UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

☑ **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: 001-35068

TALPHERA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**41-2193603**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

1850 Gateway Drive, Suite 175
San Mateo, CA 94404
(650) 216-3500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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, $0.001 par value	**TLPH**	**The Nasdaq Global 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 Section 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 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 Exchange Act Rule 12b-2) Yes ☐ No ☑

The aggregate market value of the voting stock held by non-affiliates of the registrant on June 30, 2024 (the last business day of the registrant's most recently completed second fiscal quarter), based upon the last sale price reported on the Nasdaq Global Market on that date, was approximately $13.2 million. The calculation excludes 2,138,442 shares of the registrant's common stock held by current executive officers, directors and principal stockholder that the registrant has concluded are affiliates of the registrant. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of March 17, 2025, the number of outstanding shares of the registrant's common stock was 17,098,345.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's notice of annual meeting of stockholders and proxy statement to be filed pursuant to Regulation 14A within 120 days after Registrant's fiscal year end of December 31, 2024 (the "2025 Proxy Statement"), are incorporated by reference into Part III of this report.

Unless the context indicates otherwise, the terms "Talphera," "we," "us" and "our" refer to Talphera, Inc., and its consolidated subsidiary. "Niyad" and "Fedsyra" are trademarks, and "Zalviso" are registered trademarks, all owned by Talphera, Inc. This Annual Report also contains trademarks and trade names that are the property of their respective owners.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Annual Report, contains statements that discuss future events or expectations, projections of results of operations or financial condition, trends in our business, business prospects and strategies and other "forward-looking" information. In some cases, you can identify "forward-looking statements" by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These forward-looking statements are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. These forward-looking statements may relate to, among other things, our expectations regarding the scope, progress, expansion, and costs of researching, developing and commercializing our product candidates; our opportunity to benefit from various regulatory incentives; expectations for our financial results, revenue, operating expenses and other financial measures in future periods; and the adequacy of our sources of liquidity to satisfy our working capital needs, capital expenditures, and other liquidity requirements. These are only some of the factors that may affect the forward-looking statements contained in this Annual Report. For a discussion identifying additional important factors that could cause actual results to vary materially from those anticipated in the forward-looking statements, see "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" in this Annual Report. You should review these risk factors for a more complete understanding of the risks associated with an investment in our securities. However, we operate in a competitive and rapidly changing environment and new risks and uncertainties emerge, are identified or become apparent from time to time. It is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report. You should be aware that the forward-looking statements contained in this Annual Report are based on our current views and assumptions. We undertake no obligation to revise or update any forward-looking statements made in this Annual Report to reflect events or circumstances after the date hereof or to reflect new information or the occurrence of unanticipated events, except as required by law.

Summary of Principal Risk Factors

Our business is subject to numerous risks, as more fully described in this section below this summary. You should read these risks before you invest in our common stock. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy. In particular, our risks include:

- There is substantial doubt regarding our ability to continue as a going concern. We require additional capital and may be unable to raise such capital, which would force us to delay, reduce or eliminate our commercialization efforts and product development programs and could cause us to be unable to continue to operate as a going concern and cease operations.
- Our common stock may be delisted from The Nasdaq Global Market if we cannot regain compliance with Nasdaq's continued listing requirements, which could limit our ability to raise additional capital in the future, limit our investors' ability to make transactions in our common stock and subject us to additional trading restrictions.
- We may fail to realize the benefits expected from our acquisition of Lowell Therapeutics, Inc., or Lowell, which could adversely affect our stock price.
- Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.
- Our development efforts might not generate successful product candidates.
- We may fail to properly conduct and/or successfully complete our clinical trial for our lead product candidate, Niyad™.
- If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- If we experience delays or difficulties in enrolling patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- If serious adverse effects or unexpected characteristics of our product candidates are identified during development, we may need to abandon or limit the development of some or all of our product candidates.
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- The process for obtaining approval of a Premarket Approval, or PMA, application or New Drug Application, or NDA, is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources.
- Our expectations for U.S. Food and Drug Administration, or FDA, approvability of our product candidates may be inaccurate.
- We may experience difficulties in retaining our existing employees and managing our operations.
- If we, or current and potential partners, are unable to compete effectively, our products may not reach their commercial potential.
- Coverage and adequate reimbursement may not be available for our product candidates, if approved, in the United States and in Europe, which could make it difficult for us, or our partners, to sell our products profitably.
- The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.
- If we or our partners are unable to establish and maintain relationships with group purchasing organizations any future revenues or future profitability could be jeopardized.
- Existing and future legislation may increase the difficulty and cost for us to commercialize our products and affect the prices we may obtain.
- We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.
- To fund our operations, and capital requirements, we may sell additional equity securities, which may result in dilution to our stockholders, or debt securities, which may impose restrictions on our business.
- We have not yet generated significant product revenue and may never be profitable.
- We rely on third party manufacturers and suppliers for our product candidates in Asia and the United States.
- We rely on single sources of supply for the active pharmaceutical ingredients and finished product for our nafamostat-based product candidates and any disruptions in the chain of supply may cause a delay in developing our product candidates.
- Manufacturing issues may arise that could delay or increase costs related to product development and regulatory approval.

- We rely on third parties to conduct, supervise and monitor our clinical trials.
- Our relationships with clinical investigators, health care professionals, consultants, commercial partners, third-party payers, hospitals, and other customers are subject to applicable anti-kickback, fraud and abuse and other healthcare laws, which could expose us to significant penalties.
- Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.
- Business interruptions could delay our operations and sales efforts.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- We may acquire companies, product candidates or products or engage in strategic transactions.
- We face potential product liability claims and, if such claims are successful, we may incur substantial liability.
- Our employees, agents and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.
- If we cannot defend our issued patents from third party claims or if our pending patent applications fail to issue, our business could be adversely affected.
- Litigation involving patents, patent applications and other proprietary rights is expensive and time consuming.
- It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.
- We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.
- Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be payable to the United States Patent and Trademark Office and various foreign governmental patent agencies annually in several stages over the lifetime of the patents and/or applications.
- We may not be able to enforce our intellectual property rights throughout the world.
- We have not yet registered our trademarks in all our potential markets, and failure to secure those registrations could adversely affect our business.
- The market price of our common stock has historically been and may continue to be highly volatile.
- Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.
- We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.
- Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.
- Litigation may substantially increase our costs and harm our business.
- Our involvement in securities-related class action and related derivative litigation could divert our resources and management's attention and harm our business.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.
- Our effective tax rate may fluctuate, we may be adversely affected by changes in tax laws and regulations, and we may incur obligations in tax jurisdictions in excess of accrued amounts.
- Macroeconomic uncertainties, including inflationary pressures, supply chain disruptions, labor shortages, significant volatility in global markets and recession risks have in the past and may continue to adversely affect our business, future results of operations, and financial condition, the effects of which remain uncertain.
- We previously identified a material weakness in our internal control over financial reporting. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations.

