.

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following three levels:

- *Level 1:* Observable inputs such as unadjusted quoted prices in active markets for identical assets or liabilities at the measurement date.
- *Level 2:* Inputs (other than quoted prices included in Level 1) that are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- *Level 3:* Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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

	September 30, 2025			
	Level 1	Level 2	Level 3	Total
Current assets:				
Cash equivalents:				
Money market funds	$ 3,675	$ —	$ —	$ 3,675
Commercial paper	—	1,245	—	1,245
U.S. Treasury bills	—	498	—	498
Total cash equivalents	3,675	1,743	—	5,418
Short-term investments:				
Commercial paper	—	3,386	—	3,386
U.S. Treasury bills	—	3,491	—	3,491
U.S. Government sponsored entities - mortgage backed securities	—	1,737	—	1,737
Total short-term investments	—	8,614	—	8,614
Total assets measured at fair value	$ 3,675	$ 10,357	$ —	$ 14,032

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Current assets:				
Cash equivalents:				
Money market funds	$ 6,117	$ —	$ —	$ 6,117
Commercial paper	—	746	—	746
U.S. Treasury bills	—	749	—	749
Total cash equivalents	6,117	1,495	—	7,612
Short-term investments:				
Commercial paper	—	6,573	—	6,573
U.S. Treasury bills	—	3,227	—	3,227
U.S. Government sponsored entities - mortgage-backed securities	—	934	—	934
Total short-term investments	—	10,734	—	10,734
Total assets measured at fair value	$ 6,117	$ 12,229	$ —	$ 18,346

Money market funds are highly liquid investments which are actively traded. The pricing information on the Company's money market funds is based on quoted prices in active markets for identical securities. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

Commercial paper, Corporate debt securities, U.S. Treasury bills and U.S. Government sponsored entities - mortgage-backed are classified as Level 2 within the hierarchy and are carried at fair value with unrealized gains and losses included in other comprehensive loss as a component of stockholders' equity until realized. The Company estimates the fair values of these securities by taking into consideration valuations obtained from third-party pricing sources.

During the nine months ended September 30, 2025, there were no transfers between Level 1, Level 2 and Level 3.

The following table presents information about the Company's financial liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values (in thousands).

	September 30, 2025			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Promissory Note	$ —	$ —	$ 8,900	$ 8,900
Warrant Liability	—	—	2,600	2,600
Total liabilities measured at fair value	$ —	$ —	$ 11,500	$ 11,500

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Warrant Liability	$ —	$ —	$ 1,700	$ 1,700
Total liabilities measured at fair value	$ —	$ —	$ 1,700	$ 1,700

The following provides a reconciliation for all liabilities measured at fair value using Level 3 inputs for the nine months ended September 30, 2025 and 2024 (in thousands):

Promissory Note liability	
Balance at December 31, 2024	$ —
Issuance of Promissory Note	8,923
Change in Fair Value of Promissory Note	(323)
Balance at March 31, 2025	8,600
Change in Fair Value of Promissory Note	(100)
Balance at June 30, 2025	8,500
Change in Fair Value of Promissory Note	400
Balance at September 30, 2025	$ 8,900

Warrant liability	
Balance at December 31, 2024	$ 1,700
Issuance of Lender Warrants	1,077
Change in Fair Value of Tranche B Warrants	(1,200)
Change in Fair Value of Lender Warrants	(177)
Balance at March 31, 2025	1,400
Change in Fair Value of Tranche B Warrants	(200)
Change in Fair Value of Lender Warrants	(200)
Balance at June 30, 2025	1,000
Change in Fair Value of Tranche B Warrants	800
Change in Fair Value of Lender Warrants	800
Balance at September 30, 2025	$ 2,600

Balance at December 31, 2023	$ 11,190
Change in Fair Value of Warrants	(5,590)
Balance at March 31, 2024	5,600
Change in Fair Value of Warrants	(2,300)
Balance at June 30, 2024	3,300
Forfeiture of warrants	(200)
Change in Fair Value of Warrants	300
Balance at September 30, 2024	$ 3,400

The following table presents information as to cost, unrealized gains and losses and fair value determination of the Company's financial assets measured at fair value on a recurring basis (in thousands):

	September 30, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Current assets:				
Cash equivalents:				
Money market funds	$ 3,675	$ —	$ —	$ 3,675
Commercial paper	1,245	—	—	1,245
U.S. Treasury bills	498	—	—	498
Total cash equivalents	5,418	—	—	5,418
Short-term investments:				
Commercial paper	3,385	1		3,386
U.S. Treasury bills	3,491	—		3,491
U.S. Government sponsored entities - mortgage-backed securities	1,737	—	—	1,737
Total short-term investments	8,613	1	—	8,614
Total assets measured at fair value	$ 14,031	$ 1	$ —	$ 14,032

As of September 30, 2025, the contractual maturities of all available-for-sale investments were less than 12 months. The Company periodically reviews the available-for-sale investments for other-than-temporary impairment loss. The Company had short-term investments in unrealized gain positions as of September 30, 2025.

	December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Current assets:				
Cash equivalents:				
Money market funds	$ 6,117	$ —	$ —	$ 6,117
Commercial paper	746	—	—	746
U.S. Treasury bills	749	—	—	749
Total cash equivalents	7,612	—	—	7,612
Short-term investments:				
Commercial paper	6,571	2	—	6,573
U.S. Treasury bills	3,225	2	—	3,227
U.S. Government sponsored entities - mortgage backed securities	934	—	—	934
Total short-term investments	10,730	4	—	10,734
Total assets measured at fair value	$ 18,342	$ 4	$ —	$ 18,346

As of December 31, 2024, the contractual maturities of all available-for-sale investments were less than 12 months. The Company periodically reviews the available-for-sale for other-than-temporary impairment loss. The Company had short-term investments in unrealized gain positions as of December 31, 2024.

4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2025	December 31, 2024
Accrued payroll and other employee benefits	$ 703	$ 531
Accrued professional fees	283	286
Accrued other	39	49
Total accrued expenses	$ 1,025	$ 866

5. Promissory Note

On February 28, 2025 (the "Closing Date"), the Company executed the Loan Agreement with Avenue Venture Opportunities Fund II, L.P. ("Lender") and Avenue Capital Management II, L.P., as administrative agent and collateral agent, for growth capital loans in an aggregate principal amount of up to $32,500,000 (the "Loan"), with (i) $10,000,000 funded on the Closing Date ("Tranche 1"), (ii) up to $7,500,000 to be made available to the Company between September 1, 2025 and March 31, 2026, subject to, among other things, the Company's achievement of certain milestones with respect to certain of its ongoing clinical trials ("Tranche 2") and (iii) up to $15,000,000 to be made available to the Company between October 1, 2025 and March 31, 2026,

subject to, among other things, (a) the Company's achievement of additional milestones with respect to certain of its ongoing clinical trials and (b) the mutual written agreement of the Company and the Lender (upon its investment committee approval). At the closing date, up to $1,000,000 of the principal outstanding may be converted into shares of the Company's unrestricted, freely tradable common stock at a price equal to 20% premium to the exercise price of the warrants (see note 6 for further description of the warrants) at the Lender's option. Upon drawing Tranche 2, $1,000,000 will be added to the conversion option for a total of $2,000,000. The Company will make interest only payments until the 18 month anniversary of the Closing Date, subject to a 6-month extension upon the Company's achievement of certain milestones with respect to certain of its ongoing clinical trials and funding of the full amount under Tranche 2. The Loan is evidenced by a promissory note and bears interest at an annual rate equal to the greater of (a) the sum of 5.00% plus the prime rate as reported in The Wall Street Journal and (b) 12.75%. The Loan is secured by a lien upon and security interest in all of the Company's assets, including intellectual property, subject to agreed exceptions. The maturity date of the Loan is September 1, 2028 (the "Maturity Date").

As of September 30, 2025, future promissory note payments are as follows (in thousands):

2025	$	326
2026		2,515
2027		5,780
2028		4,286
Future promissory note payments	$	12,907

The Company determined the promissory note was eligible for the fair value election, and the Company elected to account for the promissory note at fair value. The Company allocated the gross proceeds on a relative fair value basis. The initial fair of the promissory notes was $8.9 million. The valuation methodology was a scenario-based analysis utilizing a discounted cash flow framework to value the "straight debt" portion of the Notes and Black-Scholes to value the conversion feature associated with the Notes. Major inputs/assumptions associated with the fair value of the Notes include: a) Calibrated Discount Rate of 13.7%, b) Scenario Weighting for Repayment through Maturity of 80%, c) Scenario Weighting for Repayment through Milestone of 20%, d) Timing of Milestone of 12/31/25, and e) Volatility used in Black-Scholes to value conversion feature of 100%. The fair value of the Lender Warrants was estimated using Black-Scholes (see Note 6).

As of the balance sheet date of September 30, 2025, the value of the promissory note was $8.9 million, with a change in fair value of $0.4 million and $23,000 for the three and nine months ended September 30, 2025, respectively, being recorded in the unaudited condensed consolidated statements of operations in other income/(expense).

6. Common Stock and Stockholders' Equity (Deficit)

Authorized Shares

The Company's current Amended and Restated Certificate of Incorporation authorizes 500,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

On January 19, 2024, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain accredited investors, in which the Company sold the following securities to the accredited investors in a private placement transaction (the "2024 Private Placement"): (i) an aggregate of 4,985,610 shares of common stock; (ii) to certain investors, in lieu of shares of common stock, pre-funded warrants (the "Pre-Funded Warrants") to purchase an aggregate of 306,506 shares of common stock and exercisable at any time; (iii) Tranche A Common Warrants (the "Tranche A Common Warrants") to purchase an aggregate of up to 2,646,058 shares of common stock (or Pre-Funded Warrants in lieu thereof and, in such case, shares of common stock issuable upon exercise of such Pre-Funded Warrants); and (iv) Tranche B Common Warrants (the "Tranche B Common Warrants" and together with the Tranche A Common Warrants, the "Common Warrants") to purchase an aggregate of up to 2,646,058 shares of common stock (or Pre-Funded Warrants in lieu thereof and, in such case, shares of common stock issuable upon exercise of such Pre-Funded Warrants). At date of issuance, the fair value of the common stock was $8.5 million using the relative fair value method and is included in equity at September 30, 2025.

The Company issued placement agent warrants ("Placement Agent Warrants") to purchase 67,908 shares of common stock at the initial closing of the 2024 Private Placement and 7,839 shares of common stock at the second closing of the 2024 Private Placement, at an exercise price of $0.0001 per share. Each Placement Agent Warrant was accompanied by one Tranche A Common Warrant to purchase one half of a share of common stock and one Tranche B Warrant to purchase one half of a share of common stock, for an aggregate of 75,746 Common Warrants.

The initial closing of the 2024 Private Placement occurred on January 23, 2024 and the second closing occurred on February 5, 2024. Gross proceeds from the transaction were $20.4 million with net proceeds of approximately $19.0 million after deducting $1.4 million in commissions and other transaction costs.

Shelf Registration Statement and At the Market Offering

In August 2023, the Company filed a shelf registration statement on Form S-3 (the "Shelf Registration Statement"). The Shelf Registration Statement permits the offering, issuance and sale of common stock, preferred stock, debt securities and warrants having an aggregate offering price of up to $100.0 million in one or more offerings and in any combination of the foregoing.

The Shelf Registration Statement contains two prospectuses, a base prospectus and an at-the-market offering prospectus, as supplemented on March 29, 2024 (as supplemented, the "Original Prospectus Supplement"), that covered the offering, issuance and sale of up to $17.3 million of common stock pursuant to an at-the-market offering agreement ("ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), acting as sales agent ("ATM Facility").

On November 1, 2024, the Company closed an underwritten public offering of 2,720,000 shares of its common stock at a price to the public of $3.75 per share pursuant to the Shelf Registration Statement (the "2024 Follow-On"). The gross proceeds from the offering, before deducting underwriting discounts and commissions and offering expenses, were $10.2 million.

In connection with the 2024 Follow-on, on October 30, 2024, the Company suspended sales of common stock under the ATM Facility pursuant to the Original Prospectus Supplement, and until December 20, 2024, did not offer for sale any shares of common stock. The Company filed a prospectus supplement (the "2024 Prospectus Supplement") to the Shelf Registration Statement with the Securities and Exchange Commission ("SEC") on December 20, 2024 providing for the sale of shares of common stock under the ATM Facility having an aggregate gross sales price of up to $4.45 million.

The Company intends to use the net proceeds from the ATM Facility for general corporate purposes, which may include research and development expenses, clinical trial expenses, capital expenditures and working capital. The ATM Facility will terminate upon the earlier of (i) the sale of all of the shares of our common stock provided for in the at the market offering prospectus or (ii) termination of the ATM Agreement as permitted therein. The ATM Agreement may be terminated at any time by either party upon written notice. During the nine months ended September 30, 2025, there were 760,130 shares sold under the ATM Facility for net proceeds of $1.7 million, after deducting $109,000 of commissions and settlement expenses. As of September 30, 2025, the Company has sold 861,652 shares of common stock for net proceeds of approximately $2.0 million, after deducting $146,000 of commissions and settlement expenses paid under the ATM Facility. As of September 30, 2025, approximately $2.6 million remained available under the ATM Facility for the offer and sale of shares of common stock pursuant to the 2024 Prospectus Supplement.

Common Stock Warrants

In October 2022, Private CalciMedica granted warrants to certain officers and directors to purchase 496,970 shares of common stock. In conjunction with the Merger, the warrants converted to 14,313 warrants of the Company at an exercise price of $10.42. The warrants have a 10-year term and vest ratably over 12 and 48 months. At the date of issuance, the fair value of the warrants collectively was $125,000 and was determined utilizing Black-Scholes and will be recognized as general and administrative expense over the vesting periods. Assumptions used in the valuation were as follows: expected term of ten years, risk free rate of 4.10%, volatility of 82% and a dividend yield of zero. The warrants are classified as equity, and the Company expensed zero and $2,000 to general and administrative expense for the three months ended September 30, 2025 and 2024, respectively, and $1,000 and $5,000 to general and administrative expense for the nine months ended September 30, 2025 and 2024, respectively.

In connection with the 2024 Private Placement, the Company issued Tranche A Common Warrants, Tranche B Common Warrants and Pre-Funded Warrants. Tranche A Common Warrants were exercisable until July 29, 2024. The Tranche B Common Warrants are exercisable upon the earlier of December 31, 2026 or 30 days following the Company's public disclosure of topline results from the Company's planned Phase 2 clinical trial in patients with acute kidney injury. The purchase price per share and accompanying Common Warrants was $3.827 (or $4.3915 for directors, employees or consultants of the Company participating in the 2024 Private Placement) (or $3.8269 per Pre-Funded Warrant and accompanying Common Warrants, which represented the price of $3.827 per share and accompanying Common Warrants minus the $0.0001 per share exercise price of each such Pre-Funded Warrant).

The Tranche A Common Warrants had a strike price of $5.36 per share, were not deemed equity and were classified as a liability in the Company's unaudited condensed consolidated balance sheets. At the date of issuance, the fair value of the Tranche A Common Warrants was $4.1 million utilizing Black-Scholes with the following assumptions: expected term of 0.94 years, risk-free interest rate of 4.9%, volatility of 100% and a dividend yield of zero. As of the balance sheet date of September 30, 2025, the value of the Tranche A Common Warrants was zero as the Tranche A Common Warrants expired on July 27, 2024. For the three and nine months ended September 30, 2024, there was a change in fair value of $0.2 million and $4.1 million, respectively, being recorded in the unaudited condensed consolidated statements of operations in other income/(expense).

The Tranche B Common Warrants have a strike price of $7.15 per share, are not deemed equity and are classified as a liability in the Company's unaudited condensed consolidated balance sheets. At the date of issuance, the fair value of the Tranche B Common Warrants was $7.1 million utilizing Black-Scholes with the following assumptions: expected term of 1.69 years, risk-free interest rate of 4.5%, volatility of 100% and a dividend yield of zero. As of the balance sheet date of September 30, 2025, the value of the Tranche B Common Warrants was $1.1 million, with the change in fair value of $0.8 million and $0.3 million for the three months ended September 30, 2025 and 2024, respectively, and $0.6 million and $3.7 million for the nine months ended September 30, 2025 and 2024, respectively, recorded in the unaudited condensed consolidated statements of operations in other income/(expense).

The Pre-Funded Warrants have a strike price of $0.0001 per share, are deemed equity and included in the equity section of the Company's unaudited condensed consolidated balance sheets. At date of issuance, the fair value of the Pre-Funded Warrants was $0.5 million using the relative fair value method and is included in stockholders' equity at September 30, 2025.

The Placement Agent Warrants have a strike price of $0.0001 per share, are deemed equity and included in the equity section of the Company's unaudited condensed consolidated balance sheets. At date of issuance, the fair value of the Placement Agent Warrants was $0.1 million using the relative fair value method and is included in equity at September 30, 2025.

