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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

Commission File Number 001-39538

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

Securities registered pursuant to Section 12(g) of the Act: **None**
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒
Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

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

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

As of June 30, 2024, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of common stock held by non-affiliates of the registrant computed by the closing price of the registrant's common stock on June 30, 2024 on the Nasdaq Capital Market was approximately $27.9 million. Shares of common stock held by each executive officer, director and their affiliated holders have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's Common Stock outstanding as of March 21, 2025 was 13,481,917

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement (the "Proxy Statement") for the 2025 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission not later than April 30, 2025 are incorporated by reference into Part III of this Annual Report on Form 10-K.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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 Annual Report on Form 10-K, 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 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 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 Annual Report on Form 10-K. 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 I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K. 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.
- 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.
- The addressable market of our product candidates have not been established with precision and may be smaller than we estimate.
- 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 may 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.
- The 2025 Loan and Security Agreement with Avenue Venture Opportunities Fund includes customary affirmative and negative covenants, as well as standard events of default, that could restrict our operating and financial flexibility.

EXPLANATORY NOTE

On March 20, 2023, the Delaware corporation formerly known as "Graybug Vision, Inc." completed its 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 Vision, Inc. ("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 the merger as a wholly owned subsidiary of Graybug (the "Merger"). Additionally, on March 20, 2023, the Company changed its name from "Graybug Vision, Inc." to "CalciMedica, Inc." (the "Company").

On March 17, 2023, in connection with the transactions contemplated by the Merger Agreement, Graybug filed an Amended and Restated Certificate of Incorporation effecting a reverse stock split of Graybug's common stock at a ratio of 14:1 (the "Reverse Stock Split"). As a result of the Reverse Stock Split, the number of issued and outstanding shares of Graybug's common stock immediately prior to the Reverse Stock Split was reduced into a smaller number of shares, such that every 14 shares of Graybug's common stock held by a stockholder immediately prior to the Reverse Stock Split were combined and reclassified into one share of common stock after the Reverse Stock Split. The information in this Annual Report on Form 10-K as of and for the periods prior to the effective date of the Merger gives effect to the Reverse Stock Split.

Since Private CalciMedica was determined to be the accounting acquirer in connection with the Merger, for periods prior to the Merger, the consolidated financial statements were prepared on a stand-alone basis for Private CalciMedica and did not include the combined entities' activity or financial position. Subsequent to the Merger, the consolidated financial statements as of and for the year ended December 31, 2024 include Graybug's assets and liabilities at their acquisition date fair value and the Company's and Private CalciMedica's activity from and after the Merger. Historical share and per share figures of Private CalciMedica have been retroactively restated based on the exchange ratio of 0.0288.

In this Annual Report on Form 10-K, unless the context indicates otherwise, the terms "Company," "CalciMedica," "we," "us," and "our" refer to (i) Private CalciMedica, for periods prior to the effectiveness of the Merger and (ii) CalciMedica, Inc. (as a combined company) for periods following the effectiveness of the Merger.

This Annual Report on Form 10-K contains references to trademarks belonging to other entities, which are the property of their respective holders. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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Item 1. Business.

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.

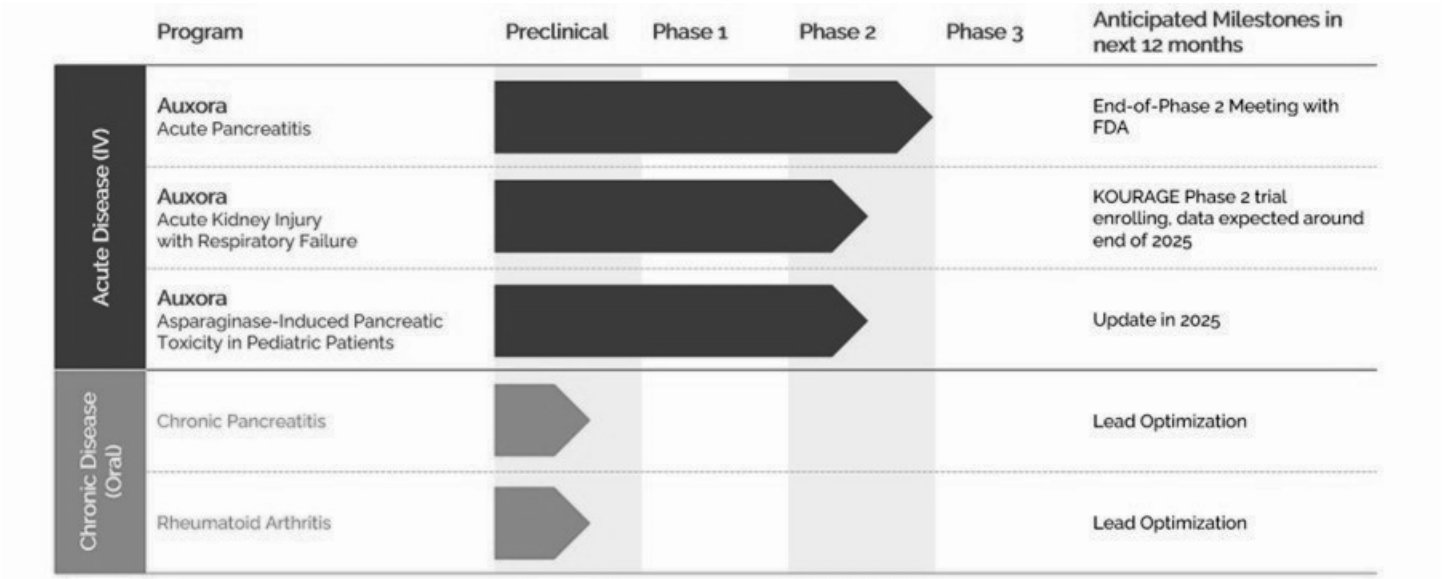
Clinical and preclinical data have demonstrated that the inhibition of CRAC channels may have a therapeutic effect based on a dual mechanism involving both anti-inflammatory and tissue cell protective activities. Our work has shown compelling evidence of the involvement of CRAC channels in a broad spectrum 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 around the end of 2025.

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 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 Investigational New Drug Application ("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.

Our Pipeline

Our product candidates are summarized in the table below:



Clinical Experience with Auxora

Our clinical experience with Auxora is summarized in the table below:

Trial	Acute Pancreatitis Phase 2a	COVID-19 Pneumonia Phase 2a	CARDEA: COVID-19 Pneumonia Phase 2	CARPO: Acute Pancreatitis Phase 2b	KOURAGE: Acute Kidney Injury Phase 2
Year	2019	2020	2021	2024	Expected 2025
Number of Patients	21	30	284	216	150
Hypoxemia at Enrollment	P/F<360	P/F<300	P/F<200	Not required	P/F<300
Expected Mortality	<10%	15-25%	15-25%	<5%	~50%
Auxora Results					
Respiratory Failure	Ventilator use	Ventilator use	33% Ventilator use	↓ 100%[2] New onset severe respiratory failure	Primary Endpoint Days ALIVE, not on a VENTILATOR and not on DIALYSIS
Severe Organ Failure	↓ Too few events	↓ Too few events	↓40% ↓ New onset AKI	↓ ~60%[2] Severe organ failure (respiratory, renal and cardio)	
Mortality	Too few events	↓50%	↓56% ↓63% in AKI subset[1]	Too few events	
Safety	Auxora has been well-tolerated in 360+ critically ill patients				

Table Notes: For illustrative purposes only. Not a head-to-head comparison. Differences exist between clinical trial design and patient populations, and caution should be exercised when comparing data across trials.

(1) 38 patients who enrolled with AKI, defined as an estimated glomerular filtration rate (eGFR) ≤ 60 ml/min/1.73 m².

(2) The high and medium dose patients showed a reduction in respiratory failure and severe organ failure compared to both the placebo and low dose patients.

We have studied Auxora in a number of clinical trials including multiple Phase 2 clinical trials conducted in the United States and internationally. Across these studies, we observed that patients treated with Auxora experienced a reduction of organ damage and a reduced time to recovery. In CARDEA, we observed a statistically significant 56% (p=0.016) relative reduction versus placebo in mortality at 30 days. Further, in a post-hoc analysis analyzing 38 patients who enrolled in CARDEA with AKI, defined as an estimated glomerular filtration rate (eGFR) ≤ 60 ml/min/1.73 m², in addition to moderate or severe respiratory failure, which was an inclusion criterion, we observed a 62.7% relative reduction versus placebo in mortality at day 30 which persisted through day 60. In CARPO, the medium and high doses of Auxora both showed a 100% relative risk reduction compared to placebo in new-onset severe respiratory failure. This effect was statistically significant for the high and medium dose arms individually (p<0.05) and for the combined high and medium doses of Auxora patients compared with the combined placebo and low dose of Auxora patients (p=0.0027). We believe the consistency of the results we observed from these trials in multiple acute critical care conditions affecting different primary organs are mutually supportive and reinforce our plans to further pursue the use of Auxora in several additional acute critical illnesses.

The results from several of our trials have been published or presented at medical meetings, including results from an open-label SOC controlled Phase 2a trial in AP, results from treating the first cohort of patients in the open-label, investigator-initiated Phase 1/2 CRSPA trial, and results from the 30-patient open-label part one portion of the Phase 2 CARDEA trial in severe and critical COVID-19 pneumonia patients, and the 284-patient blinded, randomized, controlled Part 2 component of this same trial.

Auxora for the Treatment of Acute Kidney Injury

- *Ongoing Phase 2 clinical trial.* In July 2024, we announced the first patient enrolled in KOURAGE, a Phase 2 clinical trial of Auxora for the treatment of AKI patients with AHRF. KOURAGE is a randomized, double-blind, placebo-controlled study that will evaluate 150 patients with Stage 2 and 3 AKI who have AHRF and are receiving oxygen by non-invasive mechanical ventilation, high flow nasal cannula or IMV. We expect to report data from this trial around the end of 2025.
- *Clinical observations of Auxora for AKI.* We have both clinical observations and pre-clinical data that support the development of Auxora in AKI. In our CARDEA trial, which studied Auxora in patients with severe and critical COVID-19 pneumonia, results showed a 40% reduction in newly reported AKI (a common consequence of COVID-19 pneumonia)

in Auxora-treated patients as compared to placebo-treated patients. In a post-hoc analysis analyzing 38 patients who enrolled in CARDEA with AKI, defined as an estimated glomerular filtration rate (eGFR) ≤ 60 ml/min/1.73 m², in addition to moderate or severe respiratory failure, which was an inclusion criterion, we observed a 62.7% relative reduction versus placebo in mortality at day 30 which persisted through day 60. Biomarker analysis from blood samples taken from over 190 CARDEA patients further showed that, when compared to placebo, Auxora had positive effects on cardiorenal biomarkers—increases in angiopoietin-1 and decreases in angiopoietin-2 and D-dimers—which have been linked to the prevention of endothelial damage in prior studies and were correlated with improved outcomes in CARDEA.

- *Preclinical studies for Auxora in AKI.* Our pre-clinical studies in an ischemia/reperfusion injury model of AKI in rats showed promising results, whereby animals receiving three daily doses of Auxora after injury had improvements in their GFR values while rats receiving placebo had little improvement. Further, in the setting of severe kidney injury, rats receiving Auxora survived whereas those receiving placebo died.

Auxora for the Treatment of Acute Pancreatitis

AP with SIRS

- *Completed Phase 2b clinical trial*: We completed CARPO, an international, randomized, double-blind placebo-controlled Phase 2b trial in 216 patients with AP and accompanying SIRS. In October 2024, in a plenary session at the American College of Gastroenterology annual meeting, we presented late-breaking data and previously announced data from CARPO. The trial met its primary objective with a statistically significant dose response in median time to solid food tolerance in a prespecified subgroup of patients with hyper-inflamed AP. Additionally, the medium and high doses of Auxora both showed a reduction in severe organ failure and, specifically, a 100% relative risk reduction compared to placebo in new-onset severe respiratory failure. This effect was statistically significant for the high and medium dose arms individually ($p<0.05$) and for the combined high and medium doses of Auxora patients compared with the combined placebo and low dose of Auxora patients ($p=0.0027$). There was an approximately 20% relative risk reduction for new onset necrotizing pancreatitis for patients in the high dose group compared to placebo patients and these high dose patients also had median time to medically indicated discharge of 15 hours less than placebo patients. Finally, a stratified win-ratio analysis of certain key endpoints gave a stratified 1.640 win-ratio benefit ($p=0.0372$) for the high dose patients compared to placebo patients.

- *Completed open-label Phase 2a clinical trial:* We completed a randomized, open-label Phase 2a clinical trial of Auxora in 21 patients with AP and accompanying SIRS who also had hypoxemia at presentation. Patients in this trial treated with Auxora in addition to SOC had multiple improved outcomes compared to patients treated with standard of care alone. In addition, there were several patients with severe respiratory failure at enrollment and the majority of those treated with Auxora did not require mechanical ventilation. Results from this randomized, open-label Phase 2a clinical trial conducted in the United States were published in March 2021 in the peer- reviewed journal Pancreas.

- *Ongoing planning for a potential Phase 3 clinical trial:* We plan to hold an End-of-Phase 2 meeting with the FDA around the middle of 2025 and expect to be in a position to initiate a Phase 3 program in AP and accompanying SIRS around the end of 2025 pending additional funding. We have received Fast Track designation from the FDA and orphan drug designation in the European Union ("EU") from the European Medicines Agency ("EMA") for Auxora for the treatment of AP. However, there is no guarantee that Fast Track designation will result in a faster regulatory review or regulatory approval, if at all.

Auxora for the Treatment of AIPT: Pancreatitis as a Side Effect of Treatment for Pediatric ALL

- *Ongoing Phase 1/2 clinical trial*. CRSPA, an investigator led 24-patient Phase 1/2 trial, is being conducted in the United States in children who develop AIPT related to the use of the chemotherapeutic asparaginase in the course of their treatment for ALL. We believe this work is providing valuable information on the use of Auxora in critically ill pediatric patients. The first cohort of nine patients in this trial has been completed and the data presented at ASH in December 2023 showed that all patients who received a full course of Auxora treatment had a more rapid resolution of their symptoms as compared to historical controls. These patients spent less time in the hospital or intensive care unit and blinded central reading of pancreatic imaging showed reduction in the development of significant pancreatic necrosis and the severity of acute pancreatitis as compared to the historical control group, 27% of whom had greater than 30% necrosis of their pancreas at 30 days as compared to none of the Auxora treated patients. Over 50% of patients in the control group required total parenteral nutrition ("TPN") for several weeks on average and none required TPN in the treatment group. This trial has expanded to additional sites and is over 50% enrolled, and we expect to provide an update in the second half of 2025.

Auxora for the Treatment of Acute Respiratory Failure

- *Completed double-blind Phase 2 clinical trial in hospitalized COVID-19 pneumonia patients on oxygen.* In our CARDEA trial, a Phase 2 randomized double-blind placebo-controlled trial conducted in the United States in 284 patients with severe COVID-19 pneumonia (261 having moderate and severe respiratory failure—our efficacy set) and receiving supplemental oxygen but not on mechanical ventilation, treatment with Auxora resulted in a reduced time to recovery and a 56% relative reduction in mortality at 30 days (p=0.0165) and a 33% relative reduction in mortality at 60 days (p=0.1449) compared to placebo. Both of these findings are clinically relevant particularly in light of patients needing additional therapies on top of the current standard of care. Time to recovery was seven days for Auxora-treated patients compared to ten days for patients receiving placebo (p=0.098). Data from this study was published in April 2022 in the peer-reviewed journal *Critical Care*.

Potential Additional Indications

- *Oral candidate for the treatment of chronic inflammatory and immunological diseases.* We are also developing oral CRAC channel inhibitors for use in chronic inflammatory indications. We have animal model data with several compounds suggesting CRAC channel inhibition may be useful in treating chronic pancreatitis, rheumatoid arthritis, ulcerative colitis and allergic asthma. 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.

- *Auxora for the treatment of acute ulcerative colitis*. Recent animal data indicates that CRAC channel inhibition by zegocractin or CM4620 (active ingredient in Auxora) may be useful in the treatment of inflammatory bowel disease, such as ulcerative colitis. In a preclinical study performed with scientists from Charite – University Medicine, Berlin and New York University Grossman School of Medicine, it was shown that zegocractin, administered orally to mice every other day for a period of 30 days produced a significant reduction in intestinal inflammation in a model of ulcerative colitis. This work was published in EMBO Molecular Medicine in August 2022.

- *Auxora for the treatment of allergic asthma*. Zegocractin was studied in mouse models of asthmatic airway inflammation and influenza A virus infection to determine if inhibition of CRAC channels reduces asthmatic inflammation without interfering with the antiviral response. Researchers from New York University Grossman School of Medicine showed that oral administration of zegocractin significantly lowered both peribronchiolar inflammation and lung mucus production in the asthma model and did not impact viral response in the influenza A model. This work was published in Science Advances in October 2022.

- *Auxora for the treatment of traumatic brain injury.* CM5480 is a proprietary tool compound that is an Orai1-selective inhibitor like zegocractin, and using this compound it was shown that blocking Orai1 CRAC channels protected mice from brain damage following controlled cortical impact, a model of traumatic brain injury. The results supported the interpretation that CM5480 worked by suppressing the activation of brain microglia, which are immune cells residing in the central nervous system. This work was published in the Journal of Neurotrauma in 2019. Since zegocractin (the active ingredient in Auxora)and CM5480 are both brain penetrant, it is possible that patients with traumatic brain injury could be effectively treated with Auxora.

Our Strategy

We are a company focused on the discovery and development of CRAC channel inhibitors. We intend to develop therapeutics to treat acute critical illnesses including AKI, AP, ARDS or ARHF, and chronic inflammatory and immunologic diseases potentially including chronic pancreatitis and rheumatoid arthritis. Our strategy to achieve this is as follows:

- **Leverage our proprietary CRAC channel inhibition science to develop drugs to treat acute critical illness and chronic inflammatory diseases where there are no effective therapies.** Given that CRAC channels are found on many cell types in addition to immune cells, we believe that there will be a number of inflammatory and immunologic indications that can be targeted with the novel mechanism of action afforded by CRAC channel inhibitors. These indications can range from acute critical illnesses, the focus of our current efforts to date, to chronic inflammatory and immunologic conditions. Our portfolio of proprietary compounds with different pharmaceutical properties enables us to explore these indications with agents selected and formulated specifically for each unique clinical setting.

- **Develop Auxora for the treatment of AKI.** AKI represents a significant unmet medical need as there are no disease-modifying therapies to either prevent or treat AKI. We have a body of clinical observations and pre-clinical data that support the development of Auxora in this acute critical disease. In July 2024, we announced the first patient enrolled in KOURAGE, a Phase 2 clinical trial of Auxora for the treatment of AKI patients with AHRF. KOURAGE is a randomized, double-blind, placebo-controlled study that will evaluate 150 patients with Stage 2 and 3 AKI who have AHRF and are

receiving oxygen by non-invasive mechanical ventilation, high flow nasal cannula or IMV. We expect to report data from this trial around the end of 2025.

- **Develop Auxora for the treatment of patients with AP and accompanying SIRS.** AP represents an unmet need in critical care medicine as there are no disease-modifying therapies. We believe we have shown that Auxora-treated AP patients with SIRS have better outcomes than SOC-treated control patients in both a Phase 2a and a Phase 2b clinical trial. We plan to hold an End-of-Phase 2 meeting with the FDA around the middle of 2025 and expect to be in a position to initiate a Phase 3 program in AP and accompanying SIRS around the end of 2025 pending additional funding.
- **Develop Auxora for the treatment AIPT.** CRSPA, an open-label 24-patient Phase 1/2 clinical trial, is currently being conducted in pediatric patients with AIPT. The first cohort of nine patients in this trial has been completed and the results from this cohort as well as results from a blinded matched historical control group were presented at ASH 2023. While initially a single-center trial, CRSPA has been expanded to additional sites and is over 50% enrolled. We expect to provide an update in the second half of 2025.
- **Demonstrate the efficacy of Auxora for the treatment of patients with AHRF and ARDS caused by multiple etiologies.** We have completed CARDEA, a Phase 2 randomized double-blind, placebo-controlled trial in patients with severe COVID-19 pneumonia and receiving supplemental oxygen, but not on mechanical ventilation, and with our collaborator we have completed the enrollment and treatment of patients of a Phase 2 clinical trial in mechanically ventilated COVID-19 pneumonia ARDS patients. Results from this trial may inform the design of a Phase 2 clinical trial for the treatment of AHRF and/or ARDS and we are evaluating next steps for potential clinical development of Auxora in patients with AHRF and ARDS.
- **Advance a second CRAC channel inhibitor into clinical development for the treatment of an additional inflammatory indication.** We believe that there are multiple indications, including some chronic inflammatory and immunologic indications, that could potentially be treated with CRAC channel inhibitors from our portfolio of compounds, including orally available compounds. At present time, we have paused IND enabling preclinical work on these compounds to focus resources on our clinical programs; however, we expect to continue certain research activities to validate CRAC channel inhibition as a potential mechanism in other promising inflammatory and immunologic diseases and could restart IND enabling work in the future should we receive additional funding.
- **Explore additional indications for Auxora.** Pre-clinical work in both acute ulcerative colitis, allergic asthma, pulmonary arterial hypertension, and traumatic brain injury have shown that zegocractin, the active molecule in Auxora, reduces inflammation and symptoms of these diseases in animal models.
- **Pursue licensing and partnership opportunities for Auxora and other compounds in our portfolio.** Development of Auxora in different geographies, and commercialization of Auxora in acute critical care indications that will require access to hospital emergency rooms, may benefit from partners with existing development capability and/or commercial channels and sales forces. We are exploring these types of relationships. In addition, we may elect to partner other of our compounds for specific indications.

Our Team

Our executive team is led by A. Rachel Leheny, Ph.D., our chief executive officer, who has more than 30 years of experience in the life sciences industry as a scientist, venture capital investor and investment banking research analyst. Kenneth Stauderman, Ph.D., a co-founder and our chief scientific officer with more than 30 years of experience in drug discovery and development, is a leading expert in CRAC channels and led the discovery of some of the foundational work in this field. Sudarshan Hebbar, M.D., our chief medical officer, has more than 15 years of clinical development and product development experience and was previously a practicing nephrologist and critical care physician. Raven Jaeger, MS, our chief regulatory officer, has over 20 years of regulatory affairs experience with several marketing approvals in serious diseases with high-unmet medical need.

Our Science

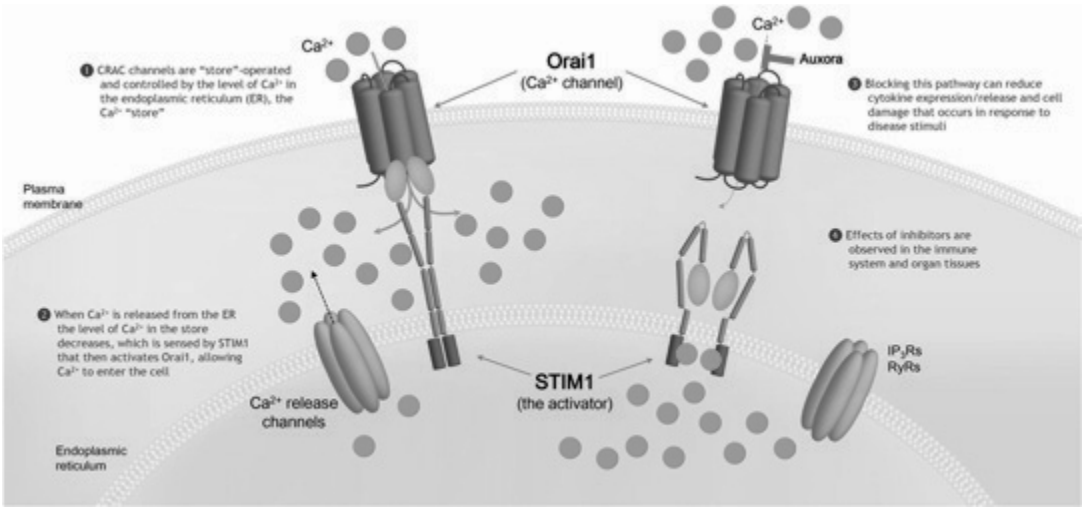
Essential Roles of Calcium Signaling

Calcium serves as an essential messenger for intracellular signals and plays diverse and important roles in biological systems. The major storehouse for calcium in a cell is a compartment called the endoplasmic reticulum ("ER"). Calcium is found there at average concentrations that are 1,000 to 5,000-fold higher than in a cell's interior or cytoplasm. When an outside signal stimulates a cell in a particular way, the stored calcium is rapidly and periodically released from the ER into the cell interior, resulting in activation of a number of key cellular processes affecting synthesis and release of other signaling molecules, cell growth, differentiation and division. These processes include, for example, gene transcription and protein kinase signaling. In response to sufficient external stress on the cell, release of calcium from these intracellular stores can trigger cell death.

CRAC Channels

A specific set of calcium-transporting ion channels known as CRAC channels are responsible, among other things, for replenishing the calcium stores in the ER. The two principal proteins that comprise CRAC channels are the ER calcium-sensing protein Stomal Interaction Molecule 1 ("STIM1") and the cellular membrane calcium channel protein Orai1. When cells are stimulated in particular physiological ways, intracellular messengers are generated that cause the periodic release of calcium from the ER. The release of calcium from the ER is then sensed by STIM1, which unfolds and activates, or opens, the Orai1 calcium channel triggering an influx of calcium into the cell. In certain pathological conditions, however, CRAC channels can be activated in non-physiological ways, such as by a toxin that can cause excessive release of calcium from the ER, leading to overactivation of CRAC channels.

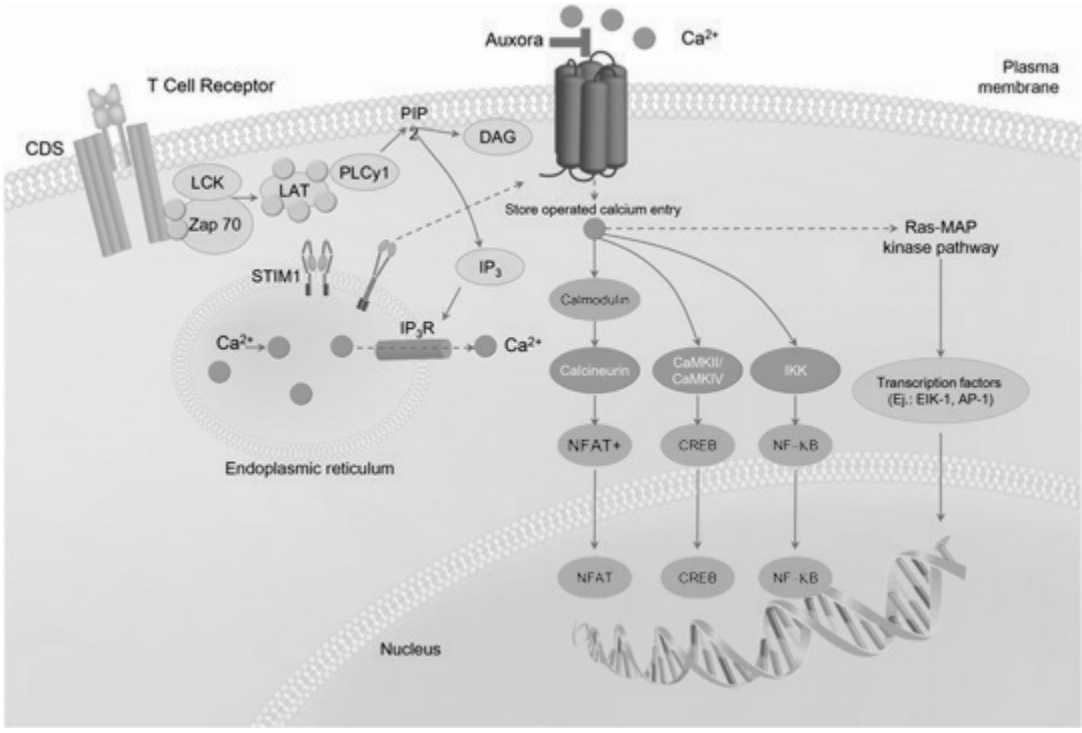
Depending upon the extent of activation and the cell or tissue involved, calcium influx through CRAC channels can regulate calcium-dependent inflammatory pathways or can activate cell injury pathways. For example, in immune cells like T lymphocytes, activation of CRAC channels plays a key role in initiating the adaptive immune response and the generation of inflammatory cytokines. In certain acute critical illnesses such as AP, CRAC channels on affected organ tissue cells can become overactivated, resulting in excess calcium entry that is toxic to cells, causing cellular injury or death that can exacerbate an accompanying inflammatory response.