The summary risk factors described above should be read together with the text of the full risk factors below in the section entitled “Risk Factors” and the other information set forth in this Annual Report on Form 10-K, including our financial statements and the related notes, as well as in other documents that we file with the U.S. Securities and Exchange Commission. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations, and future growth prospects.

TALPHERA, INC.

2024 ANNUAL REPORT ON FORM 10-K

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PART I

Item 1. Business

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings.

Our Portfolio

Our portfolio consists of nafamostat product candidates and pre-filled syringe product candidates, as further described below.

Nafamostat Product Candidates

In January 2022, we acquired Lowell Therapeutics, Inc., or Lowell, a privately held company, pursuant to the Agreement and Plan of Merger, dated as of November 14, 2021, or the Merger Agreement, in a transaction for consideration of approximately $32.5 million plus net cash acquired and certain other adjustments, and which includes up to approximately $26.0 million of contingent consideration payable in cash or stock at our option, upon the achievement of regulatory and sales-based milestones, or the Merger Agreement. In connection with the Merger Agreement, we acquired Niyad™ and LTX-608 (lyophilized vials of nafamostat for infusion into the extracorporeal circuit or direct IV infusion to the patient, respectively), an in-process research and development, or IPR&D, asset. For additional information regarding the Merger Agreement, see Note 4, "Asset Acquisition" to the consolidated financial statements in this Annual Report on Form 10-K for additional information.

Product/Product Candidate	Description	Target Use	Status
Niyad	Lyophilized vial containing nafamostat for infusion	Regional anticoagulant for infusion into the extracorporeal circuit	Received an investigational device exemption, or IDE, and Breakthrough Device Designation from the United States Food and Drug Administration, or FDA, and registrational trial is ongoing.
LTX-608	Lyophilized vial containing nafamostat for infusion	IV infusion for disseminated intravascular coagulation, or DIC, acute respiratory distress syndrome, or ARDS, acute pancreatitis, or as an anti-viral treatment	IND will be evaluated for submission following toxicology evaluation to enable Phase 2 study.

Niyad

We are developing Niyad to become the first and only FDA-approved regional anticoagulant for use in adult patients undergoing continuous renal replacement therapy, or CRRT. Niyad is infused into the extracorporeal circuit, such as the dialysis circuit during continuous renal replacement therapy, or CRRT, for acute kidney injury, or AKI, patients in the hospital. In the future, Niyad may have benefit for use in chronic kidney disease patients undergoing intermittent hemodialysis, or IHD, in dialysis centers. Our initial priority is for use during CRRT, which is the focus of the current registrational study. Niyad is being studied under an Investigational Device Exemption, or IDE, and has received Breakthrough Device Designation from the FDA and an ICD-10 procedural code from the U.S. Centers for Medicare & Medicaid Services. While not approved for commercial use in the United States, the active drug component of Niyad, nafamostat, has been approved and used in Japan and South Korea for over 30 years as a regional anticoagulant for the dialysis circuit, disseminated intravascular coagulation and acute pancreatitis. Niyad has the potential for six years of data exclusivity upon FDA approval of the device. In addition, we have filed an international patent application pursuant to the Patent Cooperation Treaty (PCT) for its use as an anticoagulant as described. Niyad is a lyophilized formulation of nafamostat, a broad-spectrum, synthetic serine protease inhibitor, which has a half-life of 8 minutes, with anticoagulant, anti-inflammatory and potential anti-viral activities.

The Niyad NEPHRO CRRT Study, which has received both IDE approval from the FDA and central Institutional Review Board, or IRB, approval, is designed as a prospective, double-blinded trial to be conducted at up to 14 U.S. hospital intensive care units. NEPHRO CRRT stands for Nafamostat Efficacy in Phase 3 Registrational Continuous Renal Replacement Therapy Study. We have initiated the NEPHRO study and we plan to submit an application for Premarket Approval, or PMA, to the FDA upon completion of the trial. The study will enroll and evaluate 70 adult patients undergoing renal replacement therapy, who cannot tolerate heparin or are at risk for bleeding. The primary endpoint of the study is mean post-filter activated clotting time using Niyad versus placebo over the first 24 hours. Key secondary endpoints include filter lifespan, number of filter changes over 72 hours, number of transfusions over 72 hours and dialysis efficacy (based on urea concentration) over the first 24 hours. We believe that decades of commercial use and post-marketing safety data available for nafamostat in Japan and South Korea can help guide and support our Niyad development efforts in the United States.

LTX-608

LTX-608 is our nafamostat formulation for direct IV infusion being explored as an investigational product for one or more of the following indications: antiviral treatment, or treatment of ARDS, DIC or acute pancreatitis. For example, third-party studies have been conducted outside the U.S. in COVID patients where initial results demonstrated that nafamostat shortens time to clinical improvement, increasing the recovery rate and lowering the mortality rate when combined with standard of care, or SOC, compared to SOC alone, in the category of the sickest COVID patients. We are currently evaluating the initial indication on which we will target and focus our resources. Nafamostat is already approved for DIC and acute pancreatitis in Japan and South Korea, which may favor focusing on one of those indications first. Nafamostat has the potential for five years of data exclusivity as a new chemical entity, or NCE, upon the first FDA approval of a new drug application that is independent from any exclusivity arising from issuance of our pending patent applications. We currently have a pending patent application for Niyad with claims drawn to priming of the extracorporeal circuit and blood flow when using nafamostat, and multiple LTX-608 pending patent applications that include claims drawn to use of nafamostat in DIC, acute pancreatitis, as an antiviral agent, in ARDS and in other conditions.