In May 2024, the Company granted a warrant to a consulting firm affiliated with its former interim chief financial officer to purchase 10,000 shares of common stock. At the date of issuance, the fair value of the warrant was $20,000 and was determined utilizing Black-Scholes and will be recognized as general and administrative expense over the vesting periods. Assumptions used in the valuation were as follows: expected term of twelve months, risk free rate of 4.42%, volatility of 89% and a dividend yield of zero. The warrant is classified as equity, and the Company expensed zero and $5,000 for the three months ended September 30, 2025 and 2024, respectively and $7,000 and $8,000 for the nine months ended September 30, 2025 and 2024, respectively, to general and administrative expense.

In connection with the Loan, pursuant to the funding of Tranche 1 on the Closing Date, the Company issued to the Lender a warrant to purchase 641,163 shares of common stock of the Company (the "Warrant") at an exercise price per share equal to $2.32 (the "Stock Purchase Price") and are classified as a liability in the Company's unaudited condensed consolidated balance sheets. At the date of issuance, the fair value of the Warrant was $1.1 million and was determined utilizing Black-Scholes with the following assumptions: expected term of 5.0 years, risk-free interest rate of 4.0%, volatility of 100% and a dividend yield of zero. The Warrant is exercisable until February 28, 2030 (the "Expiration Date") and upon a change of control, the Lender would be entitled to receive the shares of common stock underlying the Warrant without payment of the exercise price. As of the balance sheet date September 30, 2025, the value of the Warrant was $1.5 million, with a change in fair value of $0.8 million and $0.4 million for the three and nine months ended September 30, 2025, respectively, being recorded in the unaudited condensed consolidated statements of operations in other income/(expense).

7. Stock-based Compensation

2006 Equity Incentive Plan and Amendment to 2006 Plan

Private CalciMedica adopted an equity incentive plan in 2006 ("2006 Plan") that provides for the issuance of common stock to employees, non-employee directors and consultants. Recipients of incentive stock options are eligible to purchase common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The 2006 Plan provides for the grant of incentive stock options, non-statutory stock options and stock purchase rights. The maximum contractual term of options granted under the 2006 Plan is ten years. The options generally vest 25% on the first anniversary of the grant date, with the balance vesting ratably over the following 36 months. In connection with the Merger, the Company assumed the 2006 Plan and all stock options issued and outstanding under the 2006 Plan.

2023 Equity Incentive Plan

The Company adopted the 2023 Equity Incentive Plan (the "2023 Plan"), which became effective at the closing of the Merger and replaced its 2020 Equity Incentive Plan (the "2020 Plan") on the effective date of the Merger. As of the effective date of the Merger, there were 1,000,000 shares of the Company's common stock available for grant under the 2023 Plan. In addition, the share reserve is subject to annual increases each January 1 for the first ten years following approval of the 2023 Plan of up to 5% of shares of the Company's common stock outstanding (or a lesser number determined by the Company's board of directors). Effective January 1, 2024, the shares reserved for issuance under the 2023 Plan was increased by 287,725 shares of the Company's common stock. Effective March 28, 2024, the Board approved an increase of 1,500,000 shares of the Company's common stock reserved under the 2023 Plan, which was subsequently approved by the stockholders of the Company on August 27, 2024. As of January 1, 2025 an additional 674,095 shares of the Company's common stock were added to the plan per the annual increase. On April 23, 2025 the Board approved an increase of 600,000 shares of the Company's common stock reserved for issuance under the 2023 Plan, which was subsequently approved by the stockholders of the Company on June 24, 2025. As of September 30, 2025, 105,022 shares of the Company's common stock were available for grant under the 2023 Plan.

2023 Employee Stock Purchase Plan

The Company adopted the 2023 Employee Stock Purchase Plan (the "2023 ESPP") which became effective at the closing of the Merger. As of the effective time of the Merger, there were 65,000 shares of the Company's common stock reserved for issuance under the 2023 ESPP. In addition, the share reserve is subject to annual increases each January 1 for the first ten years following approval of the 2023 ESPP of the lesser of (i) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, (ii) 195,000 shares of the Company's common stock, or (iii) such lesser number of shares of the Company's common stock as determined by the Company's board of directors. An annual increase of 57,545 and 134,819 shares of the Company's common stock was automatically added to the share reserve under the 2023 ESPP on January 1, 2024 and 2025, respectively. As of September 30, 2025, 257,364 shares of the Company's common stock were available for grant under the 2023 ESPP.

As of September 30, 2025, no shares have been issued under the 2023 ESPP.

The following table summarizes the stock option transactions for the 2023 Plan:

	Total Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	2,824,443	$ 5.51	8.15	$ 316
Granted	2,029,152	1.57	9.62	3,046
Exercised	(15,187)	1.55	—	—
Forfeited/Cancelled	(55,000)	3.36	—	—
Outstanding at September 30, 2025	4,783,408	$ 3.88	8.33	$ 3,096
Vested and exercisable at September 30, 2025	2,406,584	$ 4.83	7.60	$ 1,147

There were 15,187 options exercised and 2,029,152 options granted during the nine months ended September 30, 2025. The weighted-average fair value of options granted during the nine months ended September 30, 2025 and 2024 was $1.33 and $4.17 per share, respectively. The total fair value of shares vested was $2.2 million and $1.6 million for the nine months ended September 30, 2025 and 2024, respectively.

As of September 30, 2025, stock-based compensation not yet recognized is $5.0 million, which the Company expects to recognize over an estimated weighted-average term of 2.4 years.

The following are the underlying assumptions in Black-Scholes to determine the fair value of the stock option grants for the nine months ended September 30, 2025 and 2024:

	Nine Months Ended September 30,	
	2025	2024
Risk free interest rate	3.50%	3.11%
Expected volatility	101%	96%
Expected term (years)	5.86	6.01
Expected dividend yield	0%	0%

Restricted Stock Units ("RSU's")

The fair value of RSU's is determined on the date of grant based on the market price of the Company's common stock on that date. The aggregate grant date fair value of RSU's vested during the nine months ended September 30, 2025 was zero.

The following table summarizes restricted stock unit activity for the CalciMedica Plans:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2024	40,000	$ 3.50
Outstanding at September 30, 2025	40,000	$ 3.50
Vested and exercisable at September 30, 2025	—	$ —

Stock-based Compensation Expense

Stock-based compensation expense recognized for options, RSU's and Common Stock Warrants granted was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Research and development	$ 219	$ 273	$ 777	$ 634
General and administrative	407	508	1,572	1,047
Total stock-based compensation expense	$ 626	$ 781	$ 2,349	$ 1,681

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following at September 30, 2025:

	September 30, 2025
Common stock warrants	3,993,784
Stock options issued and outstanding	4,783,408
Restricted stock units outstanding	40,000
Shares available for issuance under the 2023 Plan	105,022
Shares available under the 2023 ESPP	257,364
Total	9,179,578

8. Commitments and Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues liabilities for such matters when future expenditures are probable and such expenditures can be reasonably estimated.

The Company has historically entered into contracts in the normal course of business with contract development and manufacturing organizations, for the manufacturing process development and the preclinical/clinical supply manufacturing, and our vendors for preclinical research studies and other services or products for operating purposes. These contracts generally provide for termination on notice of 60 to 90 days. As of September 30, 2025, there are four such contracts related to the CMO for the development of Auxora for $0.5 million of associated costs, still in effect for future services, and there were no unpaid cancellation or other related costs.

The Company is also, from time to time, a party or subject to various other legal proceedings and claims, either asserted or unasserted, which arise in the ordinary course of business. Some of these proceedings have involved, and may involve in the future, claims that are subject to substantial uncertainties and unascertainable damages.

Operating Lease Agreements

The Company has an operating lease for office space in La Jolla, California. In December 2024, an amendment was executed for a twelve month term as of January 1, 2025 and therefore qualifies for the short-term lease exception. Base rent for this lease is approximately $10,500 monthly.

Rent expense for the three months ended September 30, 2025 and 2024 was $32,000 and $30,000, respectively, and for the nine months ended September 30, 2025 and 2024 was $95,000 and $90,000, respectively, which is included in operating expenses.

9. Employee Benefits

In January 2007, Private CalciMedica adopted a defined contribution 401(k) plan for substantially all employees. There were no contributions made by the Company to the 401(k) plan for the three and nine months ended September 30, 2025 and 2024, respectively.

10. Income Taxes

The Company did not record a provision or benefit for income taxes during the three and nine months ended September 30, 2025 and 2024 due to continuing losses. As of both September 30, 2025 and December 31, 2024, the Company continues to maintain a full valuation allowance against all of its deferred tax assets in light of its history of cumulative net losses.

11. Net Loss Per Share

The following table sets forth the computation of basic and diluted net loss per share (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Numerator:				
Net loss	$ (7,804)	$ (5,618)	$ (18,802)	$ (9,442)
Denominator				
Basic and diluted				
Weighted-average common shares outstanding, basic and diluted	14,053,042	10,752,713	13,847,445	10,323,344
Weighted-average pre-funded warrants outstanding, basic and diluted	306,506	306,506	306,506	281,896
Weighted-average placement agent warrants outstanding, basic and diluted	75,745	75,745	75,745	69,291
Weighted-average lender warrants outstanding, basic and diluted	641,163		504,945	—
Weighted-average number of shares used to calculate basic and diluted net loss per share	15,076,456	11,134,964	14,734,641	10,674,531
Net loss per share - basic and diluted	$ (0.52)	$ (0.50)	$ (1.28)	$ (0.88)

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	As of September 30,	
	2025	2024
Stock options to purchase common stock	4,783,408	2,724,443
Restricted stock units	40,000	—
Warrants to purchase common stock	3,611,531	2,970,368
Total	8,434,939	5,694,811

12. Subsequent Event

The Company filed a prospectus supplement (the "2025 Prospectus Supplement") to the Shelf Registration Statement with the SEC on November 6, 2025 providing for the sale of shares of common stock under the ATM Facility having an aggregate gross sales price of up to $9.7 million.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and related notes for the year ended December 31, 2024 included in our Annual Report on Form 10-K filed with the SEC on March 27, 2025. In addition to historical financial information, this discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties. You should carefully read the sections entitled "Special Note Regarding Forward-Looking Statements" and "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

Overview

We are a clinical-stage biopharmaceutical company focused on developing therapeutics that treat serious illnesses driven by inflammatory and immunologic processes and direct cellular damage. Our product candidates act upon calcium release-activated calcium ("CRAC") channels and would constitute a new class of drugs.

Clinical and preclinical data have demonstrated that the inhibition of CRAC channels may have a therapeutic effect based on a dual mechanism involving both anti-inflammatory and tissue cell protective activities. Our work has shown compelling evidence of the involvement of CRAC channels in a broad spectrum of both acute critical illnesses and chronic diseases that have the common thread of inflammation or immunologic activity in their pathogenesis. We intend to leverage our CRAC channel inhibitor platform to develop therapeutics for indications where this dual mechanism of action has the potential for clinical benefit.

Our lead product candidate is Auxora, a potent and selective intravenous formulated small molecule CRAC channel inhibitor containing the active compound zegocractin (formerly referred to as CM4620) that, in animal models, reduced acute epithelial and/or endothelial cell injury and inflammation in organs, such as the pancreas, lungs and kidneys. Multiple Phase 2 clinical trials with Auxora have been conducted: an open-label Phase 2a trial in acute pancreatitis ("AP") with accompanying systematic inflammatory response syndrome ("SIRS"), an international, randomized, double-blind placebo-controlled Phase 2b trial in AP with SIRS (which we refer to as "CARPO"), an investigator led open-label Phase 1/2 trial in asparaginase-induced pancreatic toxicity ("AIPT") (which we also refer to as "CRSPA") in which the first cohort of patients has been completed, a placebo-controlled double-blind Phase 2 trial in severe COVID-19 pneumonia (which we also refer to as "CARDEA") and an investigator led open-label Phase 2a trial in COVID-19 pneumonia patients with acute respiratory distress syndrome ("ARDS"). We observed in all of these trials that patients treated with Auxora experienced a reduction of organ damage and reduced time to recovery. We believe the consistency of the results we observed from these trials in two different acute critical care conditions are mutually supportive and reinforce our plans to further pursue the use of Auxora in several additional acute critical illnesses, including acute kidney injury ("AKI") with associated acute hypoxemic respiratory failure ("AHRF"), in which we are currently conducting a Phase 2 trial (which we also refer to as "KOURAGE") with data expected in the first half of 2026. Additionally, we have had positive engagement with the FDA regarding the design of a pivotal trial in AP. We expect to finalize the pivotal trial design in the first half of 2026.

Additionally, we have compiled additional preclinical data supporting the potential to use CRAC channel inhibition for both chronic and acute inflammatory and immunologic diseases. We have animal model data suggesting CRAC channel inhibition may be useful in treating pulmonary arterial hypertension, chronic pancreatitis, rheumatoid arthritis, ulcerative colitis, allergic asthma, and traumatic brain injury. We have several available product candidates that may be suitable for potential oral dosing. Pending additional funding, we have paused IND enabling preclinical work on these compounds to focus resources on our clinical programs. We expect to continue certain research activities to validate CRAC channel inhibition as a potential mechanism in other promising inflammatory and immunologic diseases.

In August 2023, we filed a shelf registration statement on Form S-3 (the "Shelf Registration Statement"), which contains two prospectuses, a base prospectus and an at the market offering prospectus, as supplemented on March 29, 2024 (as supplemented, the "Original Prospectus Supplement") that covered the offering, issuance and sale of up to $17.3 million of common stock pursuant to an at the market offering agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright") acting as sales agent (the "ATM Facility"). The Shelf Registration Statement permits the offering, issuance and sale of common stock, preferred stock, debt securities and warrants having an aggregate offering price of up to $100.0 million in one or more offerings and in any combination of the foregoing.

In January 2024, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain accredited investors, in which we sold the following securities to the accredited investors in a private placement transaction (the "2024 Private Placement"): (i) an aggregate of 4,985,610 shares of our common stock; (ii) to certain investors, in lieu of shares, pre-funded warrants (the "Pre-Funded Warrants") to purchase an aggregate of 306,506 shares of our common stock; (iii) Tranche A Common Warrants (the "Tranche A Common Warrants") to purchase an aggregate of up to 2,646,058 shares of our common stock (or Pre-Funded Warrants in lieu thereof and, in such case, shares of our common stock issuable upon exercise of such Pre-Funded Warrants); and (iv) Tranche B Common Warrants (the "Tranche B Common Warrants" and together with the Tranche A Common Warrants, the "Common Warrants") to purchase an aggregate of up to 2,646,058 shares of our common stock (or Pre-Funded Warrants in lieu thereof and, in such case, shares of our common stock issuable upon exercise of such Pre-Funded Warrants). The purchase price per share and accompanying Common Warrants was $3.827 (or $4.3915 for directors, employees or consultants participating in the 2024 Private Placement) (or $3.8269 per Pre-Funded Warrant and accompanying Common Warrants, which represented the price of $3.827 per share and accompanying Common Warrants minus the $0.0001 per share exercise price of each such Pre-Funded Warrant).

The initial closing of the 2024 Private Placement occurred on January 23, 2024 and the second closing occurred on February 5, 2024. Gross proceeds from the transaction were $20.4 million with net proceeds of approximately $19.0 million after deducting $1.4 million in commissions and other transaction costs. The Tranche A Common Warrants expired unexercised on July 27, 2024.

On November 1, 2024, we closed an underwritten public offering of 2,720,000 shares of our common stock at a price to the public of $3.75 per share pursuant to the Shelf Registration Statement (the "2024 Follow-On"). The gross proceeds from the offering, before deducting underwriting discounts and commissions and offering expenses, were $10.2 million.

In connection with the 2024 Follow-On, on October 30, 2024, we suspended sales of common stock under the ATM Facility pursuant to the Original Prospectus Supplement, and until December 20, 2024, did not offer for sale any shares of common stock pursuant to the ATM Agreement. We filed a prospectus supplement (the "2024 Prospectus Supplement") to the Shelf Registration Statement with the SEC on December 20, 2024 providing for the sale of shares of common stock pursuant to the ATM Facility having an aggregate gross sales price of up to $4.45 million. As of September 30, 2025, we sold an aggregate of 861,652 shares of common stock for net proceeds of approximately $2.0 million, after deducting $146,000 of commissions and settlement expenses paid under the ATM Facility. As of September 30, 2025, approximately $2.6 million remained available under the ATM Facility for the offer and sale of shares of common stock pursuant to the 2024 Prospectus Supplement.

We filed a prospectus supplement (the "2025 Prospectus Supplement") to the Shelf Registration Statement with the SEC on November 6, 2025 providing for the sale of shares of common stock under the ATM Facility having an aggregate gross sales price of up to $9.7 million.

On February 28, 2025 (the "Closing Date"), we entered into a Loan and Security Agreement and the Supplement to the Loan and Security Agreement (together, the "Loan Agreement") with Avenue Venture Opportunities Fund II, L.P. ("Lender") and Avenue Capital Management II, L.P., as administrative agent and collateral agent, for growth capital loans in an aggregate principal amount of up to $32,500,000 (the "Loan"), with (i) $10,000,000 funded on the Closing Date ("Tranche 1"), (ii) up to $7,500,000 to be made available to us between September 1, 2025 and March 31, 2026, subject to, among other things, the Company's achievement of certain milestones with respect to certain of its ongoing clinical trials ("Tranche 2") and (iii) up to $15,000,000 to be made available to us between October 1, 2025 and March 31, 2026, subject to, among other things, (a) our achievement of additional milestones with respect to certain of its ongoing clinical trials and (b) the mutual written agreement of us and the Lender (upon its investment committee approval). We will make interest only payments until the 18 month anniversary of the Closing Date, subject to a 6-month extension upon our achievement of certain milestones with respect to certain of its ongoing clinical trials and funding of the full amount under Tranche 2. The Loan bears interest at an annual rate equal to the greater of (a) the sum of 5.00% plus the prime rate as reported in The Wall Street Journal and (b) 12.75%. The Loan is secured by a lien upon and security interest in all of our assets, including intellectual property, subject to agreed exceptions. The maturity date of the Loan is September 1, 2028 (the "Maturity Date").