CRAC channels serve to replenish calcium levels in the ER and to provide calcium for cellular signaling events.

There is strong evidence linking STIM1 and Orai1 to the way the cell replenishes its calcium stores and to the physiological consequences of disrupting these proteins from both *in vitro* and *in vivo* models, including animal gene knock-out or knock-in models, and human genetics. This linkage is true at both the cellular and phenotypic levels. At the cellular level, manipulating STIM1 or Orai1 activity by genetic inactivation or enhancement has been shown to impact calcium transport. Inactivating STIM1 or Orai1 was shown to decrease calcium entry into cells, whereas creating mutations in STIM1 or Orai1 that enhance their activity was shown to increase calcium influx. At the phenotypic level, people with homozygous genetic deficiencies in the genes encoding Orai1 or STIM1 develop the life-threatening condition of severe combined immunodeficiency. Because these individuals lack the ability to mount an effective immune response, they suffer from an extreme risk of contracting life-threatening infections. People with a heterozygous genotype for the mutated genes encoding Orai1 or STIM1 do not have any notable conditions resulting from or associated with these genetic deficiencies despite a partial reduction in the functional activity of the Orai1 or STIM1 proteins.

In lymphocytes, CRAC channels are critically responsible for controlling the entry of calcium that subsequently initiates calcium-dependent events. Within minutes of activating CRAC channels, alterations in intracellular calcium levels result in both (a) the inhibition of lymphocyte migration and (b) the activation of immune cell activity. Both of these elements of CRAC channel biology are central to identifying potential therapies. Effects of prolonged calcium signaling supported by both calcium release from the ER and CRAC channel-mediated calcium entry include stimulation of cell proliferation; expression of immune-activated genes; production of cytokines and chemokines; and lymphocyte differentiation. These longer-duration effects, too, are central to the backdrop for therapeutic intervention. For example, genes triggered by calcium release and subsequent calcium entry through CRAC channels include many activators of inflammation. This mechanism involves various signaling proteins, including two in particular, calcineurin and a transcription factor called nuclear factor of activated T cells ("NFAT"), which form a critical link between calcium elevations and transcriptional activation. Calcineurin is a calcium- activated enzyme that removes inhibitory components from NFAT, triggering it to enter the nucleus and function as a transcription factor. Calcineurin has a well-validated immunoregulatory role; it is the target of two broadly prescribed immunosuppressive molecules, cyclosporine and tacrolimus. NFAT is expressed in a wide spectrum of immune cells and its activity drives inflammation via the production of many pro-inflammatory cytokines such as interleukin-6 ("IL-6"); tumor necrosis factor alpha ("TNF∝"); and interleukin-2 ("IL-2").



Increased levels of intracellular calcium mediated by CRAC channels activate a number of inflammatory pathways.

Inflammatory diseases including AP, respiratory failure, kidney injury or traumatic brain injury are associated with activation or overactivation of CRAC channels. Preclinical experiments have shown that the inhibition of CRAC channels has the potential to provide therapeutic benefit in these and other diseases. Multiple compounds have been identified in the scientific literature that inhibit CRAC channels, but few of these have advanced to clinical trials as a result of unsuitable pharmaceutical properties required for potential therapeutic use.

Advantages to Our Approach

We believe CRAC channels are promising drug targets as they are present on critical organ tissues (such as endothelium cells) and on immune system cells (such as T cells). Overactivation of these channels can lead to organ damage and cytokine-mediated pro-inflammatory processes. CRAC channel activation plays a critical role in endothelial damage and serves as the proximal step in T cell production of pro-inflammatory cytokines. We believe the key advantages of CRAC channel inhibition science are:

- Our CRAC channel inhibitors provide a dual mechanism to reduce cellular damage by both blocking direct tissue damage and down-regulating inflammation.
- Our CRAC channel inhibitors act upstream of several approved drugs (such as cyclosporin) affecting multiple pro-inflammatory pathways. This translates into down-regulation of multiple cytokines produced by the immune system in a disease state and may provide broader acting anti-inflammatory action compared to drugs that target a single cytokine.
- Our CRAC channel inhibitors are small molecule drugs that provide rapid onset of immunomodulatory action as well as rapid offset which can provide rapid recovery of immunocompetence.
- We believe that there may be underlying biological pathways common to a number of acute critical illnesses, including those indications we are pursuing, so that there could be the potential for a single agent to treat patients sharing this underlying biology regardless of disease.
- Our proprietary IV lipid nanoemulsion used in Auxora enhances the delivery of our drug to lipophilic organ tissues such as the pancreas, lung and kidney.
- Certain of our proprietary CRAC channel inhibitors are orally bioavailable and can potentially be used to treat chronic inflammatory and immunologic conditions.
- Our approach is applicable to both acute and chronic inflammatory and immunologic diseases.

Auxora, a Selective CRAC Channel Inhibitor

We are developing Auxora, a proprietary IV-formulated CRAC channel inhibitor, for several indications, including the treatment of severe AP, AIPT, AKI, severe acute respiratory diseases including AHRF, and ARDS, and other acute inflammatory diseases associated with dysregulation of intracellular calcium in organ tissues. We hold worldwide rights to the active ingredient in Auxora, zegocractin, which was previously referred to as CM4620. Auxora inhibits the transport of calcium into cells by inhibiting the Orai1 CRAC channel. Testing of Auxora in an *in vitro* selectivity panel screen showed that the compound was highly selective over many other ion channels, receptors or transporters, which is consistent with the lack of sequence or structural similarity of CRAC channels with other channels.

Auxora is specifically formulated as an IV lipid nanoemulsion that is designed to facilitate the rapid delivery to lipophilic organ tissues such as the pancreas, lung and kidney, which we believe makes it a promising product candidate for the treatment of acute critical illnesses. The nanoemulsion is composed of nanometer-sized lipid droplets suspended in water. Auxora dissolves into the lipid particles that, once infused, move quickly through the body and are attracted to lipophilic tissues that are hard-to-reach for aqueous solutions and hydrophilic drugs. We believe it is critically important to block CRAC channel activity as soon as possible in these acute indications to prevent further tissue damage and decrease morbidity or mortality. Auxora was well-tolerated in single dose and multiple dose Phase 1 clinical trials in healthy adults, and in both the Phase 2 COVID-19 clinical trials and the Phase 2a and 2b AP clinical trials.

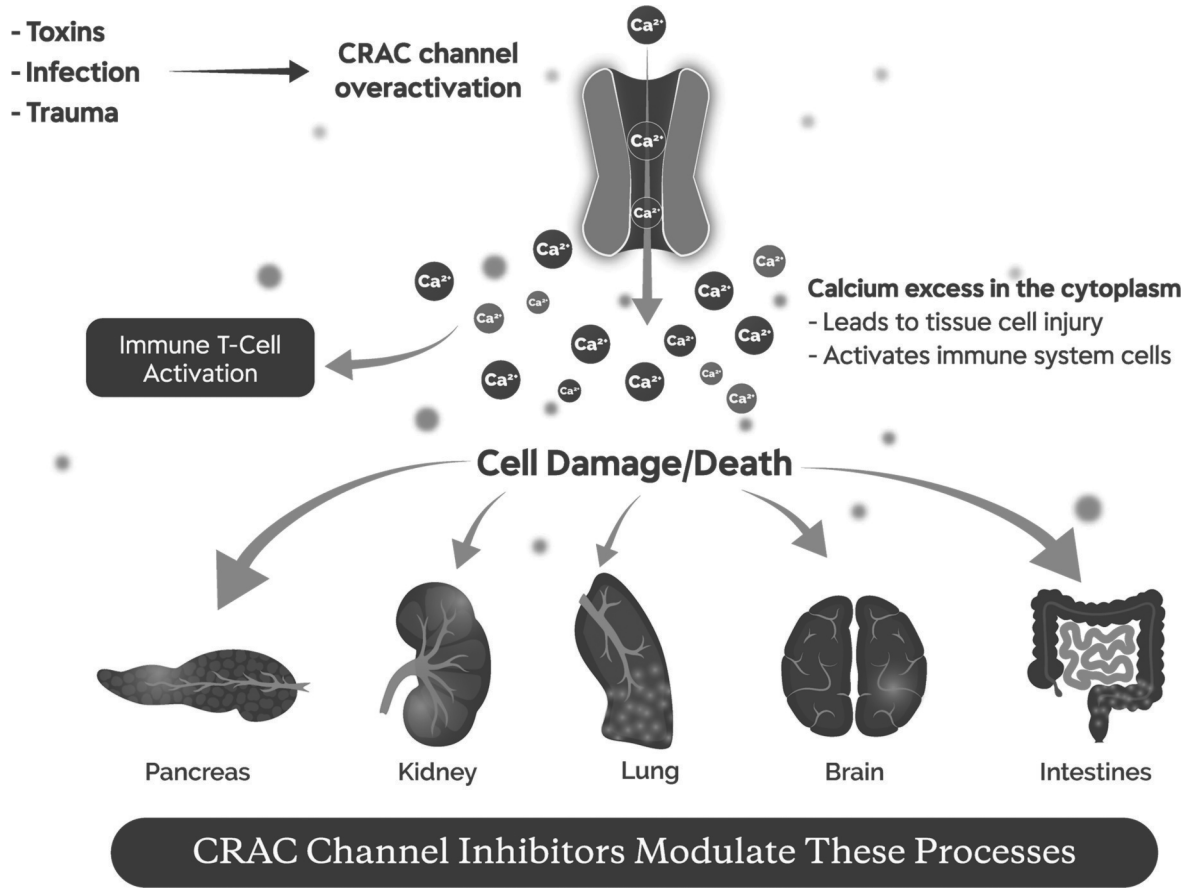
Preclinical Evidence for Anti-Inflammatory Activity of Zegocractin, the Active Ingredient in Auxora

In vitro treatment of activated human peripheral blood mononuclear cells ("PBMCs"), which are predominantly lymphocytes, with zegocractin (the active compound in Auxora) resulted in a concentration-dependent inhibition of the release of a number of pro-inflammatory cytokines including IL-2 and interleukin-17 ("IL-17") when measured at 48 hours. The breadth of the spectrum of cytokines inhibited by zegocractin is consistent with the central role of calcium signaling in the inflammatory response.

PBMC Cytokines	Zegocractin (Active compound in Auxora) Mean IC in nM
IL-2	59
IL-17	120
IL-6	135
IFNγ	138
TNFα	225
IL-10	303
IL-4	879

Zegocractin inhibited the release of a number of cytokines from activated human PBMCs.

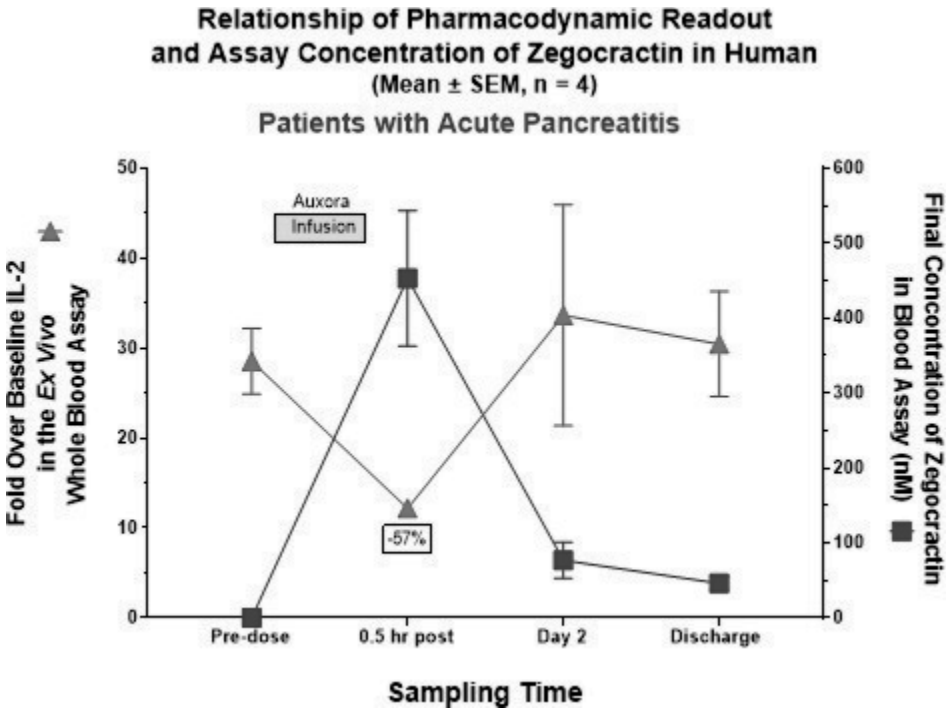
The role of calcium and CRAC channels in inflammation extends beyond lymphocytes and other immune cells. Excess calcium in cells in tissues such as kidney, pancreas, lung and the nervous system leads to cell damage or activation of cell death pathways causing tissue damage and organ failure. These processes, in turn, trigger inflammatory immune responses that further exacerbate cell damage and cell death and can accelerate tissue damage and organ failure.



CRAC channel overactivation causes cell damage, leading to cell death and triggering an inflammatory immune response.

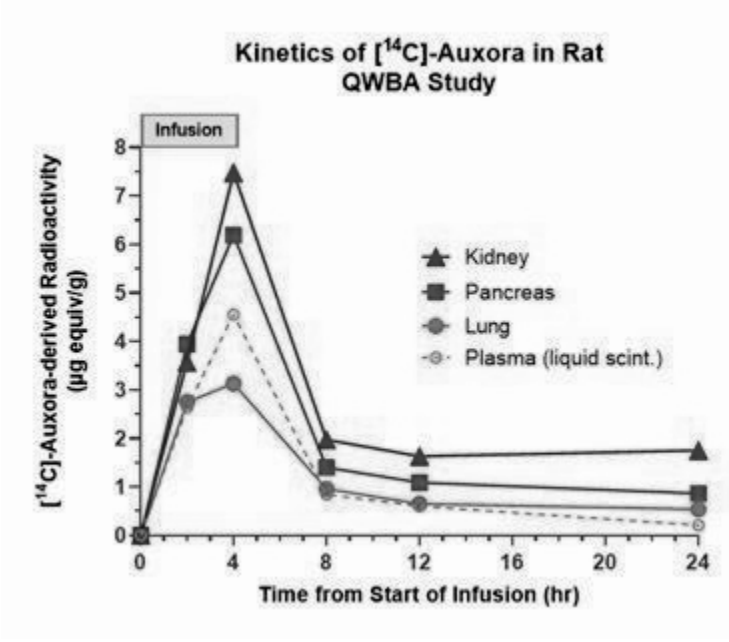
Pharmacodynamic Profile of Auxora

Auxora is a proprietary lipid nanoemulsion IV formulation of the small molecule zegocractin that is administered by IV infusion. To test the activity of Auxora, we have developed an assay using ex vivo blood samples in which we stimulate IL-2 release as a surrogate pharmacodynamic ("PD") marker for immune system activity. After administration, Auxora rapidly redistributes from the blood into lipophilic tissues and is predominantly cleared through the biliary system. Thereafter, the remaining drug is gradually cleared from lipophilic tissues over the course of a few months resulting in trace plasma levels without biological or clinical activity reported to date. Additional toxicity studies will be performed during Phase 3 development and may further address the safety of Auxora as it is cleared from the body. Auxora has demonstrated a rapid onset of immunomodulatory action within 30 minutes post-dosing in this assay performed on blood samples from patients with AP and treated with Auxora. Recovery of IL-2 release was observed within 24-48 hours following dosing completion, indicating offset of immunomodulation.



Auxora has a rapid on-off effect as demonstrated by the onset of immunomodulation after dosing and the recovery of the immune system after the drug infusion is stopped.

We believe that the timely termination of drug action is an important feature of Auxora as it may limit the potential for long-term immunosuppressive effects of prolonged CRAC channel inhibition, which have not been seen in clinical trials to date. In a rat model, administration of Auxora led to high levels of drug exposure in kidneys, pancreas, lung and plasma at two hours and four hours after the start of a four-hour infusion. By eight hours, drug levels dropped, consistent with rapid drug redistribution and/or clearance.



Auxora led to rapid increase in drug levels in the pancreas, lung, kidney and plasma after administration to rats.

Potency and Selectivity of Auxora

Zegocractin (the active molecule in Auxora) is among the most potent CRAC channel inhibitors reported in the scientific literature, as observed in published experiments performed in our labs, including experiments published in the journal *Cell Calcium*. The data in the figure below illustrate that Auxora potently inhibits Orai1-containing CRAC channels, as 50% of the activity of the channel can be inhibited with nanomolar ("nM") concentrations of compound. Further, the compound is selective compared to other channels. For example, on two channels important in cardiac (heart) function, even micromolar ("**µM**") quantities of zegocractin do not achieve measurable inhibition of the activity of those channels. All compounds in our portfolio of potential drug candidates have properties similar to those indicated in the table below.

Channel	Effect of Zegocractin	Orai1 CRAC Channel Selectivity Ratio
Human Orai1-containing CRAC channels	IC_{50} = 119 nM	–
Human voltage-gated Ca channels (cardiac)	<10% inhibition at 10 µM	>100-fold
Human hERG K channels (cardiac)	<10% inhibition at 10 µM	>100-fold

IC50 = concentration producing 50% inhibition of channel activity. Activity of each channel was assessed by electrophysiological (electrical) measurements of either calcium ion (Ca2+) or potassium ion (K+) flow through the indicated channel. The maximum soluble concentration of compound (10 µM) was tested on the cardiac channels.

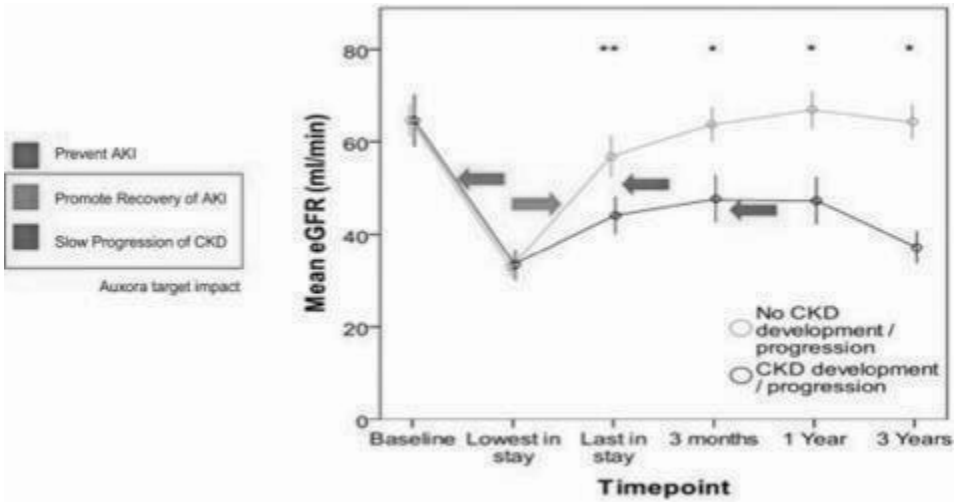
(1) Assay performed by us in 2011-2012.
(2) Assay performed by a contracted vendor in 2012.

Auxora for the Treatment of Acute Kidney Injury

There are recent examples in the scientific literature where CRAC channel inhibition was shown to reduce damage in animal models of AKI. We have conducted preclinical studies of Auxora in a rat model of AKI. Additionally, we have observed in our clinical trials that Auxora-treated patients appear to have less complications of kidney injury or failure in the setting of acute critical illness. In July 2024, we announced the first patient enrolled in KOURAGE, a Phase 2 clinical trial of Auxora for the treatment of AKI patients with AHRF. We expect to report data from this trial around the end of 2025.

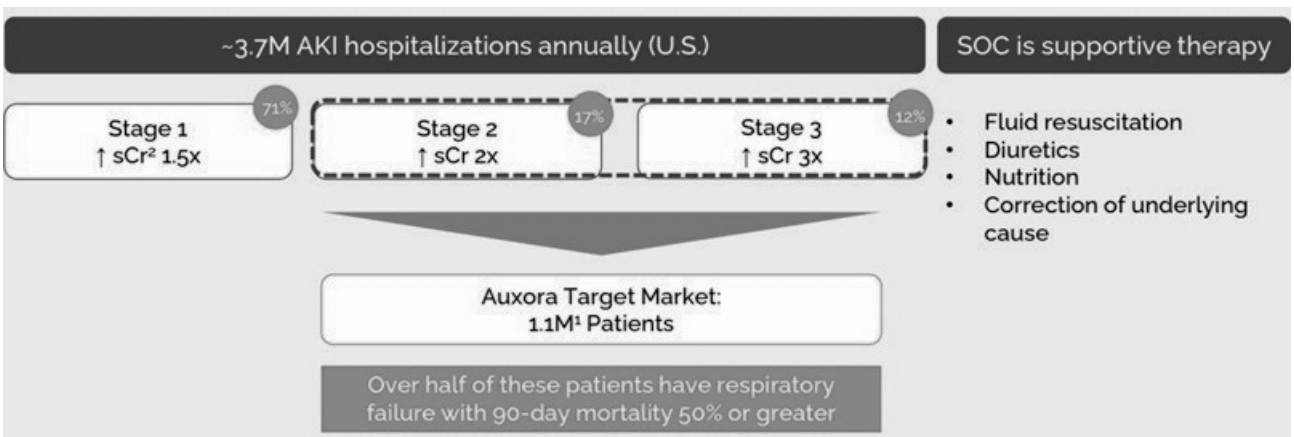
Acute Kidney Injury Background

AKI is marked by three distinct phases, the initial injury, the recovery from that injury and then the long-term damage resulting from the initial injury. Patients who do not recover completely from the initial injury are at risk for long-term damage. We believe the administration of Auxora to patients with more severe AKI will result in a greater proportion of patients recovering completely from the initial injury, and in so doing, will lessen the long term complications of the initial injury. This is illustrated in the figure below. AKI is classified as Stage 1, Stage 2 and Stage 3 depending on the seriousness of the disease as measured by serum creatinine and urine output and may progress from one stage to the next as a patient's condition worsens. Stage 1 patients have an increase in serum creatinine of ≥ 0.3 mg/dL or 1.5 to 1.9 times baseline or urine output of <0.5 mL/kg/hour for six to 12 hours. Stage 2 patients have an increase in serum creatinine to 2.0 to 2.9 times baseline or urine output of <0.5 mL/kg/hour for 12 to 24 hours. Stage 3 patients have an increase in serum creatinine to ≥ 3.0 times baseline, an increase in serum creatinine of ≥ 0.3 mg/dL to ≥ 4.0 mg/dL, urine output of <0.3 mL/kg/ hour for ≥ 24 hours, anuria for ≥ 12 hours or initiation of kidney replacement therapy.



Time course of acute kidney injury and progression to chronic kidney disease.

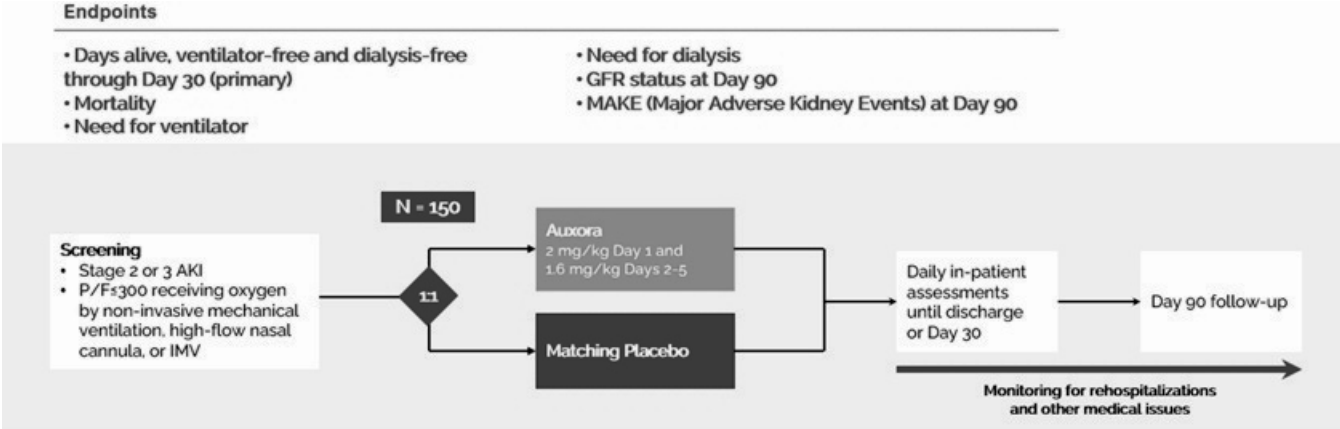
AKI is caused by several factors including infection, trauma and myocardial infarction. According to the Healthcare Cost and Utilization project, there are more than 3.7 million patients hospitalized each year who have AKI in the US. Of these, 71% have Stage 1, 17% have Stage 2 and 12% have Stage 3 so that Stage 2 and Stage 3 patients represent an incidence of over 1 million per year in the US alone. Additionally, over half of the Stage 2 and Stage 3 patients will have some form of respiratory failure and in these patients the expected mortality while hospitalized and up to 90 days post discharge is 50% or more. Currently there are no drugs that directly treat AKI and standard of care includes fluids, diuretics, nutritional support, and correction of the underlying cause of the AKI. Patients who suffer AKI may over the course of months develop chronic kidney disease and may go into end-stage renal failure. The goal of treatment would include reducing the need for dialysis, kidney transplantation, long-term illness and death.



Early treatment with Auxora could offer significant benefits to AKI patients and prevent disease progression.

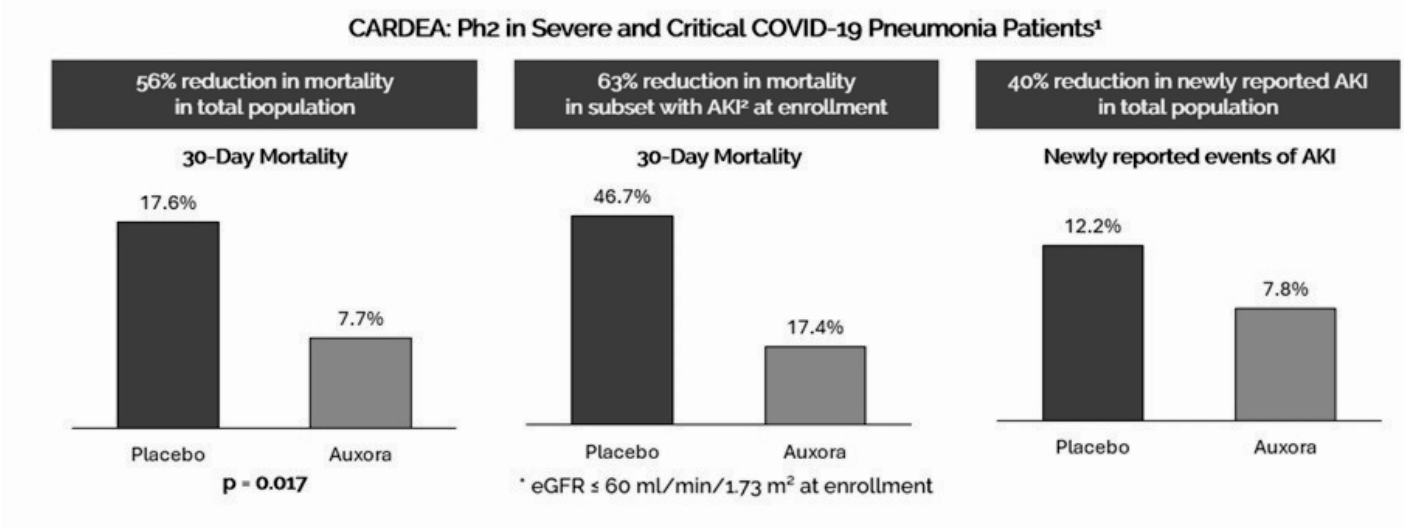
KOURAGE: Ongoing Phase 2 Clinical Trial in Severe Acute Kidney Injury

KOURAGE is a randomized, double-blind, placebo-controlled study that will evaluate 150 patients with Stage 2 and 3 AKI who have AHRF and are receiving oxygen by non-invasive mechanical ventilation, high flow nasal cannula or IMV. Patients will be stratified by classification of stage of AKI as well as the use of IMV. Patients will receive either a four-hour infusion of Auxora or placebo at 1.25 mL/kg as a first dose, after which they will receive Auxora or placebo at 1.0 mL/kg at hours 24, 48, 72 and 96. The primary endpoint of the trial will be evaluation of patients through day 30 to determine days alive, ventilator-free and dialysis-free. Secondary endpoints will include a composite of all-cause mortality, decrease in eGFR, and the incidence of dialysis over a period of 90 days, also known as MAKE-90. The first patient was enrolled in KOURAGE in July 2024, and we anticipate data to be available around the end of 2025.