The Market Opportunity for Nafamostat Products

The current market landscape for anticoagulants used during CRRT includes heparin, a systemic anticoagulant that anticoagulates both the patient and the extracorporeal circuit, and citrate, a regional anticoagulant used for anticoagulation of the circuit only and is primarily being used off-label by physicians. Regiocit, which is a branded form of citrate in the United States, has not been approved for regional anticoagulation and is authorized under an Emergency Use Authorization, or EUA, while other forms of citrate are being used off-label for regional anticoagulation of the extracorporeal circuit. No anticoagulant is used during CRRT in 29% of cases, the default decision when physicians are concerned with the safety of heparin or citrate. According to our market research, when an anticoagulant is not used for CRRT, frequent filter clogging is the most commonly encountered unintended result, with 20-25% of research respondents stating that due to such clogging issues increased blood transfusions were needed. Since the citrate anticoagulant alternative has not received FDA approval for anticoagulation of the extracorporeal circuit, we believe that nafamostat, if approved for use in regional anticoagulation in CRRT and other procedures, may be beneficial in certain patient populations where current products may be contraindicated. Our market research indicated physicians chose not to use current anticoagulation products because of a number of concerns, including hypocalcemia, citrate lock, calcium shortages, and nursing time required to administer and monitor citrate, among other concerns.

We believe that nafamostat, which has a short half-life, may provide regional anticoagulation with potential benefits over existing products. For example, in a 1991 clinical study undertaken to elucidate the relationship between various anticoagulants and the incidence of bleeding complications during continuous hemofiltration, or CHF, and continuous hemodiafiltration, or CHDF, the incidence of bleeding during CHF and/or CDHF with heparin was 66.7% as compared to 4.3% with nafamostat.

We believe Niyad’s peak sales potential may exceed $200 million annually in the United States if it is approved for use during CRRT and IHD, based on an estimated addressable population of 500,000 patients undergoing CRRT of $575 million, and an estimated addressable population of 350,000 patients undergoing IHD of $3.5 billion. Exposure of blood to the dialysis filter causes clotting, which is a major limitation to care during CRRT, as it leads to inefficient dialysis, causes blood loss and depletes limited resources. Circuit clotting is the most frequent cause of therapy interruption in circuit dialysis procedures.

We also believe that nafamostat has the potential for use in other indications. LTX-608 is the name for our potential second nafamostat product candidate. We are evaluating the first targeted indication for LTX-608; however, since nafamostat is approved in Japan and South Korea for DIC and acute pancreatitis, one of these may be the first targeted indication for LTX-608. Our estimate of the number of DIC patients annually is over 250,000.

Competition for Nafamostat Products

Niyad is the first nafamostat product candidate we are developing to be used as a regional anticoagulant for the extracorporeal circuit. There are currently no products approved by the FDA for use as a regional anticoagulant in the extracorporeal circuit. If approved, Niyad would be the first and only product approved for this indication. As discussed above, the current standards of care being used today are heparin and citrate. Heparin is a systemic anticoagulant and cannot be used in patients who are at risk of bleeding. Citrate is complex to administer and requires significant human resource time and attention given the nature of the product, and cannot be used in patients with liver failure, which is approximately 43% of acute kidney injury patients. Based on our research of the CRRT market, heparin is used approximately 43% of the time, while citrate is used approximately 28% of the time. The remaining 29% of the time there is no anticoagulant used which is partly driven by the safety concerns with heparin or citrate. We believe the primary opportunity for Niyad is within the 57% of the market that uses either citrate or no anticoagulant.

We are evaluating the second targeted indication for our nafamostat product development candidate, LTX-608. Since nafamostat is approved in Japan and South Korea for the treatment of DIC and acute pancreatitis, we may focus on of these indications for development of our first LTX-608 product candidate.

Pre-filled Syringe (PFS) Product Candidates

Fedsyra and Phenylephrine

The PFS product candidates are ready-to-use formulations of active ingredients that are currently approved in the United States in concentrated formulations that must be diluted prior to administration to patients, and more recently in ready-to-use vial, and in the case of ephedrine, ready-to-use pre-filled syringe formulations. Hospitals currently purchase ready-to-use, pre-filled syringe presentations of these active ingredients mainly from compounding facilities that have not obtained FDA approval for the products, or manually dilute the products in-house. There are two recently FDA-approved pre-filled ephedrine syringe products available on the market, which may impact our decision on submitting an NDA and further pursuing an approval. Our product candidates have been developed in a ready-to-use strength and pre-filled into syringes that can be immediately administered to patients, eliminating the need for calculations and additional dilution and filling steps. Aguettant pre-filled syringes are focused on delivering commonly used medicines safely and efficiently. Perioperative medication errors continue, and pre-filled syringes are preferred for improving safety while containing costs. We believe that, if approved, our pre-filled syringe products may offer significant benefits to hospitals and surgery centers and avoid potential disadvantages of the currently available compounded products. We are currently focusing our resources on the registrational trial for Niyad and have therefore de-prioritized development of our pre-filled syringe product candidates. Given the two other FDA-approved products recently made available on the market, it is possible we will decide not to further pursue our pre-filled syringe product candidates.

The Market Opportunity for Pre-Filled Syringe Products

Our product candidates are innovative ready-to-use formulations of molecules that are currently approved in a concentrated formulation that must be diluted prior to administration to patients, and more recently in ready-to-use vial and, in the case of ephedrine, pre-filled syringe formulations. Hospitals primarily purchase non-FDA approved ready-to-use, pre-filled syringe products mainly from compounding facilities, or manually dilute the products in-house, but the two recently FDA approved pre-filled ephedrine products are gaining share. Our product candidates have been developed in a ready-to-use strength and pre-filled into syringes that can be immediately administered to patients, potentially eliminating the need for on-the-spot calculations and additional dilution and filling steps. We therefore believe that, if approved, our products could offer significant benefits to hospitals and surgery centers over the current compounded products. Given the two FDA-approved products recently made available on the market, it is possible we will decide not to further pursue our pre-filled syringe product candidates.

Competition for Pre-filled Syringe Products

Hospitals currently purchase non-FDA approved ready-to-use, pre-filled syringe ephedrine and phenylephrine products from compounding facilities and, in the case of ephedrine, two recently FDA-approved pre-filled syringe formulations, or manually dilute the products in-house. Our pre-filled syringe product candidates are being developed in a ready-to-use strength and pre-filled into syringes that can be immediately administered to patients, potentially eliminating the need for calculations and additional dilution and filling steps. We therefore believe that, if approved, our products may offer significant benefits to hospitals and surgery centers over the current compounded products. In addition, our pre-filled syringe product candidates will also compete with existing generic versions of concentrated vial forms of product, ready-to-use diluted vial forms of product, and for Fedsyra, two recently FDA-approved pre-filled syringes with a different formulation and concentration than our product candidate. As a result of the two recently FDA-approved pre-filled ephedrine syringes made available on the market, it is possible we will decide not to further pursue our pre-filled syringe product candidates.