Our ability to generate revenue from product sales sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Through September 30, 2025, our operations have been funded primarily by aggregate net proceeds of $190.2 million from the issuance of convertible preferred stock, convertible promissory notes, promissory notes, common stock, and the Merger. Since inception we have had significant operating losses, except for the three month period ending March 31, 2024. Our net loss was $18.8 million for the nine months ended September 30, 2025. Included in the net loss for the nine months ended September 30, 2025 were total operating expenses of $18.7 million and interest expense of $1.1 million, offset by a non-cash gain from the fair value adjustment to our warrant liability and promissory note of $0.2 million, interest income of $0.6 million and other income of $0.3 million. As of September 30, 2025, we had an accumulated deficit of $178.6 million and $14.1 million in cash, cash equivalents and short-term investments. We expect that our cash, cash equivalents and short-term investments will enable us to fund our current operating plan into the second half of 2026. As a result, there is substantial doubt about our ability to continue as a going concern.

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. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. In particular, we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, as well as hire additional personnel, pay fees to outside consultants, lawyers and accountants, and incur other increased costs associated with being a public company. In addition, if and when we seek and obtain regulatory approval to commercialize any product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

We have not had any products approved for sale and, therefore, have not generated any product revenue. We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and

strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Components of Operating Results

Research and Development Expenses

Our research and development expenses have included:

- personnel costs, which include salaries, benefits and stock-based compensation;
- expenses incurred under agreements with consultants, third-party contract organizations that conduct research and development activities on our behalf;
- costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical studies and previously planned and ongoing clinical trials;
- laboratory supplies and materials used for internal research and development activities;

Most of our historical research and development expenses have been related to the preclinical and clinical development of Auxora. We have not reported program costs since inception because we have not tracked or recorded our research and development expenses on a program-by-program basis historically due to the fact that these costs do not necessarily correlate to the overall research and development efforts attributable to such programs and these costs can vary significantly from period to period. We have historically used our personnel and infrastructure resources across the breadth of our research and development activities, which are directed toward identifying and developing product candidates.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and 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.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in conducting clinical trials, manufacturing and otherwise advancing our programs. 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.

Because of the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration and completion costs of the current or future preclinical studies and clinical trials or if, when, or to what extent we will generate revenues from the commercialization and sale of our product candidates or if we even continue to pursue such product development, commercialization or sales. We may never succeed in achieving regulatory approval for our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our remaining product candidates, to the extent we continue to pursue such activities, will depend on a variety of factors, including:

- successful completion of preclinical studies and initiation of clinical trials for Auxora, our other current product candidates and any future product candidates;
- successful enrollment and completion of our clinical trials for Auxora and any clinical trials for future product candidates;
- data from our clinical programs that support an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- acceptance by the FDA, regulatory authorities in Europe, Canada or other regulatory agencies of the IND applications, clinical trial applications and/or other regulatory filings for Auxora, our other current product candidates and any future product candidates;
- expansion and maintenance of a workforce of experienced scientists and others to continue to develop our product candidates;
- successful application for and receipt of marketing approvals from applicable regulatory authorities;
- obtainment and maintenance of intellectual property protection and regulatory exclusivity for our product candidates;
- arrangements with third-party manufacturers for, or establishment of, clinical and commercial active pharmaceutical ingredient (“API”) and drug product manufacturing capabilities;
- establishment of sales, marketing and distribution capabilities and successful launch of commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;

- effective competition with other therapies;
- obtainment and maintenance of coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- maintenance, enforcement, defense and protection of our rights in our intellectual property portfolio;
- avoidance of infringement, misappropriation or other violations with respect to others' intellectual property or proprietary rights; and
- maintenance of a continued acceptable safety profile of our products following receipt of any marketing approvals.

We may never succeed in achieving regulatory approval for any of our remaining product candidates. We may obtain unexpected results from our preclinical studies and subsequent clinical trials, if any. We may elect to discontinue, delay or modify future clinical trials or preclinical activities of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current preclinical product candidates. For example, if the FDA, or another regulatory authority, were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or future clinical trials, if any, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development.

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to increase for the foreseeable future as we continue to implement our business strategy, which includes advancing Auxora through clinical development and other product candidates further into clinical development, expanding our research and development efforts, including hiring additional personnel to support our research and development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs, depreciation expense and other expenses for outside professional services, including legal related to intellectual property and corporate matters, human resources, audit and accounting services and facility-related fees not otherwise included in research and development expenses. Personnel costs consist of salaries, benefits and equity-based compensation expense for our personnel in executive, finance and accounting, business operations and other administrative functions. We expect our general and administrative expenses to increase over the next several years to support our continued research and development activities, manufacturing activities, increased costs of expanding our operations and operating as a public company. These increases will likely include increases related to the hiring of additional personnel and legal, regulatory and other fees and services associated with maintaining compliance with stock exchange listing rules and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company.

Other Income

Our other income includes (i) interest income and expense and non-cash changes in the fair value of the promissory note; (ii) non-cash changes in the fair value of our warrant liabilities; and (iii) other non-operating income.

Results of Operations

Comparison of the Three Months Ended September 30, 2025 and 2024

The following sets forth our results of operations (in thousands):

	Three Months Ended September 30,		Change	
	2025	2024	Amount	%
Operating expenses:				
Research and development	$ 3,851	$ 3,546	$ 305	9%
General and administrative	1,767	2,190	(423)	(19%)
Total operating expenses	5,618	5,736	(118)	(2%)
Loss from operations	(5,618)	(5,736)	118	(2%)
Other income (expense)	(2,186)	118	(2,304)	(1953%)
Net loss	$ (7,804)	$ (5,618)	$ (2,186)	39%

Research and Development Expenses

Research and development expenses comprised (in thousands):

	Three Months Ended September 30,		Change	
	2025	2024	Amount	%
Preclinical studies and clinical trial-related activities	$ 2,158	$ 1,629	$ 529	32%
Chemistry, manufacturing and controls	415	431	(16)	(4%)
Personnel costs	934	934	—	0%
Consultants and other costs	344	552	(208)	(38%)
Total research and development expenses	$ 3,851	$ 3,546	$ 305	9%

Research and development expenses were $3.9 million for the three months ended September 30, 2025, compared to $3.6 million for the three months ended September 30, 2024. The increase of $0.3 million was due primarily to an increase of $0.5 million in clinical trial and preclinical activities, offset by a decrease of $0.2 million in consultants and other costs.

General and Administrative Expenses

General and administrative expenses to support our business activities comprised (in thousands):

	Three Months Ended September 30,		Change	
	2025	2024	Amount	%
Personnel costs	$ 1,108	$ 1,096	$ 12	1%
Facility costs	129	114	15	13%
Professional services	393	657	(264)	(40%)
Consultants and other costs	137	323	(186)	(58%)
Total general and administrative expenses	$ 1,767	$ 2,190	$ (423)	(19%)

General and administrative expenses were $1.8 million for the three months ended September 30, 2025, compared to $2.2 million for the three months ended September 30, 2024. The decrease of $0.4 million was primarily related a decrease in professional services of $0.2 million and a decrease in consultants and other costs of $0.2 million.

Other Income (Expense)

Other income (expense) for the three months ended September 30, 2025 was expense of $2.2 million, compared to other income of $0.1 million for the three months ended September 30, 2024. The increase of $2.3 million in other expenses was due to a non-cash $1.9 million increase in fair value adjustments to our financial instruments, which resulted in net expense of $2.0 million compared to $0.1 million expense for the three months ended September 30, 2025 and 2024, respectively, an increase in interest expense associated with our promissory note of $0.3 million for the three months ended September 30, 2025 and a decrease of $0.1 million of interest income as of September 30, 2025.

Comparison of the Nine Months Ended September 30, 2025 and 2024

The following sets forth our results of operations (in thousands):

	Nine Months Ended September 30,		Change	
	2025	2024	Amount	%
Operating expenses:				
Research and development	$ 12,127	$ 10,647	$ 1,480	14%
General and administrative	6,609	7,385	(776)	(11%)
Total operating expenses	18,736	18,032	704	4%
Loss from operations	(18,736)	(18,032)	(704)	4%
Other income (expense)	(66)	8,590	(8,656)	(101%)
Net loss	$ (18,802)	$ (9,442)	$ (9,360)	99%

Research and Development Expenses

Research and development expenses comprised (in thousands):

	Nine Months Ended September 30,		Change	
	2025	2024	Amount	%
Preclinical studies and clinical trial-related activities	$ 6,290	$ 4,809	$ 1,481	31%
Chemistry, manufacturing and controls	1,265	1,590	(325)	(20%)
Personnel	2,903	2,666	237	9%
Consultants and other costs	1,669	1,582	87	5%
Total research and development expenses	$ 12,127	$ 10,647	$ 1,480	14%

Research and development expenses were $12.1 million for the nine months ended September 30, 2025, compared to $10.6 million for the nine months ended September 30, 2024. The increase of $1.5 million was due primarily to an increase of $1.5 million in clinical trial and preclinical activities, an increase of $0.2 million in personnel costs and an increase in consultants and other costs of $0.1 million. These were all offset by a decrease of $0.3 million in chemistry, manufacturing and control activities in regard to our Phase 2 clinical trials of Auxora.

General and Administrative Expenses

General and administrative expenses to support our business activities comprised (in thousands):

	Nine Months Ended September 30,		Change	
	2025	2024	Amount	%
Personnel costs	$ 3,788	$ 2,802	$ 986	35%
Facility costs	411	403	8	2%
Professional services	1,731	2,430	(699)	(29%)
Consultants and other costs	679	1,750	(1,071)	(61%)
Total general and administrative expenses	$ 6,609	$ 7,385	$ (776)	(11%)

General and administrative expenses were $6.6 million for the nine months ended September 30, 2025, compared to $7.4 million for the nine months ended September 30, 2024. The decrease of $0.8 million was primarily related to a decrease in consultants and other costs of $1.1 million driven by transactions costs associated with the 2024 Private Placement as of the nine months ended September 30, 2024 and professional services of $0.7 million. These costs were partially offset by an increase in personnel costs of $1.0 million driven by non-cash stock based compensation of $0.5 million for the nine months ended September 30, 2025.

Other Income (Expense)

Other income (expense) for the nine months ended September 30, 2025 was expense of $0.1 million, compared to other income of $8.6 million for the nine months ended September 30, 2024. The increase of $8.7 million in expenses was due to the non-cash fair value adjustments to our financial instruments which resulted in a net gain of $0.2 million compared to a $7.8 million gain for the nine months ended September 30, 2025 and 2024, respectively. Additionally, we had an increase in interest expense associated with our promissory note issued pursuant to the Loan Agreement of $1.1 million and a decrease in interest income of $0.2 million driven by the balances of our cash equivalents and short-term investments. These decreases were offset by miscellaneous income of $0.2 million for the nine months ended September 30, 2025.

Liquidity and Capital Resources

Overview

As of September 30, 2025 we had cash, cash equivalents and short-term investments of $14.1 million.

As further described below, on February 28, 2025, the Company entered into the Loan Agreement with Avenue Venture Opportunities Fund II, L.P. and Avenue Capital Management II, L.P. for an initial $10.0 million of gross proceeds. During the three months ended September 30, 2025, we sold an aggregate of 270,057 shares of common stock for net proceeds of $777,000 after deducting $76,000 of commissions and settlement expenses paid under the ATM Facility. As of September 30, 2025, our remaining capacity for sales of common stock under the ATM Facility was $2.6 million. On November 6, 2025, we filed the 2025 Prospectus Supplement which increased our capacity for sales under the ATM Facility to $9.7 million.

The accompanying unaudited condensed consolidated financial statements have been prepared on a basis which assumes we are a going concern and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from any uncertainty related to our ability to continue as a going concern. Based on our current operating plans, we believe our cash, cash equivalents and short-term investments may not be sufficient to fund our operations for the period one year following the issuance of the accompanying financial statements. Specifically, we expect that our cash, cash equivalents and short-term investments will allow us to fund the current operating plan into the second half of 2026. As a result, there is substantial doubt about the Company's ability to continue as a going concern. In addition, our current cash, cash equivalents and short-term investments will not be sufficient to fund any of our product candidates through regulatory approval, nor will it be sufficient to pursue additional indications for Auxora, nor will it be sufficient to fund clinical work on other product candidates in our portfolio aside from Auxora, and we will need to raise substantial additional capital to complete the development and commercialization of our product candidates.

If we are unable to maintain sufficient financial resources, our business, financial condition and results of operations will be materially and adversely affected. To fund our operations in both the near term and long term, we will need to raise additional capital to develop our product candidates and implement our operating plans. There can be no assurance that we will be able to obtain the needed financing on acceptable terms or at all. Additionally, equity or debt financings may have a dilutive effect on the holdings of our existing stockholders. In addition, the terms of the Loan Agreement contain certain restrictions on incurring additional indebtedness.

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 progress, costs and results of our ongoing clinical trials of Auxora and our planned trials for our other product candidates;
- the scope, progress, results and costs of discovery research, preclinical development, laboratory testing and clinical trials for our product candidates, including our ongoing clinical trials of Auxora;
- the number of, and development requirements for, other product candidates that we pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to enter into contract manufacturing arrangements for supply of API and manufacture of drug product for our product candidates and the terms of such arrangements;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment or receipt of milestones and receipt of other collaboration-based revenues, if any;
- the costs and timing of any future commercialization activities, including product manufacturing, sales, marketing and distribution, for any of our product candidates for which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims;
- the extent to which we acquire or in-license other products, product candidates, technologies or data referencing rights;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations;
- our ability to service and comply with the terms of our outstanding indebtedness;
- the impacts of global health pandemics, geopolitical conflicts and economic uncertainty, including tariffs and other trade measures, rising interest rates and inflation on our business and operations, including clinical trials, collaborators, CROs and employees; and

- the costs of operating as a public company.

Since we commenced operations in October 2006, we have primarily financed our operations through private placements of our preferred stock, convertible promissory notes, promissory notes, warrants, common stock, and through the Merger. We have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially for the foreseeable future. The development of drug product candidates is highly capital intensive. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory and quality capabilities. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution. Furthermore, we have incurred and expect to continue 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 attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. The global credit and financial markets have experienced extreme volatility, including in liquidity and credit availability, declines in consumer confidence, declines in economic growth, and uncertainty about economic stability. There can be no assurance that deterioration in credit and financial markets and confidence in economic conditions will not occur. If equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive.

We expect to finance our longer-term expected future cash requirements and obligations through a combination of existing cash, cash equivalents and short-term investments and equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. To continue to finance our operations, we will need to raise additional capital, which cannot be assured. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. However, we may be unable to raise additional funds or enter into such other arrangement when needed or on favorable terms, if at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

In August 2023, we filed the Shelf Registration Statement, which contains two prospectuses, a base prospectus and the Original Prospectus Supplement that covered the offering, issuance and sale of up to $17.3 million of common stock pursuant to the ATM Agreement with Wainwright, acting as sales agent. The Shelf Registration Statement permits the offering, issuance and sale of common stock, preferred stock, debt securities and warrants having an aggregate offering price of up to $100.0 million in one or more offerings and in any combination of the foregoing.

In January 2024, we entered into the Purchase Agreement with certain accredited investors, in which we sold the following securities to the accredited investors the 2024 Private Placement: (i) an aggregate of 4,985,610 shares of our common stock; (ii) to certain investors, in lieu of shares, Pre-Funded Warrants to purchase an aggregate of 306,506 shares of our common stock; (iii) Tranche A Common Warrants to purchase an aggregate of up to 2,646,058 shares of our common stock (or Pre-Funded Warrants in lieu thereof and, in such case, shares of our common stock issuable upon exercise of such Pre-Funded Warrants); and (iv) Tranche B Common Warrants to purchase an aggregate of up to 2,646,058 shares of our common stock (or Pre-Funded Warrants in lieu thereof and, in such case, shares of our common stock issuable upon exercise of such Pre-Funded Warrants). The purchase price per share and accompanying Common Warrants was $3.827 (or $4.3915 for directors, employees or consultants participating in the 2024 Private Placement) (or $3.8269 per Pre-Funded Warrant and accompanying Common Warrants, which represented the price of $3.827 per share and accompanying Common Warrants minus the $0.0001 per share exercise price of each such Pre-Funded Warrant).

The initial closing of the 2024 Private Placement occurred on January 23, 2024 and the second closing occurred on February 5, 2024. Gross proceeds from the transaction were $20.4 million with net proceeds of approximately $19.0 million after deducting $1.4 million in commissions and other transaction costs. The Tranche A Common Warrants expired unexercised on July 27, 2024.