Clinical Observations Supporting the Potential Use of Auxora in Acute Kidney Injury

While the purpose of CARDEA was to test Auxora in severe COVID-19 pneumonia patients, AKI was reported in a number of patients as it is a common sequalae of this disease. We observed ~40% reduction in the frequency of newly reported AKI in patients treated with Auxora compared with placebo patients. In addition, in a post-hoc analysis analyzing 38 patients who enrolled in CARDEA with AKI, defined as an estimated glomerular filtration rate (eGFR) ≤ 60 ml/min/1.73 m², in addition to moderate or severe respiratory failure, which was an inclusion criterion, we observed a 62.7% relative reduction versus placebo in mortality at day 30 which persisted through day 60.

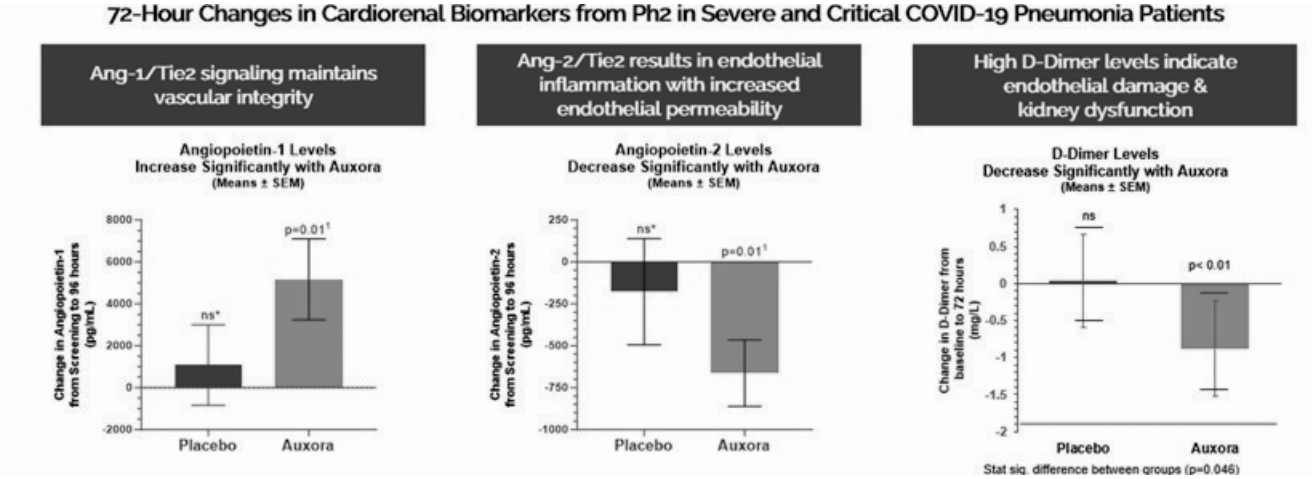


Reduction in Mortality and Newly Reported AKI in CARDEA.

(1) N = 261 in efficacy data set, 281 in safety outcome data set

(2) 38 patients who enrolled with AKI, defined as an estimated glomerular filtration rate (eGFR) ≤ 60 ml/min/1.73 m²

Biomarker analysis from blood samples taken from over 190 CARDEA patients further showed that Auxora had a positive impact on biomarkers in these patients. For example, Angiopoietin-1, Angiopoietin-2, and D-dimer levels are biomarkers for vascular endothelial cells. Angiopoietin-1 levels correlate with the maintenance of vascular integrity while Angiopoietin-2 and D-dimer levels correlate with endothelial inflammation and malfunction. We observed that Angiopoietin-1 levels increased more in patients treated with Auxora compared to placebo while Angiopoietin-2 and D-dimer levels decreased more. These changes were statistically significant and suggest a potential application for Auxora in AKI where endothelial cell function is compromised. Finally, work by others demonstrated that elevated serum IL - 17 levels, a CRAC channel mediated cytokine, were differentially elevated in critically ill patients with Stage 2 and 3 AKI when compared to those without AKI and the extent of elevation was independently associated with both hospital mortality and long-term adverse outcomes.

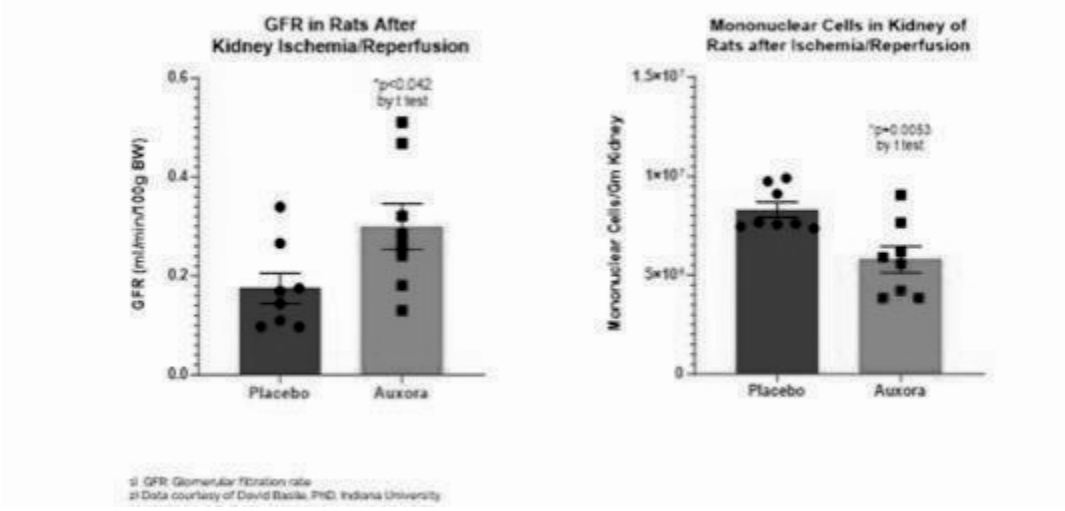


Angiopoietin-1 levels show a statistically significant greater increase in Auxora-treated patients compared to placebo patients while Angiopoietin-2 and D-dimer levels show a statistically greater decrease.

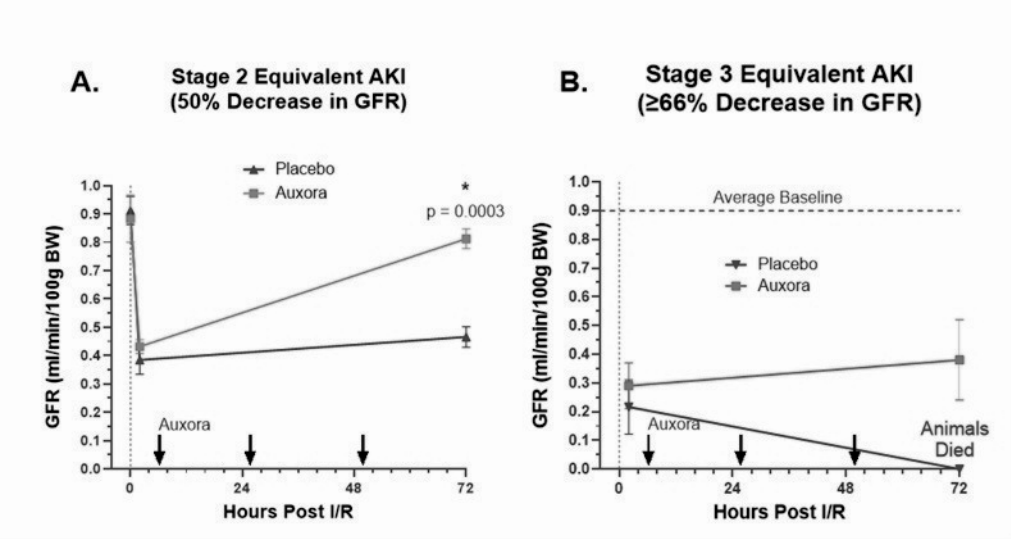
Preclinical Studies with Auxora in Acute Kidney Injury

In collaboration with researchers at Indiana University, we have conducted a series of studies referred to as Study 1 and Study 2 comparing Auxora with placebo in a rat model of AKI. In Study 1, AKI was induced in a rat model through ischemia reperfusion injury ("I/R"), a transient ligation of the renal artery, while control animals underwent sham-surgery. Within 30 minutes of injury, the animals were treated with a single intravenous infusion of either 16 mg/kg of Auxora or placebo over a period of four hours. GFR, an important indicator of kidney function, was evaluated at 24 hours post-injury. Study 2 evaluated recovery of kidney function following I/R similar to Study 1 but varying in intensity to mimic different severity of disease. In Study 2, GFR was measured two to four hours after injury but before treatment, and treatment with 16 mg/kg of Auxora or placebo was administered at six, 24 and 48 hours post-injury, with GFR again evaluated at 72 hours.

Results from Study 1 showed that at 24 hours post-injury, GFR was significantly higher in rats treated with Auxora 30 minutes after injury versus placebo (61%, $p<0.05$). Additionally, animals treated with Auxora showed a reduction in mononuclear (Th17 producing) cells in the kidney of approximately 50% as compared to those treated with placebo. In Study 2, in a group of animals with initial GFR reductions of approximately 50%, similar to Stage 2 AKI, GFR at 72 hours was significantly greater in Auxora-treated animals as compared to placebo-treated animals (0.81±0.03 vs. 0.47±0.04 ml/min/100g respectively; $p<0.001$). In a group of animals with GFR reductions ≥66%, similar to Stage 3 AKI, placebo-treated rats experienced 100% mortality by 72 hours while Auxora-treated rats had no mortality at 72 hours and were stable, showing modest recovery of kidney function. These results indicate that Auxora has the ability to hasten the recovery of kidney function and improve survival in rat models of AKI.



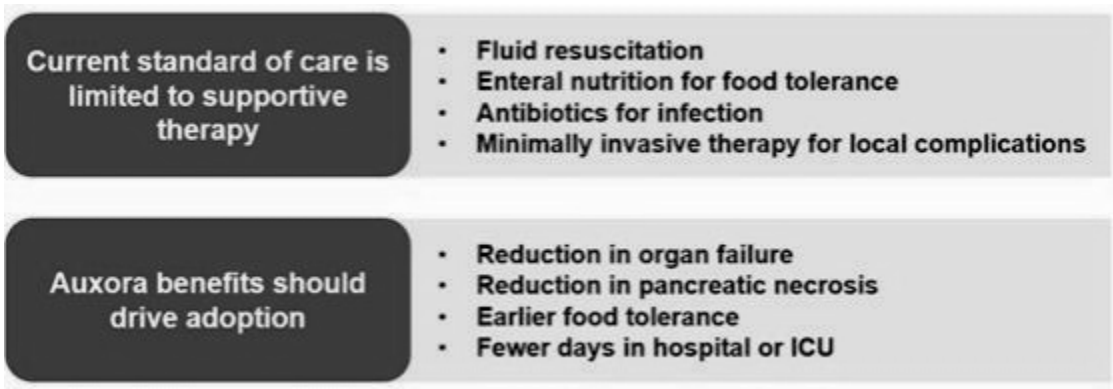
Study 1 results showing greater recovery of GFR in Auxora treated rats versus placebo as well as a reduction on mononuclear (Th17 producing cells.



Study 2 results show the effects of Auxora on recovery of renal function after establishment of renal functional impairment. GFR is shown at two hours and 72 hours post I/R. Panel A: results from rats with initial loss of GFR of approximately 50% between two to four hours post I/R show that the recovery of GFR is greater in Auxora treated animals (n=5) compared to placebo (n=4). Panel B: results from rats with an initial loss of GFR ≥ 66% show that placebo-treated rats (n=3) did not survive while Auxora-treated rats (n=2) survived.

Auxora for the Treatment of Acute Pancreatitis

We have conducted two Phase 2 clinical trials of Auxora in AP. In a Phase 2a clinical trial of Auxora in AP patients with SIRS along with hypoxemia predicted to have moderate or severe AP, Auxora treatment was associated with reduced local and systemic inflammation, improved ability to tolerate solid food, and shorter hospital stays. In CARPO, the medium and high doses of Auxora both showed a 100% relative risk reduction compared to placebo in new-onset severe respiratory failure. This effect was statistically significant for the high and medium dose arms individually ($p<0.05$) and for the combined high and medium doses of Auxora patients compared with the combined placebo and low dose of Auxora patients ($p=0.0027$). We have received Fast Track designation from the FDA and orphan drug designation in the EU from the EMA for Auxora for the treatment of AP. However, there is no guarantee that Fast Track designation will result in a faster regulatory review or regulatory approval. We plan to hold an End-of-Phase 2 meeting with the FDA around the middle of 2025 and expect to be in a position to initiate a Phase 3 program in AP and accompanying SIRS around the end of 2025 pending additional funding.

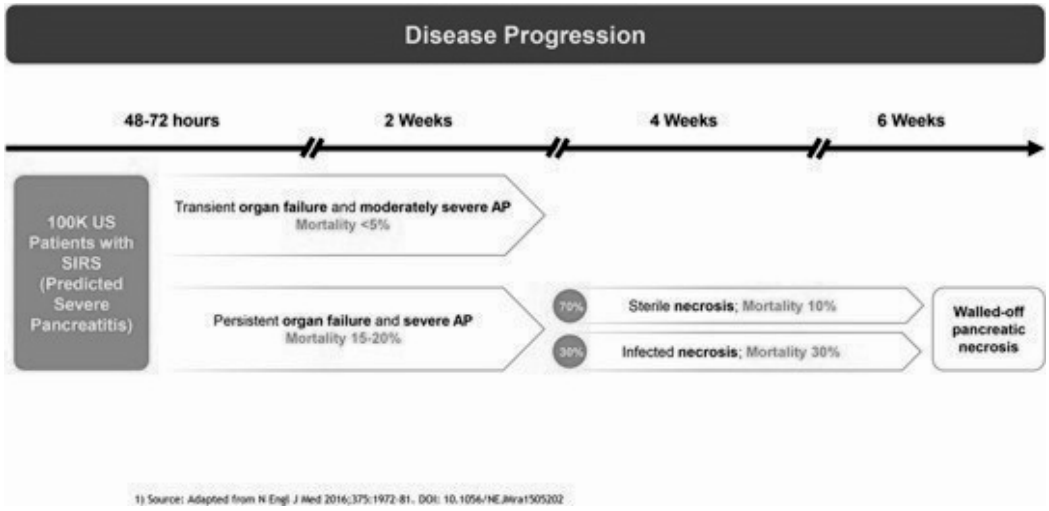


Treatment with Auxora could offer significant benefits to AP patients and prevent disease progression.

Acute Pancreatitis Background

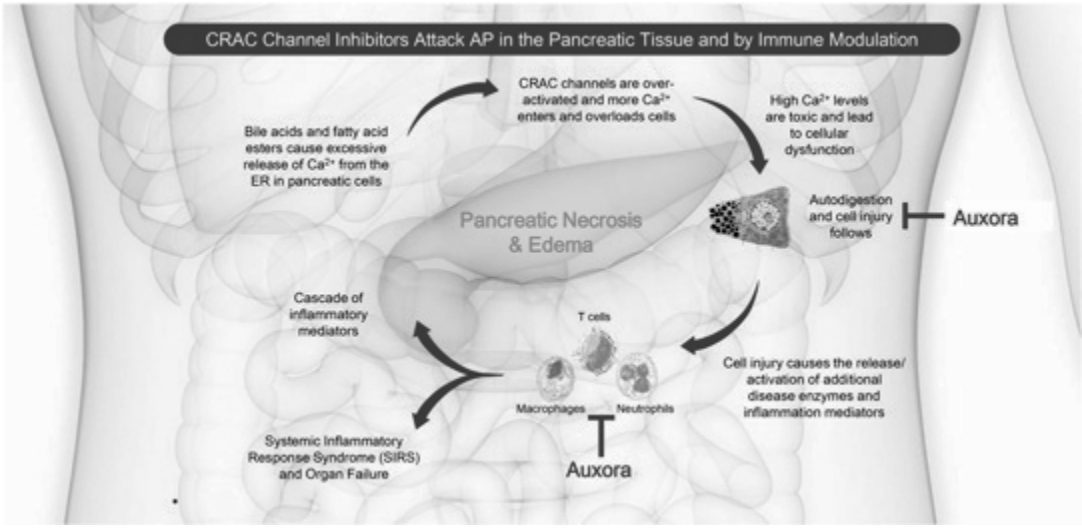
Acute pancreatitis is an acute inflammatory process of the pancreas that presents as severe upper abdominal pain, often accompanied by nausea and vomiting. During episodes of the disease, inflammation of the pancreas occurs, which can lead to pancreatic cell death or necrosis and systemic inflammation. Normal pancreatic functions, such as the secretion of digestive enzymes required to break down carbohydrates and fats, are disabled. There are no approved therapies for AP but most cases are mild and resolved after several days of supportive care, including avoiding oral feeding in the short term to not further aggravate the pancreas. Most patients are hospitalized and require IV fluids and monitoring for development of more severe symptoms.

Severe complications arise because of the acute inflammatory response that takes place in the pancreas. These complications can lead to SIRS, in which the function of other tissues or organs, including the lung, may be compromised. Approximately one third of patients with severe AP develop acute lung injury or ARDS. Lung failure accounts for approximately 60% of deaths associated with AP in developed countries.



There are an estimated 300,000 hospitalizations for AP annually in the United States. Mortality in mild AP is less than 1% but climbs to 20-30% in patients with persistent, severe disease. Approximately 40% of hospitalized AP patients present with SIRS and are predicted to have moderate or severe disease, with 15% actually developing severe AP. The target population for Auxora in our ongoing Phase 2b clinical trial is AP patients with accompanying SIRS, which we estimate to be approximately 100,000 patients per year in the United States alone.

Leading causes of AP are gallstones and resulting elevated levels of bile salts, and alcohol metabolites, together accounting for 60-80% of all cases depending on the specific population examined. Other causes include: hypertriglyceridemia, familial (genetic) types, hypercalcemia, abdominal injury or trauma (including endoscopic retrograde cholangiopancreatography), cancer, drug-induced, or autoimmune, each making up smaller slices of the total AP population. These different causes all appear to lead to a common mechanism in which calcium within pancreatic cells drives pathology.



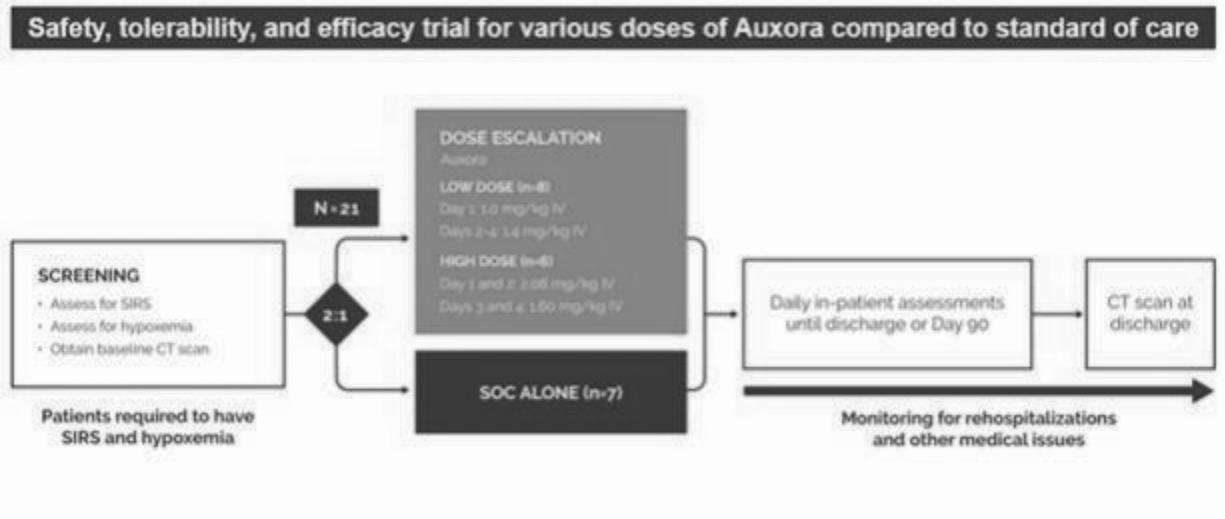
Inhibition of CRAC channels has the potential to impact multiple pathologies associated with AP.

Excessive signaling through calcium-dependent pathways has been linked to multiple pathologies associated with AP. A primary function of the pancreas is to produce enzymes that are required to digest food. The secretion of these enzymes from the pancreas is dependent on the periodic release of calcium from internal stores in cells called the pancreatic acinar cells. In AP, aberrant activation of these cells results in elevated, toxic levels of intracellular calcium and, as a consequence, the inappropriate activation of digestive enzymes inside the cells causes the acinar cells to self-digest.

Acute pancreatitis is also associated with a high level of inflammation. In some patients, the release of inflammatory cytokines and the triggering of SIRS can lead to life-threatening distal organ failure. Previous studies have established a strong link between calcium signaling and the release of inflammatory cytokines. The most frequent systemic complications in severe cases of AP are respiratory dysfunctions ranging from hypoxemia to ARDS. As in the case with ARDS from other underlying causes, AP-associated ARDS is the result of both increased vascular permeability and an increase in inflammation, which we believe are CRAC channel-dependent processes.

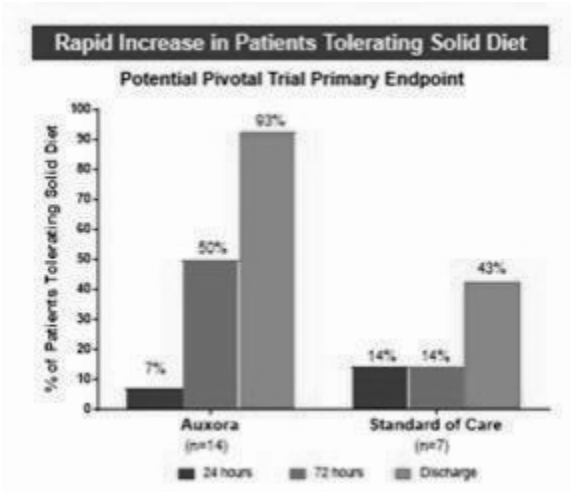
Complete Phase 2a Clinical Trial in Acute Pancreatitis

We completed a Phase 2a clinical trial of Auxora in 21 patients with AP with predicted severe or moderately severe disease as determined by the presence of SIRS and hypoxemia. Patients were enrolled in two cohorts. Fourteen patients received Auxora plus SOC and seven received SOC only. The Auxora- treated patients received a daily IV dose of Auxora for up to four days. As an early-stage proof of concept trial, this trial was not powered for statistical significance for any of the endpoints.



Trial design for Auxora AP Phase 2a clinical trial.

The primary symptom associated with AP is severe upper abdominal pain. Patients with AP are unable to tolerate any solid food without an increase in pain or the occurrence of nausea or vomiting until the pancreatitis resolves. In this clinical trial, only one patient in the Auxora-treated group and one patient in the SOC group were tolerating solid food at study entry. After 72 hours, seven of 14 Auxora patients were tolerating solid food while only one of seven SOC patients was tolerating solid food. At the time of hospital discharge, 13 of 14 Auxora patients could tolerate solid food compared to three of seven SOC patients.



Acute pancreatitis patients treated with Auxora were able to tolerate food sooner than matched controls.

Auxora was generally well-tolerated in the trial. Treatment-emergent adverse events ("TEAEs") were reported in 12 (86%) patients receiving Auxora and four (43%) patients receiving SOC alone. The majority of adverse events ("AEs") in patients treated with Auxora were mild and considered resolved or resolving at the end of the trial. Severe TEAEs occurred in two patients (14%) receiving Auxora and two patients (29%) receiving SOC alone. Three patients (21%) treated with Auxora and two patients (29%) treated with SOC alone developed serious adverse events ("SAEs"). One death occurred in the Auxora treatment arm which was attributed to abdominal compartment syndrome and multi-organ failure. None of the AEs were deemed to be Auxora-related by the principal investigators. A summary of AEs reported in two or more patients receiving Auxora is listed below.

Total Number of Patients Receiving Auxora	n=14	
Number of Patients (%) Reporting ≥1 treatment-emergent event	n	%
Hypokalemia (low potassium levels in the blood)	2	14
Headache	2	14
Malnutrition	2	14
Confusional State	2	14
Acute Respiratory Distress Syndrome	2	14

Summary of Adverse Events Reported by Two or More Patients Receiving Auxora.

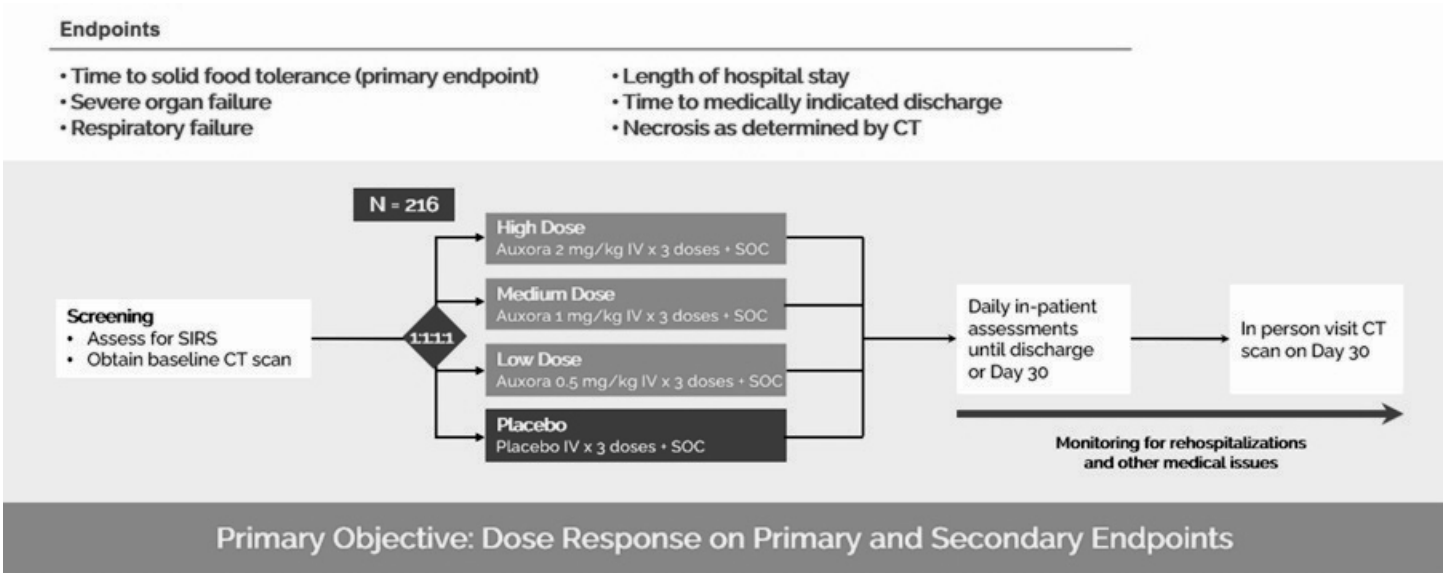
The following SAEs occurred in patients treated with Auxora: death, non-infective cystitis, acute pancreatitis, sepsis, ARDS, hypoxic-ischemic encephalopathy (a type of brain dysfunction), pneumonia, respiratory failure and pulseless electrical activity. None of the SAEs were deemed to be Auxora-related by the principal investigators.

CARPO: Completed Phase 2b Clinical Trial in Acute Pancreatitis

We completed CARPO, a randomized, double-blind placebo-controlled Phase 2b clinical trial in patients with AP and accompanying SIRS. This was a randomized, double-blind, placebo-controlled trial examining three dose levels of Auxora versus placebo. The clinical trial randomized patients 1:1:1:1 into one of four cohorts: high dose (2.0 mg/kg), medium dose (1.0 mg/kg), low dose (0.5 mg/kg), and matching placebo. Study drug was given intravenously over four hours once daily for three consecutive days. The primary objective of CARPO was to determine the optimal dosing regimen of Auxora that would effectively reduce the severity of AP and improve clinical outcomes. Secondary objectives included assessing the safety and tolerability of the varying doses of Auxora. The primary endpoint for determination of a dose response was time to solid food tolerance. The secondary endpoint for the determination

of a dose response was the development of severe respiratory failure. Additional endpoints that were evaluated with the purpose of constructing a composite endpoint for a future Phase 3 trial included time to severe organ failure, medically indicated discharge, length of hospital stay, and the development of necrotizing pancreatitis, defined as pancreatic or extra-pancreatic necrosis. Time to solid food tolerance was defined as the time from the start of the first infusion of study drug to the time when the patient was able to eat ≥ 50% of a low fat, ≥ 500-calorie solid meal without an increase in abdominal pain or vomiting in the two hours after that meal and all subsequent meals while hospitalized. Severe respiratory failure was defined as respiratory failure that required the use of IMV or the use for ≥ 48 hours use of either high flow nasal cannula (HFNC) or non-invasive mechanical ventilation ("NIMV"). Time to medically indicated discharge was defined as the time from the start of the first infusion of study drug to the time where all three of the following criteria were met: the patient tolerated solid food; abdominal pain was controlled or resolved, which was defined by a reduction in pain, as assessed by the PNRS scale, of ≥50% from the peak level in the first 24 hours and no use of opioids; there was no clinical evidence of an infection that required continued hospitalization. A win ratio was calculated for each Auxora dose group compared to placebo using a hierarchical composite of mortality, new onset severe respiratory failure, necrotizing pancreatitis, and time to medically indicated discharge.