Our Strategy

Our strategy is focused on developing, obtaining approval, and commercializing Niyad. We intend to expand our portfolio to include additional acute care therapies for use in medically supervised settings.

Sales and Marketing

Our sales and marketing resources are focused on pre-launch activities for Niyad. We are currently evaluating the market opportunity as well as the strategy for a potential launch of Niyad with either internal resources, or with a potential commercial partner. If we submit an NDA, and if approved, the pre-filled syringe product candidates will not require a significant sales force as we expect this will mainly be sold through contracting with hospital networks, wholesalers and group purchasing organizations.

Pharmaceutical and Device Manufacturing and Supply

For Niyad, we rely on contract manufacturers to produce our development batches, and if approved by the FDA, we will rely on contract manufacturers for commercial supply of Niyad. We currently have a single contract manufacturer that is producing the nafamostat API for Niyad, and a separate contract manufacturer producing the finished product used for development, both of which can support eventual commercial needs. We are in discussions with a back-up manufacturer of Niyad to ensure there is not a single source of supply.

If we pursue the pre-filled syringe product candidates, Aguettant will be our sole sourced manufacturer of our commercial supply of pre-filled syringe products. Aguettant currently has their own manufacturing facilities, where they produce pre-filled syringes for the European market. We will purchase the pre-filled syringes from Aguettant under our existing supply agreement if and when the FDA approves the pre-filled syringe products for marketing.

DSUVIA Divestment

We divested DSUVIA to Alora Pharmaceuticals, LLC, or Alora, in April 2023, who agreed to continue to commercialize the product and pay us royalties, sales-based milestone and other payments, as defined in the DSUVIA Agreement (see Note 3, “Discontinued Operations” to the consolidated financial statements to this Annual Report on Form 10-K for additional information regarding the DSUVIA Agreement). We will continue marketing DSUVIA to the Department of Defense, or DoD. We have no plans to further develop or commercialize any of our other sufentanil sublingual products that were previously our product candidates.

In January 2024, we entered into an agreement with XOMA (US) LLC, or XOMA, whereby we have sold our rights to all payments for services performed to support sales of DSUVIA to the DoD by Alora under the Marketing Agreement, and sales milestones we are entitled to under the DSUVIA Agreement with Alora, until XOMA receives a certain specified return on its investment, after which we will share equally in the payments earned on sales to the Department of Defense, milestones and other payments from Alora (see Note 7, “Sale of Future Payments” to the consolidated financial statements to this Annual Report on Form 10-K for additional information). This transaction was consummated to provide further funding for the development of our lead product candidate, Niyad. In October 2024, Alora notified us that they are discontinuing their DSUVIA sales efforts to non-DoD customers. At this time, we are uncertain as to the impact of this decision on sales of DSUVIA to the DoD, but we expect to be able to continue to market DSUVIA to the DoD until all inventory is sold or Alora makes the decision to no longer provide the supply of DSUVIA to the DoD. We are working to attempt to facilitate a longer-term supply arrangement for DSUVIA, but there are no assurances we will be successful.

Intellectual Property

We seek patent protection in the United States and internationally for our product candidates. Our policy is to pursue, maintain and defend patent rights developed internally or acquired externally and to protect the technology, inventions and improvements that are commercially important to the development of our business. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents granted to us in the future will be commercially useful in protecting our technology. We also rely on trade secrets to protect our commercial products and product candidates. Our commercial success also depends in part on our non-infringement of the patents or proprietary rights of third parties. For a more comprehensive discussion of the risks related to our intellectual property, please see "Risk Factors—Risks Related to Our Intellectual Property" appearing elsewhere in this Form 10-K.

Our success will depend significantly on our ability to:

- obtain and maintain patent and other proprietary protection for our product candidates;
- defend our patents;
- preserve the confidentiality of our trade secrets; and
- operate our business without infringing or misappropriating patents and other third-party proprietary rights.

We have established and continue to build proprietary positions for our product candidates in the United States and abroad. We continue to seek to obtain and expand our patent protection directed to both compositions of matter and delivery devices, as well as methods of treatment related to our product candidates Niyad and LTX-608.

We have recently filed for additional patent coverage in the United States and Europe. If issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, we expect that these patents will extend into 2045, excluding any additional term for potential patent term adjustments or patent term extensions in the United States. We note that the patent laws of foreign countries differ from those in United States, and the degree of protection afforded by foreign patents may be different from the protection offered by U.S. patents. The patent applications that we have filed and have not yet been granted may fail to result in issued patents in the United States or in foreign countries. Even if the patents do successfully issue, third parties may challenge the patents.

Pursuant to the DSUVIA Agreement, Alora acquired all patents and trademarks related to DSUVIA and DZUVEO. In addition, we and Alora entered into an intellectual property agreement pursuant to which Alora granted fully-paid, royalty-free and perpetual licenses to us under certain specified intellectual property rights acquired by Alora under the DSUVIA Agreement for, among other things, the development, manufacture, commercialization and exploitation of certain products, including Zalviso.

Further, we seek trademark protection in the United States and internationally where available and when appropriate.

Government 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, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of pharmaceutical and medical device products, which must be approved by the FDA before they may legally be marketed in the United States.

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. The process of obtaining regulatory approvals and complying with applicable laws and regulations requires the expenditure of substantial time and financial resources. Failure to comply at any time during the product development and approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, Warning Letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

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

- completion of non-clinical laboratory tests, animal trials and formulation studies according to Good Laboratory and Manufacturing Practices regulations;
- submission to the FDA of an investigational new drug, or IND, application which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices, or GCP, to establish the clinical safety and efficacy of the proposed drug product for its intended use;
- submission to the FDA of an NDA for a new drug product;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug product and the drug substance(s) are produced to assess compliance with cGMP;
- payment of application, annual program fees; and
- FDA review and approval of the NDA.

The testing and approval process requires substantial time, effort and financial resources and we cannot be certain that approval for our product candidates will be granted on a timely basis, if at all.