On November 1, 2024, we closed the 2024 Follow-On. The gross proceeds from the offering, before deducting underwriting discounts and commissions and offering expenses, were $10.2 million.

In connection with the 2024 Follow-On, on October 30, 2024, we suspended sales of common stock under the ATM Facility pursuant to the Original Prospectus Supplement, and until December 20, 2024, did not offer for sale any shares of common stock. We filed the 2024 Prospectus Supplement with the SEC on December 20, 2024 providing for the sale of shares of common stock under the ATM Facility having an aggregate gross sales price of up to $4.45 million of shares of common stock. As of September 30, 2025, we sold an aggregate of 861,652 shares of common stock for net proceeds of approximately $2.0 million, after deducting $146,000 of commissions and settlement expenses paid under the ATM Facility. As of September 30, 2025, our remaining capacity

for sales of common stock under the ATM Facility was $2.6 million. On November 6, 2025, we filed the 2025 Prospectus Supplement which increased our capacity for sales of common stock under the ATM Facility of up to $9.7 million.

On February 28, 2025, we entered into the Loan Agreement with Avenue Venture Opportunities Fund II, L.P. and Avenue Capital Management II, L.P., as administrative agent and collateral agent, for growth capital loans in an aggregate principal amount of up to $32,500,000, with (i) Tranche 1 for $10,000,000 funded on the Closing Date, (ii) Tranche 2 for up to $7,500,000 to be made available to the Company between September 1, 2025 and March 31, 2026, subject to, among other things, our achievement of certain milestones with respect to certain of its ongoing clinical trials and (iii) Tranche 3 for up to $15,000,000 to be made available to the Company between October 1, 2025 and March 31, 2026, subject to, among other things, (a) our achievement of additional milestones with respect to certain of its ongoing clinical trials and (b) the mutual written agreement of the Company and the Lender (upon its investment committee approval). We will make interest only payments until the 18 month anniversary of the Closing Date, subject to a 6-month extension upon our achievement of certain milestones with respect to certain of its ongoing clinical trials and funding of the full amount under Tranche 2. The Loan bears interest at an annual rate equal to the greater of (a) the sum of 5.00% plus the prime rate as reported in The Wall Street Journal and (b) 12.75%. The Loan is secured by a lien upon and security interest in all of our assets, including intellectual property, subject to agreed exceptions. The Maturity Date of the Loan is September 1, 2028.

Our operations through September 30, 2025, have been funded primarily by aggregate net proceeds of $190.2 million from the issuance of convertible preferred stock, convertible notes, promissory notes, common stock, and the Merger. Since inception, we have had significant operating losses, except for the three month period ending March 31, 2024. Our net loss for the nine months ended September 30, 2025 was $18.8 million and consisted of total operating expenses of $18.7 million and interest expense of $1.1 million offset by a non-cash gain from the fair value adjustment to our warrant liability and promissory note of $0.2 million, interest income of $0.6 million and other income of $0.2 million. For the nine months ended September 30, 2024, our net loss was $9.4 million consisting of $18.0 million of operating expenses offset by a non-cash gain from the fair value adjustment to our warrant liability of $7.8 million and interest income of $0.8 million. As of September 30, 2025, we had an accumulated deficit of $178.6 million and $14.1 million in cash, cash equivalents and short-term investments. During the nine months ended September 30, 2025, cash used in operations was $16.3 million, primarily due to cash outlays for operations. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Cash Flows

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

	Nine Months Ended September 30,	
	2025	2024
Net cash provided by (used in):		
Operating activities	$ (16,326)	$ (16,174)
Investing activities	2,403	744
Financing activities	11,458	19,052
Net (decrease) increase in cash and cash equivalents	$ (2,465)	$ 3,622

Net Cash Used in Operating Activities

Cash used in operating activities of $16.3 million during the nine months ended September 30, 2025 was attributable to our net loss of $18.8 million, offset by non-cash items of $2.2 million and a net change in our operating assets and liabilities of $0.3 million. Non-cash items consisted primarily of $2.3 million of stock-based compensation and debt issuance costs of $0.4 million as result of the debt financing in the first quarter of 2025 offset by $0.2 million due to a change in our warrant liabilities and accretion on our short term investments of $0.3 million.

Cash used in operating activities of $16.2 million during the nine months ended September 30, 2024 was attributable to our net loss of $9.4 million, non-cash items of $5.8 million and a net change in our operating assets and liabilities of $1.0 million. Non-cash items consisted primarily of $7.8 million due to a change in our warrant liability and accretion on our short term investments of $0.5 million offset by $1.7 million of stock-based compensation and transaction costs of $0.8 million as a result of the 2024 Private Placement in the first quarter of 2024.

Net Cash Provided by Investing Activities

Cash provided by investing activities of $2.4 million for the nine months ended September 30, 2025 consisted of purchases of short-term investments of $17.8 million, offset by the maturing of short-term investments of $15.4 million.

Cash provided by investing activities of $0.7 million for the nine months ended September 30, 2024 consisted of the purchase of short-term investments of $18.8 million, offset by maturing of short-term investments of $19.5 million.

Net Cash Provided by Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2025 was $11.5 million comprised of the debt financing of $9.7 million and $1.8 million as a result of our ATM.

Cash provided by financing activities for the nine months ended September 30, 2024 was $19.1 million comprised of the sale and issuance of common stock of $20.4 million in the 2024 Private Placement and $0.1 million as a result of our ATM Facility, offset by transaction costs of $1.4 million.

Material Cash Requirements

Our material cash requirements from known contractual obligations consist primarily of our lease obligation. We lease office and laboratory space in La Jolla, California with monthly rent expense of approximately $10,000 pursuant to a 12 month lease agreement that commenced in January 2023 and was amended and renewed in December 2023 for an additional 12 month term with monthly rent expense of approximately $10,000. In December 2024, an amendment was executed for a 12 month term with monthly rent expense of approximately $10,500. Over the next three months, we expect cash requirements for our lease obligation to be approximately $32,000.

We enter into contracts in the normal course of business with third-party service providers for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice, and therefore, we believe that our non-cancelable obligations under these agreements are not material and we cannot reasonably estimate the timing of if and when they will occur. We could also enter into additional research, manufacturing, supplier and other agreements in the future, which may require up-front payments and even long-term commitments of cash.

We may also, from time to time, become party or subject to various other legal proceedings and claims, either asserted or unasserted, which arise in the ordinary course of business. Some of these proceedings have involved, and may involve in the future, claims that are subject to substantial uncertainties and unascertainable damages.

Critical Accounting Policies and Significant Judgments and Estimates

Our 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 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 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. 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.

Research and Development Costs

We incur substantial expenses associated with clinical trials. Accounting for clinical trials relating to activities performed by CROs and other external vendors requires management to make estimates in regard to the timing and accounting for these expenses. We estimate costs of research and development activities conducted by service providers, which include the conduct of sponsored research, preclinical studies and contract manufacturing activities. The diverse nature of services being provided under CRO and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain clinical activities complicates the estimation of accruals for services rendered by CROs and other vendors in connection with clinical trials. We record the estimated costs of research and development activities based upon the number of services provided but not yet invoiced and include these costs in the accrued and other current liabilities on the balance sheets and within research and development expense on the statements of operations, and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received. In estimating the duration of a clinical trial, we evaluate the start-up, treatment and wrap-up periods, compensation arrangements and services rendered attributable to each clinical trial and fluctuations are regularly tested against payment plans and trial completion assumptions.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. We make estimates in determining the accrued liabilities and prepaid expense balances in each reporting period. As actual costs become known, we adjust our accrued liabilities or prepaid expenses. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Our expenses related to clinical trials are based on patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that may be used to conduct and manage clinical trials on our behalf. We generally accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we modify our estimates of accrued expenses accordingly on a prospective basis.

Fair Value of the Promissory Note

The Company elected the fair value option for the promissory note and estimated the fair value based on a discounted cash flow analysis, a form of the Income Approach. Several different settlement scenarios were considered, and probability weighted to arrive at the final valuation. Increases or decreases in the fair value of the promissory note can result from updates to assumptions such as the expected timing or probability of the different settlement scenarios, or changes in discount rates. Judgment is used in determining these assumptions as of the initial valuation date and at each subsequent reporting period. Updates to assumptions could have a significant impact on our results of operations in any given period.

Valuation of Common Warrants

Common Warrants were valued using Black-Scholes utilizing the following inputs; (i) a risk-free interest rate (ii) volatility based on the expected term of the Common Warrant (iii) and an exercise price and stock price on the date of the transaction. Several different scenarios were considered, and probability weighted to arrive at the final valuation. Increases or decreases in the fair value of the Common Warrants can result from updates to assumptions such as the expected timing or probability of the different settlement scenarios. Judgment is used in determining these assumptions as of the initial valuation date and at each subsequent reporting period. Updates to assumptions could have a significant impact on our results of operations in any given period.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies 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. We will cease to be an emerging growth company on December 31, 2025. 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 are also a "smaller reporting company," as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), because both the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company 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 as of June 30th. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recently Adopted Accounting Pronouncements

None.

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

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q.

Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we are involved in legal proceedings arising in the ordinary course of our business.

The ultimate outcome of any litigation is uncertain and unfavorable outcomes could have a negative impact on our results of operations and financial condition. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

We currently believe there is no litigation pending that could, individually or in the aggregate, have a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors.

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, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding to invest in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. We cannot assure you that any of the events discussed below will not occur. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially. In such event, the trading price of our common stock could decline and you might lose all or part of your investment. The risk factors set forth below that are marked with an asterisk (*) did not appear as separate risk factors in, or contain changes to the similarly titled risk factor included in Item 1A. of our Annual Report on Form 10-K, filed with the SEC on March 27, 2025.

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

We are a clinical-stage biopharmaceutical company with a limited operating history. We have a history of net losses and anticipate that we will incur significant losses in the future. We have never generated any revenue from product sales and may never be profitable.*

We are a clinical-stage biopharmaceutical company with a limited operating history that may make it difficult to evaluate the success of our business to date and assess our future viability. We commenced operations in October 2006, have no products approved for commercial sale and have never generated any revenue. We have devoted substantially all of our resources to organizing and staffing our company, business planning, establishing and maintaining our intellectual property portfolio, raising capital, developing our product candidates, undertaking research and development activities, and providing general and administrative support for these operations. We are conducting several clinical trials and preclinical studies for our lead product candidate, Auxora, which is currently in an ongoing Phase 2 trial in AKI with AHRF and a Phase 1/2 clinical trial in pediatric patients with AIPT as a side effect of pediatric acute lymphoblastic leukemia treatment with asparaginase. We recently completed a Phase 2b trial for Auxora in AP and accompanying SIRS and are planning a Phase 3 trial in this indication, and we previously completed a Phase 2 trial in COVID-19 pneumonia patients with ARDS.

Our other pipeline programs, which include new product candidates, are in preclinical development. As of September 30, 2025, we had an accumulated deficit of $178.6 million and a net loss of $18.8 million for the nine months ended September 30, 2025. Other than the three months ended March 31, 2024, we have incurred net losses since our inception. We have never generated revenue from product sales and we expect that it will be several years, if ever, before we have a product candidate ready for commercialization. We expect to incur increasing levels of operating losses over the next several years and for the foreseeable future as we advance our product candidates through clinical development. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital.

To become and remain profitable, we must develop and eventually commercialize product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, finding external manufacturing capacity sufficient to meet commercial demand, marketing and selling those product candidates for which we may obtain marketing approval and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenue that is significant or large enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. 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 would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Our need for additional capital raises substantial doubt about our ability to continue as a going concern. We will need to obtain substantial additional funding to complete the development and any commercialization of our product candidates. If we are unable to raise this capital when needed, on acceptable terms, or at all, we may be forced to delay, reduce or eliminate the development of our product candidates or other operations.*

Since we commenced operations in October 2006, we have primarily financed our operations through private placements of our preferred stock, convertible promissory notes, promissory notes, warrants, and common stock and through the Merger. We have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially for the foreseeable future. The development of drug product candidates is highly capital intensive. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory and quality capabilities. In addition,

if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

This Quarterly Report on Form 10-Q includes disclosures regarding management's assessment of our ability to continue as a going concern as our current liquidity position and recurring losses from operations since inception and negative cash flows from operating activities raise substantial doubt about our ability to continue as a going concern. As of September 30, 2025, we had $14.1 million in cash, cash equivalents and short-term investments. Based on our current operating plans, we believe our existing resources will be sufficient to fund our current operations through certain clinical milestones into the second half of 2026. As a result, there is substantial doubt about our ability to continue as a going concern. In addition, our current cash, cash equivalents and short-term investments will not be sufficient to fund any of our product candidates through regulatory approval, nor will it be sufficient to pursue additional indications for Auxora like AHRF, nor will it be sufficient to fund clinical trials on other product candidates in our portfolio aside from the ongoing KOURAGE trial of Auxora, and we will need to raise substantial additional capital to complete the development and any commercialization of our product candidates.

The accompanying unaudited condensed consolidated financial statements have been prepared on a basis which assumes we are a going concern and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from any uncertainty related to our ability to continue as a going concern.

We have based these estimates on assumptions that may prove to be incorrect or require adjustment as a result of business decisions, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the progress, costs and results of our ongoing clinical trials of Auxora and our planned trials for our other product candidates;
- the scope, progress, results and costs of discovery research, preclinical development, laboratory testing and clinical trials for our product candidates, including our ongoing clinical trials of Auxora;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient ("API") and manufacture of drug product for our product candidates and the terms of such arrangements;
- the costs and timing of any future commercialization activities, including product manufacturing, sales, marketing and distribution, for any of our product candidates for which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property-related claims;
- the extent to which we acquire or in-license other products, product candidates, technologies or data referencing rights;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment or receipt of milestones and receipt of other collaboration-based revenues, if any;
- the number of, and development requirements for, other product candidates that we pursue;
- our ability to service and comply with the terms of our outstanding indebtedness;
- the impacts of the ongoing or future international conflicts and potential future bank failures and international tariffs; and
- the costs of operating as a public company.

Because we do not expect to generate revenue from product candidate sales for many years, if at all, we will need to obtain substantial additional funding in connection with our continuing operations and expected increases in expenses. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. 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. The impacts of the ongoing or future international conflicts and potential future bank failures and international tariffs on capital markets may affect the

availability, amount and type of financing available to us in the future. In addition, the terms of the Loan Agreement contain certain restrictions on incurring additional indebtedness. Furthermore, due to our public float and limitations set forth in General Instructions I.B.6 of Form S-3, we are limited in the amount of securities we can sell under our Shelf Registration Statement. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could adversely affect our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through equity offerings, debt financings or other capital sources, including potentially grants, collaborations, licenses or other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, 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 further limiting or restricting our ability to take specific actions, such as limitations on our ability to incur debt, make capital expenditures or declare dividends. For example, our Loan Agreement includes negative covenants restricting us from, among other things, transferring collateral, incurring additional indebtedness, paying cash dividends or making other distributions, making investments, creating liens and selling assets, in each case subject to certain exceptions.

If we raise funds through collaborations 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 when needed, we may be required to delay, limit, reduce or terminate our proprietary product candidate development process or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Attempting to secure additional financing may also divert our management from our day-to-day activities, which may impair or delay our ability to develop our proprietary platform. In addition, demands on our cash resources may change as a result of many factors currently unknown to us including, but not limited to, any unforeseen costs we may incur as a result of preclinical study or clinical trial delays, or disruptions in the manufacturing of our product candidates, due to the ongoing or future international conflicts, potential future bank failures, international tariffs or other causes, and we may need to seek additional funds sooner than planned. If we are unable to obtain funding on a timely basis or at all, we may be required to significantly curtail or stop one or more of our research or development programs.

Any acquisitions or strategic collaborations may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities or subject us to other risks.*

From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products and technologies, intellectual property rights, technologies or businesses. Any acquisition or strategic partnership may entail numerous risks, including, but not limited to:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent or unknown liabilities;
- assimilation of operations, intellectual property and products or product candidates of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product candidates and initiatives in pursuing such an acquisition or a strategic partnership;
- retention of key employees, the loss of key personnel and uncertainties about our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals, and the possibility of disagreements or disputes with such other party; and

- our inability to generate revenue from acquired products, product candidates, intellectual property rights, technologies, and/or businesses sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

On February 28, 2025, we entered into the Loan Agreement with Avenue Venture Opportunities Fund (the "Lender"), for (i) an initial growth capital loan in the principal amount of $10,000,000 funded on March 3, 2025 (ii) up to $7,500,000 to be made available to us between September 1, 2025 and March 31, 2026, subject to, among other things, our achievement of certain milestones with respect to certain of its ongoing clinical trials and (iii) up to $15,000,000 to be made available to us between October 1, 2025 and March 31, 2026, subject to, among other things, (a) our achievement of additional milestones with respect to certain of our ongoing clinical trials and (b) the mutual written agreement of us and the Lender (upon its investment committee approval).

In addition, if we engage in acquisitions or strategic partnerships, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses or acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our growth or limit access to technology or drugs that may be important to the development of our business.