216 patients were enrolled into the study in 37 centers. The median (25th %, 75th %) patient age was 43 (34, 57) years and the study groups were balanced with respect to sex, race, ethnicity, median BMI and alcohol consumption.



Trial design for CARPO, Phase 2b clinical trial in AP.

CARPO met its study objective by showing a dose response for time to solid food tolerance as well as other clinical endpoints. The primary endpoint of median time to solid food tolerance in the pre-specified subgroup of patients with hyper-inflammatory acute pancreatitis showed a statistically significant dose response with placebo patients requiring 4.7 days to tolerate solid food and patients in the high dose group showing a 1.9 day improvement (41.0% relative risk reduction) when compared to placebo, the medium dose group a 2.1 day improvement (43.6% relative risk reduction) and the low dose group a 1.5 day improvement (31.0% relative risk reduction). In patients without hyper-inflammatory AP, Auxora did not show a measurable benefit due to the patients tolerating solid food relatively quickly in all treatment groups.

Auxora additionally showed a reduction in severe organ failure. Specifically, new onset severe respiratory failure was reduced by 100% ($p=0.0027$) in the combined medium and high dose patient population when compared to the combined placebo and low dose patient population. Additionally, this effect was statistically significant for the high and medium dose arms individually compared to the placebo arm($p<0.05$). Further, Auxora reduced new onset persistent respiratory failure by 64.2% ($p=0.0476$) when comparing these same patient groups.

Reduced Severe Organ Failure

	Placebo	0.5 mg/kg	1.0 mg/kg	2.0 mg/kg
Respiratory	4/53 (7.5%)	5/52 (9.6%)	2/56 (3.6%)	2/53 (3.8%)
Renal	1/53 (1.9%)	2/52 (3.8%)	1/56 (1.8%)	0/53 (0.0%)
Cardiovascular	1/53 (1.9%)	3/52 (5.8%)	1/56 (1.8%)	1/53 (1.9%)
Any Severe Organ Failure	5/53 (9.4%)	5/52 (9.6%)	2/56 (3.6%)	2/53 (3.8%)

Severe Respiratory Failure: Receiving invasive mechanical ventilation (IMV) OR use of either high flow nasal cannula (HFNC) or non-invasive mechanical ventilation (NIMV) for ≥ 48 hours
Severe Renal Failure: Initiation of renal replacement therapy
Severe Cardiovascular Failure: Use of vasopressor or inotropic support for ≥48 hours

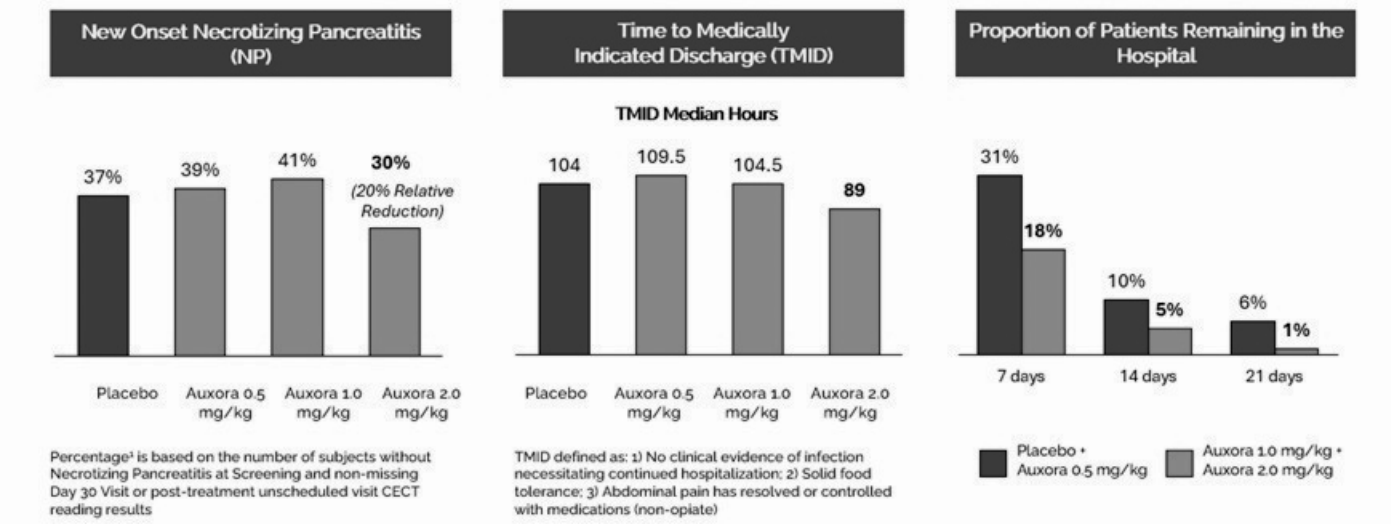
Prevented New Onset Severe Respiratory Failure

	Placebo	0.5 mg/kg	1.0 mg/kg	2.0 mg/kg
New Onset Severe Respiratory Failure	4/47 (8.5%)	4/48 (8.3%)	0/52 (0%)	0/50 (0%)
Difference		-0.2%	-8.5%	-8.5%
Relative Reduction		2%	100%	100%
p-value		NM	<0.05	<0.05

	Placebo + 0.5 mg/kg	1.0 mg/kg + 2.0 mg/kg
New Onset Severe Respiratory Failure	8/95 (8.4%)	0/102 (0%)
Difference		-8.4 %
Relative Reduction		100%
p-value		<0.01

Reduction in Severe Organ Failure and New Onset Severe Respiratory Failure in CARPO.

There was an approximately 20% relative risk reduction for new onset necrotizing pancreatitis for patients in the high dose group compared to placebo patients and these high dose patients also had median time to medically indicated discharge of 15 hours less than placebo patients.



Reduction in Severe Organ Failure and New Onset Severe Respiratory Failure in CARPO.

Finally, a stratified win-ratio analysis of certain key endpoints gave a stratified 1.640 win-ratio benefit (p=0.0372) for the high dose patients compared to placebo patients.

Win Ratio	All-cause Mortality	New Onset Severe Respiratory Failure	Necrotizing Pancreatitis	Time to Medically Indicated Discharge	Total Wins
Placebo wins	0	0	374	546	920
Auxora 2.0 mg/kg dose wins	0	208	615	730	1553

Stratified Win Ratio: 1.640 | p-value: 0.0372 | 95% CI: 1.030 – 2.612

Win-Ratio analysis of key endpoints in CARPO.

As in prior Phase 2 trials, Auxora was well-tolerated. There was a trend of decreasing treatment emergent serious adverse event (TESAE) rates with increasing doses of drug. Additionally, there were no drug-related TESAEs or deaths in patients receiving the high dose of Auxora.

CRSPA: Ongoing Open-Label Phase 1/2 Clinical Trial in AIPT (Pancreatitis as a Side Effect of Pediatric ALL Treatment)

CRSPA is a 24-patient open-label Phase 1/2 investigator-sponsored clinical trial being conducted by St. Jude Children's Research Hospital ("JCRH") and exploring Auxora as a potential therapy in pediatric patients that develop AIPT as a result of treatment for their underlying acute lymphoblastic leukemia ("ALL"). Current therapies for ALL result in long term survival for over 90% of pediatric ALL patients. One of the mainstays of therapy in these patients is asparaginase (e.g., ONCASPAR™ and RYLAYZE™), an enzyme that degrades the amino acid asparagine, which is essential for the leukemic cells to survive. However, the administration of asparaginase triggers the development of pancreatitis or AIPT in 7-10% of patients of the over 3,000 pediatric ALL patients treated per year in the US, with similar numbers in Europe. AIPT is a severe complication characterized by intense abdominal pain, nausea, vomiting and SIRS. AIPT can lead to further chronic problems such as insulin dependence, exocrine pancreatic insufficiency and chronic pain. Many of these children can no longer be treated with asparaginase which can have a negative impact on their recovery from ALL. It has been shown that over 50% of patients with AIPT develop pseudocysts or pancreatic necrosis. There is currently no disease modifying treatment for AIPT and standard of care only addresses the symptoms of the disease.

In CRSPA, pediatric patients suffering from AIPT are enrolled and treated with four daily doses of Auxora with the primary endpoints of safety, tolerability and the reduction in development of complications of AIPT, including necrotizing pancreatitis and SIRS. Investigators at SJCRH presented results from the first cohort of the CRSPA study at the ASH meeting in December 2023. This cohort of patients consists of nine children (average age 8.2 years) with ALL who have developed AIPT (referred to as AAP in the abstract). Eight of nine patients in the CRSPA study received a full regimen of four daily doses of Auxora at dose level 1 (30mg/m^2 on day one and 42mg/m^{2}on days two through four) administered as a four-hour infusion. Results from these patients were compared to a matched historical control group of 16 patients out of a total of 51 patients who developed AIPT within 30 days of receiving asparaginase in the Total Therapy XVI study ("T16") being conducted at SJCRH. The comparison showed that Auxora reduced the average number of days patients spent in the hospital from 13.4 to 6.3 days. The need for ICU care was also reduced, with three control patients (18.8%) requiring ICU care compared to one treated patient (12.5%), and the average number of days in the ICU was reduced from five to three days. Additionally, no patients in the CRSPA study required TPN, compared to 68.8% in the historical matched control group, who required 27 days of nutritional support on average. Finally, blinded central reading of pancreatic imaging showed a reduction in the development of significant pancreatic necrosis (≥30%) and the severity of acute pancreatitis by computed tomography severity index ("CTSI") scoring in patients treated with Auxora compared to the matched historical cohort. Based on these results, investigators have established the dose level used in this cohort as the recommended Phase 2 dose ("RP2D") of Auxora for children with ALL experiencing AIPT and will continue to enroll an additional 15 patients at this dose level to reach full enrollment at 24 patients. CRSPA has expanded to additional sites and is over 50% enrolled, and we expect to provide an update in the second half of 2025.

	Total 16 (T16): All AIPT	**Matched T16 AIPT cohort**	**CRSPA evaluable for efficacy**
Patients with AIPT	51	16	8
Age: mean (range)	10.3 (2.2-19.4)	9 (2.2-18.4)	8.2 (3.1-17.6)
Female (%)	17 (33.3%)	5 (31.3%)	3 (37.5%)
Low-risk therapy (%)	9 (17.6%)	1 (6.3%)	2 (25%)
Hospital days (range)	12.1 (2-70)	13.4 (2-27)	6.3 (5-8)
ICU needed (%)	11 (21.6%)	3 (18.8%)	1 (12.5%)

ICU days mean (range)	5.1 (1-9)	5 (3-7)	3
TPN needed (%)	27 (52.9%)	11 (68.8%)	0
TPN days mean (range)	37.7 (3-153)	27.2 (4-63)	NA
≥30% pancreatic necrosis (%)	NA	4 (26.7%) *	0
CTSI mean (range)	NA	5.4 (0-10) *	2.4 (0-4)
CTSI ≥ 7 (%)	NA	4 (26.7%) *	0

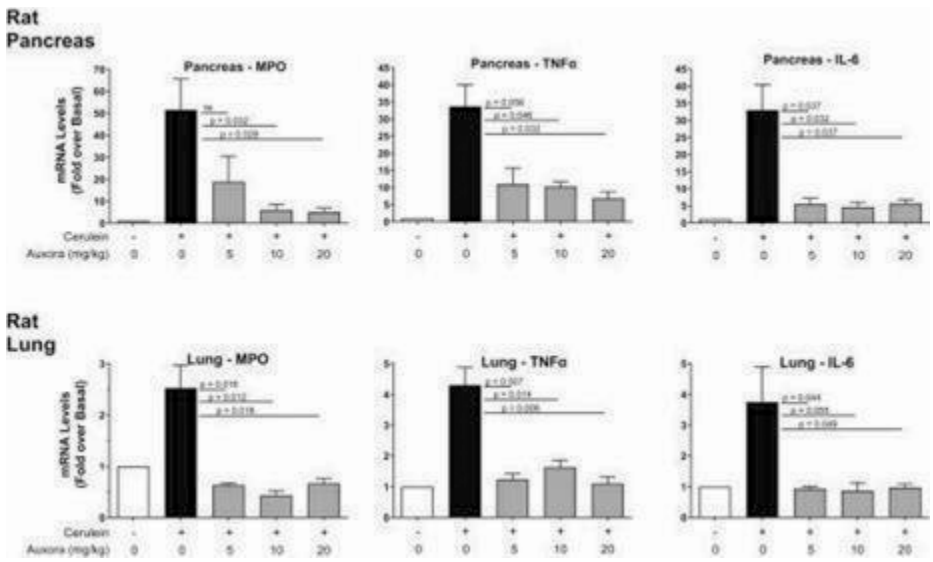
*One patient in matched T16 cohort was unable to be evaluated for pancreatic necrosis or a CTSI score.

CTSI score definitions:
0-3 mild acute pancreatitis
4-6 moderately severe acute pancreatitis
≥7 severe acute pancreatitis

According to clinical data published by Mauney, et. al., in the Journal of Pediatric Gastroenterology and Nutrition in March 2022, patients who developed AIPT had a median length of stay in the hospital of ten days consistent with that seen in the T16 database which is greater than the six day median length of stay for patients treated with Auxora, reflecting a faster resolution of symptoms.

Preclinical Studies with Auxora in AP

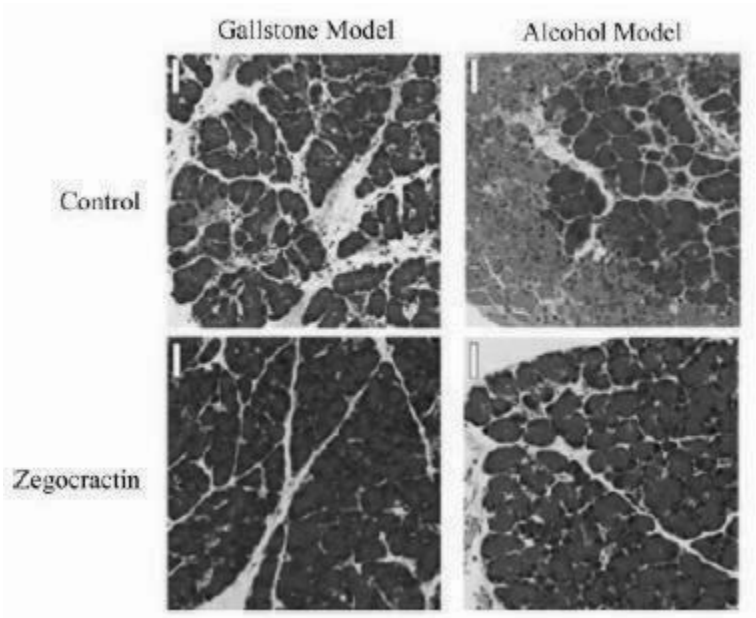
Treatment with Auxora led to a decrease in inflammatory markers in both the pancreas and the lung in a cerulein-induced rat model of AP. In this AP model, rats were given four hourly intraperitoneal injections of cerulein to induce pancreatitis and Auxora was given in a therapeutic mode by a four-hour intravenous infusion, starting 30 minutes after the first cerulein injection. Animals were examined 30 minutes after the end of infusion. Cerulein overstimulates pancreatic acinar cells, causing overactivation of CRAC channels, premature activation of digestive enzymes, mitochondrial dysfunction and death of the acinar cells, as well as enhanced accumulation of cytokines. Auxora administered post-insult decreased the acinar cell damage (50% as measured by histopathology) and decreased mRNA transcript levels (measured by quantitative real-time polymerase chain reaction) of myeloperoxidase ("MPO") (80-90%) a biomarker of neutrophil activation, and the inflammatory cytokines TNFα (80-90%), and IL-6 (80-90%) in the pancreas. Similar to AP in patients, inflammatory signals in the cerulein model are also observed in the lungs. The anti-inflammatory effects of Auxora in the pancreas were mirrored in lung tissue.



Auxora inhibited the expression of MPO, TNFα and IL-6 in the cerulein-induced acute pancreatitis model in both the pancreas and lung. These results have been published in The Journal of Physiology.

Consistent with the data described above, treatment with the active ingredient in Auxora, zegocractin, decreased pancreatic damage in two other models of AP in mice, gallstone and alcohol models. AP in a gallstone model was elicited by retrograde pancreatic ductal injection of a bile acid and in the alcohol model by intraperitoneal injections of a fatty acid and ethanol. Both bile acids and fatty acids + ethanol induce AP by overactivation of CRAC channels. Zegocractin was given by intraperitoneal injection in a therapeutic mode at one and 13 hours after disease induction and animals were examined 24 hours after disease induction. Under these conditions,

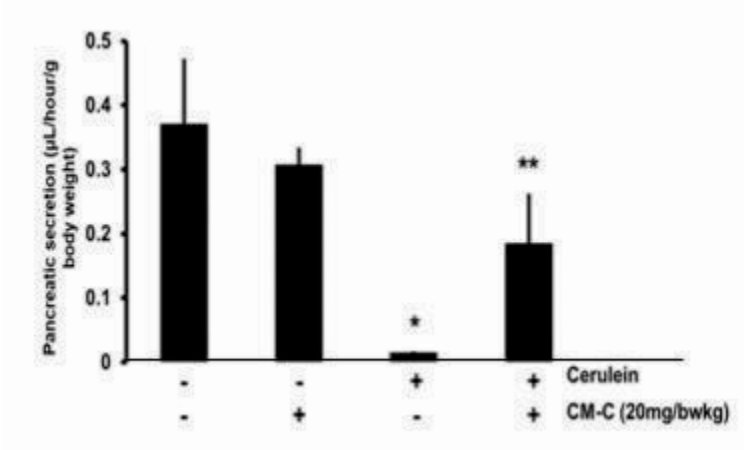
zegocractin decreased the amount of inflammation, edema and acinar cell damage (each close to 50% as measured by histopathology; see the figure below).



Zegocractin decreases pancreatic damage in two models of AP in mice. Shown are histology photomicrographs of the pancreas. The top panels are examples from control animals in both the gallstone (left) and alcohol (right) models showing the presence of inflammatory cells (small dark dots), edema (white areas) and acinar cell necrosis (light red). Bottom panels are from animals treated with Zegocractin, showing reduced inflammation, edema and necrosis. White bars = 50 m.

The ability of the pancreas to secrete digestive enzymes, fluid and bicarbonate is critical for the ability to digest food. Various toxins, including an alcohol metabolite, fatty acid ethyl ester, or bile acids can cause the premature activation of these digestive enzymes within the pancreas, leading to self-digestion and pancreatic cell death. One of the primary treatments for AP has been to completely stop all orally administered food for several days. A sign of the resolution of a case of AP is the ability to tolerate food, requiring functioning pancreatic ductal cells and appropriate secretion of digestive enzymes, fluid and bicarbonate. Thus, restoration of pancreatic ductal cell secretion is thought to be a critical element in the treatment of AP.

CRAC channel inhibition preserved pancreatic ductal fluid secretion in the cerulein-induced AP model in mice as well as in gallstone and alcohol models of AP. The mouse cerulein-induced AP model was performed like the rat model described above, except that seven hourly injections of cerulein were used and animals were examined 12 hours after the first cerulein injection. AP in the gallstone model was elicited by retrograde pancreatic ductal injection of a bile acid and in the alcohol model by intraperitoneal injections of a fatty acid and ethanol. Pancreatic fluid secretion was measured by collection of pancreatic juice from the pancreatic duct over a 30 minute period. In all three models, CM5480, a preclinical CRAC channel inhibitor model compound, given by intraperitoneal injection after disease onset was able to preserve pancreatic ductal fluid flow, suggesting that CRAC channel inhibition may have a direct protective effect on ductal cells that could help resolve AP.



CM5480 (CM-C) treatment led to the preservation of pancreatic ductal secretion in a cerulein-induced acute pancreatitis model.

Auxora for the Treatment of Acute Respiratory Failure

The pathology of COVID-19 is consistent with both a significant increase in the levels of inflammatory cytokines and with the associated deterioration of lung barrier function that can culminate in ARDS. In the first quarter of 2020, we recognized that observations from our clinical trial of Auxora in patients with AP provided support for conducting a clinical trial to assess the potential of Auxora in severe COVID-19 pneumonia patients. In AP patients presenting with markedly elevated levels of IL-6, there was a significant reduction in IL-6 levels over the course of therapy in patients who were treated with Auxora versus SOC alone. Of the four AP patients enrolled in our Phase 2a clinical trial who presented with respiratory failure and were treated with Auxora, only one required intubation and mechanical ventilation. There was only one patient in the SOC control group with respiratory failure and this patient required intubation and mechanical ventilation. This preliminary data and the strong preclinical rationale both led us to propose that Auxora may have therapeutic benefit in the treatment of other diseases with respiratory failure, including severe COVID-19 pneumonia.

In April 2020, we initiated a clinical trial to test Auxora in COVID-19 patients hospitalized and requiring oxygen therapy but not on ventilators. This trial was initially conducted as a Phase 2 randomized, open-label clinical trial in severe COVID-19 pneumonia patients with varying degrees of respiratory failure where time to survival, blood oxygen levels, ventilator use and mortality were evaluated. At our first safety analysis of the data we observed that patients receiving Auxora with SOC were less likely to be placed on mechanical ventilation or to die, and they experienced a reduced time to recovery than those treated with SOC alone. After 30 patients were enrolled in this first part of the trial (Part 1), the FDA recommended that we move to Part 2 of the trial and study Auxora in a randomized, double-blind, placebo-controlled clinical trial. Part 2 was initiated in September 2020, completed in the third quarter of 2021, and enrolled 284 severe COVID-19 pneumonia patients. We observed that patients treated with Auxora experienced a reduced time to recovery, higher rate of recovery and reduced mortality.

COVID-19 and Acute Respiratory Failure Background

COVID-19 is a disease caused by the SARS-CoV-2 virus, a pandemic strain of coronavirus. Respiratory illness is the most common symptom associated with COVID-19; severity ranges from mild disease to life-threatening ARDS.

Most cases of COVID-19 occur approximately four to five days after exposure to the virus. Patients present with symptoms that include fever, dry cough, body ache, sore throat and diarrhea. As the disease progresses, some patients develop shortness of breath resulting from lung injury and are hospitalized. In the majority of these patients, this condition resolves over time, but in up to 20% of patients, it progresses to moderate to severe ARDS requiring mechanical ventilation.

Disease progression in severe COVID-19 has similarities to that of severe community-acquired pneumonia caused by other viruses besides SARS-CoV-2 or by bacteria. The immune response to severe COVID-19 infection may result in overproduction of early response proinflammatory cytokines and may also result in complement and coagulation dysfunction, leading to an increased risk of vascular hyperpermeability, respiratory failure, multi-organ failure, and sometimes death.

Completed Phase 2 Clinical Trial in Hospitalized COVID-19 Severe Pneumonia Patients on Oxygen (CARDEA)

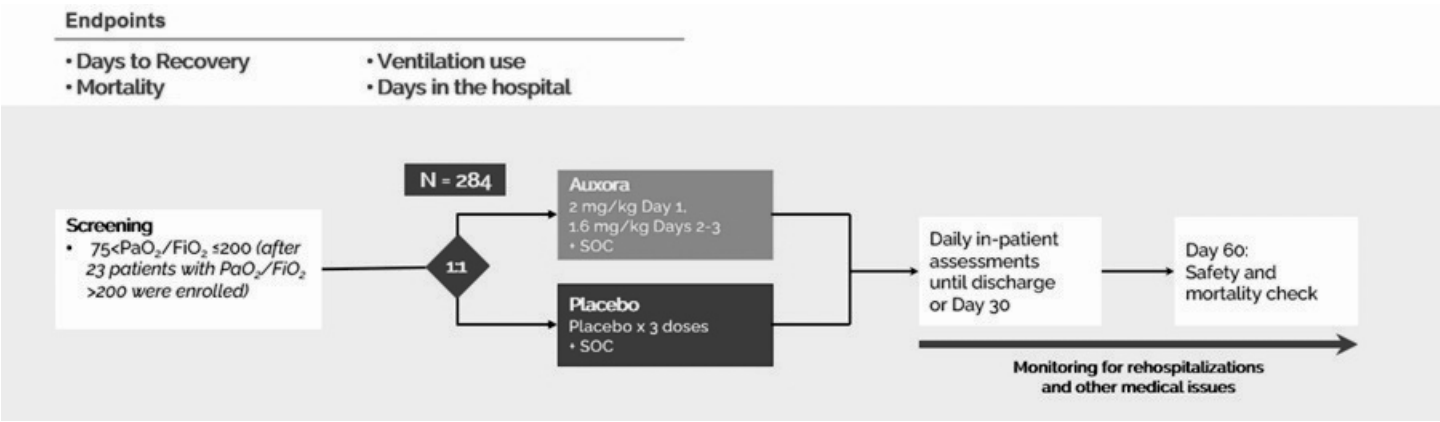
In September 2020, we began enrollment of our CARDEA trial, a Phase 2, randomized, double-blind, placebo- controlled trial evaluating the addition of Auxora to corticosteroids and standard of care in adults with severe COVID-19 pneumonia. Eligible patients were adults with more than one symptom consistent with COVID-19 infection, a diagnosis of COVID-19 confirmed by laboratory testing using polymerase chain reaction or other assay, and pneumonia documented by chest imaging. Patients were also required to be receiving oxygen therapy using either a high flow or low flow nasal cannula at the time of enrollment and, for the 261 patients in the efficacy analysis set, to have at the time of enrollment, a baseline imputed PaO_2/FiO_2 ratio > 75 and ≤ 200.

There were an additional 23 patients in the trial with 200<PaO2/FiO2<300 who were enrolled prior to the first independent data monitoring committee meeting, where it was determined those less hypoxemic patients all recovered and were less likely to need therapy beyond current standard of care so going forward, mild ARDS patients, e.g., patients with PaO_2/FiO_2>200, were then excluded from enrollment. The PaO_2/FiO_2 was imputed from a SpO_2/FiO_2 determined by pulse oximetry using a non-linear equation. Patients could not be receiving either non-invasive or invasive mechanical ventilation at the time of enrolment. The primary endpoint was time to recovery through Day 60, with secondary endpoints of all-cause mortality at Day 30 and Day 60. All patients received corticosteroids and 99% of patients received anticoagulation treatment as part of their standard of care.

The major findings of the CARDEA Phase 2 trial as reported in April 2022 in the peer-reviewed journal *Critical Care* are as follows:

- Time to recovery was seven vs. ten days (P = 0.0979) for patients who received Auxora vs. placebo, respectively.
- Day 30 all-cause mortality was 7.7% with Auxora vs. 17.6%, with placebo (P = 0.0165).

- Day 60 all-cause mortality was 13.8% with Auxora vs. 20.6% with placebo (P = 0.1449).
- Serious adverse events occurred in 24.1% of patients treated with Auxora vs. 35% of patients receiving Placebo (P = 0.0616).



SOC included 100% corticosteroid use and 99% anticoagulation use

Trial design for double-blind Phase 2 clinical trial in hospitalized COVID-19 pneumonia patients on oxygen (Part 2).

	Placebo	Auxora
Number of patients	131	130
Male %	70.2%	64.6%
White %	74.8%	65.4%
Median Age	61	60
Median BMI	31.0	31.1
Median Time from Symptom Onset	12.0 days	11.0 days
% HFNC	62.6%	62.3%
Median Screening PF value	104.0	106.7
PF ≤ 100	44.3%	45.4%
Median CRP	74.0	69.8

Baseline demographics were balanced across the treatment groups in the blinded Phase 2 trial of Auxora in severe COVID-19 pneumonia.