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

- *Phase 1.* The product is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. 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.* Involves trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted conditions and to determine dosage tolerance and optimal dosage and schedule.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical safety and efficacy in an expanded patient population at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an Institutional Review Board, or 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 or biological product has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal trials and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP and QSR for medical device requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

The results of product development, preclinical trials and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on our drug products, proposed labeling and other relevant information, will be submitted to the FDA as part of an NDA for a new drug product, requesting approval to market the product in the United States. The submission of an NDA is subject to the payment of a substantial user fee; a waiver of such fee may be obtained

under certain limited circumstances. During its review of an NDA, the FDA may inspect our manufacturers for GMP and QSR compliance, and our pivotal clinical trial sites for GCP compliance.

In addition, under the Pediatric Research Equity Act, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

The approval process is lengthy and difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA issues a Complete Response Letter at the conclusion of its review if the NDA is not yet deemed ready for approval. A Complete Response Letter generally outlines the deficiencies in the submission and may require substantial additional testing or information for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

If a product candidate does receive regulatory approval, the approval may be limited to specific conditions and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. A REMS, which can include a medication guide, patient package insert, a communication plan, elements to assure safe use and implementation system, must include a timetable for assessment of the REMS. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. In addition, the FDA may require post-approval testing which involves clinical trials designed to further assess a drug product's safety and effectiveness after the NDA.

Post-Approval Requirements

Any drug products for which we receive FDA approval 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 clinical safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. Phase 4 clinical trials are conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication or when otherwise requested by the FDA in the form of post marketing requirements or commitments. Failure to promptly conduct any required Phase 4 clinical trials could result in withdrawal of NDA approval. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Drug products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers of drug products must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Drug product manufacturers and other entities involved in the manufacturing and distribution of approved drug products 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. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, packaging, labeling, storage and shipment of the drug product. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release.

The FDA may withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, Warning Letters, holds on clinical trials, product recalls or seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

Medical Devices

Niyad, our nafamostat product in development for use as a regional anticoagulant for infusion into the extracorporeal circuit, is regulated by the FDA as a medical device since it achieves its primary intended purposes outside the body. Niyad is being studied under an Investigational Device Exemption, or IDE, and has received Breakthrough Device Designation from the FDA. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness. Niyad is a Class III device as it is novel and not eligible to demonstrate substantial equivalence to a predicate device under the 510(k) process. Class III devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, nonclinical study and clinical trial data, manufacturing information and labeling. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

In the United States, a device that presents a "significant risk" to human health, as defined by the FDA, must be the subject of an IDE application to the FDA that has to be approved by the FDA prior to the commencement of human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibition of promotion, recordkeeping, and reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The commencement or completion of any clinical trial may be delayed or halted, by the FDA or an IRB.

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA's review of a PMA application generally takes between one and three years but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer-term safety and effectiveness data for the device. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use.

The Breakthrough Devices Program is a voluntary program intended to expedite the review, development, assessment and review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions for which no approved or cleared treatment exists or that offer significant advantages over existing approved or cleared alternatives. All submissions for devices designated as breakthrough devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources, as needed. Although breakthrough designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. Breakthrough designation may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, breakthrough designation does not ensure that we will ultimately obtain FDA approval.

Pervasive and Continuing Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. These include:

- the FDA's QSR, which requires manufacturers, including their suppliers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label uses;

- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;

- medical device recalls, which require that manufacturers report to the FDA any recall of a medical device, provided the recall was initiated to either reduce a risk to health posed by the device, or to remedy a violation of the FDCA caused by the device that may present a risk to health; and

- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to sell any products outside of the United States.

Controlled Substances Regulations

Ephedrine is a scheduled listed chemical product under the Combat Methamphetamine Epidemic Act of 2005. Under this law, DEA applies strict controls and quotas on importation of ephedrine containing drug products.

The Drug Supply Chain Security Act of 2013, or DSCSA, imposes obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements are that manufacturers must provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. Further, manufacturers have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Unforeseen delays to the drug substance and drug product manufacture and supply chain may occur due to delays, errors or other unforeseen problems with the permitting and quota process. Also, any one of our suppliers, contract manufacturers, laboratories, packagers and/or distributors could be the subject of DEA violations and enforcement could lead to delays or even loss of DEA license by the contractors.

Federal and State Fraud and Abuse and Data Privacy and Security and Transparency Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical and medical device products, federal and state healthcare laws restrict certain business practices in the pharmaceutical and medical device industries. These laws include, but are not limited to, anti-kickback, false claims, data privacy and security, and transparency statutes and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for, purchasing, leasing, ordering or arranging for the purchasing, leasing or ordering of any item or service reimbursable under Medicare, Medicaid or other federal healthcare program. The term "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and/or formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices involving remuneration that may be alleged to be intended to induce purchasing, leasing or ordering may be subject to scrutiny if they do not qualify for an exception or safe harbor. The failure to satisfy all of the requirements of an applicable exception or safe harbor do 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.

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Rather, if "one purpose" of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. In addition, the Affordable Care Act codified case law that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute also constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below).

The federal civil False Claims Act and related laws prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval 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. 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. Companies also have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

Further, the Civil Monetary Penalties Law imposes civil penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to, among others, a federal healthcare program that the person knows or should know is for a medical or other item or service that was not provided as claimed or is false or fraudulent.

Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third party payers, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up 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 U.S. 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.

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, or HITECH, and their implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information primarily on covered entities, business associates and their covered subcontractors. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates that are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four 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 federal courts to enforce

the federal HIPAA laws 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 differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. International laws, such as the European Union General Data Protection Regulation, or GDPR, (EU 2016/679) and Swiss Federal Act on Data Protection, regulate the processing of personal data within the European Union and between countries in the European Union and countries outside of the European Union, including the United States. Failure to provide adequate privacy protections and maintain compliance with safe harbor mechanisms could jeopardize business transactions across borders and result in significant penalties.