The terms of the Loan Agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility.*

The Loan Agreement includes customary affirmative and negative covenants, as well as standard events of default, including an event of default based on the occurrence of a material adverse event. The negative covenants include, among others, restrictions on us transferring collateral, incurring additional indebtedness, paying cash dividends or making other distributions, making investments, creating liens, and selling assets, in each case subject to certain exceptions. These restrictive covenants could limit our flexibility in operating our business and our ability to pursue business opportunities that we or our stockholders may consider beneficial. In addition, the Lender could declare a default upon the occurrence of an event that it interprets could have a material adverse effect, as defined in the Loan Agreement. Upon the occurrence and continuance of an event of default, the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. Any declaration by the Lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. We may not have enough available cash or be able to raise additional funds through equity or debt financing to repay these outstanding obligations at the time any event of default occurs. Further, if we raise any additional capital through debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

If we are unable to maintain our listing on Nasdaq, it could become more difficult to sell our common stock in the public market.

Our common stock was previously delisted from the Nasdaq Stock Market LLC ("Nasdaq") and on June 12, 2023, Nasdaq approved our application to relist our common stock and we began trading on June 14, 2023 on the Nasdaq Capital Market. If we are unable to continue to meet Nasdaq's listing standards for any reason, our common stock could be delisted from Nasdaq. If delisted, we may seek to list our securities on a different stock exchange or, if one or more broker-dealer market makers comply with applicable requirements, the OTC. Listing on such other market or exchange could reduce the liquidity of our common stock. If our common stock were to trade in the OTC market, an investor would find it more difficult to dispose of, or to obtain accurate quotations for the price of, the common stock.

A delisting from Nasdaq and failure to obtain listing on another market or exchange would subject our common stock to so-called penny stock rules that impose additional sales practice and market-making requirements on broker-dealers who sell or make a market in such securities. Consequently, removal from Nasdaq and failure to obtain listing on another market or exchange could affect the ability or willingness of broker-dealers to sell or make a market in our common stock and the ability of purchasers of our common stock to sell their securities in the secondary market.

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

Our proprietary CRAC channel inhibition science 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 use and expand our science to build a pipeline of product candidates.

We are seeking to identify and develop a broad pipeline of product candidates using our proprietary CRAC channel inhibitor science to address acute critical illness and chronic inflammatory and immunologic diseases where there are no effective therapies. Our lead product candidate, Auxora, recently completed a Phase 2b clinical trial and we have only completed two randomized, blinded placebo-controlled trials with Auxora to date. We are not aware of any FDA approved therapeutics utilizing similar technology. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our proprietary CRAC channel inhibition science is both preliminary and limited. Additionally, there are no drugs currently approved for the treatment of AP and as a result the FDA has not established the endpoints that will be required for approval in this indication. 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.

Given the novelty of our CRAC channel inhibition science, 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 relevant experience with the indications that we are pursuing, the regulatory pathway with the FDA and comparable regulatory authorities may be more complex and time-consuming. There can be no assurance as to the length of clinical development, the number of patients that the FDA may require to be enrolled in clinical trials to establish the safety and efficacy of our product candidates, or that the data generated in these clinical trials will be acceptable to the FDA to support marketing approvals. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

Our business is highly dependent on the success of our product candidates, in particular Auxora, and we may fail to develop Auxora successfully or be unable to obtain regulatory approval.

Our future success is dependent on our ability to complete clinical trials in a timely and successful manner and obtain marketing approval for and successfully commercialize Auxora, our lead product candidate. We are investing the majority of our efforts and financial resources in the research and development of Auxora for multiple indications. Auxora is currently in several studies: an ongoing Phase 1/2 clinical trial, for which the first cohort was completed, in pediatric patients with AIPT as a side effect of pediatric acute lymphoblastic leukemia treatment with asparaginase; and a Phase 2 trial in AKI that we initiated in July 2024. Auxora was also studied in a completed Phase 2b clinical trial in AP and accompanying SIRS and a completed Phase 2 trial in COVID-19 pneumonia patients with ARDS which may inform the design of clinical development in AHRS and/or ARDS due to a broad range of etiologies. We also have additional preclinical product candidates that will need to progress through IND application enabling studies prior to clinical development. None of our product candidates have advanced into late-stage or pivotal trials for the indications for which we are pursuing development. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates.

Although certain of our employees have prior experience with clinical trials, regulatory approvals and manufacturing of pharmaceutical products, we have not previously completed any late-stage or pivotal clinical trials or submitted a new drug application ("NDA") to the FDA or regulatory approval filings to comparable foreign authorities for any product candidate, and Auxora may not be successful in clinical trials and may not receive any regulatory approval. The FDA and other comparable global regulatory authorities can delay, limit or deny approval of a product candidate for many reasons. Any delay in obtaining, or inability to obtain, applicable regulatory approval will delay or harm our ability to successfully commercialize Auxora and harm our business, financial condition, results of operations and prospects.

Furthermore, because Auxora is our most advanced product candidate, if our clinical trials of Auxora encounter safety, efficacy or manufacturing problems, development delays, regulatory issues or other problems, our development plans for Auxora and our other product candidates in our pipeline could be significantly impaired, which could harm our business, financial condition, results of operations and prospects.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidate in late-stage clinical trials for regulatory approval or in obtaining marketing approval thereafter. Given our early stage of development, it may be several years, if at all, before we have demonstrated the safety and efficacy of a treatment sufficient to warrant approval for commercialization. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

Clinical development is a lengthy, expensive and uncertain process. The results of preclinical studies and early clinical trials are not always predictive of future results. Any product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

The research and development of drugs is extremely risky. Only a small percentage of programs that enter the clinical development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate in humans. Clinical testing is expensive, can take many years to complete and its outcome is uncertain. Moreover, 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.

The results of preclinical studies and early clinical trials of product candidates, even those with the same or similar mechanisms of action, may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. While

we have previously received results, some preliminary, from two randomized, blinded placebo-controlled trials, one small blinded randomized SOC controlled trial, one small randomized open-label placebo-controlled trial, one small open-label single site trial, and one small open label investigator sponsored clinical trial, we do not know how Auxora will perform in the ongoing Phase 2 clinical trials or in future clinical trials with larger sample sizes. Results of clinical trials with smaller sample sizes, such as our completed SOC-controlled Phase 2a clinical trial of Auxora in 21 patients with AP and accompanying SIRS plus hypoxemia, can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. In general, clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

To date, we have not completed any clinical trials that the FDA has confirmed or accepted as late-stage or pivotal clinical trials for any of our product candidates. We cannot guarantee that any clinical trials will be initiated or conducted as planned or completed on schedule, if at all. We also cannot be sure that submission of an IND or similar application will result in the FDA or other regulatory authority, as applicable, allowing clinical trials to begin in a timely manner, if at all.

Moreover, even if these trials begin, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Any of these events could cause delays and interruptions in our clinical trials, which could adversely affect our business.

We may experience delays in site initiation and patient enrollment, failures to comply with study protocols, delays in the manufacture of our product candidates for clinical testing and other difficulties in starting or completing our clinical trials. Other events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- delays in reaching a consensus with regulatory agencies, the FDA or foreign regulatory authorities, on trial design or implementation;
- delays in reaching agreement on acceptable terms with prospective clinical research organizations (“CROs”), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting and training suitable clinical investigators;
- delays in obtaining required institutional review board (“IRB”) or independent ethics committee (“IEC”) approval at each clinical trial site;
- delays in recruiting suitable patients to participate in our clinical trials;
- imposition of a clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment or equivalent foreign application or amendment, as a result of a new safety finding that presents unreasonable risk to clinical trial participants, or after a negative finding from an inspection of our clinical trial operations or study sites;
- failure by our CROs, other third parties or us to adhere to the trial protocol or good clinical practice (“GCP”);
- third-party contractors or clinical investigators becoming debarred or suspended or otherwise penalized by the FDA or other comparable foreign regulatory authorities for violations of applicable regulatory requirements;
- delays in the testing, validation, manufacturing and delivery of our product candidates to the treatment sites, including due to supply or manufacturing related delays, being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practices (“cGMP”), regulations or other applicable requirements, or infections or cross-contaminations of our product candidates in the manufacturing process;
- delays in having subjects’ complete participation in a study or return for post-treatment follow-up;
- changes to the clinical trial protocols;
- clinical trial sites or subjects deviating from the trial protocol or dropping out of a study;
- changes in the SOC on which a clinical development plan was based, which may require new or additional trials;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;

- the cost of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization, and delays or failure by our such manufacturers or us to make any necessary changes to such manufacturing process;
- occurrence of adverse events ("AEs") associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of an AE in a trial of the same class of agents as our product candidate conducted by other companies;
- we conducted a significant portion of our CARPO trial in India and, to the extent that we conduct clinical trials in foreign countries, the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in SOC, provision of healthcare services or cultural customs;
- patients in different geographies, including foreign countries, may show differences in clinical outcomes than expected due to differences in underlying disease etiologies or genetic factors;
- conducting clinical trials in a foreign country may also present additional administrative burdens or delays associated with foreign regulatory schemes including different requirements for clinical trial protocols;
- conducting clinical trials in a foreign country may introduce political and economic risks relevant to such foreign countries;
- receiving untimely or unfavorable feedback from applicable regulatory authorities regarding the trial or requests from regulatory authorities to modify the design of a trial;
- suspensions or terminations by us, the IRBs (or the IECs) of the institutions at which such trials are being conducted, by the data safety monitoring board ("DSMB"), for such trial or by regulatory authorities due to a number of factors, including those described above;
- lack of adequate funding;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; or
- disruptions at the FDA and other governmental agencies caused by funding or staffing shortages.

In addition, disruptions caused by international conflicts may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to raise capital, generate revenues from product candidate sales and enter into or maintain collaboration arrangements. For example, if enrollment in a clinical trial is slowed, certain of our expenses related to the trial would not decrease and therefore the overall costs to complete the trial would increase. In addition, if we make manufacturing changes to our product candidates, we may need to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring product candidates to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

One of our product candidates is, and potential future product candidates may be, developed for the treatment of a pediatric population, for which safety concerns may be particularly scrutinized by regulatory agencies. Trials involving pediatric populations can be difficult to conduct, can be quite costly and, like other clinical trials, may not yield the anticipated results. In addition, pediatric trials are more dependent on a smaller number of specialized clinical trial sites, which in turn can limit site availability and make the trials more expensive to conduct. In addition, as interest in pediatric indications grows as a result of the Research to Accelerate Cures and Equity Act and other market forces, trial recruitment may become even more difficult due to competition for eligible patients. Moreover, it may be challenging to ensure that pediatric or adolescent patients adhere to clinical trial protocols.

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

We conducted a significant portion of our CARPO trial in India, and regulatory authorities may not accept data from such trial or any future clinical trials we conduct outside the United States or the applicable foreign jurisdiction.

We conducted a significant portion of our CARPO trial in India. The acceptance of trial data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable non-U.S. regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from non-U.S. clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of non-U.S. data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many non-U.S. regulatory authorities have similar approval requirements. In addition, such non-U.S. trials would be subject to the applicable local laws of the non-U.S. jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable non-U.S. regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable non-U.S. regulatory authority does not accept such data or believes that additional data is necessary to supplement such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical 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;
- the failure of enrolled subjects in foreign countries to adhere to clinical protocol as a result of differences in SOC;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

We depend on enrollment of patients in our clinical trials for our product candidates. If we experience delays or difficulties enrolling patients in our clinical trials, our research and development efforts and business, financial condition, results of operations and prospects could be adversely affected.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients to participate in each study. These trials may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, subject withdrawal from the trial or AEs. These types of developments could cause us to delay the trial or halt further development. Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. In addition, there may be limited patient pools from which to draw for clinical studies. In addition to the rarity of some diseases, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure or to assure their disease is either severe enough or not too advanced to include them in a clinical trial.

Participant enrollment in clinical trials depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain research subject consents;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the availability of competing clinical trials;
- patients' perceptions of risk in traveling to clinical sites (for patients in non-hospitalized clinical trial settings);
- the availability of new drugs approved for the indication the clinical trial is investigating; and

- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies.

These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Preliminary, interim and topline data from our clinical trials may change as more participant data becomes available, and are subject to audit and verification procedures that could result in material changes in the final data.

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

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 to be material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

SAEs, undesirable side effects or other unexpected properties of our product candidates 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 thereby limiting the commercial potential of such product candidate.

As we continue developing Auxora and initiate clinical trials of our additional product candidates, Serious Adverse Events ("SAEs"), undesirable side effects, relapse of disease or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the SAEs or undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective or in which efficacy is more pronounced or durable.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to our therapies. Because of our planned dose escalation design for our clinical trials, undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Additionally, results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics, which may stem from our product candidates specifically or may be due to an illness from which the clinical trial subject is suffering.

If unacceptable side effects arise in the development of our product candidates such that there is no longer a positive benefit risk, we, the FDA, the IRBs at the institutions in which our trials are conducted or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, and inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death.

Even if we believe our product candidates initially show promise in early clinical trials, side effects of product candidates may only be detectable after they are tested in larger, longer and more extensive clinical trials or, in some cases, after they are made available

to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor. If serious adverse or unexpected side effects are identified during development or after approval (including pursuant to any toxicity studies, including reproductive toxicity studies) and are determined to be attributed to our product candidates, we may be required to develop a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Product-related side effects could also result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations and prospects.

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such product candidates, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw or limit approvals of such product candidate, or seek an injunction against its manufacture or distribution;
- 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 candidate;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way a product candidate is administered or conduct additional clinical trials;
- the product candidate may become less competitive;
- we may decide to remove the product candidate from the marketplace; and
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could seriously harm our business.

We may seek special designations by the regulatory authorities to expedite regulatory approvals, but may not be successful in receiving such designations, and even if received, they may not benefit the development and regulatory approval process.

We may seek various designations by the regulatory authorities for any product candidates that we develop, such as Fast Track designation or Breakthrough Therapy designation.

If a product candidate is intended for the treatment of a serious condition and nonclinical or clinical data demonstrate the potential to address unmet medical need for this condition, a product sponsor may apply for Fast Track designation from the FDA. The sponsor of a product candidate with Fast Track designation has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the candidate may be eligible for priority review if the relevant criteria are met. A product candidate with Fast Track designation may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. We have received Fast Track designation for Auxora for the treatment of AP, and we may receive Fast Track designation for other product candidates in the future; however, we may not experience a faster development process, review or approval compared to conventional FDA approval timelines, and the FDA may still decline to approve Auxora or our other designated product candidates. The FDA may rescind the Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program or for any other reason.

A Breakthrough Therapy is defined by the FDA as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, 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 product candidates 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. The designation also includes all of the Fast Track designation benefits, including eligibility for rolling review of an NDA submission.

Seeking and obtaining these designations is dependent upon results of our clinical program, and whether and when we may have the data from our clinical programs to support an application to obtain any such designation is uncertain. Even if we do receive the designations we may apply for, we may not experience a faster development process, review or approval compared to conventional FDA or similar foreign regulatory authorities' procedures, as applicable. The FDA or similar foreign regulatory authorities, as applicable, may rescind any granted designations if it believes that the designation is no longer supported by data from our clinical development program.

We may seek orphan drug designation for our product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Similarly, in the European Union, the European Commission grants orphan drug designation after receiving the opinion of the European Medicines Agency ("EMA") Committee for Orphan Medicinal Products on an orphan drug designation application. Orphan drug designation is intended to promote the development of drugs that are (1) intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (2) either (a) affecting not more than five in 10,000 persons in Europe, or (b) when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug; and (3) for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or if such a method exists, the product will be of significant benefit to those affected by the condition). In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor. We have received orphan drug designation for Auxora for the treatment of AP in the European Union, and we may receive orphan drug designation for other product candidates in the future; however, we may not experience a faster development process, review or approval compared to conventional approval timelines, and the European Commission and EMA may still decline to approve Auxora or our other designated product candidates. The European Commission and EMA may rescind the orphan drug designation if it believes that the designation is no longer supported by data from our clinical development program or for any other reason.

Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same or similar drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if, at the end of the fifth year, it is established that the drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified.

Even if we obtain orphan drug exclusivity for any of our product candidates that obtain approval, that exclusivity may not effectively protect those product candidates from competition because different therapies can be approved for the same condition. Even after an orphan drug is approved, the FDA or comparable foreign authorities can subsequently approve another drug for the same condition if the relevant authority concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek orphan drug designation for applicable indications for our product candidates, we may never receive such designations. Even if we do receive such designations, we may not enjoy the benefits of those designations.

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

We may in the future seek an accelerated approval for our one or more of our product candidates. Under the accelerated approval program, 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 such 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. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback 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 or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA 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. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates would result in a longer time period to commercialization of such product candidates, if any, could increase the cost of development of such candidates and could harm our competitive position in the marketplace.

Our product candidates must meet extensive regulatory requirements before they can be commercialized and any regulatory approval may contain limitations or conditions that require substantial additional development expenses or limit our ability to successfully commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution 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, we are not 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. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

To date, we have not submitted an NDA or other marketing authorization application to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any product candidates.

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 or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. 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 and comparable foreign regulatory authorities. In particular, because we are seeking to identify and develop product candidates using new technologies, there is heightened risk that the FDA or other regulatory authorities may impose additional requirements prior to granting marketing approval, including enhanced safety studies or monitoring. Furthermore, as more product candidates within a particular class of products proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change.