Overall mortality was significantly reduced with Auxora treatment in the 261-patient efficacy dataset. At 30 days, the mortality rate for Auxora-treated patients with 7.7% compared to 17.6% for placebo (HR 0.42 and p=0.023) – a relative decrease of 56%. At 60 days, Auxora treatment was associated with a 13.8% mortality rate compared to 20.6% for placebo (HR 0.63 and p=0.130) – a relative decrease of 33%. Both of these findings are clinically relevant particularly in light of patients needing additional therapies on top of current standard of care. Patients treated with Auxora plus SOC demonstrated a trend toward a faster median time to recovery than those treated with SOC plus placebo. Our primary recovery endpoint was determined in the 261-patient efficacy analysis set where Auxora treatment demonstrated a trend toward a reduced time to recovery with a median of seven days compared to ten days with placebo (p=0.098). In an FDA-required supplementary analysis of our primary endpoint in the 284 patient safety analysis set (which included 23 patients with mild COVID-19 pneumonia (P/F 201 to 300)), the median recovery time for Auxora treated patients was maintained at seven days, while the median recovery time for placebo treated patients decreased to eight days (p=0.042). In both analysis sets, the percent of patients that recovered in the trial was higher when Auxora was added to SOC therapy. The recovery rate ratio, defined as the percent of patients who did not recover on placebo compared to the percent that did not recover with Auxora, was 1.25 for the efficacy analysis set and 1.30 for the safety analysis set. This means that not only did patients treated with Auxora plus SOC demonstrate a trend toward a reduced time to recovery, but that they were more likely to recover than patients treated with placebo plus SOC.

Other key findings in the study were that patients receiving Auxora saw their PaO2/FiO2 ratios recover more quickly than patients receiving placebo and proportionally fewer patients receiving Auxora required ventilation over their course of treatment than patients receiving placebo. There were also fewer patients with reported serious adverse events in the Auxora treated group than in those receiving placebo. These findings are all clinically relevant, particularly given the relative risk reduction in mortality for patients

receiving Auxora in addition to standard of care. Finally, there were improvements in a number of inflammatory biomarkers in Auxora treated patients versus those receiving placebo. Specifically, C-reactive protein, ferritin and d-dimer levels dropped over the course of six days and were lower than placebo over that time. CD-25 levels, which are a surrogate for the expansion of pro-inflammatory CD25+CD8 T cells that have been associated with mortality, were statistically significantly lower in Auxora patients compared to placebo.

Improvement in Median 24-hour P/F Ratio from Baseline

Patients	% Increase on Day 3	% Increase on Day 7
Placebo	40%	70%
Auxora-treated	58%	105%
Treatment effect	Up to 50% greater improvement (p<0.01 on day 7)	

Ventilator use in Patients at Day 60

Patients	# of Ventilated Pts	% Pt
Placebo	36	27.5%
Auxora-treated	24	18.5%
Treatment effect	33% relative risk reduction (p=0.18)	

Serious Adverse Events

Patients	# Adverse Events	% Pt
Placebo	101	35%
Auxora-treated	75	24%
Treatment effect	30% relative risk reduction (p=0.0618)	

Time to Recovery and Length of Hospital Stay

Patients	Time to Recovery	Median Hospital Stay
Placebo	10 days	11 days
Auxora-treated	7 days	8.5 days
Treatment effect	3 days (p=0.09)	> 2 days

Auxora positive effects compared to placebo on multiple clinical endpoints in CARDEA (N=261)

CD-25 (sIL-2R)

Measurement	Placebo Patients	Auxora Patients
Mean Reduction from Baseline	75	300
Treatment effect: Statistically significant reduction for Auxora (p=0.0375) versus smaller not ss reduction for Placebo.		

CD-25 is a surrogate for the expansion of pro-inflammatory $CD25^+CD^8$ T cells which have been associated with mortality (Xie, M., et al. (2021). *Clinical & translational immunology*, 10(2), e1251).

C-Reactive Protein (CRP)

Measurement	Placebo Patients	Auxora Patients
Mean Baseline Value	92.57	94.57
Mean Day 3 Value	47.94	49.07
Mean Day 6 Value	57.66	31.69
Treatment effect: Continued effect through day 6 with 66% decrease for Auxora versus 48% for Placebo		

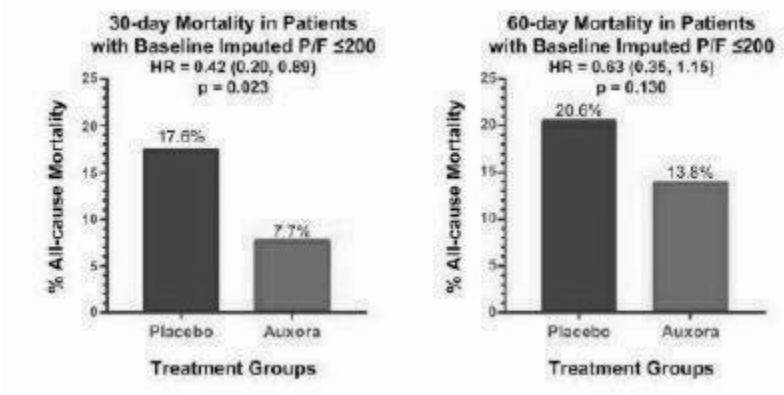
Ferritin

Measurement	Placebo Patients	Auxora Patients
Mean Baseline Value	1032.85	1000.51
Mean Day 3 Value	795.92	731.53
Mean Day 6 Value	783.15	616.86
Treatment effect: Continued effect through day 6 with 38% decrease for Auxora versus leveling off at 24% for Placebo		

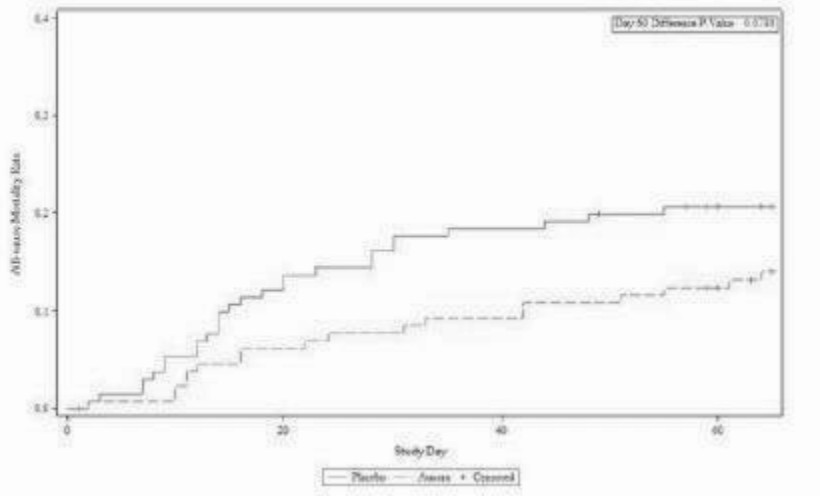
D-dimer

Measurement	Placebo Patients	Auxora Patients
Mean Baseline Value	1.98	2.45
Mean Day 3 Value	2.02	1.54
Mean Day 6 Value	2.67	1.67
Treatment effect: 32% decrease maintained through day 6 for Auxora versus increases for Placebo		

Auxora positive effects compared to placebo on multiple biomarkers of respiratory inflammation in CARDEA (N=261)



Auxora plus SOC demonstrated a significant decrease in mortality compared to placebo plus SOC. (N=261)



Kaplan Meier curve of mortality. Auxora plus SOC (blue), placebo plus SOC (red). (N=261)

Auxora was generally well-tolerated in our CARDEA trial. The number of adverse events in the blinded part of the study was similar between the two treatment groups (patients randomized to Auxora (331); patients randomized to placebo (342)). Fewer patients randomized to Auxora (34, 24.1%) had SAEs compared to patients randomized to Placebo (49, 35.0%). There were five SAEs that the investigators reported as possibly related to Auxora: increase in alanine aminotransferase (an indicator of liver dysfunction), increase in aspartate aminotransferase (an indicator of liver dysfunction), cardiac arrest, respiratory failure and shock. Two of these (increase in alanine aminotransferase and increase in aspartate aminotransferase) occurred in only two patients. There were no SAEs that required expedited safety reporting to institutional review boards or to the FDA. Three patients randomized to Auxora and five patients randomized to placebo discontinued study drug.

Planning for Additional Clinical Trials in AHRF and ARDS

Based on the mechanism of action of Auxora and the reduction in ventilator use that was observed in our COVID-19 pneumonia and AP clinical trials, we believe that Auxora has the potential to bring therapeutic benefit to a broader population of patients suffering from AHRF and ARDS. Our recent work elucidating the activity of Auxora in an LPS-induced mouse model of respiratory failure confirmed that the drug down-regulates inflammatory cytokines in the lungs and likely protects the lung endothelium from damage.

The broader ARDS patient populations include many etiologies including sepsis, viral pneumonia, bacterial pneumonia and trauma. The incidence of ARDS is estimated to be approximately 190,000 cases per year in the United States alone, with sepsis being the most common cause. We believe that the Auxora clinical data in COVID-19 pneumonia suggests that Auxora can potentially be used in most ARDS settings. We are currently evaluating opportunities to continue clinical development of Auxora in the setting of acute respiratory failure particularly in partnership with sponsors such as government agencies both in the US and outside of the US.

Preclinical studies for Chronic Inflammatory and Immunological Diseases

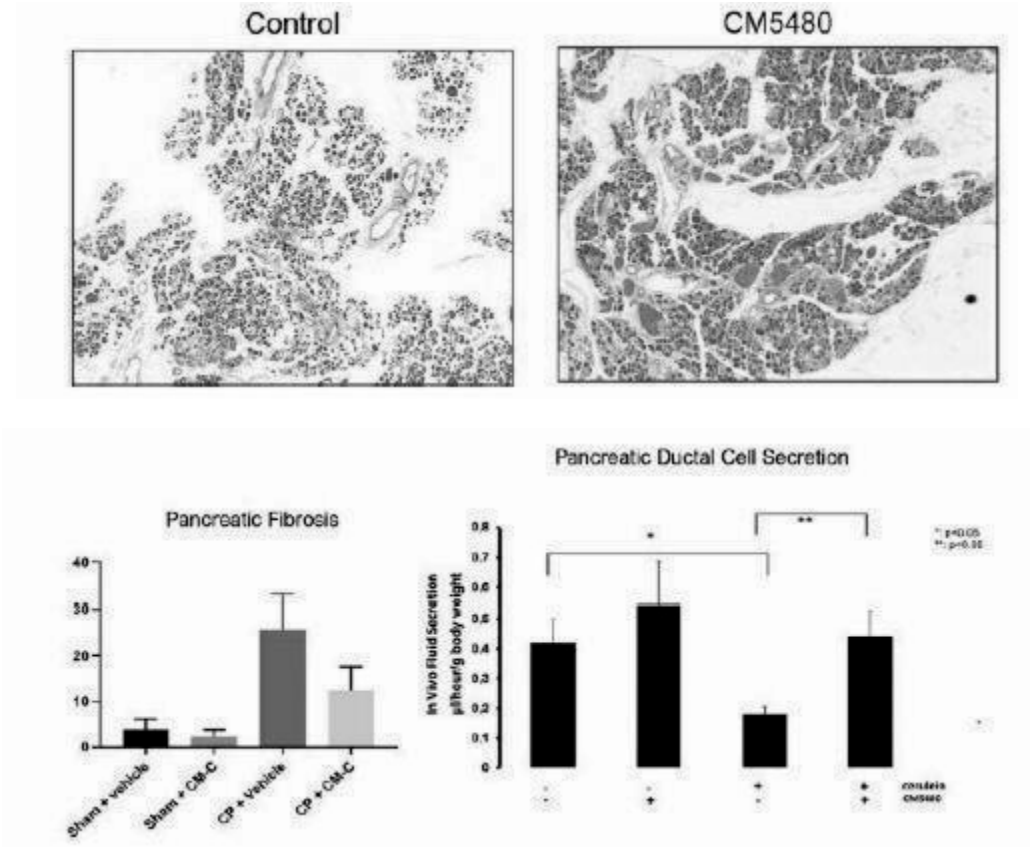
We are developing oral CRAC channel inhibitors that we intend to take into indications which are not treated in a critical care setting such as chronic inflammatory and immunological diseases. We have obtained or generated preclinical data that support the use of CRAC channel inhibitors in indications such as chronic pancreatitis, rheumatoid arthritis, asthma and psoriasis where an IV formulation would not represent a viable therapeutic approach. Repeated attacks of AP, as well as heavy alcohol use and genetic anomalies, can lead to the development of chronic pancreatitis, a debilitating disease characterized by pain, fibrosis and declining pancreatic function that increases the risk of developing pancreatic cancer by a factor of ten to 100. According to the Pancreatitis Foundation, approximately 140,000 people suffer from chronic pancreatitis in the United States alone. We believe this will be considered an orphan indication and intend to apply for orphan designation with the FDA. While there are numerous treatments for rheumatoid arthritis, most patients require injectable immunomodulatory drugs as the disease progresses. The need for safe oral therapies for more advanced patients persists. We are evaluating chronic pancreatitis and rheumatoid arthritis as potential first indications for our potential oral drug candidates.

Preclinical Study with a CRAC Channel Inhibitor in Chronic Pancreatitis

Our preclinical studies of CM5480, a proprietary compound, in chronic pancreatitis suggest that CRAC channel inhibition may decrease fibrosis and organ dysfunction in this setting. We have performed certain IND-enabling preclinical studies with multiple

proprietary compounds in order to identify one or more candidates with good pharmaceutical properties. CM6336, one such oral CRAC channel inhibitor in our pipeline, is structurally distinct from CM5480 but with potentially improved pharmacokinetic properties.

We tested CM5480 in a mouse model of chronic pancreatitis, in which animals are given eight hourly injections of cerulein per day on five occasions, each separated by two intervening cerulein-free days. CM5480, a model compound, was given by once-daily intraperitoneal injections for nine days starting after the third round of cerulein injections. The cerulein injections produced pancreatic fibrosis and reductions in pancreatic epithelial (mostly acinar) cells and ductal cell secretion. We found that CM5480 reduced pancreatic fibrosis by 50%, modestly increased epithelial cells, and restored pancreatic ductal cell secretion. These results suggest that there is the potential to treat chronic pancreatitis with a CRAC channel inhibitor, especially one that can be readily administered to patients, such as with an oral formulation.

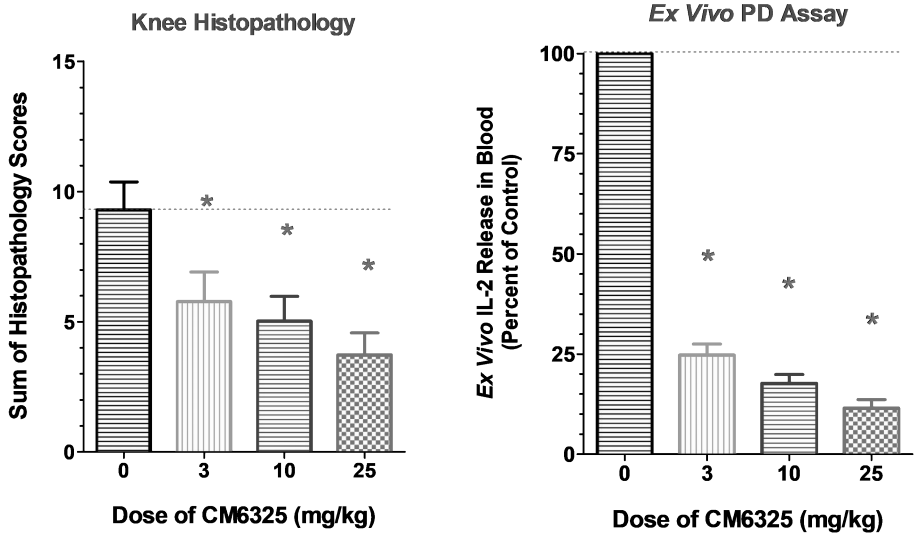


CM5480 (CM-C) reduced acinar cell necrosis (top panels), prevented the formation of fibrosis (bottom left) and restored pancreatic ductal secretion (bottom right) in a mouse model of chronic pancreatitis.

Preclinical Studies with CRAC Channel Inhibitors in Models of Rheumatoid Arthritis

Previous work by us and others has indicated that inhibition of Orai1 CRAC channels may be an effective treatment for rheumatoid arthritis. A 2015 study published in the *British Journal of Pharmacology* examined the effects of YM-58483 (aka BTP-2), a model CRAC channel blocker, and showed that the compound produced significant improvements in arthritis severity scores in a mouse model of collagen-induced arthritis ("CIA"). Likewise, a 2017 published study in the *Journal of Pharmacological Sciences* showed that localized reduction of Orai1 mRNA in the joints and lymph nodes reduced the severity of arthritis in a mouse CIA model.

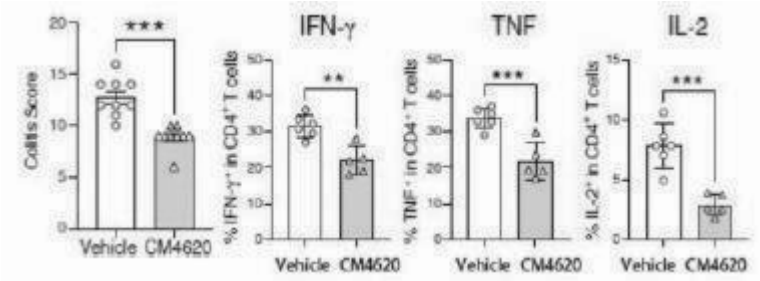
Consistent with the findings above, in our preclinical studies we have demonstrated that several of our Orai1-selective CRAC channel blockers are efficacious at reducing histopathology in a rat model of CIA. Thus, zegocractin (CM4620) and model compounds CM5480 and CM6325 when dosed orally once-daily at 25 mg/kg produced significant reductions in knee histopathology that averaged 61%, 76% and 71%, respectively. Data from a representative study with CM6325 is shown below. In this study, the reductions in knee histopathology scores corresponded with reductions in a pharmacodynamic measure of stimulated IL-2 release in an ex vivo blood assay.



*CM6325 produced significant and dose-related reductions in summed knee histopathology scores (composed of measures of inflammation, pannus formation, cartilage damage and bone resorption) in rat model of collagen-induced arthritis. Blood samples taken at the end of the study showed that a pharmacodynamic (PD) readout, stimulated IL-2 release, was also decreased by CM6325 in a significant and dose-related manner. *p < 0.05*

Preclinical Study in Inflammatory Bowel Disease

Recent animal data indicates that CRAC channel inhibition by zegocractin (CM4620) may be effective in the treatment of inflammatory bowel disease, such as ulcerative colitis. In a preclinical study performed with scientists from Charite – University Medicine, Berlin and New York University Grossman School of Medicine, it was shown that zegocractin administered orally to mice every other day for a period of 30 days produced a significant reduction in intestinal inflammation in a model of ulcerative colitis. Consistent with the anti-inflammatory action of zegocractin, reductions in the frequencies of IFN-γ, TNFα and IL-2 producing CD4 T cells were also observed in T cells isolated and stimulated *ex vivo* at the end of the study. These data, published in 2022 in the journal *EMBO Molecular Medicine,* suggest that zegocractin could be effective in treating patients with acute flares of inflammatory bowel disease.

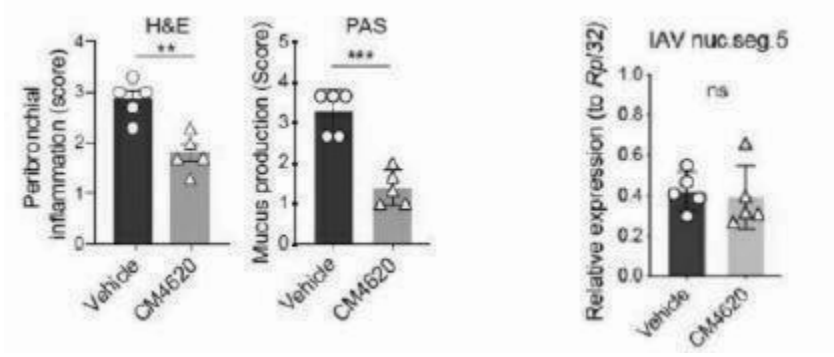


Systemic administration of CM4620 (zegocractin) alleviates colon inflammation in mice. Histological sections of distal and proximal colon were scored for the presence of inflammatory cells (Colitis Score). CD4+ T cells were isolated from animals after treatment with vehicle or CM4620 and stimulated ex vivo with a phorbol ester (PMA) + ionomycin for 4 hours. Frequencies (%) of IFN-γ, TNFα and IL-2 T cells were then determined.

Preclinical Study in Allergic Asthma

The effectiveness of zegocractin (CM4620) was compared in mouse models of asthmatic airway inflammation and influenza A virus infection to determine if inhibition of CRAC channels reduces asthmatic inflammation without interfering with the antiviral response. Researchers from New York University Grossman School of Medicine showed that in a model of allergic airway inflammation oral administration of zegocractin significantly lowered both peribronchiolar inflammation and lung mucus production. Conversely, there was no effect of zegocractin on lung viral load in a model of influenza A virus infection. These results indicate zegocractin may

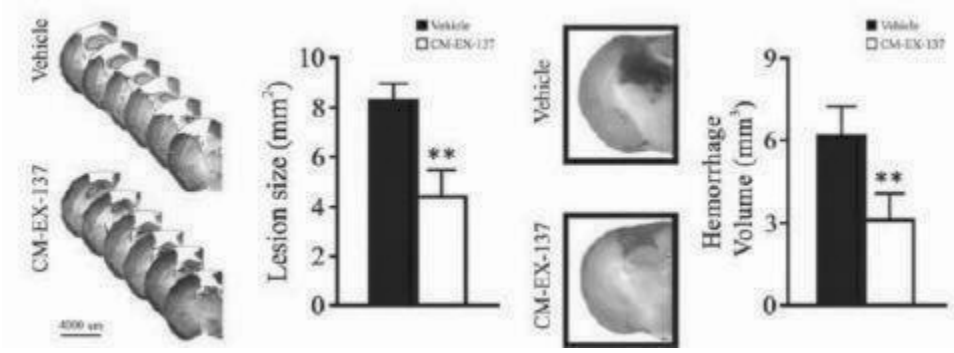
be an effective treatment for allergic asthma but will not decrease the anti-viral response to a viral infection. These data were published in the journal *Science Advances in* 2022.



CM4620 (zegocractin) reduces lung inflammation in a mouse model of allergic asthma but does not compromise adaptive immunity to influenza A virus infection. Lung sections from control and CM4620 treated asthmatic mice were stained with hematoxylin and eosin (H&E) or periodic acid- Schiff (PAS) to detect inflammation and mucus production, respectively. Influenza A virus (IAV) expression was quantified in lung by quantitative RT-PCR of RNA for nuclear segment 5 of IAV (a specific probe for IAV), and is presented as expression relative to the housekeeping gene Rpl32.

Preclinical Study in Traumatic Brain Injury

In a preclinical study performed with investigators at the San Francisco Veterans Affairs Hospital and UCSF, CM5480, a proprietary tool compound, was tested in a mouse model of traumatic brain injury in which animals were subjected to a controlled cortical impact with an automated impactor to induce brain injury. It was observed that treatment with CM5480 led to significant protection of mice from traumatic brain injury as determined by decreased lesion size, brain hemorrhage and improved neurological deficits with decreased microglial activation. This study was published in *the Journal of Neurotrauma* in 2019.



CM5480 (CM-EX-137) reduced injury in a traumatic brain injury model in mice.

P-Values and Confidence Intervals

The conventional method for measuring the statistical significance of a result is known as the "p-value," which represents the probability of obtaining results at least as extreme as those that were observed in the study presuming that the null hypothesis of no effect is true. Generally, a p-value less than 0.05 is considered statistically significant and may be supportive of a finding of efficacy by regulatory authorities. However, regulatory authorities, including the FDA, do not rely on strict statistical significance thresholds as criteria for marketing approval and maintain the flexibility to evaluate the overall risks and benefits of a treatment. A confidence interval ("**CI**") is a range of values within which the true value has a specified probability to exist. It is conventional to set the confidence interval at 95%, which means 95 of 100 times, the confidence interval will contain the true value. If the confidence interval does not contain the value of zero (the null value), it can be assumed that there is a statistically significant effect.

Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We intend to build a commercial infrastructure to support sales of our product candidates. We expect to manage sales, marketing and distribution

through internal resources and third-party relationships. While we may commit significant financial and management resources to commercial activities, we will also consider collaborating with one or more pharmaceutical companies to enhance our commercial capabilities. As our future product candidates progress through our pipeline, our commercial plans may change. Clinical data, the size of the development programs, the size of our target markets, the size of a commercial infrastructure and manufacturing needs may all influence our commercialization strategies.

Manufacturing

We do not own or operate manufacturing facilities for the production of any of our product candidates and potential future products, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently rely, and expect to continue to rely for the foreseeable future, on contract manufacturing organizations ("CMOs") for all our required raw materials, drug substance and drug product needs for preclinical research, clinical trials and initial commercialization. We do not have long-term agreements with any of these third parties. We also do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates and potential future products and do not plan to enter into any until we are further into clinical development. If any of our products are approved by any regulatory agency, we intend to enter into agreements with a CMO and one or more back-up manufacturers for the commercial production of those products. Development and commercial quantities of any products that we develop will need to be manufactured in facilities, and by processes, that comply with the requirements of the FDA and the regulatory agencies of other jurisdictions in which we are conducting clinical research or seeking marketing approval.

Competition

The pharmaceutical and biotechnology industries are characterized by intense competition and rapid innovation. While we believe that our product candidates, as well as our development experience and scientific knowledge may provide significant advantages relative to current approaches and therapies in the treatment of acute critical illnesses and chronic inflammatory and immunologic diseases, our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. We face potential competition from many different sources, including large multinational pharmaceutical companies, established biotechnology companies and specialty pharmaceutical companies, and universities and other research institutions. Many of these groups have materially greater financial, manufacturing, marketing, research and drug development resources than we do. Large pharmaceutical companies in particular have extensive expertise in preclinical and clinical testing and in obtaining regulatory approvals for drugs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

We are a clinical-stage biopharmaceutical company focused on developing therapeutics that treat serious acute inflammatory illnesses driven by hyperinflammation processes and direct cellular damage. The molecular targets we are addressing are CRAC channels, and our most advanced clinical candidate, Auxora, is in clinical trials for AP with accompanying SIRS, AIPT, and AKI with AHRF. Other companies, including Daiichi-Sankyo Company, Limited, Rhizen Pharmaceuticals AG, PRCL Research, Inc., Vivreon Biosciences, LLC, Medshine Discovery, Inc., Eldec Pharmaceuticals, and ChemiCare srl, have CRAC channel inhibitors (including both small molecules, peptides, and monoclonal antibodies) in clinical or preclinical development for various indications. Several of these have reached Phase 1 or Phase 2 clinical trials in indications we are not currently pursuing. Any of these companies could elect to re-direct their efforts and compounds to indications we are pursuing.

With respect to our lead indication, AP with accompanying SIRS, we are developing Auxora as a disease-modifying product candidate, whereas most other drug treatments and approaches in clinical development focus on addressing symptoms or sequelae. These include various types of pain medications, anti-inflammatories, anti-coagulants, antibiotics, fluids and feeding regimens. Ionis Pharmaceuticals has an approved drug and Amryt Pharma Plc and Regeneron Pharmaceuticals, Inc. also have agents in development that seek to reduce the risk of subsequent attacks of AP after a sentinel attack (known as recurrent AP) due to a particular etiology (familial chylomicronemia syndrome ("FCS"). FCS patients represent less than 2% of the AP population.

With respect to AIPT, there is currently no disease modifying treatment for patients who develop pancreatic toxicity as a result of asparaginase treatment for ALL. The current SOC addresses symptoms like pain, the inability to eat, and infection, and withdraws asparaginase, a key component of the ALL treatment regimen.

With respect to our efforts in other acute critical illnesses with Auxora, there are a number of companies that are potential competitors, particularly those with anti-inflammatory technologies. In the area of AKI, most companies in the space are pursuing strategies to prevent AKI in high risk populations. There is one ongoing clinical trial to treat AKI in the setting of sepsis, i.e., sepsis-associated AKI or SA-AKI. Other than this drug candidate, to our knowledge, there are no other novel compounds currently in clinical development in the US that are intended to treat rather than prevent AKI. If, however, a strategy to prevent AKI were to be effective, the number of patients we are targeting for Auxora could decrease. In the area of respiratory failure, acute lung injury and, specifically, COVID-19 pneumonia, there are a number of companies pursuing anti-inflammatory approaches to treating these diseases. Currently, Roche's tocilizumab, Lilly's baricitinib, SOBI's anakinra and dexamethasone are all approved under EUAs to treat severe COVID-19 pneumonia patients on oxygen. Sanofi's sarilumab which has the same mechanism of action as tocilizumab has also been recommended

for use in severe COVID-19 pneumonia by WHO. Some of these drugs as well as others currently in development for COVID-19 pneumonia may prove efficacious in broader respiratory failure, particularly respiratory failure caused by viral pneumonias, and in other acute critical illnesses as well.