Additionally, the federal Physician Payments Sunshine Act within the Affordable Care Act and its implementing regulations, require that certain manufacturers of drugs, devices, biologicals and medical supplies, for which federal healthcare program payment is available, report information related to certain payments or other transfers of value made or distributed to physicians, (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of such providers and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

Also, many states have similar healthcare statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. FDA and some states require the posting of information relating to clinical studies. In addition, certain states such as California require pharmaceutical companies to implement a comprehensive compliance program that includes a limit on expenditures for, or payments to, individual medical or health professionals. Moreover, several states have enacted legislation requiring pharmaceutical manufacturers to, among other things, file periodic reports with the state, make periodic public disclosures on sales and marketing activities, report information related to drug pricing, require the registration of sales representatives, and prohibit certain other sales and marketing practices.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion of products from reimbursement under government programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, 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 will be 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 and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Pharmaceutical Coverage, Pricing and Reimbursement

In both domestic and foreign markets, sales of any of our product candidates, if approved, will depend in part on the availability of coverage and adequate reimbursement from third-party payers. Third-party payers include government health administrative authorities, managed care providers, private health insurers and other organizations. Sales of our product candidates, if approved, will depend substantially, both domestically and abroad, on the extent to which the costs of such products will be paid by third-party payers. These third-party payers are increasingly focused on containing healthcare costs by challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the coverage and reimbursement status of newly approved healthcare products. Such payers 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. Third-party payers and hospitals may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such products. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact utilization. Because each third-party payer individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming, costly and sometimes unpredictable process. We or our providers may be required to provide scientific and clinical support for the use of any product to each third-party payer and hospital separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of products for which we receive regulatory approval. This process could delay the market acceptance of any such product and could have a negative effect on our future revenues and operating results. We cannot be certain that any of our product candidates, if approved, will be considered medically necessary or cost-effective. Because coverage and reimbursement determinations are made on a

payer-by-payer basis, obtaining acceptable coverage and reimbursement from one payer does not guarantee that we will obtain similar acceptable coverage or reimbursement from another payer. If we or our partners are unable to obtain and maintain coverage of, and adequate reimbursement and payment levels for, the products from third-party payers, physicians may limit how much or under what circumstances they will prescribe or administer them. This in turn could affect our or our partners' ability to successfully commercialize products and impact our profitability, results of operations, financial condition and future success. Third-party payers, government healthcare programs, wholesalers, group purchasing organizations, and hospitals frequently require that companies negotiate agreements that provide discounts or rebates from list prices. We expect increasing pressure to offer larger discounts or discounts to a greater number of these organizations to maintain acceptable reimbursement levels for and access to products for which we receive regulatory approval. Net prices for drugs may be reduced by these mandatory discounts or rebates required by government healthcare programs, private payers, wholesalers, group purchasing organizations, hospitals, and by any future relaxation of laws that presently restrict imports of drugs from policy and payment limitations in setting their own reimbursement policies. In addition, if competitors reduce the prices of their products, or otherwise demonstrate that they are better or more cost effective than products for which we receive regulatory approval, this may result in a greater level of reimbursement for their products relative to our products, which would reduce sales of our products and harm our results of operations.

There have been, and there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to commercialize products profitably. We anticipate that the federal and state legislatures and the private sector will continue to consider and may adopt and implement healthcare policies, such as the Affordable Care Act, intended to curb rising healthcare costs. These cost containment measures may include: controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government health care programs; controls on healthcare providers; challenges to or limits on the pricing of drugs, including pricing controls, or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; and public funding for cost effectiveness research, which may be used by government and private third-party payers to make coverage and payment decisions. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In addition, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for our products from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

Healthcare Reform

In the United States and foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state level that seek to reduce healthcare costs. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, any negotiated prices for our future products will likely be lower than the prices we might otherwise obtain from non-governmental payers. Moreover, private payers often follow federal healthcare coverage policy and payment limitations in setting their own payment rates.

Furthermore, political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental change. Initiatives to reduce the federal deficit and to reform healthcare delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls on pharmaceuticals and other fundamental changes to the healthcare delivery system. Any proposed or actual changes could limit or eliminate our spending on development projects and affect our ultimate profitability.

In the United States, the Affordable Care Act was enacted in an effort to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, impose new taxes and fees on the health industry and impose additional health policy reforms. There have been amendments to, and judicial, executive branch and Congressional challenges to, certain aspects of the Affordable Care Act. For example, the Inflation Reduction Act of 2022, or 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 and creating a new manufacturer discount program. In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. Aggregate reductions of Medicare payments to providers went into effect on April 1, 2013, and will stay in effect through 2032 unless Congressional action is taken. The American Taxpayer Relief Act further reduced Medicare payments to several providers, including hospitals. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, which began on January 1, 2024. It is possible that there will be additional health reform measures.

Legislative and regulatory proposals have been made to expand post-approval requirements and further restrict sales and promotional activities for pharmaceutical and medical device products. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes will be, if any, on products for which we receive regulatory approval.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our products may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing and reform government program reimbursement methodologies for drugs. For example, the IRA, among other things (i) directs the U.S. Department of Health and Human Services , or HHS, to negotiate the price of certain high-expenditure, single-source drugs that have been on the market for at least 7 years covered under Medicare, or the Medicare Drug Price Negotiation Program, and (ii) 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, 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 are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing.

Further, there may continue to be additional proposals relating to the reform of the U.S. healthcare system, some of which could further limit the prices we are able to charge for products for which we receive marketing approval, or the amounts of reimbursement available for our products once approved. If future legislation were to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our business. Managed care organizations, as well as Medicaid and other government agencies, continue to seek price discounts. Some states have implemented, and other states are considering, price controls or patient access constraints under the Medicaid program, and some states are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid-eligible. Due to the volatility in the current economic and market dynamics, we are unable to predict the impact of any unforeseen or unknown legislative, regulatory, payer or policy actions, which may include cost containment and other healthcare reform measures. Such policy actions could have a material adverse impact on our profitability.

Employees and Human Capital Resources

As of December 31, 2024, we employed 13 full-time employees, approximately 85% of whom work out of our corporate offices in San Mateo, CA. Talphera is committed to pay equity, regardless of gender or race/ethnicity, and conducts pay equity analyses on an annual basis.

We invest in our workforce by offering competitive salaries, wages, and benefits. We endeavor to foster a strong sense of ownership by offering all employees stock options and restricted stock units under our broad-based stock incentive program. We also offer comprehensive and locally relevant benefits for all eligible employees. We recognize and support the growth and development of our employees.

None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Corporate Information

We were originally incorporated as SuRx, Inc. in Delaware on July 13, 2005. We subsequently changed our name to AcelRx Pharmaceuticals, Inc, and in January 2024, to Talphera, Inc. We file electronically with the U.S. Securities and Exchange Commission, or SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We make available on our website at www.talphera.com, free of charge, copies of these reports as soon as reasonably practicable after filing these reports with, or furnishing them to, the SEC.

Item 1A. Risk Factors

Our operations and financial results are subject to various risks and uncertainties. You should carefully consider the risks described below, together with all of the other information in this report, including our financial statements and notes thereto. If any of the following risks actually materialize, our business, financial condition, results of operations, liquidity, and future prospects could be materially harmed, the price of our common stock could decline, and you could lose part or all of your investment.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.