The FDA or 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 or comparable foreign regulatory agencies for approval;
- serious and unexpected product candidate-related side effects may be experienced by participants in our clinical trials;
- serious and unexpected results from preclinical toxicity studies that will be completed in conjunction with late stage clinical trials;
- 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 SOC is potentially different from that of the United States;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation 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 application for regulatory approval or other submissions 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 or facilities of our or our third-party suppliers or manufacturers with which we or any of our potential 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 candidate 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 and comparable foreign regulatory authorities in reviewing new products based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals.

Even if we eventually complete clinical trials and receive approval to commercialize our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and/or the implementation of a REMS. The FDA or the comparable foreign regulatory authority also may approve a product candidate for a more limited indication or patient population than we originally requested or may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Manufacturers of our product candidates and manufacturers' facilities are also required to comply with cGMP regulations and other similar regulatory requirements, which include requirements related to quality control and quality assurance, as well as the corresponding maintenance of records and documentation. Further, regulatory authorities must approve these manufacturing facilities before they can be used to manufacture our product candidates, if approved, and these facilities are subject to continual review and periodic inspections by the FDA and other comparable foreign regulatory authorities for compliance with cGMP regulations and other similar regulatory requirements.

Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and could adversely impact our business, financial condition, results of operations and prospects.

We will need to obtain FDA approval of any proposed product names, including Auxora, and any failure or delay associated with such approval may adversely affect our business.

Any name we intend to use for our current or future product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the United States Patent and Trademark Office ("USPTO"). The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. The FDA may also object to a product name if it believes the name inappropriately implies medical claims or contributes to an overstatement of efficacy. If the FDA objects to any of our proposed product names, we may be required to adopt alternative names for our product candidates. If we adopt alternative names, we would lose any goodwill or brand recognition developed for previously used names and marks as well as the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

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

If the FDA, EMA or any other comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the drug product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration requirements and continued compliance with cGMPs and GCP requirements, for any clinical trials that we conduct post-approval.

In addition, any regulatory approvals that we receive for our present or future 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. The FDA may also require REMS 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.

Later discovery of previously unknown problems with a product candidate, 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, among other things:

- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the marketing or manufacturing of the product candidate, withdrawal of the product candidate from the market, or voluntary or mandatory product candidate recalls;
- fines, untitled or warning letters or holds on clinical trials;
- refusal by the FDA, the EMA or any other comparable foreign regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product candidate approvals;
- product candidate seizure or detention, or refusal to permit the import or export of product candidates; and
- injunctions or the imposition of civil or criminal penalties.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our or our collaborators' ability to commercialize our product candidates, and harm our business, financial condition, results of operations and prospects.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and other regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. 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 inspectional observations made by regulatory authorities. 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.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

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

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also required that companies enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which could adversely affect our business, financial condition, results of operations and prospects.

Disruptions at the FDA and other government agencies caused by funding shortages, statutory, regulatory and policy changes, 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, or approved or commercialized in a timely manner or at all, which could negatively impact our business.*

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, including executive orders, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies such as the EMA, following its relocation to Amsterdam and corresponding staff changes, 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 product candidates 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 has shut down several times and certain

regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities, including the current government shutdown which is ongoing.

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

We may not identify or discover other product candidates and may fail to capitalize on our proprietary platform or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

Our business depends upon our ability to identify, develop and commercialize product candidates. A key element of our strategy is to discover and develop additional product candidates based upon our CRAC channel inhibitor science. We are seeking to do so through our internal research programs, and may also explore strategic collaborations for the discovery of new product candidates. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. In addition, targets for different indications may require changes to our manufacturing processes, which may slow down development or make it impossible to manufacture our product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology or technology platform used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- we may choose to cease development if we determine that clinical results do not show promise;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

Because we have limited resources, we must choose to pursue and fund the development of specific types of treatment, or treatment for a specific indication, and we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for our product candidates could be inaccurate, and if we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate.

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

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

- decreased demand for any product candidate that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- increased insurance costs;
- the inability to commercialize any product candidate that we may develop; and
- injury to our reputation and significant negative media attention.

Any such outcomes could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Manufacturing, Commercialization and Reliance on Third Parties

We rely on third parties to conduct and perform most of our research, preclinical studies and clinical trials. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements, fail to meet projected clinical trial enrollment schedules or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not have the ability to conduct most aspects of our preclinical studies or clinical trials in-house. As a result, we are and expect to remain dependent on third parties to conduct or otherwise support our ongoing clinical trials and any future clinical trials of our product candidates. Specifically, CROs, clinical investigators, and consultants play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the member states of the EEA, and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with investigational product produced under cGMP regulations (and similar foreign requirements). Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

CROs, clinical trial investigators or other third parties on which we rely may not devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or any comparable foreign regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. Further, under certain circumstances, these third parties may terminate their agreements with us upon as little as 30 days prior written notice. Entering into arrangements with alternative CROs, clinical trial investigators or other third parties involves additional cost and requires management focus and time, in addition to requiring a transition period when a new CRO, clinical trial investigator or other third party begins work. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

In addition, with respect to investigator-sponsored trials that are being conducted with Auxora (the CRSPA trial with SJCRH) and may be conducted in the future, we do not and would not control the design or conduct of these trials, and it is possible that the FDA will not view these investigator-sponsored trials as providing adequate support for future clinical trials or market approval, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. We expect that such arrangements will provide us certain information rights with respect to the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory submissions, resulting from the investigator-sponsored trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates, or if the data proves to be inadequate compared to the firsthand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future

clinical trials ourselves may be adversely affected. The investigators may design clinical trials with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results compared to clinical trials that we may design on our own. Negative results in investigator- sponsored clinical trials could have a material adverse effect on our efforts to obtain regulatory approval for our product candidates and the public perception of our product candidates. Additionally, the FDA may disagree with the sufficiency of our right of reference to the preclinical or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA may require us to obtain and submit additional preclinical or clinical data.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We contract with third parties for the manufacturing and supply of certain goods and services for our product candidates for use in preclinical studies and clinical trials, which supply may become limited or interrupted or may not be of satisfactory quality and quantity.*

We do not have any manufacturing facilities. We produce in our laboratory relatively small quantities of product for evaluation in our research programs. We rely on third parties for the manufacture of most of our product candidates for preclinical testing and all of our product candidates for clinical testing and we will continue to rely on such third parties for commercial manufacture if any of our product candidates are approved. We currently have limited manufacturing arrangements for preclinical and clinical trial materials for each of our product candidates, including Auxora, and one component of the latter is provided by a single source supplier in China, and will continue to be for the intermediate future. In addition, our single source supplier in China and any other foreign suppliers we may utilize in the future may be subject to U.S. legislation, similar to what is proposed in the BIOSECURE Act considered by Congress in 2024, sanctions, trade restrictions and other foreign regulatory requirements, which may limit, delay, prevent or impair our ability to obtain preclinical and clinical trial materials for our product candidates. This reliance increases the risk that we will not have sufficient quantities of our product candidates or products, if approved, or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Furthermore, all entities involved in the preparation of product candidates for clinical trials or commercial sale, including our existing contract manufacturers for our product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of an NDA on a timely basis and must adhere to the FDA's GLP regulations and cGMP regulations enforced by the FDA through its facilities inspection program. Comparable foreign regulatory authorities may require compliance with similar requirements. Our facilities and quality systems, and those of our third-party contract manufacturers, must pass a pre-approval inspection for compliance with the applicable regulations as a condition of marketing approval of our product candidates. We do not control the manufacturing activities of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations, although the FDA will hold us responsible for any such non-compliance with respect to our product candidates and any future approved products.

In the event that any of our contracted third parties fails to comply with such requirements or to perform their obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, including due to the ongoing or future international conflicts or other geopolitical or macroeconomic conditions, including international tariffs, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of a third-party contractor could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture a certain aspect of our product candidates may be unique or proprietary to the third-party performing such process and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if we attempt to establish new third-party arrangements for these product candidates or methods. If we are required to or voluntarily change a third-party contractor for any reason, we will be required to verify that the new third party maintains facilities, processes and procedures that comply with quality standards and with all applicable regulations and guidelines. 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.

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

- in the event of approval, to initiate or continue clinical trials of our product candidates;
- delays in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- loss of the cooperation of future collaborators;
- subjecting our or any third-party manufacturing facilities to additional inspections by regulatory authorities; or
- requirements to cease development to market and commercialize our product candidates, an inability to meet commercial demands for our current or any other future product candidates, if approved.

Any approved product candidates may fail to achieve the degree of market acceptance by physicians, patients, hospitals, healthcare payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. Our CRAC channel inhibitors are a relatively novel technology, and no CRAC channel inhibitor-based therapy has been approved to date. Public perception may be influenced by third-party claims, such as claims that CRAC channel inhibitors are unsafe, ineffective and, consequently, our approach may not gain the acceptance of the public or the medical community. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- our ability to offer our product candidates for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the availability of coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved by applicable regulatory authorities;
- the strength of marketing and distribution support; and
- the prevalence and severity of any side effects.

For example, Auxora is an injectable emulsion drug product that must be administered intravenously over four hours, and this dosing regimen may be inconvenient for some physicians or patients.

If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue and we may not become profitable.

We may not be able to successfully commercialize our product candidates due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell our product candidates profitably.

Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our product candidates. Therefore, coverage and adequate reimbursement are critical to a new product's acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, there is no uniform policy among third-party payors for coverage and reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Therefore, one third-party payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third- party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and

- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process, with uncertain results, that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our product candidates to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved product candidates, and coverage may not be available, or may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting drug prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

Reimbursement may not be available for any product that we commercialize and, if coverage and reimbursement are available, the level of reimbursement may not be adequate. Obtaining reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Additionally, we expect our future products to potentially be more expensive than other therapeutics due to the personalized and proprietary product selection process of our product candidates, as well as our individualized approach to patient treatment, which requires patient hospitalization, in some cases intensive care unit admission and the potential administration of combination therapies, all of which increases costs and may result in reimbursement payment rates which may not be adequate or may require co-payments that patients find unacceptably high. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved product candidates that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, the Centers for Medicare & Medicaid Services (“CMS”) revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System, which may result in reduced Medicare payments.

We expect to experience pricing pressures in connection with the sale of any of our 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 medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Outside of the United States, many countries require approval of the sale price of a product before it can be marketed, and the pricing review period only begins after marketing or product licensing approval is granted. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Member states are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost- effectiveness of a particular product candidate to currently available therapies. To obtain reimbursement or pricing approval in some of these countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, new products are facing increasingly high barriers to entry. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue, if any, we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if such product candidates obtain marketing approval.

If any of our product candidates are approved for marketing and commercialization and we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates, we will be unable to successfully commercialize our product candidates if and when they are approved.

We have no sales, marketing or distribution capabilities or experience. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization, which would be expensive and time consuming, or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our product candidates if and when they are approved.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of such product revenue to us are likely to be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such product candidates outside of the United States, which would limit our ability to realize their full market potential.

In order to market any product candidates outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our ability to realize the full market potential of our product candidates will be harmed.

Risks Related to Our Industry and Business Operations

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.*

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical, legal, sales and marketing and other personnel. We are highly dependent on our management and scientific personnel. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result.

We conduct substantially all of our operations at our facility in La Jolla, California. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

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. We may face additional challenges in recruiting individuals due to hardship we have experienced, including the uncertainty around our ability to continue as a going concern. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with certain of our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our

employment at any time, with or without notice. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

Dr. Rachel Leheny, our Chief Executive Officer and a member of our Board of Directors, and Eric W. Roberts, our Chief Business Officer and a member of our Board of Directors, also provide services for Valence, an investment fund that is one of our significant stockholders.

Our Chief Executive Officer and member of our Board of Directors, Dr. Leheny, and our Chief Business Officer and member of our Board of Directors, Mr. Roberts, are the co-founders of Valence Life Sciences ("Valence"), are employed as managing directors of Valence and beneficially own the shares of the company held by Valence. Entities affiliated with Valence together with Dr. Leheny and Mr. Roberts beneficially own a significant portion of our common stock. Although we expect that each of Dr. Leheny and Mr. Roberts will devote on average at least 40 hours per week to our company and remain highly active in our management, they will also continue to devote time to Valence. Because Dr. Leheny and Mr. Roberts are not required to work exclusively for us, their attention to other activities could slow our operations, which could adversely affect our business. In addition, although we do not believe Valence currently has any investments that conflict with our interests, in the future Valence may invest in companies that may compete with us for business opportunities or develop products that are competitive with ours. As a result, Dr. Leheny's and Mr. Roberts' interests may not be aligned with the interests of our other stockholders, and they may from time to time be incentivized to take certain actions that benefit their other interests and that our other stockholders do not view as being in their interest as investors in our company.

We expect to expand our development, regulatory and operational capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.*

As of September 30, 2025, we employed 15 full-time employees, seven of whom were primarily engaged in research and development activities. We also engage various consultants that are primarily engaged in research and development activities. As we advance our research and development programs, we may be required to further increase the number of our employees, particularly in the areas of clinical development, quality, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage any future growth, we must:

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

Our need to effectively execute our growth strategy requires that we:

- discover new product candidates, develop the process and analytical methods for IND-enabling studies and regulatory submissions, complete the required IND-enabling studies for each, and receive approval from the FDA and other regulatory authorities to initiate clinical trials for such product candidates;
- manage our clinical trials effectively;
- identify, recruit, retain, incentivize and integrate additional employees;
- maintain sufficient quantities of drug product for clinical supply and establish manufacturing capabilities or arrangements with third-party manufacturers for commercial supply, if and when approved; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our product candidates 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 in order to devote a substantial amount of time, 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. Furthermore, the United States is currently experiencing an increasingly competitive labor market and we are uncertain as to the employment environment in the future, or how that environment will impact our workforce, including our ability to hire or retain qualified employees, consultants, contractors or other key personnel to facilitate our growth.

We face substantial competition, which may result in others discovering, developing or commercializing product candidates more quickly or marketing them more successfully than us.

The development and commercialization of new product candidates is highly competitive. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop therapies for the treatment of acute critical illnesses. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any product candidates that we may develop or that would render any product candidates that we may develop obsolete or non-competitive. Our competitors also may obtain marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Moreover, with the proliferation of new drugs and therapies into critical illnesses, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical.

The amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for product candidates will likely need to show a risk benefit profile that is competitive with or more favorable than products approved prior to ours in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those product candidates or product candidate candidates, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product business, financial condition, results of operations and prospects could be adversely affected.

There is significant investment across the biotechnology and pharmaceutical industries in developing novel and proprietary therapies for acute critical illnesses. We face substantial and increasing competition on multiple fronts, including from larger companies with access to more resources and capital, as well as more experience in research and development, clinical trials and commercialization. Smaller or earlier-stage companies as well as academic institutions, government agencies and public and private research institutions may also prove to be significant competitors. Additionally, we may face competition in hiring scientific and management personnel, establishing clinical trial sites, recruiting patients to participate in clinical trials and acquiring technologies complementary to, or necessary for our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any product candidates that we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be their efficacy, safety, convenience, price and degree of reimbursement.

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

The key competitive factors affecting the success of all of our programs are likely to be the possibility of other companies developing drugs that address the same disease indications that we are aiming to address. Some of these markets are limited and significant competition could reduce the number of patients we are able to reach. If we are not successful in developing, commercializing and achieving higher levels of reimbursement than our competitors, we will not be able to compete against them and our business would be adversely affected.

We may wish to form collaborations in the future with respect to our product candidates, but may not be able to do so or realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.

The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We may, in the future, decide to collaborate with other biopharmaceutical companies for the development and potential commercialization of those product candidates, including in territories outside the United States or for certain indications. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third-party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third-party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the

terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of our technologies, product candidates and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidates. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to our strategies. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of 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 product candidates or bring them to market and generate product revenue.

Our product candidates may also require specific components to work effectively and efficiently, and rights to those components may be held by others. We may be unable to in-license any compositions, 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 would 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.

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with Auxora and any future product candidates;
- a collaborator with marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may 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 causes the delay or termination of the research, development, or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Our (or the third parties with whom we work) actual or perceived failure to comply with applicable data protection laws, regulations, and other obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and mass arbitration demands, and/or adverse publicity and could negatively affect our operating results and business.*

We and the third parties with whom we work may be subject to federal, state, and foreign data protection laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations that address privacy and data security. In the United States, numerous federal, state, and local laws and regulations, including federal and state health information privacy laws, state data breach notification laws, personal data protection laws, federal, state, and local consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws govern the collection, use, disclosure, and protection of health-related and other personal data. In addition, we obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under federal HIPAA, as amended by the HITECH. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use, or disclose individually identifiable protected information provided by a HIPAA-covered entity or business associate in a manner that is not authorized or permitted by HIPAA.

Additionally, new privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. For example, the CCPA requires covered companies to provide certain disclosures to California consumers (including business representatives and employees who are California residents) and provide such consumers data protection and privacy rights, including the ability to opt-out of certain sales or sharing of personal data. The CCPA provides for administrative penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal data. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CPRA expanded the CCPA's requirements, including by adding a right for consumers to correct their personal data and establishing a regulatory agency to implement and enforce the law. Moreover, a number of other states have enacted data protection laws, and similar laws are being considered in several other states, as well as at the federal and local levels. Although these laws exempt some data processed in the context of clinical trials, these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products and services involving data are offered, all of which may harm our business, financial condition, results of operations and prospects.