Our commercial opportunity could be substantially limited in the event that our competitors develop and commercialize products that are more effective, safer, more convenient or cheaper than our product candidates. In geographies that are critical to our commercial success, competitors may also obtain regulatory approvals before us, resulting in our competitors building a strong market position in advance of our product's entry. We believe the competitive factors that will determine the success of our programs will be the efficacy, safety, pricing and reimbursement, and convenience of our future product candidates.

Intellectual Property

We have developed and continue to expand our patent portfolio for Auxora. As of December 31, 2024, we have issued patents and pending patent applications in the United States and other countries throughout the world directed to compositions of matter, various methods of use, formulations, and synthetic processes. For patents directed to compositions covering Auxora, we own four issued U.S. patents and over 60 issued patents world-wide. We also have one pending U.S. patent application and seven pending patent applications in Argentina, Japan, Canada, China and India directed to compositions covering Auxora. Composition of matter patents for Auxora have expirations ranging from 2031 and 2036 with Auxora and other pre-clinical drugs having world-wide composition of matter patents to 2036, not including any patent term adjustment or any patent term extension.

For patents and patent applications directed to methods of using Auxora for the treatment of AP, as of December 31, 2024, we own two issued U.S. patents and over 30 issued patents world-wide. We also own four U.S. patent applications, and 21 pending patent applications in the following jurisdictions: Argentina, Australia, Canada, China, Europe, Hong Kong, India and Japan for AP and other indications. These issued patents and any patents issuing from pending U.S. and ex-U.S. applications are expected to expire between 2031-2046, not including any patent term adjustment or any patent term extension. We have also filed one U.S. patent application, and applications in Australia, Canada, China, Europe and Japan directed to using a subject's P/F ratio (the ratio of arterial oxygen pressure to fractional inspired oxygen) as a biomarker when treating acute lung injury and acute respiratory distress syndrome with Auxora. Any patents ultimately issuing from these applications are expected to expire around 2043, not including any patent term adjustment or patent term extension. We jointly own U.S. patent application direct to treatment of pediatric pancreatitis. Any patents ultimately issuing from this application are expected to expire around 2046.

Additionally, we jointly own one issued U.S. patent and, 13 issued patents world-wide directed to treatment for stroke and traumatic brain injury. These patents are expected to expire around 2036, not including any patent term adjustment or patent term extension. Also, we have filed one U.S patent application directed to treatment of non-alcoholic fatty liver disease using Auxora. Any patents ultimately issuing from this application are expected to expire around 2044, not including any patent term adjustment or patent term extension.

Moreover, for patent protection directed to formulations and crystalline forms of Auxora, we have filed one U.S. patent application, one granted in each Australia, China, and Mexico, and seven pending applications in the following jurisdictions: Australia, Brazil, Canada, Europe, Japan, and South Korea. Any patents that ultimately issue from these patent applications are expected to expire around 2038, not including any patent term adjustment or patent term extension.

With respect to the synthetic of Auxora, we have filed two U.S. patent applications, and pending applications in Canada, China, Europe, India, Japan, and South Korea. Any patents ultimately issuing from these applications are expected to expire around 2040, not including any patent term adjustment or any patent term extension.

Beyond patent coverage for Auxora, we have 18 issued U.S. patents, six issued patents world-wide, and a pending PCT application directed to CRAC channel inhibitors and their uses.

In addition to patent protection, we rely on trade secret protection and know-how to expand our proprietary position around our chemistry, technology, and other discoveries and inventions that we consider important to our business.

Government Regulation and Product Approval

As a pharmaceutical company that operates in the United States, we are subject to extensive regulation. Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products such as those we are developing. Product candidates that we develop must be approved by the FDA, before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in a foreign country. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be

important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act ("FDCA"), and its implementing regulations. A new drug must be approved by the FDA pursuant to a new drug application ("NDA") before it may be legally marketed in the United States. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. Sanctions brought by the FDA and the Department of Justice ("DOJ"), or other governmental entities, could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

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

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice ("GLP") regulations and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board ("IRB") at each clinical site before each trial may be initiated;
- preparation of clinical trial material in accordance with current Good Manufacturing Practices ("cGMPs");
- performance of adequate and well-controlled human clinical trials in accordance with applicable regulations, including the FDA's good clinical practice ("GCP") regulations to establish the safety and efficacy of the proposed drug for its proposed indication;
- submission to the FDA of an NDA, including payment of application user fees, after completion of all pivotal trials, and which provides substantive evidence of the products' candidates safety and efficacy from results of nonclinical testing and clinical trials;
- a determination by the FDA within 60 days of its receipt of an NDA that the application is sufficiently complete to permit a substantive review, in which case the NDA is filed for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA's cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA to assess compliance with GCP regulations and data integrity, among other things;
- satisfactory completion of an FDA advisory committee review, if applicable; and
- FDA review and approval of the NDA, including consideration of the views on the FDA advisory committee, if one was involved, prior to any commercial marketing or sale of the drug in the United States.

Before testing any compound with potential therapeutic value in humans, the drug candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies, to assess the potential safety and activity of the drug candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is an exemption from the FDCA that allows an unapproved product to be shipped in interstate commerce for use in an investigational clinical trial and a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose complete or partial clinical holds on an IND for a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Submission of a study protocol, therefore, may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the drug candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research participants provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Information related to the investigational product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the U.S. registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The drug candidate is initially introduced into healthy human participants and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion, and the side effects associated with increasing doses and if possible, to gain early evidence of effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2*. The drug candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases or conditions and to determine dosage tolerance, optimal dosage and dosing schedule. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3*. The drug candidate is administered to an expanded patient population to further evaluate dosage and clinical efficacy at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall benefit/risk ratio of the product and provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

Post-approval studies, or Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected AEs or any finding from tests in laboratory animals that suggests a significant risk for human participants. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research participants or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final

drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

There are also various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with the research. In each of these areas, the FDA and other regulatory authorities have broad regulatory and enforcement powers, including the ability to levy fines and civil penalties.

U.S. Review and Approval Processes

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug candidate, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. Data may come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product to the satisfaction of the FDA. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances.

In addition, the PREA requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors are required to submit PSPs to the agency for review within sixty days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 clinical trial. The FDA and the sponsor must reach an agreement on the PSP although a sponsor can submit amendments to an agreed upon PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials or other clinical development programs. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data need to be collected before the pediatric clinical trials begin. Unless otherwise required by regulation, the Pediatric Research Equity Act does not apply to any drug for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

The FDA reviews all NDAs submitted to determine if they are substantially complete before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA must be resubmitted with the additional information. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the PDUFA guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted. The current review goal for priority NDAs for new-molecular entities is six months from the filing date, or eight months from the date of receipt in light of the 60-day filing period. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes independent clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and typically follows the advisory committee's recommendations.

Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical sites to assure that the clinical trial was conducted in compliance with IND study requirements and GCP requirements by each of the entities involved in the clinical trials, including clinical investigators and any third- party CROs. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific

indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or (an) additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. For example, the FDA may require Phase 4 testing, which involves clinical trials designed to further assess a drug safety and effectiveness, and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized; the FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. The FDA may also determine that a REMS is necessary to ensure that the benefits of the drug outweigh its risks and to ensure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS during the application review process; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. If an orphan designated product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan exclusivity.

Expedited Development and Review Programs and Accelerated Approval

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a fast track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA is submitted, the product candidate may be eligible for priority review. With regard to a fast track product, 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.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review. A product is eligible for priority review if it is designed to treat a serious condition, and if approved, would provide a significant improvement in the treatment, diagnosis or prevention of a serious condition compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review

applications with priority review designations within six months of the filing date as compared to ten months of the filing date for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life- threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify the predicted clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required clinical trials, or if such trials fail to verify the predicted clinical benefit. In addition, the FDA requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

A sponsor may seek FDA designation of a drug candidate as a "breakthrough therapy" if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. The FDA must take certain actions with respect to breakthrough therapies, such as holding timely meetings and providing advice to the product sponsor, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Fast track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval but may expedite the development, review, or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In addition, such designations or shortened review periods may not provide a material commercial advantage.

Post-Approval Requirements

Any drug products manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long term stability of the drug product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented.

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

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

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

The FDA closely regulates the marketing, labeling, advertising and promotion of drug products, including promotional activities involving the internet and industry-sponsored educational activities. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion by manufacturers of uses or patient populations that are not described in the product's approved labeling (known as "off label uses"). Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA") which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of wholesale drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. Most recently, the Drug Supply Chain Security Act ("DSCSA") was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States. The DSCSA mandates phased-in and resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors, and dispensers over a 10 year period that is expected to culminate in November 2023.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years, as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent.

The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

In addition, the Hatch-Waxman Amendments to the FDCA authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute and also enacted Section 505(b)(2) of the FDCA. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application ("ANDA"), to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug ("RLD"). Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. In contrast, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant

would need to conduct additional clinical trials or nonclinical studies; for example, they may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. The FDA may then approve the new product for all or some of the label indications for which the RLD has been approved, or for any new indication sought by the Section 505(b)(2) applicant, as applicable Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve an ANDA or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the RLD or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the RLD holder. The FDCA also provides three years of marketing exclusivity for an NDA, or a supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA filed under section 505(b)(1) of the FDCA. However, an applicant submitting a full NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and adequate and well- controlled clinical trials necessary to demonstrate safety and effectiveness.

Orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of non-patent market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Federal and State Fraud and Abuse, Data Privacy and Security of Health Information, and Transparency Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state healthcare laws and regulations restrict business practices in the biopharmaceutical industry. These laws may impact, among other things, our current and future business operations, including our clinical research activities, and proposed sales, marketing and education programs and may constrain the business or financial arrangements and relationships with healthcare providers and other parties through which we market, sell and distribute our products for which we obtain marketing approval. These laws include anti-kickback and false claims laws and regulations, data privacy and security of health information, and transparency laws and regulations, including, without limitation, those laws described below.

The U.S. federal Anti-Kickback Statute prohibits any person or entity from, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The U.S. federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil FCA or the civil monetary penalties laws.

Federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil FCA, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. Actions under these laws may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. A claim includes "any request or demand" for money or property presented to the U.S. government.

Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product and for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") also created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement 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. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations, impose specified requirements on certain types of individuals and entities, including covered entities, business associates and their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities, which include certain healthcare providers, healthcare clearinghouses and health plans, that create, receive, maintain or transmit individually identifiable health information in connection with providing a service for or on behalf of a covered entity as well as their covered subcontractors. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which are not pre-empted by HIPAA, differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) annually report information related to certain payments or other transfers of value made or distributed to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing, and state and local laws that require the registration of pharmaceutical sales representatives.

In addition, certain states require, the registration of manufacturers and wholesale distributors of pharmaceutical products. All of our activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti- fraud and abuse laws, implementation of corporate compliance programs, reporting of payments or transfers of value to healthcare professionals, and additional data privacy and security requirements.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we or our collaborators obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such drug products.

In the United States, third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers and other organizations. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. Such payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. We or our collaborators may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Nonetheless, our product candidates may not be considered medically necessary or cost-effective. Moreover, the process for determining whether a third-party payor will provide coverage for a drug product may be separate from the process for setting the price of a drug product or for establishing the reimbursement rate that such a payor will pay for the drug product. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, one payor's determination to provide coverage for a drug product does not ensure that other payors will also provide coverage for the drug product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

If we elect to participate in certain governmental programs, we may be required to participate in discount and rebate programs, which may result in prices for our future products that will likely be lower than the prices we might otherwise obtain. For example, drug manufacturers participating under the Medicaid Drug Rebate Program must pay rebates on prescription drugs to state Medicaid programs.

Different pricing and reimbursement schemes exist in other countries. In the EU, 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. 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 drug candidate to currently 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, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we or our collaborators receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we or our collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act ("Cures Act") was signed into law. The Cures Act, among other things, was intended to modernize the regulation of drugs and devices and to spur innovation. Legislative proposals continue to be discussed in the U.S. Congress as potentially leading to a future "Cures 2.0" bill that is expected to have bipartisan support. In addition, in August 2017, the FDA Reauthorization Act was signed into law, which reauthorized the FDA's user fee programs and included additional drug product provisions. The legislative reauthorization was completed in 2022, which reauthorized four of the largest FDA user fee programs for the next five-year cycle. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

In addition, a primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors in the United States have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other healthcare funding and applying new payment methodologies. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively "Affordable Care Act"), was enacted, which substantially changed the way healthcare is financed by both the government and private insurers, and continues to significantly impact the U.S. pharmaceutical industry.

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 to the Department of Health and Human Services ("HHS") beginning on January 1, 2022, subject to enforcement via civil money penalties.

There have been amendments to and executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act since its enactment, and it is possible that there will be additional challenges and amendments to the Affordable Care Act in the future. For example, on August 16, 2022, the Inflation Reduction Act of 2022 ("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 possible that the Affordable Care Act will be subject to additional challenges in the future. 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.

Other legislative changes have also been proposed and adopted in the United States since the Affordable Care Act was enacted that affect health care expenditures. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and will remain in effect until 2032, unless additional Congressional action is taken.

There has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which has resulted in several Congressional inquiries, presidential executive orders and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for 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. In addition, 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 for the first 10 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 15 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, an 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. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, particularly given recent U.S. Presidential and Congressional elections. We anticipate that such new laws will result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition, and results of operations. Additionally, health reform initiatives may arise in the future.

Privacy and Security Laws

In the United States and in addition to federal laws described above, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. For instance, the California Consumer Privacy Act ("CCPA"), created individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA, among other things, imposes data privacy obligations on covered companies and provides privacy rights to California residents, including the right to access and delete their personal data, opt out of certain personal data sharing, and receive detailed information about how their personal data is used. The CCPA also includes a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Further, the California Privacy Rights Act ("CPRA") includes provisions that require us to incur additional costs and expenses in an effort to comply. Both the CCPA and CPRA have in the past and continue to impact our business activities depending on how they are interpreted and exemplifies the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to

personal data and protected health information. Other U.S. states have begun enacting their own laws similar to the CCPA, and we expect more states to pass similar laws in the future.

We also are subject to applicable data protection laws in the jurisdictions in which we are established or in which we sell or market our products or run clinical trials. For example, if we conduct EU-based clinical trials, we will be subject to the EU General Data Protection Regulation ("EU GDPR") in relation to our collection, control, processing and other use of personal data of data participants within the European Economic Area ("EEA") (i.e., data relating to an identifiable living individual). The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing activities and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data participants (in a concise, intelligible and easily accessible form) how their personal data is to be used, imposes limitations on retention of personal data; defines for the first time pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. If in the future we conducted clinical trials in the EU we would be subject to EU rules with respect to cross-border transfers of personal data out of the EU and EEA. We would be subject to the supervision of local data protection authorities in those EU jurisdictions where we conduct our trials or are otherwise subject to the GDPR. Fines for certain breaches of the GDPR are significant: up to the greater of €20 million or 4% of total global annual turnover. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, or potential civil claims including class action type litigation.

In addition, the GDPR includes restrictions on cross-border data transfers. Certain aspects of cross-border data transfers under the GDPR are uncertain as the result of legal proceedings in the EU. This may increase the complexity of transferring personal data across borders. The GDPR will increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Although there are legal mechanisms to allow for the transfer of personal data from the EEA to the United States, they are subject to legal challenges and uncertainty about compliance with EU data protection laws remains and there are similar uncertainties around data transfers to and from the United Kingdom.

The U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act of 1977 ("FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Importantly, United States authorities that enforce the FCPA, including the Department of Justice, deem most healthcare professionals and other employees of foreign hospitals, clinics, research facilities and medical schools in countries with public health care or public education systems to be "foreign officials" under the FCPA. We also may be implicated under the FCPA for activities by our partners, collaborators, contract research organizations, vendors or other agents. If and when we interact with foreign healthcare professionals and researchers in testing and marketing our products abroad, we must have policies and procedures in place sufficient to prevent us and agents acting on our behalf from providing any bribe, gift or gratuity, including excessive or lavish meals, travel or entertainment in connection with marketing our products and services or securing required permits and approvals such as those needed to initiate clinical trials in foreign jurisdictions.

Europe/Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we or our potential collaborators obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of an application for a clinical trial authorization ("CTA") much like the IND prior to the commencement of human clinical trials. In the EU, for example, a CTA must be submitted to each country's national health authority and an application made to an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements and a favorable ethics committee opinion has been issued, clinical trial development may proceed.

Following the United Kingdom's departure from the EU on January 31, 2020, the United Kingdom followed the same regulations as the EU until the end of 2020, during the so-called Transition Period. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency ("MHRA") is the United Kingdom's standalone medicines and medical devices regulator. As a result of the Northern Ireland protocol, different rules will apply in Northern Ireland than in England, Wales, and Scotland, together, Great Britain ("GB");

broadly, Northern Ireland will continue to follow the EU regulatory regime, but its national competent authority will remain the MHRA. The MHRA has recently published detailed guidance for industry and organizations to follow from January 1, 2021 now that the Transition Period is over, which will be updated as the United Kingdom's regulatory position on medicinal products evolves over time. The guidance includes clinical trials, marketing authorizations, importing, exporting, and pharmacovigilance and is relevant to any business involved in the research, development, or commercialization of medicines in the United Kingdom.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug under EU regulatory systems, we must submit a marketing authorization application either under the so-called centralized or national authorization procedures.

Centralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the European Commission following a favorable opinion by the EMA that is valid in all EU member states, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases, other immune dysfunctions and viral diseases. The centralized procedure is optional for other products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health or which contain a new active substance for indications other than those specified to be compulsory.

National authorization procedures. There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorizations in more than one EU Member State of medicinal products that have not yet been authorized in any EU Member State and that do not fall within the mandatory scope of the centralized procedure.
- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

The EMA grants orphan drug designation to promote the development of products for the treatment, prevention or diagnosis of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 people in the EU. In addition, orphan drug designation can be granted if the drug is intended for a life threatening or chronically debilitating condition in the EU and without incentives it is unlikely that sales of the drug in the EU would be sufficient to justify the investment required to develop the drug. Orphan drug designation is only available if there is no other satisfactory method approved in the EU of diagnosing, preventing or treating the condition, or if such a method exists, the proposed orphan drug will be of significant benefit to patients. Orphan drug designation provides opportunities for free or reduced-fee protocol assistance, fee reductions for marketing authorization applications and other post-authorization activities and ten years of market exclusivity following drug approval, which can be extended to 12 years if trials are conducted in accordance with an agreed-upon pediatric investigational plan. The exclusivity period may be reduced to six years if the designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

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

Facilities

Our corporate headquarters are located in La Jolla, California, where we lease approximately 2,850 square feet of office and laboratory space pursuant to a lease agreement. We believe that our existing facilities are adequate for the foreseeable future. As we expand, we believe that suitable additional and/or alternative spaces will be available in the future on commercially reasonable terms, if required.

Employees and Human Capital Resources

As of December 31, 2024, we had 14 full-time employees, seven of whom were primarily engaged in research and development activities. A total of four employees have an M.D., Ph.D. or Pharm.D. degree. Most of our employees are located in La Jolla, California. None of our employees are represented by a labor union, and we consider our employee relations to be good. We also engage various consultants that are primarily engaged in research and development activities.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards and cash-based performance bonus awards.

Corporate Information

We originally formed in May 2011 as Graybug, LLC, which was converted into a corporation in February 2015. Our corporate headquarters are located at 505 Coast Boulevard South, Suite 307, La Jolla, CA 92037, and our telephone number is (858) 952-5500. Our corporate website address is https://calcimedica.com/. Information contained on, or accessible through, our website shall not be deemed incorporated into and is not a part of this Annual Report on Form 10-K. Our periodic and current reports are available on our website, free of charge, as soon as reasonably practicable after filing. We may use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the SEC. These disclosures will be included under the Investor Relations section of our website at ir.calcimedica.com. We have included our website in this Annual Report on Form 10-K solely as an inactive textual reference.

On March 20, 2023, Graybug, now known as CalciMedica, Inc., completed the Merger with Private CalciMedica, in accordance with the terms of the Merger Agreement, whereby Merger Sub merged into Private CalciMedica, with Private CalciMedica surviving as Graybug's wholly owned subsidiary. Pursuant to the Merger Agreement, Graybug changed its name to CalciMedica, Inc.

On December 31, 2024, Private CalciMedica was dissolved and combined into CalciMedica, Inc.

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 Annual Report on Form 10-K, 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.

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 December 31, 2024, we had an accumulated deficit of $159.8 million and a net loss of $13.7 million for the year ended December 31, 2024. 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.

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, warrants and common stock, through the Merger with Graybug and through an underwritten public offering. 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.

As of December 31, 2024, we had $18.7 million in cash, cash equivalents and short-term investments. Based on our current operating plans, we believe our existing resources, including the net proceeds of $9.7 million from the Loan and Security Agreement with Avenue Venture Opportunities Fund entered into on February 28, 2025, will be sufficient to fund our current operations through certain clinical milestones into the middle of 2026. However, 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.

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;

- the impacts of the ongoing or future international conflicts and potential future bank failures; 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 on capital markets may affect the availability, amount and type of financing available to us in the future. 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.

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 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 (the "Closing Date"), we entered into a Loan and Security Agreement ("2025 LSA") 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 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 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).

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 2025 LSA 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 2025 LSA 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 2025 LSA. 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 2025 LSA. 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 a 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 an 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, including for 35 days beginning on December 22, 2018, 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.

If a 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, 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. 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 December 31, 2024, we employed 14 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.

In addition, the new 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.

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 $296.8 million and nil, 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. Under current law, our federal NOLs generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income. 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 NOLs 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, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (the "Tax Act"), the Coronavirus Aid, Relief, and Economic Security Act and the Inflation Reduction Act ("IRA") enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. 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.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted that affect healthcare expenditures. These changes 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. 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 may 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 may become involved in disputes, claims and lawsuits relating to our business operations. In particular, we may 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.

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, and bank failures. 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.

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 1B. Unresolved Staff Comments.

None

Item 1C. Cybersecurity.

Risk management and strategy

We have implemented and maintain information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and our clinical trial data ("Information Systems and Data").

Depending on the environment and system, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: an incident response and disaster recovery plan, disaster recovery testing, data encryption for certain data, asset management, system monitoring and multi-factor authentication for certain systems, employee training and cybersecurity insurance.

We use a third-party information technology consultant to help identify, assess and manage the Company's cybersecurity threats and risks. This consultant reports to and works with our management team, including our Chief Scientific Officer and President and Chief Operating Officer to identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods and tools including for example by subscribing to reports and services that identify cybersecurity threats, leveraging certain system monitoring tools, and leveraging tools provided through Microsoft Office 365.

Our assessment and management of material risks from cybersecurity threats are taken into account as part of the Company's risk management processes. For example, our senior management works with our information technology consultant to evaluate material risks from cybersecurity threats against our overall business objectives.

We use third-party service providers, including cybersecurity consultants, to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats.

We use third-party service providers to perform a variety of critical functions throughout our business, such as hosting providers, application providers, contract research organizations, contract manufacturing organizations, and other third-party service providers. We review the cybersecurity risks associated with the use of these providers. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment and due diligence designed to help identify cybersecurity risks associated with a vendor, as well as the imposition of security related contractual obligations on the vendor.

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

Governance

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

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our Chief Scientific Officer, President and Chief Operating Officer, Chief Financial Officer, Vice President Finance and General Counsel who also serves as our compliance officer. These members of management have prior work experience in various roles involving managing information security programs and are informed about and monitor the prevention, mitigation, detection and remediation of cybersecurity incidents.

Our Chief Scientific Officer and our President and Chief Operating Officer are responsible for engaging appropriate personnel and companies, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant employees and personnel. Our President and Chief Operating Officer is also responsible for managing budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

We have adopted a Cybersecurity Incident Response Policy which is designed to escalate certain cybersecurity incidents to a Cybersecurity Incident Management Team consisting of our Chief Scientific Officer, President and Chief Operating Officer, General Counsel and our information technology consultant. Depending on the circumstances, cybersecurity incidents are reported to our Chief Executive Officer and Chief Financial Officer. Senior management works to help the Company mitigate and remediate cybersecurity incidents of which they are notified in addition to notifying the Audit Committee of the Board of Directors, as appropriate.

The Audit Committee of the Board of Directors receives periodic reports as needed from management concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The Audit Committee also has access to various reports, summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties.

Our corporate headquarters are located in La Jolla, California, where we lease approximately 2,850 square feet of office space. The existing lease will expire on December 31, 2025. We believe that our existing facilities are adequate for our current needs.

Item 3. Legal Proceedings.

From time to time, we may be 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 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock trades on The Nasdaq Capital Market under the symbol "CALC."

Holders of Record

As of March 21, 2025, there were approximately 70 holders of record of our common stock. Certain shares of our common stock are held in "street" name and thus the actual number of beneficial owners of such shares is not known or included in the foregoing number.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings for use in the operation of our business and do not intend to declare or pay any cash dividends in the foreseeable future. Any future determination to pay dividends on our capital stock would be at the discretion of our board of directors, subject to applicable laws, and would depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors considers relevant.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Recent Sales of Unregistered Securities

On May 17, 2024, in connection with services provided under a consulting agreement (the "Danforth Consulting Agreement") with Danforth Advisors, LLC ("Danforth"), a company affiliated with Dan Geffken, our former Interim Chief Financial Officer, we granted to SG Dan Equity Holdings, LLC, a company affiliated with Mr. Geffken ("SG Dan Equity"), a warrant ("SG 2024 Warrant") to purchase 10,000 shares of our common stock at an exercise price of $5.45 per share (subject to adjustment as provided therein), which vest in equal monthly installments over a period of one year from the grant date and which are subject to accelerated vesting if the Danforth Consulting Agreement is terminated prior to May 17, 2025 . The SG 2024 Warrant is exercisable until May 24, 2034, unless earlier terminated. The SG 2024 Warrant shall terminate in the event of certain change of control transactions or asset transfers (as provided therein) unless exercised immediately prior to any such transaction.

The issuance of securities described above was deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act as a transaction by an issuer not involving a public offering. The recipient of the securities in such transaction represented that it was an accredited investor as defined in Regulation D promulgated under the Securities Act and of its intention to acquire the securities for its own account for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the electronic records representing such securities in such transaction. The recipient received adequate information about us.

Use of Proceeds

Not applicable.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our audited consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. 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 around the end of 2025.

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 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 "Current Prospectus Supplement") with the SEC on December 20, 2024 for an aggregate gross sales price of up to $4,450,000 of shares of common stock to be sold pursuant to the ATM Facility. As of December 31, 2024, we sold an aggregate of 101,522 shares of common stock for net proceeds of $319,000 after deducting $13,000 of commissions paid under the ATM Facility and approximately $4.5 million remains available for sale under the ATM Facility. As of December 31, 2024, $89.5 million remained available for sale under the Shelf Registration Statement.

On February 28, 2025 (the "Closing Date"), the Company 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 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). 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 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").

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 December 31, 2024, our operations have been funded primarily by aggregate net proceeds of $178.7 million from the issuance of convertible preferred stock, convertible notes, warrants, 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 $13.7 million for the year ended December 31, 2024. Included in the net loss for the year ended December 31, 2024 were total operating expenses of $24.2 million, offset by a gain from the fair value adjustment to our warrant liability of $9.5 million and interest income of $1.0 million. As of December 31, 2024, we had an accumulated deficit of $159.8 million and $18.7 million in cash, cash equivalents and short-term investments.

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 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 and change in fair value of our convertible promissory notes; (ii) changes in the fair value of our warrant liabilities; and (iii) other non-operating income.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

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

	Year Ended December 31,		Change	
	2024	2023	Amount	%
Operating expenses:				
Research and development	$ 14,478	$ 15,859	$ (1,381)	(9%)
General and administrative	9,726	22,216	(12,490)	(56%)
Total operating expenses	24,204	38,075	(13,871)	(36%)
Loss from operations	(24,204)	(38,075)	13,871	(36%)
Other income	10,504	3,718	6,786	183%
Net loss	$ (13,700)	$ (34,357)	$ 20,657	(60%)

Research and Development Expenses

Research and development expenses comprised (in thousands):

	Year Ended December 31,		Change	
	2024	2023	Amount	%
Preclinical studies and clinical trial-related activities	$ 6,294	$ 5,939	$ 355	6%
Chemistry, manufacturing and controls	2,314	1,006	1,308	130%
Personnel	3,722	7,071	(3,349)	(47%)
Consultants and other costs	2,148	1,843	305	17%
Total research and development expenses	$ 14,478	$ 15,859	$ (1,381)	(9%)

Research and development expenses were $14.5 million for the year ended December 31, 2024, compared to $15.9 million for the year ended December 31, 2023. The decrease of $1.4 million was due primarily to a decrease in personnel expense of $3.3 million driven by a one-time charge for the acceleration of vesting of stock options of $1.9

million and a one-time severance charge of $1.6 million as a result of the Merger for the year ended December 31, 2023. This was partially offset by an increase of $1.3 million in chemistry, manufacturing and control activities in regard to our Phase 2 clinical trials of Auxora, costs related to our preclinical studies of $0.3 million and consultants and other costs of $0.3 million.