We have incurred significant net losses since our inception in July 2005. In addition, we have generated negative cash flows from operations and we expect to incur significant losses in 2025 and the foreseeable future. These conditions raise substantial doubt about our ability to continue as a going concern.

We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. To date, we have financed our operations primarily through the issuance of equity securities, borrowings and royalty financings. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenues. We expect to continue to incur substantial expenses as we support research and development activities for our product candidates. If our product candidates are not successfully developed or commercialized in the U.S., or if revenues are insufficient following marketing approval, we will not achieve profitability and our business may fail. Our success is also dependent on current and future collaborations to market our products outside of the United States, which may not materialize or prove to be successful.

We require additional capital and may be unable to raise such capital, which would force us to delay, reduce or eliminate our commercialization efforts and product development programs and could cause us to be unable to continue to operate as a going concern and cease operations.

Launch of a commercial pharmaceutical or medical device product and the required development activities associated with those products can be time consuming and costly. We expect to incur significant expenditures in connection with supporting our research and development activities for our product candidates.

Clinical trials, regulatory reviews, and the launch of a commercial product are expensive activities. In addition, commercialization costs for our product candidates, if approved, in the United States may be significantly higher than estimated as a result of technical difficulties or otherwise. Revenues may be lower than expected and costs to produce such revenues may exceed those revenues. We will need to seek additional capital to continue operations. Such capital demands could be substantial. In the future, we may seek to raise such additional capital through public or private equity offerings, debt securities, a new debt facility, monetizing or securitizing certain assets, entering into product development, license or distribution agreements with third parties, or divesting any of our product candidates. Such arrangements may not be available on favorable terms, if at all.

If we are unsuccessful in efforts to raise additional capital, based on our current levels of operating expenses, our current capital is not expected to be sufficient to fund our operations for the next twelve months. These conditions raise substantial doubt about our ability to continue as a going concern.

The consolidated financial statements for the year ended December 31, 2024, were prepared on the basis of a going concern, which contemplates that we will be able to realize our assets and discharge liabilities in the normal course of business. These financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Future events and circumstances, including those beyond our control, may cause us to consume capital more rapidly than we currently anticipate. Furthermore, any product development, licensing, distribution or sale agreements that we enter into may require us to relinquish valuable rights. We may not be able to obtain sufficient additional funding or enter into a strategic transaction in a timely manner. If adequate funds are not available, we would be required to reduce our workforce, reduce the scope of, or cease, the development and subsequent potential commercial launch of our product candidates in advance of the date on which we exhaust our cash resources to ensure that we have sufficient capital to meet our obligations and continue on a path designed to preserve stockholder value.

Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- further scale back or discontinue the development of our product candidates;
- seek corporate partners for our product candidates on terms that might be less favorable than might otherwise be available; or
- relinquish, or license on unfavorable terms, our rights to technologies, products or product candidates that we otherwise would seek to develop or commercialize ourselves.

During the past several years, domestic and international financial markets have experienced, and they may continue to experience, extreme disruption from time to time, including, among other things, high volatility, significant declines in stock prices and severely diminished liquidity and credit availability for both borrowers and investors. Such adverse capital and credit market conditions could make it more difficult to obtain additional capital on favorable terms, or at all, which could have a material adverse effect on our business and growth prospects. For example, our ability to raise additional capital may be adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the U.S. and worldwide resulting from the ongoing military conflicts between Hamas and Israel, and between Russia and Ukraine and related sanctions imposed against Russia.

To fund our operations and capital requirements, we may sell additional equity securities, which may result in dilution to our stockholders, or debt securities, or enter into a new debt facility which may impose restrictions on our business.

We expect that significant additional capital will be needed in the future to continue our planned operations and capital requirements. In the long-term, our existing capital resources will not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to sustain our operations. In order to raise additional funds to support our operations, we may sell additional equity securities. We may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. Selling additional equity securities may result in dilution to our existing stockholders and new investors may be materially diluted by subsequent sales. Incurring additional indebtedness, including through the sale of debt securities or entering into a new debt facility, would result in increased fixed payment obligations and could also result in additional restrictive covenants, such as

limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions, such as minimum cash balances, that could adversely impact our ability to conduct our business. Sales of equity or debt securities may also provide new investors with rights superior to our existing stockholders. If we are unable to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected, and we may not be able to meet our debt service obligations.

We have not yet generated significant product revenue and may never be profitable.

Our ability to generate revenue from commercial sales and/or royalties and achieve profitability depends on our ability, alone and with collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize our products. We do not anticipate generating significant near-term revenues from our product candidates, if approved, in the United States. Our ability to generate future revenues from product sales depends heavily on the success in:

- obtaining and maintaining regulatory approval for our product candidates in the United States; and
- launching and commercializing our product candidates, if approved, in the United States by building, internally or through collaborations, an institutionally focused sales force, which may require additional funding.

Because of the numerous risks and uncertainties associated with launching a commercial pharmaceutical or medical device product, necessary product development activities and the regulatory environment, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are delayed in receiving regulatory approval for our product candidates in the United States, or if we are required by the FDA to complete activities in addition to those we currently anticipate or have already completed.

In October 2024, Alora notified us that they are discontinuing their DSUVIA sales efforts to non-DoD customers. At this time, we are uncertain as to the impact of this decision on sales of DSUVIA to the DoD, but we expect to be able to continue to market DSUVIA to the DoD until all inventory is sold or Alora makes the decision to no longer provide the supply of DSUVIA to the DoD. We are working to attempt to facilitate a longer-term supply arrangement for DSUVIA, but there are no assurances we will be successful. The XOMA Threshold may never be attained, and we may never realize sufficient payments from our retained future interest in DSUVIA from Alora to become profitable. Although we had a collaboration agreement with Grünenthal for commercialization of Zalviso in Europe and Australia, Grünenthal was unable to achieve a level of commercial sales of Zalviso to trigger sales milestone payments that would have been payable to us.

Even if our product candidates are approved in the United States, or the XOMA Threshold is attained, we may not become profitable and may need to obtain additional funding to continue operations.

Future sales of DSUVIA to the DoD are not predictable, may occur on an irregular basis and may not meet our expectations due to various U.S. government-related factors that are beyond our control and into which we have little to no visibility, including the timing and extent of future U.S. military deployments.