Internationally, virtually every jurisdiction in which we operate has established its own data security and privacy legal framework that may also apply to health-related and other personal data obtained outside of the United States. For example, the EU has adopted the EU GDPR and the United Kingdom has adopted the UK General Data Protection Regulation (collectively, "GDPR"), which imposes strict requirements for processing the personal data of individuals within the EEA and the United Kingdom. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to 20 million euros, 17.5 million pounds sterling under the UK GDPR, or in each case, up to 4% of the annual global revenue of the noncompliant company, whichever is greater, as well as private litigation related to the processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data.

Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the United Kingdom's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the United Kingdom, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and United Kingdom to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Moreover, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered individuals (i.e., individuals and entities located in or controlled by individuals or entities located in those jurisdictions) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to transfer data in connection with certain transactions or agreements.

In addition, the India Digital Personal Data Protection Act 2023 ("DPDP") came into force in 2024. Like the GDPR, the DPDP has extra-territorial reach and failure to comply with the DPDP may lead to substantial fines. A significant portion of our CARPO trial was conducted in India and we and certain third parties with whom we work may be subject to the DPDP.

We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, clinical trial subjects about whom we or the third parties with whom we work obtain information, as well as the providers who share this information with us, contractually limit our ability to use and disclose the information. We publish privacy policies, marketing materials, whitepapers, and other statements such as statements related to compliance with certain certifications or self-regulatory principles, concerning data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our employees, personnel, and third parties with whom we work may use AI and machine learning ("ML") technologies to perform their work, and the disclosure and use of personal data in AI/ML technologies is subject to various privacy laws and other privacy obligations. For example, we may use AI/ML technologies to process patient or clinical trial participant data in the course of our business. Governments have passed and are likely to pass additional laws regulating AI/ML technologies. Our use of such technologies could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use AI/ML technologies, it could make our business less efficient and result in competitive disadvantages.

Obligations related to data 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, which 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. Failure by us or third parties with whom we work to comply with U.S. and international data protection laws, regulations, and other obligations could result in significant consequences, including without limitation government enforcement actions (which could include investigations, civil or criminal penalties, audits inspections), private litigation or mass arbitration demands, additional reporting requirements or oversight, bans on processing personal data, data breach reporting requirements and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with data protection or privacy obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Our information technology systems, or those of our CROs, contractors, consultants, or other third parties with whom we work, may fail or suffer security breaches, loss or leakage of data, and other disruptions, which could result in a material disruption of our product candidates' development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal data, including health-related information) (collectively, "sensitive information").

As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, which could result in material adverse impacts to our business, including the theft of our sensitive information, have increased in frequency and sophistication. Despite our implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our information technology systems and those of our third-party CROs, contractors, consultants, and other third parties with whom we work are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, sophisticated nation-state and nation-state supported actors, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering attacks, malicious code, credential stuffing attacks, credential harvesting, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, attacks enhanced or facilitated by AI, and other means to affect service reliability and threaten the confidentiality, integrity and availability of our sensitive information), which may compromise our or the third parties with whom we work systems infrastructure or lead to data leakage. For example, we have experienced phishing attacks in the past and we may be a target of phishing attacks or other cyber-attacks in the future. 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 information 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. To the extent that any disruption or security breach were to result in a loss of, or damage to, our sensitive information or applications (or those of the third parties with whom we work), or inappropriate disclosure of sensitive information, we could incur liability and reputational damage, and the further development and commercialization of our product candidates could be delayed. It may be difficult or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our

efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

We also have outsourced elements of our operations to third parties, and as a result we manage a number of third parties who have access to our sensitive information. We rely on these third parties and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. 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. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. 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 the third parties with whom we work supply chains have not been compromised.

While we invest in our information security systems, we cannot assure you that our data protection efforts and our investment in information technology will prevent breakdowns, data leakages, breaches in our systems or other cyber incidents that could have an adverse effect upon our reputation, business, financial condition, results or operations and prospects. We may not be successful in preventing or detecting cyber-attacks or mitigating their effects, or we may be perceived as having failed to do so. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as hardware and/or software, including that of the third parties with whom we work), but we have not, and in the future may not, however, be able to detect and remediate all such vulnerabilities, including on a timely basis. Further, we have (and may in the future) experienced delays in developing and deploying remedial measures and patches designed to address any such identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident. For example, if a cyber-attack were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, sensitive information (including trade secrets or other intellectual property, proprietary business information, and personal data), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal data, including personal data regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal data, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business (and that of the third parties with whom we work).

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

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

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

As of December 31, 2024, we had federal and state net operating loss ("NOL") carryforwards of approximately $296.9 million and zero, respectively. $102.2 million of our federal NOLs were generated prior to 2018 and will begin to expire in 2026, unless previously utilized, but may be used to offset up to 100% of future taxable income before expiration. Our federal NOLs generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards in a taxable year is limited to 80% of taxable income in such year. It is uncertain if and to what extent various states will conform to federal tax law. We also have federal and state research and development credit carryforwards totaling $13.3 million and $3.1 million, respectively. The federal research and development credit carryforwards will begin to expire in 2027, unless previously utilized. The state research and development credits do not expire.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50 percentage point change (by value) in its equity ownership over a rolling three-year period, the corporation's ability to use its pre-change NOL carryforwards and certain other tax attributes to offset its post-change income or taxes may be limited. This could limit the amount of NOL carryforwards or other applicable tax attributes that we can utilize annually to offset future taxable income or tax liabilities. We have not undertaken a Section 382 study, and it is possible that we have previously undergone one or more ownership changes so that our use of net operating losses is subject to limitation. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre-change NOLs to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our NOL carryforwards and other tax attributes, which could adversely affect our future cash flows.

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

New income, sales, use, or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified, or applied adversely to us. For example, the U.S. government recently enacted legislation commonly referred to as the One Big Beautiful Bill Act ("OBBBA"), that (along with other recent U.S. federal tax reform) has resulted in significant changes to the taxation of business entities including, among other changes, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified or sunset in future years. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations.*

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

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act"), substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the U.S. pharmaceutical industry. As another example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive healthcare provisions and amendments to existing laws, including a requirement that all manufacturers of drugs and biological products covered under Medicare Part B report the product's average sales price, or ASP, to Department of Health and Human Services ("HHS") beginning on January 1, 2022, subject to enforcement via civil money penalties.

Since its enactment, there have been amendments to and judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act. For example, on August 16, 2022, the IRA was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is unclear how any such challenges and the healthcare reform measures of the second Trump administration will impact the Affordable Care Act, our business, or financial condition. Additionally, in its June 2024 decision in *Loper Bright Enterprises v. Raimondo*, the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper Bright* decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted that affect healthcare expenditures. For example, on July 4, 2025, the OBBBA, was signed into law which is expected to reduce Medicaid spending and

enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. OBBBA also narrows access to Affordable Care Act marketplace exchange enrollment and declines to extend the Affordable Care Act enhanced advanced premium tax credits, set to expire in 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. These changes also include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to legislative amendments to the statute, will remain in effect until 2032, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. In addition, new laws may result in additional reductions in Medicare and other healthcare funding, which may adversely affect customer demand and affordability for our product candidates and, accordingly, the results of our financial operations.

Also, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries, presidential executive orders, and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. On January 5, 2024, the FDA approved Florida's Section 804 Importation Program ("SIP") proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. At the federal level, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs that have been on the market for at least 7 years covered under Medicare (the "Medicare Drug Price Negotiation Program") and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

We expect that these and other healthcare reform measures that may be adopted in the future, particularly in light of the recent U.S. Presidential and Congressional elections, may result in more rigorous coverage criteria and lower reimbursement and in additional downward pressure on the price that we receive for any approved product. The current presidential administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions and proposals include, for example, (1) reducing agency workforce and cutting programs; (2) rescinding a previous executive order tasking the Center for Medicare and Medicaid Innovation to consider new payment and healthcare models to limit drug spending; (3) eliminating the previous executive order that directed HHS to establish an AI task force and develop a strategic plan; (4) directing HHS and other agencies to lower prescription drug costs for Medicare through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (5) imposing tariffs on imported pharmaceutical products; and (6) directing certain federal agencies to enforce existing law regarding hospital and plan price transparency and by standardizing prices across hospitals and health plans. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA. Any reduction in reimbursement from Medicare or other government-funded 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, once marketing approval is obtained.

In the European Union, coverage and reimbursement status of any product candidates for which we obtain regulatory approval are provided for by the national laws of member states. The requirements may differ across the EU member states. Also, at national level, actions have been taken to enact transparency and anti-gift laws (similar to the US Physician Payments Sunshine Act) regarding payments between pharmaceutical companies and health care professionals.

We are subject to applicable fraud and abuse, transparency, government price reporting, and other healthcare laws and regulations. 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 will play a primary role in the recommendation and prescription of any future product candidates we may develop and any product candidates for which we obtain marketing approval. Our current and future arrangements with clinical investigators, third-party payors, healthcare provider and customers expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we research, market, sell and distribute our product candidates. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits any person or entity from, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, and purchasers, on the other the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but these exceptions and safe harbors are narrowly drawn. Practices that are alleged to be intended to induce prescribing, purchases or recommendations, or include any payments of more than fair market value, may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws, such as the civil False Claims Act ("FCA"), which can be enforced by private citizens through civil qui tam actions, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment of federal funds, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. For example, pharmaceutical companies have been prosecuted under the FCA in connection with, among other things their alleged off-label promotion of drugs, engaging in improper consulting arrangements with physicians, concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and providing free product to customers with the expectation that the customers would bill federal health care programs for the product. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;
- HIPAA which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective business associates and covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the federal transparency requirements under the Physician Payments Sunshine Act, created under the Affordable Care Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to report to CMS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members;

- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and
- state and foreign laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other health care providers; state and local laws that require the registration of pharmaceutical sales representatives; and state health information privacy laws, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus requiring additional compliance efforts.

We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of our product candidates, if approved, and have received equity awards as compensation for services provided to us. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use our product candidates, if approved, to be in violation of applicable laws.

Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to significant investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and applicable non-U.S. regulators, provide accurate information to the FDA and applicable non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for Auxora, any future product candidates, and other proprietary technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad,

our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize Auxora, any future product candidates, and other proprietary technologies if approved, may be adversely affected.

Our commercial success will depend in part on our ability to obtain and maintain a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to Auxora, any future product candidates, and other proprietary technologies we develop. If we are unable to obtain or maintain patent protection with respect to Auxora, any future product candidates, and other proprietary technologies we may develop, our business, financial condition, results of operations, and prospects could be materially harmed.

The patent position of biotechnology and pharmaceutical companies is highly uncertain and involves complex legal, scientific, and factual questions and has been the subject of frequent litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our patent applications may not result in patents being issued which protect Auxora, any future product candidates, and other proprietary technologies we may develop or which effectively prevent others from commercializing competitive technologies and products. Further, no consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently or may in the future own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting Auxora, any future product candidates, and other proprietary technologies and their uses by obtaining, defending and enforcing patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or may otherwise not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use and sell our potential product candidates;
- other parties may have designed around our claims or developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same composition of matter, methods or formulations or by claiming subject matter that could dominate our patent position;
- any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any products or product candidates that we may develop;
- because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to Auxora, any future product candidates, and other proprietary technologies and their uses;
- 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 any application with an effective filing date before March 16, 2013;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing product candidates in those countries.

The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, or maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into

non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection for such output. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use Auxora, any future product candidates, and other proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. For example:

- others may be able to make compounds that are similar to Auxora and any future product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain may not provide us with any competitive advantages;
- we may not develop additional proprietary technologies that are patentable;
- our competitors might conduct research and development activities in countries where we do not have patent rights or where patent protection is weak and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products;
- we cannot ensure that we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own expire; or
- the patents of others may have an adverse effect on our business.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before U.S. or non-U.S. patent offices.

We cannot be certain that the claims in our issued patents and pending patent applications covering Auxora or any future product candidates will be considered patentable by the USPTO, courts in the United States, or by patent offices and courts in foreign countries. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property internationally.

The strength of patents in the biotechnology and pharmaceutical fields involves complex legal and scientific questions and can be uncertain. The patent applications that we own may fail to result in issued patents with claims that cover Auxora and any future product candidates in the United States or in foreign countries. Even if such patents do successfully issue, third parties may challenge the ownership, validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful opposition to our patents could deprive us of exclusive rights necessary for the successful commercialization of Auxora and any future product candidates. Furthermore, even if they are unchallenged, our patents may not adequately protect our intellectual property, provide exclusivity for Auxora or any future product candidates or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold with respect to Auxora or any future product candidates is threatened, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, Auxora or any future product candidates.

For U.S. patent applications in which 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 patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license

on commercially reasonable terms. Our participation in an interference proceeding may fail and, even if successful, may result in substantial costs and distract our management and other employees.

For U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, or America Invents Act, was signed into law. The America Invents Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is developing regulations and procedures to govern the administration of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and in particular, the "first to file" provisions, were enacted on March 16, 2013. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. It remains unclear what impact the America Invents Act will have on the operation of our business. As such, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. Even if we obtain patents covering our product candidates, when the terms of all patents covering a product expire, our business may become subject to competition from competitive products, including generic products. Given the amount of time required for the development, testing, and regulatory review and approval of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for Auxora, our business may be materially harmed.

Depending upon the timing, duration, and specifics of any FDA marketing approval of Auxora, or any future product candidate we may develop, one or more of patents issuing from our U.S. patent applications may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, (the "Hatch-Waxman Amendments"). 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 remaining 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 drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate, or ("SPC"). If we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market Auxora and any future product candidates under patent protection would be reduced. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. 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 our revenue could be reduced.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and/or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to foreign patent agencies. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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. In such an event, our competitors might be able to enter the market with similar or identical products or technology earlier than should otherwise have been the case, which would have a material adverse effect on our business, financial condition, results of operations, and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect Auxora.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Our patent rights may be affected by developments or uncertainty in U.S. or foreign patent statutes, patent case law, USPTO rules and regulations or the rules and regulations of foreign patent offices. Obtaining and

enforcing patents in the biotechnology and pharmaceutical industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States may, at any time, enact changes to U.S. patent law and regulations, including by legislation, by regulatory rule-making, or by judicial precedent, that adversely affect the scope of patent protection available and weaken the rights of patent owners to obtain patents, enforce patent infringement and obtain injunctions and/or damages. For example, the scope of patentable subject matter under 35 U.S.C. 101 has evolved significantly over the past several years as the Court of Appeals for the Federal Circuit and the Supreme Court issued various opinions, and the USPTO modified its guidance for practitioners on multiple occasions. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. We cannot predict how decisions by the federal courts, the U.S. Congress or the USPTO may impact the value of our patent rights. For example, the Supreme Court of the United States held in Amgen v. Sanofi (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. In addition, the Federal circuit recently issued a decision, In re Cellect, LLC (2023) involving the interaction of patent term adjustment ("PTA"), terminal disclaimers, and obvious-type double patenting which may affect the patent term of any issued patents that rely on any PTA. Other countries may likewise enact changes to their patent laws in ways that adversely diminish the scope of patent protection and weaken the rights of patent owners to obtain patents, enforce patent infringement, and obtain injunctions and/or damages.

Further, the United States and other governments may, at any time, enact changes to law and regulation that create new avenues for challenging the validity of issued patents. For example, the America Invents Act created new administrative post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings that allow third parties to challenge the validity of issued patents. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In the 2013 case Assoc. for Molecular Pathology v. Myriad Genetics, Inc., for instance, the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. For example, the Inflation Reduction Act (IRA) passed by Congress authorizes the Secretary of the Department of HHS to negotiate prices directly with participating manufacturers for selected medicines covered by Medicare even if these medicines are protected by an existing patent. For small molecule medicines, the process begins seven years after initial approval by the FDA. While we do not believe that the IRA or its effects will impact our ability to obtain patents in the near future, we cannot be certain whether it will affect our patent strategy in the long run.

We may not be able to protect our intellectual property rights throughout the world.

Patents are of national or regional effect. Filing, prosecuting, and defending patents on Auxora, any future product candidates, and other proprietary technologies we develop in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights in the same manner and to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement of such patent protection is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The requirements for patentability may differ in certain countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval for a drug and its patent status. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors.

In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology or pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary

rights generally. In Europe, beginning June 1, 2023, European applications and patent may be subjected to the jurisdiction of the Unified Patent Court ("UPC"). Also, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty. As a single court system can invalidate a European patent, we, where applicable may opt out of the UPC and as such, each European patent would need to be challenged in each individual country. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may become 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 patent rights, trade secrets, or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. For example, we may have inventorship disputes arise from conflicting views regarding the contributions of different individuals named as inventors, conflicting obligations of third parties involved in developing Auxora or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition, results of operations and prospects. 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.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Our program may require the use of intellectual property rights held by third parties. The growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, Auxora may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license, on reasonable terms, proprietary rights related to any compositions, formulations, methods of use, processes or other intellectual property rights from third parties that we identify as being necessary for Auxora. Even if we are able to obtain a license to such proprietary rights, 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.