General and Administrative Expenses

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

	Year Ended December 31,		Change	
	2024	2023	Amount	%
Personnel costs	$ 3,864	$ 16,872	$ (13,008)	(77%)
Facility costs	549	595	(46)	(8%)
Professional services	3,130	3,316	(186)	(6%)
Consultants and other costs	2,183	1,433	750	52%
Total general and administrative expenses	$ 9,726	$ 22,216	$ (12,490)	(56%)

General and administrative expenses were $9.7 million for the year ended December 31, 2024, compared to $22.2 million for the year ended December 31, 2023. The decrease of $12.5 million was primarily related to a decrease in personnel costs of $13.0 million driven by a one-time charge for acceleration of vesting of stock options of $8.6 million and a one-time severance charge of $4.1 million as a result of the Merger for the year ended December 31, 2023. Additionally, professional services decreased $0.2 million due to increased costs as a result of the Merger for the year ended December 31, 2023. These costs were partially offset by an increase of $0.7 million in consultants and other costs.

Other Income

Other income for the year ended December 31, 2024 was $10.5 million, compared to $3.7 million for the year ended December 31, 2023. The increase of $6.8 million was due to the fair value adjustments to our warrant liability as a result of the 2024 Private Placement which resulted in a change in fair value adjustments for our warrants liability of $9.5 million compared to fair value adjustments to our warrant liability and convertible promissory notes for the year ended December 31, 2023, and due to an increase of $0.4 million of interest income on our cash equivalents and short-term investments due to additional funds to invest, for the year ended December 31, 2024, as compared to the year ended December 31, 2023.

Liquidity and Capital Resources

Overview

As of December 31, 2024 we had cash, cash equivalents and short-term investments of $18.7 million.

Based on our current operating plans, we believe our cash, cash equivalents and short-term investments along with the Loan Agreement entered into on February 28, 2025, will be sufficient to fund our current operations for the next twelve months from the date of this report. We expect that our cash, cash equivalents and short-term investments, will allow us to fund our operations through certain clinical milestones, into the middle of 2026. However, 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 such as AHRF, 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 (beyond 18 months), 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.

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;
- the impacts of the ongoing or future international conflicts; 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, warrants and common stock, through the Merger with Graybug and through an underwritten public offering. 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, the Company entered into the Purchase Agreement with certain accredited investors, in which the Company 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, the Company 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 Current Prospectus Supplement with the SEC on December 20, 2024 for an aggregate gross sales price of up to $4,450,000 of shares of common stock to be sold pursuant to the ATM Facility. As of December 31, 2024, we sold an aggregate of 101,522 shares of common stock for net proceeds of $319,000 after deducting $13,000 of commissions paid under the ATM Facility and approximately $4.5 million remains available for sale under the ATM Facility. As of December 31, 2024, $89.5 million remained available for sale under the Shelf Registration Statement.

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., as administrative agent and collateral agent, for growth capital loans in an aggregate principal amount of up to $32,500,000, 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). 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 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").

Our operations through December 31, 2024, have been funded primarily by aggregate net proceeds of $178.7 million from the issuance of convertible preferred stock, convertible 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 year ended December 31, 2024 was $13.7 million and consisted of total operating expenses of $24.2 million offset by a gain from the fair value adjustment to our warrant liability of $9.5 million and interest income of $1.0 million. For the year ended December 31, 2023, our net loss was $34.4 million consisting of $38.1 million of operating expenses (including $10.5 million in one-time charges related to the acceleration of vesting of the Graybug stock awards at the date of the Merger and $5.7 million of one-time severance charges as a result of the Merger). As of December 31, 2024, we had an accumulated deficit of $159.8 million and $18.7 million in cash, cash equivalents and short-term investments. During the year ended December 31, 2024, cash used in operations was $21.1 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):

	Year Ended December 31,	
	2024	2023
Net cash provided by (used in):		
Operating activities	$ (21,146)	$ (25,730)
Investing activities	(4,423)	8,884
Financing activities	27,974	20,900
Net increase in cash and cash equivalents	$ 2,405	$ 4,054

Net Cash Used in Operating Activities

Cash used in operating activities of $21.1 million during the year ended December 31, 2024 was attributable to our net loss of $13.7 million, non-cash items of $7.0 million and a net change in our operating assets and liabilities of $0.5 million. Non-cash items consisted primarily of $9.5 million due to a change in our warrant liability as a result of the 2024 Private Placement and accretion on our short-term investments of $0.6 million offset by $2.3 million of stock based compensation and $0.8 million of transaction costs allocated to warrants as a result of the 2024 Private Placement.

Cash used in operating activities of $25.7 million during the year ended December 31, 2023 was attributable to our net loss of $34.4 million and a net change in our operating assets and liabilities of $0.3 million offset by non-cash items of $8.9 million. Non-cash items consisted primarily of $12.0 million of stock-based compensation, which includes $10.5 million in one-time charges related to the acceleration of vesting of the Graybug stock awards at the date of the Merger and $0.1 million in accrued interest on our convertible promissory notes offset by $1.1 million and $2.0 million change in the fair value of our warrant liability and convertible promissory notes, respectively based on the value the warrant holder and promissory note holder received in common stock and $0.1 million of accretion on the discounts associated with our short-term investments.

Net Cash Provided by (Used in) Investing Activities

Investing activities of $4.4 million for the year ended December 31, 2024 consisted of the purchase of short-term investments of $29.0 million offset by the maturing of short-term investments of $24.6 million.

Investing activities of $8.9 million for the year ended December 31, 2023 consisted of the maturing of short-term investments of $15.1 million, offset by the purchase of short-term investments of $6.1 million and purchases of property and equipment of $0.1 million.

Net Cash Provided by Financing Activities

Cash provided by financing activities for the year ended December 31, 2024 was $28.0 million comprised of the sale and issuance of common stock of $27.9 million in the 2024 Private Placement and 2024 Follow-On offerings and $0.1 million in the ATM Facility and exercise of stock options.

Cash provided by financing activities for the year ended December 31, 2023 was $20.9 million comprised of net cash acquired as a result of the Merger of $14.9 million, the sale and issuance of common stock of $10.3 million in a private placement immediately prior to the Merger and $0.2 million in the ATM Facility, offset by transaction costs of $4.5 million.

Material Cash Requirements

Our material cash requirements from known contractual obligations consisted 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 2024 and was amended and renewed in December 2024 for an additional 12 month term with monthly rent expense of approximately $10,500. Over the next 12 months, the Company expects cash requirements for our lease obligation to be approximately $126,000.

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 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.

Valuation of 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 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 $700 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. 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, 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

See Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for information about recent accounting pronouncements, the timing of adoption, and our assessment, if any, of their potential impact on our financial condition and results of operations.

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

Interest Rate Risk

Not applicable to a "smaller reporting company" as defined under Item 10(f)(1) of Regulation S-K of the Securities Act.

Item 8. Financial Statements and Supplementary Data.

The information required by this Item 8 is included as exhibits at the end of this Annual Report on Form 10-K beginning on page F-1and listed under Item 15(a)(1) and (2), and is incorporated herein by reference.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable

Item 9A. 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 Annual Report on Form 10-K.

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 Annual Report on Form 10-K, our disclosure controls and procedures were effective at a reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f) and 15d-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer, principal financial officer and principal accounting officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2024, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in

Internal Control-Integrated Framework (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2024, our internal control over financial reporting was effective based on those criteria.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the year ended December 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 9B. Other Information.

Notice of 2025 Annual Meeting Date and Related Deadlines

As of the date of this Annual Report, we intend to hold our 2025 annual meeting of stockholders (the "2025 Annual Meeting") on or about June 24, 2025. This date is more than 30 days before the one-year anniversary of our 2024 annual meeting of stockholders (the "2024 Annual Meeting"), which was held on August 27, 2024.

Our bylaws provide that for stockholder nominations to our board of directors or other proposals to be considered at an annual meeting of stockholders, the stockholder must give timely notice thereof in writing to the Corporate Secretary at CalciMedica, Inc., 505 Coast Boulevard South, Suite 307, La Jolla, CA 92037.

Because the date of the 2025 Annual Meeting is more than 30 days before the one-year anniversary of the date of our 2024 Annual Meeting, for the stockholder notice to be timely, it must be delivered to the Corporate Secretary at our principal executive offices not earlier than 5:00 p.m. Eastern Time on the 105th day prior to the date of the 2025 Annual Meeting, March 11, 2025, and not later than 5:00 p.m. Eastern Time on the later of (1) the 90th day prior to the 2025 Annual Meeting or (2) the close of business on the tenth day following the day on which public announcement of the date of such meeting is first made by us, April 7, 2025. A stockholder's notice to the Corporate Secretary must set forth as to each matter the stockholder proposes to bring before the 2025 Annual Meeting the information required by applicable law and our bylaws.

In addition, stockholder proposals submitted pursuant to Rule 14a-8 under the Exchange Act and intended to be presented at our 2025 Annual Meeting must be received by us a reasonable time before we mail our proxy materials for the 2025 Annual Meeting. We have determined that March 18, 2025, which is the date disclosed our definitive proxy statement on Schedule 14A for our 2024 Annual Meeting, remains a reasonable time before we expect to mail our proxy materials for the 2025 Annual Meeting, and that any stockholder proposals must be received on or before the close of business on that date in order to be considered for inclusion in our proxy materials for the 2025 Annual Meeting. A stockholder's notice to the Corporate Secretary must set forth as to each matter the stockholder proposes to bring before the 2025 Annual Meeting, the information required by applicable law and our bylaws.

In addition, stockholders who intend to solicit proxies in support of director nominees other than our nominees must provide in their notice any additional information required by Rule 14a-19(b) under the Exchange Act.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by Item 10 and not set forth below will be set forth in the sections or subsections titled *Proposal No. 1 Election of Class I Directors*, *Delinquent Section 16(A) Reports*, *Board of Directors and Committees of the Board of Directors* and *Executive Officers* contained in our definitive proxy statement for our 2025 annual meeting of stockholders to be filed with the SEC not later than April 30, 2025 (the "Proxy Statement") pursuant to General Instructions G(3) of Form 10-K and is incorporated herein by reference.

We have adopted a Code of Conduct and Ethics that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or vice president of finance, or person performing similar functions. A current copy of the Code of Conduct and Ethics is available on the Corporate Governance section of our website at https://ir.calcimedica.com. If we make any substantive amendments to the Code of Conduct and Ethics or grants any waiver from a provision of the Code of Conduct and Ethics to any executive officer or director that are required to be disclosed pursuant to SEC rules, we will promptly disclose the nature of the amendment or waiver on our website or in a current report on Form 8-K.

Item 11. Executive Compensation.

The information required by this Item 11 will be set forth in the sections or subsections titled *Executive Compensation*, *Non-Employee Director Compensation,* and *Compensation Committee Interlocks and Insider Participation* contained in the Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be set forth in the sections or subsections titled *Security Ownership of Certain Beneficial Owners and Management* and *Equity Incentive Plan Compensation* contained in the Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be set forth in the sections or subsections titled *Certain Relationships and Related-Party Transactions* and *Director Independence* contained in the Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be set forth in the section titled *Proposal No. 2 Ratification of Independent Registered Public Accounting Firm* contained in the Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) *Documents filed as a part of the report:*

(1) *Financial Statements*. The following financial statements of CalciMedica, Inc., together with the report of Moss Adams LLP and Ernst & Young LLP, independent registered public accounting firms, required to be filed pursuant to Part II, Item 8 of this Annual Report are included on the following pages:

(2) *Financial Statement Schedules.* None

(3) *List of exhibits required by Item 601 of Regulation S-K.* See part (b) below.

(b) *Exhibits*

Exhibit Index

Exhibit Number	Description	Form	File No.	Exhibit Filing Date	Exhibit No.	Filed/Furnished Herewith
2.1‡	Agreement and Plan of Merger and Reorganization, dated as of November 21, 2022, by and among Graybug Vision, Inc., Camaro Merger Sub, Inc. and CalciMedica, Inc., as amended by the First Amendment, dated February 10, 2023	8-K	001-39538	March 22, 2023	2.1	
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	Description of Registrant's Common Stock	10-K	001-39538	March 28, 2024	4.2	

Exhibit Number	Description	Form	File No.	Exhibit Filing Date	Exhibit No.	Filed/Furnished Herewith
4.3	Form of Common Stock Certificate	S-1/A	333-248611	September 21, 2020	4.1	
4.4	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	
4.5	Form of Registration Rights Agreement by and among CalciMedica, Inc. and the persons party thereto.	8-K	001-39538	January 24, 2024	10.2	
4.6	Warrant to Purchase Common Stock, dated December 11, 2019, by and between the Registrant and SG DAN Equity Holdings, LLC.	S-1	333-248611	September 4, 2020	4.3	
4.7	Form of Warrant to Purchase Shares of Series D Convertible Preferred Stock of CalciMedica, Inc.	8-K	001-39538	March 22, 2023	4.2	
4.8	Warrant to Purchase Common Stock dated as of November 9, 2020, issued by CalciMedica, Inc. to SG Dan Equity Holdings, LLC.	8-K	001-39538	March 22, 2023	4.3	
4.9	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	
4.10	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	
4.11	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	
4.12	Form of Warrant to Purchase Shares of Series B Convertible Preferred Stock of CalciMedica, Inc.	S-3	333-271115	April 4, 2023	4.9	
4.13	Form of Tranche B Common Warrant.	8-K	001-39538	January 24, 2024	4.2	
4.14	Form of Pre-Funded Warrant.	8-K	001-39538	January 24, 2024	4.3	
4.15	Form of Placement Agent Warrant.	8-K	001-39538	January 24, 2024	4.4	
10.1+	Offer Letter between CalciMedica, Inc. and A. Rachel Leheny, Ph.D., dated May 20, 2020.	8-K	001-39538	March 22, 2023	10.1	

Exhibit Number	Description	Form	File No.	Exhibit Filing Date	Exhibit No.	Filed/Furnished Herewith
10.2+	Offer Letter between CalciMedica, Inc. and Eric Roberts, dated May 20, 2020.	8-K	001-39538	March 22, 2023	10.2	
10.3+	Offer Letter between CalciMedica, Inc. and Sudarshan Hebbar, M.D., dated August 24, 2015, as amended.					X
10.4+	Offer Letter between CalciMedica, Inc. and Michael Dunn, dated August 29, 2014, as amended.					X
10.5+	Offer Letter between CalciMedica, Inc. and Kenneth A. Stauderman, Ph.D., dated August 29, 2014, as amended.					X
10.6+	Offer Letter between CalciMedica, Inc. and Stephen Bardin, MBA, dated November 7, 2024.					X
10.7+	Consulting Agreement, dated as of October 26, 2020, by and between the CalciMedica, Inc. and Danforth Advisors, LLC.	8-K	001-39538	March 22, 2023	10.11	
10.8+	CalciMedica, Inc. 2023 Equity Incentive Plan.	8-K	001-39538	August 27, 2024	10.1	
10.10+	Forms of Option Grant Notice and Option Agreement under CalciMedica, Inc. 2023 Equity Incentive Plan.	8-K	001-39538	March 22, 2023	10.7	
10.11+	Forms of Restricted Stock Unit Grant Notice and Unit Award Agreement under CalciMedica, Inc. 2023 Equity Incentive Plan.	8-K	001-39538	March 22, 2023	10.8	
10.12+	CalciMedica, Inc. 2023 Employee Stock Purchase Plan.	8-K	001-39538	March 22, 2023	10.9	
10.13+	CalciMedica, Inc. 2006 Stock Plan and Form of Stock Option Agreement thereunder.	8-K	001-39538	March 22, 2023	10.10	
10.14+	2020 Equity Incentive Plan and forms of award agreements.	S-1/A	333-248611	September 21, 2020	10.3	
10.15+	2020 Employee Stock Purchase Plan and forms of award agreements.	S-1/A	333-248611	September 21, 2020	10.4	
10.16+	Form of Amendment to Stock Option Award Agreement, dated March 20, 2023, by and between Graybug Vision, Inc. and the Holder party thereto	8-K	001-39538	March 22, 2023	10.12	
10.17+	Form of Amendment to Restricted Stock Unit Award Agreement, dated March 20, 2023, by	8-K	001-39538	March 22, 2023	10.13	

Exhibit Number	Description	Form	File No.	Exhibit Filing Date	Exhibit No.	Filed/Furnished Herewith
	and between Graybug Vision, Inc. and the Holder party thereto					
10.18+	2015 Stock Incentive Plan, as amended, and forms of award agreements thereunder.	S-1	333-248611	September 4, 2020	10.2	
10.19+	Form of Indemnification Agreement.	S-1	333-248611	September 4, 2020	10.1	
10.20+	Non-Employee Director Compensation Policy.					X
10.21+	Change in Control and Severance Policy.	S-1	333-248611	September 4, 2020	10.11	
10.22	At the Market Offering Agreement, dated as of August 11, 2023, by and between CalciMedica, Inc. and H.C. Wainwright & Co., LLC	S-3	333-273949	August 11, 2023	1.2	
10.23	Securities Purchase Agreement, dated January 19, 2024, by and among CalciMedica, Inc. and the persons party thereto (Corrected)	8-K/A	001-39538	January 24, 2024	10.1*	
10.24	Underwriting Agreement, dated October 30, 2024, by and between CalciMedica, Inc. and JonesTrading Institutional Services LLC.	8-K	001-39538	October 31, 2024	1.1	
10.25	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	
10.26	Loan and Security Agreement dated February 28, 2025, by and among CalciMedica, Inc., Avenue Capital Management II, L.P., and Avenue Venture Opportunities Fund II, L.P.	8-K	001-39538	March 5, 2025	10.1	
10.27	Supplement to the Loan and Security Agreement dated February 28, 2025, by and among CalciMedica, Inc., Avenue Capital Management II, L.P., and Avenue Venture Opportunities Fund II, L.P.	8-K	001-39538	March 5, 2025	10.2	
16.1	Letter from Ernst & Young LLP to the SEC dated April 10, 2024.	8-K	001-39538	April 10, 2024	16.1	
19.1	CalciMedica, Inc. Insider Trading Policy, amended April 2023.					X
23.1	Consent of Independent Registered Public Accounting Firm - Moss Adams LLP.					X

Exhibit Number	Description	Form	File No.	Exhibit Filing Date	Exhibit No.	Filed/Furnished Herewith
23.2	Consent of Independent Registered Public Accounting Firm - Ernst & Young LLP.					X
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
97.1	CalciMedica, Inc. Incentive Compensation Recoupment Policy	10-K	001-39538	March 28, 2024	97.1	
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.

+ Indicates management contract or compensatory plan.

‡ Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

CALCIMEDICA, INC.

Date: March 27, 2025

By: /s/ A. Rachel Leheny
A. Rachel Leheny, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: March 27, 2025

By: /s/ Stephen Bardin
Stephen Bardin, MBA
Chief Financial Officer
(Principal Accounting and Financial Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints A. Rachel Leheny, Ph.D. and Stephen Bardin, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ A. Rachel Leheny **A. Rachel Leheny, Ph.D.**	Chief Executive Officer and Director *(Principle Executive Officer)*	March 27, 2025
/s/ Stephen Bardin **Stephen Bardin, MBA**	Chief Financial Officer *(Principal Accounting and Financial Officer)*	March 27, 2025
/s/ Robert N. Wilson **Robert N. Wilson**	Chairman	March 27, 2025
/s/ Alan Glicklich **Alan Glicklich, M.D., MBA**	Director	March 27, 2025
/s/ Frederic Guerard **Frederic Guerard, Pharm.D.**	Director	March 27, 2025
/s/ Fred Middleton **Fred Middleton, MBA**	Director	March 27, 2025
/s/ Eric W. Roberts **Eric W. Roberts**	Director	March 27, 2025
/s/ Allan Shaw **Allan Shaw**	Director	March 27, 2025

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of
CalciMedica, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of CalciMedica, Inc. (and subsidiaries)(the Company) as of December 31, 2024, the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity and cash flows for the year then ended, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2024, and the consolidated results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ Moss Adams LLP

San Diego, California
March 27, 2025

We have served as the Company's auditor since 2024.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of CalciMedica, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of CalciMedica, Inc. (the Company) as of December 31, 2023, the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for the year ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023, and the results of its operations and its cash flows for the year ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We served as the Company's auditor from 2008 to 2024.

San Diego, California
March 28, 2024
except for the Segment Information section of Note 2, as to which the date is
March 27, 2025

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	December 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 7,935	$ 5,530
Short-term investments	10,734	5,708
Prepaid clinical trial expenses	748	71
Other prepaid expenses and current assets	248	296
Total current assets	19,665	11,605
Property and equipment, net	119	167
Other assets	10	413
Total assets	$ 19,794	$ 12,185
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,998	$ 1,419
Accrued clinical trial costs	820	1,141
Accrued expenses	866	1,468
Total current liabilities	3,684	4,028
Long-term liabilities		
Warrant liability	1,700	—
Total liabilities	5,384	4,028
Commitments and contingencies (Note 9)		
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2024 and December 31, 2023, respectively; no shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized at December 31, 2024 and December 31, 2023; 13,481,917 and 5,754,505 issued and outstanding at December 31, 2024 and December 31, 2023, respectively	4	1
Additional paid-in capital	174,166	154,218
Accumulated deficit	(159,764)	(146,064)
Accumulated other comprehensive income	4	2
Total stockholders' equity	14,410	8,157
Total liabilities and stockholders' equity	$ 19,794	$ 12,185

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

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

	Year Ended December 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 14,478	$ 15,859
General and administrative	9,726	22,216
Total operating expenses	24,204	38,075
Loss from operations	(24,204)	(38,075)
Other income		
Change in fair value of financial instruments	9,490	3,168
Other income	1,014	550
Total other income	10,504	3,718
Net loss	$ (13,700)	$ (34,357)
Net loss per share - basic and diluted	$ (1.22)	$ (7.66)
Weighted-average number of shares outstanding used in computing net loss per share—basic and diluted	11,245,915	4,486,258

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

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

	Year Ended December 31,	
	2024	2023
Net loss	$ (13,700)	$ (34,357)
Unrealized gain on available-for-sale securities, net of tax	2	2
Comprehensive loss	$ (13,698)	$ (34,355)

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

CALCIMEDICA, INC.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2023	5,754,505	$ 1	$ 154,218	$ (146,064)	$ 2	$ 8,157
Stock-based compensation expense	—	—	2,313	—	—	2,313
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
Issuance of common shares from underwritten public offering (net of issuance costs)	2,720,000	1	9,003	—	—	9,004
Issuance of common stock from at-the-market offering (net of issuance costs)	8,950	—	49	—	—	49
Issuance of common stock from exercise of stock options	12,852	—	20	—	—	20
Unrealized gain on investments	—	—	—	—	2	2
Net loss	—	—	—	(13,700)	—	(13,700)
Balance—December 31, 2024	13,481,917	$ 4	$ 174,166	$ (159,764)	$ 4	$ 14,410

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

CALCIMEDICA, INC.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain	Total Stockholders' Equity/(Deficit)
	Shares	Amount	Shares	Amount				
Balance—December 31, 2022	84,820,880	$ 62,071	84,165	$ 1	$ 40,402	$ (111,707)	$ -	$ (71,304)
Stock-based compensation expense	—	—	—	—	12,039	—	—	12,039
Conversion of preferred stock to common stock as a result of Merger	(84,820,880)	(62,071)	2,442,852	—	62,071	—	—	62,071
Issuance of common stock to Graybug stockholders as a result of Merger and reset to par of $0.0001	—	—	1,571,433		29,218	—	—	29,218
Issuance of common shares from private placement (net of issuance costs)	—	—	596,363	—	10,340	—	—	10,340
Conversion of promissory notes into common stock	—	—	590,031	—	3,245	—	—	3,245
Conversion of Series C-2 warrants into common stock	—	—	80,254	—	442	—	—	442
Conversion of promissory note warrants into common stock	—	—	152,875	—	841	—	—	841
Merger transaction costs	—	—	—	—	(4,545)	—	—	(4,545)
Restricted stock units net settlement	—	—	143,960	—	(297)	—	—	(297)
Reclassification of warrant liability to equity	—	—	—	—	216	—	—	216
Issuance of common stock from at-the-market offering (net of issuance costs)	—	—	92,572	—	246	—	—	246
Unrealized gain on investments	—	—	—	—	—	—	2	2
Net loss	—	—	—	—	—	(34,357)	—	(34,357)
Balance—December 31, 2023	—	$ —	5,754,505	$ 1	$ 154,218	$ (146,064)	$ 2	$ 8,157

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

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

	Year Ended December 31,	
	2024	2023
Operating activities:		
Net loss	$ (13,700)	$ (34,357)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,313	12,039
Depreciation	58	58
Change in the fair value of warrant liability	(9,490)	(1,146)
Change in the fair value of convertible promissory notes	-	(2,022)
Transaction costs associated with warrants	776	—
Non-cash interest expense	-	110
Accretion of discount on short-term investment	(608)	(145)
Changes in operating assets and liabilities:		
Prepaid expenses and other current and non-current assets	(228)	2,997
Accounts payable	601	(1,427)
Accrued expenses and other liabilities	(868)	(1,837)
Net cash used in operating activities	(21,146)	(25,730)
Investing activities:		
Purchase of investments	(29,002)	(6,118)
Maturity of investments	24,587	15,080
Purchases of property and equipment	(8)	(78)
Net cash provided by (used in) investing activities	(4,423)	8,884
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	27,905	10,340
Acquisition of stock of Graybug, net of cash	—	14,859
Proceeds from exercise of stock options	20	—
Merger transaction costs	—	(4,545)
Proceeds from issuance of common stock from ATM Facility, net of issuance costs	49	246
Net cash provided by financing activities	27,974	20,900
Net increase in cash and cash equivalents	2,405	4,054
Cash and cash equivalents at beginning of period	5,530	1,476
Cash and cash equivalents at end of period	$ 7,935	$ 5,530
Supplemental cash flow information:		
Conversion of Series A, B, C-1, C-2 and D convertible preferred stock to common stock	$ —	$ 62,071
Issuance of common stock to Graybug stockholders as a result of the Merger	$ —	$ 29,218
Short-term investments assumed in the Merger	$ —	$ 9,776
Prepaid expenses and other current assets assumed in the Merger	$ —	$ 2,096
Accounts payable and accrued liabilities assumed in the Merger	$ —	$ 2,258
Conversion of C-2 warrants to common stock	$ —	$ 442
Conversion of convertible promissory notes to common stock	$ —	$ 3,245
Conversion of convertible promissory note warrants to common stock	$ —	$ 841
Financing costs included in accounts payable and accrued expenses	$ 78	$ 45
Restricted stock units net settlement	$ —	$ 297
Reclassification of warrant liability to equity	$ —	$ 216

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

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. See discussions of the transactions in connection with the Merger in Note 3 - Merger and Related Transactions.

Liquidity

The Company has experienced net losses and negative cash flows from operating activities since its inception. The Company has an accumulated deficit of $159.8 million as of December 31, 2024, and a net loss of $13.7 million for the year ended December 31, 2024. Total operating expenses for the year ended December 31, 2024 were $24.2 million. 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 December 31, 2024, the Company has completed financings from the sale of preferred stock, warrants and common stock for total net proceeds of $140.7 million, including the 204 Private Placement and 2024 Follow-On described below, and has issued convertible debt for net proceeds of $8.6 million. In connection with the Merger, the Company received approximately $29.4 million of cash, cash equivalents and short-term investments. As of December 31, 2024, the Company had cash, cash equivalents and short-term investments of approximately $18.7 million. The Company closed the 2024 Private Placement (as defined in Note 7 below) on January 23, 2024 and the second closing of this private placement 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 expenses. The Company closed a confidentially marketed public offering (the "2024 Follow On") in October 2024 of the Company's common stock for gross proceeds of $10.2 million and transaction costs of $0.9 million resulting in net proceeds of $9.3 million. 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 (see Note 13).

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, it at all, and there is no assurance that the Company will be able to enter into collaborations or other arrangements. 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, short-term investments and additional financing in February 2025, will be sufficient to fund its operations for the period of at least one year following the issuance of these financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The 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"). The consolidated financial statements include the accounts of the Company for the year ended December 31, 2024 and the Company and CalciMedica Subsidiary, Inc. for the year ended December 31, 2023. All intercompany accounts and transactions have been eliminated in consolidation.