Where we obtain licenses from or collaborate with third parties, we may not have the right to control the preparation, filing, and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business, or in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such application. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, including making royalty and milestone payments, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business. Our business would suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical or similar to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

The licensing and acquisition of third-party proprietary rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party proprietary rights that we may consider necessary or attractive in order to commercialize Auxora. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we may collaborate with U.S. and foreign academic institutions to accelerate our research development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate an exclusive license to any of the institution's proprietary rights in technology resulting from the collaboration. Regardless of such option to negotiate a license, we may

be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer, on an exclusive basis, their proprietary rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all. 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 on commercially reasonable terms, our ability to commercialize our products, and our business, financial condition, and prospects for growth, could suffer.

Third-party claims alleging intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including inter partes review, interference and reexamination proceedings before the USPTO, or oppositions and other comparable proceedings in foreign jurisdictions. The America Invents Act introduced new procedures including inter partes review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future and the outcome of such challenges. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing Auxora. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to Auxora may give rise to claims of infringement of the patent rights of others.

The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always 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. We cannot assure you that any of our current or future product candidates will not infringe existing or future patents. We may not be aware of patents that have already issued that a third party might assert are infringed by one of our current or future product candidates. Nevertheless, we are not aware of any issued patents that will prevent us from marketing Auxora.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of Auxora. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending third-party patent applications which may later result in issued patents that Auxora, any future product candidates, and other proprietary technologies may infringe, or which such third parties claim are infringed by the use of our technologies. Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize Auxora or future product candidates. Defense of these claims, regardless of their merit, could involve substantial expenses and could be a substantial diversion of management and other employee resources from our business.

If we collaborate with third parties in the development of technology in the future, our 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. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties.

Any claims of patent infringement asserted by third parties would be time-consuming and could:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing Auxora or any future product candidates until the asserted patent expires or is finally held invalid, unenforceable, or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property;
- require us to pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be willfully infringing; and/or
- require us to enter into royalty or license agreements, which may not be available on commercially reasonable terms, or at all.

If we are sued for patent infringement, we would need to demonstrate that our 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 either. Proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity before federal courts requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity or enforceability of the patents in court. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing Auxora or any future product candidates to market and be precluded from developing, manufacturing or selling Auxora or any future product candidates.

We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. We cannot be certain that any of our patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived;
- pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, Auxora, and any future product candidates or the use of Auxora and any future product candidates;
- identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims;
- patent applications in the United States are typically not published until 18 months after the priority date;
- publications in the scientific literature often lag behind actual discoveries; and
- additionally, generative artificial intelligence (AI) resources that are publicly available also present a risk that a company may inadvertently obtain, incorporate or use a third party's intellectual property.

Furthermore, 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 and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. Further, we may incorrectly determine that our technologies, products, or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or internationally that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or product candidates.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours, and others may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import Auxora and future approved products or impair our competitive position. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of Auxora. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications and may be entitled to priority over our applications in such jurisdictions.

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

If a third party prevails in a patent infringement lawsuit against us, we may have to stop making and selling the infringing product, pay substantial damages, including treble damages and attorneys' fees if we are found to be willfully infringing a third party's patents, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of Auxora. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize Auxora, which could harm our business significantly. Even if we were able to obtain a license, the rights may be nonexclusive, which may give our competitors access to the same intellectual property.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of Auxora, any future product candidates, and other proprietary technologies. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

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, and we may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

Third parties including competitors may infringe, misappropriate or otherwise violate our patents or patents that may issue to us in the future. To counter infringement or unauthorized use, we may need to or choose to file infringement claims, which can be expensive and time-consuming. We may not be able to prevent, infringement, misappropriation, or other violation of our intellectual property, particularly in countries where the laws may not protect those rights as fully as in the United States.

If we choose to go to court to stop another party from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that such patents are invalid, unenforceable, or should not be enforced against that third party for any number of reasons. 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 for patentability, including lack of novelty, obviousness, lack of written description, indefiniteness, or non-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, i.e., committed inequitable conduct. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in foreign patent offices and courts and may result in the revocation, cancellation, or amendment of any foreign patents we hold now or in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development or manufacturing partnerships that would help us bring Auxora and any future product candidates to market.

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. 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. 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 this type of litigation.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

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

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. 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.

We may rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors, and inventions agreements with employees, consultants, and advisors, to protect our trade secrets and other proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer, or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors, and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise

lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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

Our future trademarks or trade names may be unable to be obtained, challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. 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 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 trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Moreover, any trade name we have proposed to use for products in the United States, such as Auxora 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. Similar requirements exist in Europe. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. 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. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

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

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with Auxora and any future product candidates;
- a collaborator with marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may 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 causes the delay or termination of the research, development, or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

General Risk Factors

Our business operations subject us to disputes, claims and lawsuits, which may be costly and time-consuming and could materially and adversely impact our financial position and results of operations.*

From time to time, we are involved in disputes, claims and lawsuits relating to our business operations. In particular, from time to time we face claims related to the safety of our products, intellectual property matters, employment matters, tax matters, commercial disputes, competition, sales and marketing practices, environmental matters, personal injury, insurance coverage and acquisition or divestiture-related matters. Any dispute, claim or lawsuit may divert management's attention away from our business, we may incur significant expenses in addressing or defending any dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results. For example, in April 2025, a stockholder of the Company filed a complaint against the Company and two directors demanding the return of such stockholder's investment in the Company plus interest and attorneys' fees. We intend to vigorously defend ourselves in this matter.

Regardless of merit, litigation related to these disputes may be costly and time-consuming and could materially and adversely impact our financial position and results of operations if resolved against us. In addition, the uncertainty associated with litigation could lead to increased volatility in our stock price.

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

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

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

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

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our or any third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our manufacturers' facilities pending their use and disposal.

We cannot eliminate the risk of contamination, which could cause an interruption of our research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers and suppliers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, this may not be the case or and we may not eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our

resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. Any contamination by such hazardous materials could therefore adversely affect our business, financial condition, results of operations and prospects.

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

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. We intend to invest resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, including the U.S. Foreign Corrupt Practices Act (collectively, "Trade Laws"), prohibit, among other things, companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors, and other partners 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. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. 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.

The market price of our stock has been and may continue to be volatile, and you could lose all or part of your investment.*

The trading price of our common stock has been in the past, and may continue to be, highly volatile and subject to wide fluctuations in response to various factors, many of which we cannot control. Market prices for securities of early-stage pharmaceutical, biotechnology, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- our ability to obtain regulatory approvals for product candidates, and delays or failures to obtain such approvals;
- the failure of any of our product candidates, if approved for marketing and commercialization, to achieve commercial success;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- the entry into, or termination of, key agreements, including key licensing, supply or collaboration agreements;
- the initiation of material developments in, or conclusion of, disputes or litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- changes in laws or regulations applicable to our product candidates;
- the results of current, and any future, nonclinical or clinical trials of our product candidates;
- announcements by commercial partners or competitors of new commercial products, clinical progress (or the lack thereof), significant contracts, commercial relationships, or capital commitments;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- adverse publicity relating to our markets, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies competing with our potential products;

- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- the loss of key employees;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general and industry-specific economic conditions potentially affecting our research and development expenditures;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in the structure of health care payment systems;
- adverse regulatory decisions;
- trading volume of our common stock; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies or the biotechnology and pharmaceutical sectors, including as a result of disruptions to and volatility in the credit and financial markets in the United States and worldwide from geopolitical and macroeconomic events, including the ongoing Russia-Ukraine and Middle East conflicts and related sanctions, bank failures and international tariffs. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Regardless of the merits or the ultimate results of such litigation, if instituted, such litigation could result in substantial costs and diversion of management's attention and resources, which could significantly harm our profitability and reputation.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and prospects.*

We operate in a global economy, which includes utilizing third-party suppliers in several countries outside the United States. There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects. The Bureau of Industry and Security, U.S. Department of Commerce, has initiated an investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States pose a national security risk and should be subject to additional tariffs.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. Currently, several of our suppliers are located outside of the United States, and our principal suppliers of critical raw materials are located in China and Germany. The active pharmaceutical ingredients (APIs) for Auxora is manufactured in China, and our Auxora product candidate is manufactured in the United States. We also rely on specialized laboratory equipment, supplies, materials, and precursor compounds, all or part of which we believe may be ultimately sourced from multiple countries outside the United States, to advance our research and development efforts.

Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Unlike consumer goods, pharmaceuticals face

unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization in the future, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the United States and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the United States and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, tariffs and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report for the fiscal year ended December 31, 2024.

Financial reporting obligations of being a public company in the United States are expensive and time-consuming, and our management needs to devote substantial time to compliance matters.

As a publicly traded company, we incur significant additional legal, accounting and other expenses that the Company did not incur as a privately held company, including costs associated with public company reporting requirements. The obligations of being a public company in the United States require significant expenditures and will place significant demands on our management and other personnel, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the rules and regulations regarding corporate governance practices, including those under the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act") and the listing requirements of the stock exchange on which our securities are listed. These rules require the establishment and maintenance of effective disclosure and financial controls and procedures, internal control over financial reporting and changes in corporate governance practices, among many other complex rules that are often difficult to implement, monitor and maintain compliance with. In addition, 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 such insurance. Moreover, despite recent reforms made possible by the JOBS Act, the reporting requirements, rules and regulations will make some activities more time-consuming and costly, particularly after we are no longer an "emerging growth company" or a "small reporting company". We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering (i.e. December 31, 2025), (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $750 million as of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation, among other potential problems. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements and to keep pace with new regulations, otherwise we may fall out of compliance and risk becoming subject to litigation, among other potential problems.

The relative lack of public company experience of our management team may put us at a competitive disadvantage.

Our management team lacks significant public company experience, which could impair our ability to comply with legal and regulatory requirements such as, but not limited to, those imposed by the Sarbanes-Oxley Act. Our senior management does not have significant experience managing a publicly traded company. Such responsibilities include complying with federal securities laws and making required disclosures on a timely basis. Our senior management may be unable to implement programs and policies in an effective and timely manner or that adequately respond to the increased legal, regulatory and reporting requirements associated with being a publicly traded company. Our failure to comply with all applicable requirements could lead to the imposition of fines and penalties,

distract our management from attending to the management and growth of our business, result in a loss of investor confidence in our financial reports and have an adverse effect on our business and stock price.

Substantial future sales of shares of our common stock could adversely affect the market price of such shares.

If existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, or there is the perception that these sales could occur, this could adversely affect the market price of such shares and could materially impair our ability to raise capital through equity offerings in the future.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale would have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options or warrants, or the perception that such sales may occur, could adversely affect the market price of our common stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Based on the beneficial ownership of our common stock as of March 21, 2025, our executive officers, directors and holders of 5% or more of our capital stock and their respective affiliates beneficially owned a significant percentage of our voting stock. As a result, these stockholders, if continuing to act together, will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

We are a smaller reporting company. We cannot be certain whether the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors or otherwise limit our ability to raise additional funds.

We are a "smaller reporting company" under applicable securities regulations. A smaller reporting company is a company that, as of the last business day of its most recently completed fiscal quarter, has an aggregate market value of the company's voting stock held by non-affiliates, or public float, of less than $250 million, or has annual revenues less than $100 million and either no public float or public float less than $750 million. SEC rules provide that companies with a non-affiliate public float of less than $75 million may only sell shares under a Form S-3 shelf registration statement, during any 12-month period, in an amount less than or equal to one-third of the public float. If we do not meet this public float requirement, any offering by us under a Form S-3 will be limited to raising an aggregate of one-third of our public float in any 12-month period. In addition, a smaller reporting company is able to provide simplified executive compensation disclosures in its filings, is exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that an independent registered public accounting firm provide an attestation report on the effectiveness of internal control over financial reporting if its public float is less than $70 million, and has certain other reduced disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports. Reduced disclosure in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze its results of operations and financial prospects.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

The trading market for our common stock will be influenced by the research and reports that industry or equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock after the completion of the merger, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause its stock price or trading volume to decline.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our amended and restated certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. These provisions include a classified board of directors, a prohibition on actions by written consent of our stockholders, and the ability of the board of directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (the "DGCL"), which prohibits stockholders owning in excess of 15% of our voting stock from merging or combining with us in certain circumstances. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our Board of Directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing the members of management.

Our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for any state law claims for (a) any derivative action or proceeding brought on behalf of us; (b) any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our directors, officers, stockholders, employees or agents to us or our stockholders; (c) any action asserting a claim against us or any of our directors, officers, stockholders, employees or agents arising pursuant to any provision of the DGCL, the certificate of incorporation or the bylaws or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; (d) any action to interpret, apply, enforce or determine the validity of the certificate of incorporation or the bylaws; or (e) any action asserting a claim against us or any of our directors, officers, stockholders, employees or agents governed by the internal affairs doctrine; *provided*, that these choice of forum provisions do not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. The amended and restated bylaws will provide that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The choice of forum provision may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. If a court were to find the choice of forum provision contained in the bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our bylaws described above.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our products or services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Trading Arrangements

During the fiscal quarter ended September 30, 2025, none of our directors and/or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408.

Item 6. Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit Filing Date	Exhibit No.	Filed/Furnished Herewith
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-39538	March 22, 2023	3.1	
3.2	Certificate of Amendment, dated March 20, 2023 to Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-39538	March 22, 2023	3.2	
3.3	Restated Bylaws of the Registrant.	10-Q	001-39538	November 12, 2020	3.2	
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.					
4.2	Form of Common Stock Certificate	S-1/A	333-248611	September 21, 2020	4.1	
4.3	Form of Registration Rights Agreement, dated November 21, 2022, by and among CalciMedica, Inc. and the several purchasers signatory thereto.	8-K	001-39538	March 22, 2023	4.1	
4.4	Form of Registration Rights Agreement by and among CalciMedica, Inc. and the persons party thereto.	8-K	001-39538	January 24, 2024	10.2	
4.5	Warrant to Purchase Common Stock dated as of December 11, 2019, by and between the Registrant and SG Dan Equity Holdings, LLC.	S-1	333-248611	September 4, 2020	4.3	
4.6	Form of Warrant to Purchase Shares of Series D Convertible Preferred Stock of CalciMedica, Inc.	8-K	001-39538	March 22, 2023	4.2	
4.7	Warrant to Purchase Common Stock dated as of November 9, 2020, issued by the Registrant to SG Dan Equity Holdings, LLC.	8-K	001-39538	March 22, 2023	4.3	
4.8	Warrant to Purchase Common Stock, dated as of October 18, 2022, issued by CalciMedica, Inc. to SG Dan Equity Holdings, LLC.	8-K	001-39538	March 22, 2023	4.4	
4.9	Warrant to Purchase Common Stock, dated as of October 18, 2022, issued by CalciMedica, Inc. to Eric Roberts.	8-K	001-39538	March 22, 2023	4.5	
4.10	Warrant to Purchase Common Stock, dated as of October 25,2022, issued by CalciMedica, Inc. to Fred Middleton.	8-K	001-39538	March 22, 2023	4.6	
4.11	Form of Warrant to Purchase Shares of Series B Convertible Preferred Stock of CalciMedica, Inc.	S-3	333-271115	April 4, 2023	4.9	
4.12	Form of Tranche B Common Warrant	8-K	001-39538	January 24, 2024	4.2	
4.13	Form of Pre-Funded Warrant	8-K	001-39538	January 24, 2024	4.3	

Exhibit Number	Description	Form	File No.	Exhibit Filing Date	Exhibit No.	Filed/Furnished Herewith
4.14	Form of Placement Agent Warrant	8-K	001-39538	January 24, 2024	4.4	
4.15	Warrant to Purchase Common Stock, dated as of May 17, 2024, issued by the Registrant to SG Dan Equity Holdings, LLC.	10-Q	001-39538	August 12, 2024	4.16	
4.16	Warrant to Purchase Shares of Stock of CalciMedica, Inc. dated February 28, 2025, by and between CalciMedica, Inc. and Avenue Venture Opportunities Fund II, LP.	8-K	001-39538	March 5, 2025	4.1	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	Inline XBRL Instance Document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents.					X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)					X

* This certification is deemed not filed for purposes of section 18 of the Exchange Act or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of the Exchange Act.

SIGNATURES

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

CALCIMEDICA, INC.

Date: November 12, 2025

By: /s/ A. Rachel Leheny

A. Rachel Leheny, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2025

By: /s/ Stephen Bardin

Stephen Bardin, MBA
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, A. Rachel Leheny, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CalciMedica, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (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 12, 2025

By: /s/ A. Rachel Leheny

A. Rachel Leheny, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) OR 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen Bardin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CalciMedica, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (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 12, 2025

By: /s/ Stephen Bardin

Stephen Bardin, MBA
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of CalciMedica, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

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

Date: November 12, 2025

By: /s/ A. Rachel Leheny

A. Rachel Leheny, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of CalciMedica, Inc. (the "Company") on Form 10-Q for the fiscal quarter ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

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

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

Date: November 12, 2025

By: /s/ Stephen Bardin

Stephen Bardin, MBA
Chief Financial Officer
(Principal Accounting and Financial Officer)