Since Private CalciMedica was determined to be the accounting acquirer in connection with the Merger, for periods prior to the Merger, the consolidated financial statements were prepared on a stand-alone basis for Private CalciMedica and did not include the combined entities activity or financial position. Subsequent to the Merger, the consolidated financial statements as of and for the year ended December 31, 2024 include Graybug's activity from March 21, 2023 through December 31, 2024, and assets and liabilities at their acquisition date fair value. Historical share and per share figures of Private CalciMedica have been retroactively restated based on the merger exchange ratio of 0.0288.

Use of Estimates

The preparation of the Company's 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 consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to accruals for research and development expenses, 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 and cash equivalents. 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's 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 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 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 loss.

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 significant 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 consolidated balance sheets as total consolidated assets.

The following table presents information about reported segment loss and significant segment expenses for the years ended December 31, 2024 and 2023:

	Years Ended December 31,	
	2024	2023
Segment research and development *(a) (b)*	$ (13,607)	$ (13,380)
Segment general and administrative *(b)*	(8,226)	(12,598)
Stock-based compensation (see Note 8)	(2,313)	(12,039)
Depreciation expense (see Note 2)	(58)	(58)
Operating loss	$ (24,204)	$ (38,075)
Reconciliation of profit or loss		
Adjustments and reconciling items	—	—
Consolidated operating loss	$ (24,204)	$ (38,075)

a) Stock-based compensation expense of $840,000 and $2,449,000, related to research and development and $1,473,000 and $9,590,000, related to general and administration have been excluded for the years ended December 31, 2024 and 2023, respectively.

b) Depreciation expense of $31,000 and $29,000, related to research and development and $28,000 and $28,000, related general and administration have been excluded for the years ended December 31, 2024 and 2023, respectively.

Fair Value Option

As permitted under ASC 825, *Financial Instruments*, the Company has elected the fair value option to account for its convertible promissory notes due to certain embedded features within the notes. The Company recognizes the convertible promissory notes at fair value with changes in fair value recognized in the 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 consolidated statements of operations. As a result of applying the fair value option, direct costs and fees related to the convertible promissory notes 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 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 for the years ended December 31, 2024 and 2023 was $121,000 and $274,000, 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 and 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 December 31, 2024, the Company had deferred costs associated with its ATM Facility (as defined in Note 7) and expensed these costs in the Company's consolidated statement of operations.

Warrant Liability

Private CalciMedica has issued various freestanding warrants to purchase shares of its convertible preferred stock. Prior to the Merger, Private CalciMedica adjusted the carrying value of such convertible preferred stock warrants to the estimated fair value at each reporting date, with any related increases or decreases in the fair value being recorded within other income (expense) in the consolidated statements of operations and comprehensive loss. Pursuant to the Merger Agreement, the Series C convertible preferred stock warrants became warrants to purchase shares of the combined company's common stock. As a result of the Merger, the warrants no longer meet the requirements for liability accounting and, as such, Private CalciMedica adjusted the value of the warrants to the estimated fair value as of the Merger date and reclassified them to stockholders' equity (deficit).

As a result of the 2024 Private Placement, certain warrants to purchase common stock were deemed freestanding warrants and are reflected in the Company's balance sheet as a liability as of and for the period ending December 31, 2024.

Stock-Based Compensation

Stock-based compensation expense represents the cost of the grant date fair value of employee stock options 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 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 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 prior to 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 CalciMedica does not yet have sufficient historical trading history for its own stock. CalciMedica 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 interim chief financial officer in connection with its consulting agreement. CalciMedica recorded expense of $289,000 and $521,000 during years ended December 31, 2024 and 2023, respectively.

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 interim chief financial officer. The Company recorded expense of $13,000 to general and administrative expense for the year ended December 31, 2024.

Net Loss Per Share

Net loss is equivalent to net loss attributable to common stockholders for all periods presented. Basic net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. The Company calculates diluted net loss per share using the more dilutive of the (1) treasury stock method, if-converted method, or contingently issuable share method, as applicable, or (2) 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 all periods presented, the Company's outstanding preferred stock, stock options, preferred, common and convertible promissory note warrants, and outstanding convertible promissory notes were excluded from the calculation of loss per share because the effect would be antidilutive. Accordingly, in periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share.

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20)* and *Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40)*. The ASU provides guidance that simplified the accounting for certain financial instruments with characteristics of liabilities and equity. The new guidance reduced the number of accounting models for convertible debt and convertible preferred stock instruments and made certain disclosure amendments intended to improve the information provided to users. The guidance also amended the derivative guidance for the "own stock" scope exception, which exempts qualifying instruments from being accounted for as derivatives if certain criteria are met. Finally, the standard changed the way certain convertible instruments are treated when calculating earnings per share. This guidance is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years, with early adoption permitted. The Company adopted this ASU as of January 1, 2024, which did not have a material impact on its consolidated financial statements and related disclosures.

In November 2023, the FASB issued ASU 2023-07 *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. This guidance expands public entities' segment disclosures primarily by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. The amendments are required to be applied retrospectively to all prior periods presented in an

entity's financial statements. The Company adopted the new accounting standard retrospectively for the fiscal year 2024. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements related disclosures, however, we have added additional footnote disclosure as part of the adoption.

In December 2023, the FASB issued final guidance in ASU No. 2023-09, *Income Taxes (ASC 740): Improvements to Income Tax Disclosures* requiring entities to provide additional information in the rate reconciliation and disclosures about income taxes paid. For public business entities, the guidance is effective for annual periods beginning after December 15, 2024. The Company has adopted this ASU No. 2023-09 effective December 31, 2024.

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 consolidated financial statements.

3. Merger and Related Transactions

As described in Note 1 - Nature of Business, Private CalciMedica merged with a wholly-owned subsidiary of Graybug on March 20, 2023. The Merger was accounted for as a reverse recapitalization under U.S. GAAP. Private CalciMedica was considered the accounting acquirer for financial reporting purposes. This determination is based on the facts that, immediately following the Merger: (i) former Private CalciMedica stockholders owned a substantial majority of the voting rights of the combined company; Private CalciMedica designated a majority (five of seven) of the initial members of the board of directors of the combined company; and former Private CalciMedica's senior management held all key positions in senior management of the combined company. The transaction is accounted for as a reverse recapitalization of Graybug by Private CalciMedica similar to the issuance of equity for the net assets of Graybug, which are primarily cash and cash equivalents, short-term investments and other non-operating assets. It was concluded that any in-process research and development assets that remained as of the Merger would be de minimis when compared to the cash, cash equivalents and short-term investments obtained through the Merger.

Under reverse recapitalization accounting, the assets and liabilities of Graybug were recorded at their fair value, which approximated book value due to the short-term nature of the instruments. The Company's consolidated financial statements reflect the issuance of 1,571,433 shares to the former stockholders of Graybug.

Under the terms of the Merger Agreement, immediately prior to the effective time of the Merger, each outstanding share of Private CalciMedica capital stock (after giving effect to the automatic conversion of all shares of Private CalciMedica preferred stock into shares of Private CalciMedica common stock, the automatic exercise of certain Private CalciMedica warrants to purchase shares of Private CalciMedica common stock in accordance with their terms (the "Private CalciMedica warrant exercises"), the conversion of Private CalciMedica convertible promissory notes into Private CalciMedica common stock and the closing of the 2023 Private Placement (as defined and discussed in Note 7 - Convertible Preferred Stock, Common Stock, and Stockholders' Equity (Deficit)), was converted into the right to receive 0.0288 shares of Graybug common stock, which resulted in the issuance by Graybug of an aggregate of 3,946,540 shares of Graybug common stock to the stockholders of Private CalciMedica in a transaction exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), in reliance on Section 4(a)(2) of the Securities Act and the rules promulgated thereunder. In addition, Graybug assumed the Private CalciMedica 2006 Stock Plan (See Note 8 - Stock-Based Compensation), and each outstanding and unexercised option to purchase Private CalciMedica common stock and each outstanding and unexercised warrant to purchase Private CalciMedica common stock (excluding the warrants which were automatically exercised pursuant to the Private CalciMedica warrant exercises) became options and warrants, respectively, to purchase shares of Graybug common stock. Immediately following the consummation of the Merger prior Private CalciMedica and Graybug stockholders collectively own approximately 72% and 28% of the Company, respectively, on a fully diluted basis.

As part of the reverse recapitalization, Private CalciMedica received $29.4 million of cash, cash equivalents and short-term investments, net of transaction costs. Private CalciMedica also obtained prepaid and other current assets of approximately $2.1 million and assumed payables and accrued expenses of approximately $2.3 million. Private CalciMedica also incurred transaction costs of approximately $4.6 million, which is recorded as a reduction to additional paid-in capital in the accompanying consolidated statement of convertible preferred stock and stockholders' equity (deficit). The Company also recorded one-time charges of $10.5 million for the acceleration of the Graybug stock awards and $5.7 million in severance charges that are recorded in the consolidated statements of operations and comprehensive loss for the for the year ended December 31, 2023.

On March 17, 2023, in connection with the transactions contemplated by the Merger Agreement and following a special meeting of Graybug's stockholders, Graybug filed an Amended and Restated Certificate of Incorporation effecting a reverse stock split of Graybug's common stock, par value $0.0001 per share, at a ratio of 14:1.

4. Fair Value Measurements

The Company's assets and liabilities which are measured at fair value include short-term investments and warrants for common stock. The Warrants for preferred stock ("Preferred Warrants") and warrants for common stock related to the convertible promissory notes ("Convertible Promissory Note Warrants") were all accounted for at fair value prior to the Merger (see Note 7 -

Convertible Preferred Stock, Common Stock and Stockholders' Equity). All assets and liabilities recorded at fair value are revalued at each measurement period.

The Common Warrants (as defined in Note 7 below) 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 indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	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

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Current assets:				
Cash equivalents:				
Money market funds	$ 3,634	$ —	$ —	$ 3,634
Commercial paper	—	1,738	—	1,738
Total cash equivalents	3,634	1,738	—	5,372
Short-term investments:				
Commercial paper	—	5,213	—	5,213
U.S. Government sponsored entities - mortgage-backed securities	—	495	—	495
Total short-term investments	—	5,708	—	5,708
Total assets measured at fair value	$ 3,634	$ 7,446	$ —	$ 11,080

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 and U.S. Government sponsored entities - mortgage-backed are classified as Level 2 with in the hierarchy and are carried at fair value with unrealized gains and losses included in other comprehensive income (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 year ended December 31, 2024, there were no transfers between Level 1, Level 2 and Level 3.

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

	December 31, 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

No fair value liabilities existed as of December 31, 2023.

The following provides a reconciliation for all liabilities measured at fair value using Level 3 inputs for the year ended December 31, 2024 (in thousands):

Warrant liability	
Balance at December 31, 2023	$ —
Initial Fair Value of Warrants	11,190
Forfeiture of warrants	(200)
Change in Fair Value of Preferred Warrants	(9,290)
Balance at December 31, 2024	$ 1,700

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):

	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.

	December 31, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Aggregate Fair Value
Current assets:				
Cash equivalents:				
Money market funds	$ 3,634	$ —	$ —	$ 3,634
Commercial paper	1,738	—	—	1,738
Total cash equivalents	5,372	—	—	5,372
Short-term investments:				
Commercial paper	5,211	2	—	5,213
U.S Government sponsored entities - mortgage backed securities	495	—	—	495
Total short-term investments	5,706	2	—	5,708
Total assets measured at fair value	$ 11,078	$ 2	$ —	$ 11,080

As of December 31, 2023, 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, 2023.

5. Convertible Promissory Notes and Convertible Promissory Note Warrants

In April 2022, the Private CalciMedica board of directors approved a convertible promissory note financing pursuant to which it could issue and sell up to $5.0 million of notes convertible into shares of common stock (the "convertible promissory notes") and Convertible Promissory Note Warrants. The funding and issuance of the convertible promissory notes for gross proceeds of $3.5 million and Convertible Promissory Note Warrants to purchase shares of the Private CalciMedica's common stock at an exercise price of $0.01 per share took place in multiple closings through October 2022.

In November 2022, the Private CalciMedica board of directors amended the convertible promissory notes and Convertible Promissory Note Warrants to issue up to an additional $3.5 million (for a total of up to $8.5 million) and added the automatic conversion for a "de-SPAC" business combination or reverse merger transaction. In November 2022, Private CalciMedica issued additional convertible promissory notes for gross proceeds of $5.0 million and Convertible Promissory Note Warrants to purchase shares of Private CalciMedica's common stock at an exercise price of $0.01 per share. The convertible promissory notes accrued interest at a rate of 6% per annum and had a maturity date of December 31, 2023. Immediately prior to the effective time of the Merger, all outstanding convertible promissory notes and unpaid and accrued interest automatically converted into 20,487,104 shares of Private CalciMedica's common stock at a conversion price based on the equivalent valuation of the cash price paid per share by the private placement investors purchasing shares of common stock in the private placement multiplied by 0.85. Such shares of common stock were then converted into 590,031 shares of Graybug common stock at the effective time of the Merger in accordance with the Merger Agreement.

In connection with each purchase of a convertible promissory note, Private CalciMedica issued to each holder of such convertible promissory note Convertible Promissory Note Warrant to purchase shares of the Private CalciMedica's common stock at an exercise price of $0.01 per share. Each holder of the Convertible Promissory Note Warrants had the right to purchase up to a number of shares of Private CalciMedica's common stock equal to (i) 15% ("Warrant Coverage") of the principal amount of the convertible promissory note purchased by such holder concurrently therewith, divided by (ii) the cash price paid per share by the investors in the qualified financing or an initial public offering, as applicable, or in the case of a "de-SPAC" business combination or a reverse merger transaction between Private CalciMedica and a publicly traded company (a "Public Combination"), the equivalent valuation of the lower of the cash price per share by the investors purchasing shares in the publicly traded company in connection with such Public Combination or the cash price per shares by the investors purchasing shares of Private CalciMedica's common stock in connection with such Public Combination, in each case, rounding down to the nearest whole share and subject to the terms of the convertible promissory notes; provided, however, that any holder that purchased convertible promissory notes in excess of the holder's pro rata commitment (as defined in the convertible promissory notes) received a 40% Warrant Coverage on the principal amount of the convertible promissory notes that is in excess of its pro rata commitment. The Convertible Promissory Note Warrants had a five-year term. In connection with the Merger, the Convertible Promissory Note Warrants were automatically net exercised in accordance with the terms of the Convertible Promissory Note Warrants. Immediately prior to the effective time of the Merger, 5,308,047 Convertible Promissory Note Warrants were converted into 5,308,047 shares of Private CalciMedica's common stock, which were converted into 152,875 shares of Graybug's common stock, based on the principal amount of the convertible promissory note.

Prior to the Merger, the Convertible Promissory Note Warrants were not deemed equity and were classified as a liability on the balance sheets. The Convertible Promissory Note Warrants were valued using a series of Monte Carlo simulations and Black-Scholes to determine the fair value, probability weighted for difference scenarios. The Monte Carlo simulations determined the liquidity event price. The Black-Scholes warrant value is discounted from the respective event date using the risk-free rate. The Black-Scholes valuation included standard assumptions such as exercise price, expected term, risk-free rate, volatility, and a dividend yield of zero. The Company estimated initial fair value of the Convertible Promissory Note Warrants utilizing the following range of assumptions for the difference scenarios: exercise price ($0.01), risk-free rate (3.02% - 4.20%), volatility (63% - 67%),

and expected term (4.1 - 4.6 years). As of the date of the Merger, the Convertible Promissory Note Warrants which were converted into 152,871 shares of common stock were revalued, using the price of the common stock of Graybug of $5.50.

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Accrued payroll and other employee benefits	$ 531	$ 935
Accrued severance	—	89
Accrued professional fees	286	345
Accrued other	49	99
Total accrued expenses	$ 866	$ 1,468

7. Convertible Preferred Stock, Common Stock and Stockholders' 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.

Convertible Preferred Stock

Immediately prior to the effective time of the Merger, the 84,820,880 shares of Private CalciMedica preferred stock were converted into 84,820,880 outstanding shares of Private CalciMedica's common stock to be exchanged for 2,442,852 shares of Graybug's common stock.

Common Stock

Upon completion of the Merger on March 20, 2023, as the accounting acquirer, Private CalciMedica is deemed to have issued 1,571,433 shares of its common stock to Graybug shareholders.

Private Placement of Common Stock

Immediately prior to the consummation of the Merger, Private CalciMedica completed a private placement financing pursuant to which certain investors purchased approximately 20.7 million shares of Private CalciMedica's common stock (the "2023 Private Placement") for gross proceeds of approximately $10.3 million. In conjunction with the Merger, immediately prior to the effective time of the Merger, 20,706,997 shares of Private CalciMedica common stock were converted into 596,363 shares of Graybug's common stock.

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 December 31, 2024.

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. The Tranche A Common Warrants expired unexercised on July 29, 2024.

Underwritten Public Offering

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 (the "2024 Follow-On"). The gross proceeds from the offering, before deducting underwriting discounts and commissions and offering expenses, were $10.2 million. In addition, the Company granted the underwriters a 30-day

option to purchase up to an additional 408,000 shares of its common stock at the public offering price, less underwriting discounts and commissions, which option expired unexercised.

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 the 2024 Follow-On and sold 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 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 "Current Prospectus Supplement") with the SEC on December 20, 2024 for an aggregate gross sales price of up to $4,450,000 of shares of common stock to be sold pursuant to the ATM Facility.

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 year ended December 31, 2024, there were 8,950 shares sold under the ATM Facility. As of December 31, 2024, the Company has sold 101,522 shares of common stock for net proceeds of $319,000, after deducting $13,000 of commissions and settlement expenses paid under the ATM Facility and approximately $4.5 million remains available for sale under the ATM Facility. As of December 31, 2024, $89.5 million remains available for sale under the Shelf Registration Statement.

Preferred and Common Stock Warrants

The Company recognized a change in fair value of the Preferred Stock Warrants for each of the years ended December 31, 2024 and 2023 of $0 and $795,000, respectively. The change in fair value for the year ended December 31, 2023 was due to the conversion of Preferred Warrants to common stock warrants as part of the Merger.

In November 2020, Private CalciMedica granted a warrant to purchase 400,000 shares of common stock to a consulting firm affiliated with its former interim chief financial officer in connection with its consulting agreement. The warrant has a 10-year term, an exercise price of $0.19, and vests ratably over 24 months commencing on the effective date. At the date of issuance, the fair value of the warrant was determined to be $120,000, utilizing Black-Scholes with the following assumptions: expected term of ten years, risk-free rate of 0.96%, volatility of 80.0% and a dividend yield of zero, which has been recognized as general and administrative expense over the vesting period. In conjunction with the Merger, the warrant converted to 11,520 warrants of CalciMedica at an exercise price of $6.60.

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 CalciMedica 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 $6,000 and $90,000 to general and administrative expense for the years ended December 31, 2024 and 2023, 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 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 December 31, 2024, the value of the Tranche A Common Warrants was nil with the change in fair value of $4.1 million for the year ended December 31, 2024,

respectively, being recorded in consolidated statements of operations in other income as the Tranche A Common Warrants expired unexercised on July 27, 2024.

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 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 December 31, 2024, the value of the Tranche B Common Warrants was $3.4 million, with the change in fair value of $0.3 million and $3.7 million for the years ended December 31, 2024 and 2023, respectively, being recorded in the condensed consolidated statements of operations in other income.

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 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 December 31, 2024.

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 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 December 31, 2024.

In May 2024, the Company granted a warrant to a consulting firm affiliated with its 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 $13,000 to general and administrative expense for the year ended December 31, 2024.

8. Stock-based Compensation

2023 Equity Incentive Plan

The Company adopted 2023 Equity Incentive Plan (the "2023 Plan"), which became effective at the closing of the Merger and replaced our 2020 Equity Incentive Plan ("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). As of December 31, 2024, 228,475 options have been returned of which 223,743 (granted under the 2020 Plan) are unavailable for future grant. Effective January 1, 2024, the shares reserved for issuance under the 2023 Plan was increased by 287,725 shares. Effective March 28, 2024, the Board approved an increase of 1,500,000 shares reserved under the 2023 Plan. This increase was subsequently approved by the stockholders of the Company on August 27, 2024. As of December 31, 2024, 820,266 shares 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 shares of the Company's common stock was automatically added to the share reserve under the 2023 ESPP on January 1, 2024.

As of December 31, 2024, no shares have been issued under the 2023 ESPP.

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

	Total Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	1,739,270	$ 15.71	6.99	$ 76
Granted	1,326,500	4.12	9.47	4
Exercised	(12,852)	1.55	—	—
Cancelled	(228,475)	75.27	—	—
Outstanding at December 31, 2024	2,824,443	$ 5.51	8.15	$ 316
Vested and exercisable at December 31, 2024	1,350,852	$ 6.46	7.09	$ 210

There were 12,852 options exercised and 1,326,500 options granted during the year ended December 31, 2024. The weighted-average fair value of options granted during the years ended December 31, 2024 and 2023 was $4.14 and $2.34 per share, respectively. The total fair value of shares vested was $5.0 million and $11.9 million (which includes $10.5 million related to the acceleration of vesting of the Graybug stock awards at the date of the Merger) for the year ended December 31, 2024 and December 31, 2023, respectively.

As of December 31, 2024, stock-based compensation not yet recognized is $4.7 million, which the Company expects to recognize over an estimated weighted-average term of 2.8 years.

The following is the range of underlying assumptions in Black-Scholes to determine the fair value of the stock option grants for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
Risk free interest rate	3.15%	3.50%-3.56%
Expected volatility	97%	75%-76%
Expected term (years)	6.01	6.25
Expected dividend yield	0%	0%

Restricted Stock Units ("RSU")

The fair value of RSUs 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 RSUs vested during the year ended December 31, 2024 was nil.

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

	Number of Restricted Stock Units	Weighted Average Exercise Price
Outstanding at December 31, 2023	—	$ —
Granted	40,000	3.50
Exercised	—	—
Forfeited/Cancelled (expired)	—	—
Outstanding at December 31, 2024	40,000	$ 3.50
Vested and exercisable at December 31, 2024	—	$ —

Stock-based Compensation Expense

Stock-based compensation expense recognized for options and restricted stock units granted was as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development	$ 840	$ 2,449
General and administrative	1,473	9,590
Total stock-based compensation expense	$ 2,313	$ 12,039

The stock-based compensation expense for the year ended December 31, 2023, includes one-time charges for the acceleration of vesting of the Graybug stock options at the date of the Merger of $1.9 million and $8.6 million in research and development and general and administrative expenses, respectively.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following at December 31, 2024:

	December 31, 2024
Common stock warrants	3,352,621
Stock options issued and outstanding	2,824,443
Shares available for issuance under the 2023 Plan	807,414
Shares available under the 2023 ESPP	122,545
Total	7,107,023

9. 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 its 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 December 31, 2024, there are seven such contracts, with one CMO related to its development of Auxora and one acquired as a result of the Merger with approximately $1.3 million and $1.2 million of associated costs, respectively, still in effect for future services, and there were no unpaid cancellation or other related costs.

The Company 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.

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. Since the lease was amended and renewed in December 2024 for an additional twelve month term it therefore qualifies for the short-term lease exception. Base rent for this lease is approximately $10,500 monthly.

Rent expense for the years ended December 31, 2024 and 2023 was $121,000 and $274,000, respectively, which is included in operating expenses.

10. Employee Benefits

In January 2007, Private CalciMedica adopted a defined contribution 401(k) plan for substantially all employees. Contributions made by CalciMedica to the 401(k) plan were $0 and $78,000 for the years ended December 31, 2024 and 2023, respectively.

11. Income Taxes

The effective tax rate if the Company's provision (benefit) for income taxes differs from the federal statutory rate as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Tax computed at federal statutory rate	$ (2,877)	$ (7,214)
State tax, net of federal tax benefit	611	1
Permanent differences	(166)	50
Warrant liability	(1,993)	(665)
Research and development tax credits, net of uncertain positions	(1,050)	(705)
Valuation allowance	5,475	8,534
Income tax expense	$ —	$ 1

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards. Significant components of deferred tax assets (liabilities) are as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	$ 62,407	$ 58,535
Intangible assets	10,356	9,865
Tax credit carry forwards	13,506	12,403
Stock compensation	2,026	1,700
Accrued compensation	180	93
Total deferred tax assets	88,475	82,596
Deferred tax liabilities		
Fixed assets	(15)	(21)
Total deferred tax liabilities	(15)	(21)
Total net deferred tax assets	88,460	82,575
Less: valuation allowance	(88,460)	(82,575)
Net deferred taxes	$ —	$ —

The Company provided a full valuation allowance on the net deferred tax asset because management has determined that it is more-likely-than-not that the Company will not earn income sufficient to realize the deferred tax assets during the carryforward period. As of December 31, 2024, the Company has federal and state NOLs available of approximately $296.9 million and nil, respectively, to offset future taxable income, if any, for federal and state income tax purposes. The federal and state NOLs expire beginning in 2026. The Company has $194.7 million of post-2017 federal NOL carryforwards that carry forward indefinitely. In addition, under the Tax Act the amount of net operating losses generated in taxable periods beginning after December 31, 2017, that the Company is permitted to deduct in any taxable year is limited to 80% of taxable income in such year, where taxable income is determined without regard to the net operating loss deduction itself. The Tax Act generally eliminates the ability to carry back any net operating loss to prior taxable years, while allowing post-2017 unused net operating losses to be carried forward indefinitely.

As of December 31, 2024, the Company has federal and state research and development credit carryforwards available of approximately $13.3 million and $3.1 million, respectively. Federal research and development carryforwards expire beginning in 2027. State research and development carryforwards do not expire.

Pursuant to Internal Revenue Code of 1986, as amended (the "Code") specifically by IRC §382, the Company's ability to use net operating loss carryforwards to offset future taxable income is limited if the Company experiences a cumulative change in ownership of more than 50% within a three-year testing period. The Company has not completed an ownership change analysis pursuant to IRC Section 382. If ownership changes within the meaning of IRC Section 382 are identified as having occurred, the amount of remaining tax attribute carryforwards available to offset future taxable income and income tax expense in future years may be significantly reduced. Any limitation may result in the expiration of a portion of the NOL carryforwards before utilization.

The change in the Company's unrecognized tax benefits is summarized as follows (in thousands):

Balance at December 31, 2022	$ 7,506
Increase related to current year tax positions	2,846
Additions for tax positions of prior years	21
Additions in connection with the reverse merger	847
Reduction for tax positions of prior years	(140)
Balance at December 31, 2023	$ 11,080
Increase related to current year tax positions	334
Additions for tax positions of prior years	68
Balance at December 31, 2024	$ 11,482

The Company accounts for uncertainty in income taxes in accordance with ASC 740 Income Taxes. Tax positions are evaluated in a two-step process, whereby the Company first determines whether it is more likely than not that a tax position will be sustained upon examination by the tax authority, including resolutions of any related appeals or litigation processes, based on technical merit. If a tax position meets the more-likely-than-not recognition threshold it is then measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured as the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Income tax positions must meet a more likely than not recognition threshold to be recognized. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest and penalties and has not recognized interest and/ or penalties in the statements of operations and comprehensive loss for the years ended December 31, 2024 and 2023. Uncertain tax positions are evaluated based upon the facts and circumstances that exist at each reporting period. Subsequent changes in judgment based upon new information may lead to changes in recognition, derecognition,

and measurement. Adjustments may result, for example, upon resolution of an issue with the taxing authorities or expiration of a statute of limitations barring an assessment for an issue.

As of December 31, 2024, and 2023, unrecognized tax benefits associated with uncertain tax positions was approximately $11.8 million and $9.1 million respectively. If recognized, this would affect the effective tax rate, subject to valuation allowance. As of December 31, 2024, the Company did not recognize any interest and penalties associated with unrecognized tax benefits. Due to net operating losses incurred, tax years from inception remain open to examination by the Federal and State taxing jurisdictions to which we are subject. The Company is not currently under Internal Revenue Services (IRS), state or local tax examination.

12. Net Loss Per Share

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

	Year Ended December 31,	
	2024	2023
Numerator:		
Net loss	$ (13,700)	$ (34,357)
Denominator		
Basic and diluted		
Weighted-average common shares outstanding, basic and diluted	10,886,920	4,486,258
Weighted-average pre-funded warrants outstanding, basic and diluted	288,082	—
Weighted-average placement agent warrants outstanding, basic and diluted	70,913	—
Weighted-average number of shares used to calculate basic and diluted net loss per share	11,245,915	4,486,258
Net loss per share - basic and diluted	$ (1.22)	$ (7.66)

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 December 31,	
	2024	2023
Stock options to purchase common stock	2,824,443	1,739,747
Warrants to purchase common stock	2,970,368	276,437
Total	5,794,811	2,016,184

13. Subsequent Events

Loan Agreement

On February 28, 2025 (the "Closing Date"), the Company 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). 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 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").

Warrant

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"). 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.