In October 2024, Alora notified us that they are discontinuing their DSUVIA sales efforts to non-DoD customers. At this time, we are uncertain as to the impact of this decision on sales of DSUVIA to the DoD, but we expect to be able to continue to market DSUVIA to the DoD until all inventory is sold or Alora makes the decision to no longer provide the supply of DSUVIA to the DoD. We are working to attempt to facilitate a longer-term supply arrangement for DSUVIA, but there are no assurances we will be successful. Under the DSUVIA Agreement, Alora is responsible for commercializing DSUVIA except that we retain the responsibility for driving the demand within the DoD, and, if the XOMA Threshold is achieved, we will be entitled to receive quarterly payments in an amount equal to one-half of the 75% of net DSUVIA sales to the DoD. See Note 3, “Discontinued Operations” and Note 7, “Sale of Future Payments” to the consolidated financial statements to this Annual Report on Form 10-K for additional information. Future sales of DSUVIA by Alora to the DoD are not predictable, may occur on an irregular basis, and may not meet expectations due to various U.S. government-related factors that are beyond our control and into which we have little to no visibility, including the timing and extent of future U.S. military deployments. Even if Alora does generate revenue from such sales and the XOMA Threshold is achieved such that we receive payments, we may never generate revenue that is significant or predictable, which could impair our value and our ability to raise capital, expand our business or continue our operations.

Risks Related to Drug Development and Commercialization

We may fail to realize the benefits expected from our acquisition of Lowell, which could adversely affect our stock price.

Our acquisition of Lowell is our largest acquisition to date. Our primary business strategy is focused on developing, obtaining approval, and commercializing our product candidates, including Niyad and LTX-608 that we acquired from Lowell. The anticipated benefits we expect from this acquisition are, necessarily, based on projections and assumptions about the combined businesses of our company and Lowell, which may not materialize as expected or which may prove to be inaccurate. The value of our common stock could be adversely affected if we are unable to realize the anticipated benefits from the acquisition on a timely basis or at all. Achieving the benefits of the acquisition of Lowell will depend, in part, on our ability to continue to integrate the business, operations and products of Lowell successfully and efficiently with our business. The challenges involved in this integration include, but are not limited to, (i) difficulties entering new markets and integrating new product candidates with which we have no or limited direct prior experience; and (ii) successfully managing relationships with our combined supplier base.

Our failure to identify or accurately assess the magnitude of certain liabilities we assumed in the acquisition could result in unexpected litigation or regulatory exposure, unfavorable accounting charges, unexpected increases in taxes due, a loss of anticipated tax benefits or other adverse effects on our business, operating results or financial condition.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

We have experienced and may in the future experience delays in clinical trials of our product candidates. For example, to date, our Niyad clinical trial has had slower than expected site initiation and patient enrollment. Our FDA-required clinical trials for our product candidates could be delayed for a variety of reasons, including:

- inability to raise funding necessary to initiate or continue a trial;
- inability to pay significant FDA filing fees;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold by the FDA, Institutional Review Board, or IRB, or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites;
- delays in obtaining required IRB approval at each site;
- delays in recruiting suitable patients or subjects to participate in a trial;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment or being delayed in entering data to allow for clinical trial database closure;
- time required to add new clinical sites;
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials; or
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If any future FDA-required clinical trials are delayed for any reason, our development costs may increase, our approval process for our product candidates could be delayed, our ability to commercialize and commence sales of our product candidates could be materially harmed, which could have a material adverse effect on our business.

Our development efforts might not generate successful product candidates.

We plan to invest a significant portion of our efforts and financial resources in the identification or asset acquisition of our product candidates. Our ability to generate product revenue from our product candidates, which may not occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of these product candidates. The success of these product candidates and any other product candidates we may develop, in-license or acquire will depend on many factors, including the following:

- successful enrollment in, and completion of, clinical trials;
- demonstrating safety and efficacy;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates;
- developing a sales and marketing organization or outsourcing these functions to third parties;
- launching commercial sales of the product candidates, if and when approved, whether alone or selectively in collaboration with others;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payers;
- effectively competing with other products;
- a continued acceptable safety profile of the products following approval;
- enforcing and defending intellectual property rights and claims; and
- other legal, regulatory, compliance, privacy, and fraud and abuse matters.

If we do not accomplish one or more of these goals in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would harm our business.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

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 our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials could occur at any stage of testing. The outcome of early clinical trials may not be predictive of the success of later clinical trials, and interim results of a particular clinical trial do not necessarily predict final results of that trial.

Moreover, clinical data is often susceptible to multiple interpretations and analyses. 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 products.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including that:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate; enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or in receiving marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates, could allow our competitors to bring products to market before we do, and could impair our ability to successfully commercialize our product candidates, any of which may harm our business and results of operations.

If we experience delays or difficulties in enrolling patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, or analogous regulatory authorities outside the United States. In addition, some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of health care professionals;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll enough patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse effects or unexpected characteristics of our product candidates are identified during development, we may need to abandon or limit the development of some or all of our product candidates.

It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. Adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could cause us, any current or future collaborators, an institutional review board or regulatory authorities to interrupt, delay or halt clinical trials of one or more of our product candidates and could result in a more restrictive label, or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If adverse effects were to arise in patients being treated with any of our product candidates, it could require us to halt, delay or interrupt clinical trials of such product candidate or adversely affect our ability to obtain requisite approvals to advance the development and commercialization of such product candidate. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

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

We have limited financial and managerial resources. As a result, we may forego or delay the pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements.

The process for obtaining approval of a PMA or NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources.

If the FDA determines that any of the clinical work submitted, including the clinical trials, Human Factors studies and bench testing submitted for a product candidate in support of a PMA or NDA were not conducted in full compliance with the applicable protocols for these trials, studies and testing as well as with applicable regulations and standards, or if the FDA does not agree with our interpretation of the results of such trials, studies and testing, the FDA may reject the data and results. The FDA may audit some or all of our clinical trial sites to determine the integrity of our clinical data. The FDA may audit some or all of our study sites to determine the integrity of our data and may audit the data and results of bench testing. Any rejection of any of our data would negatively impact our ability to obtain marketing authorization for our product candidates and would have a material adverse effect on our business and financial condition. In addition, an NDA or PMA may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug or device approval during the review period. For example, although many products have been approved by the FDA in recent years under Section 505(b)(2) of the FDCA, objections have been raised to the FDA's interpretation of Section 505(b)(2). If challenges to the FDA's interpretation of Section 505(b) (2) are successful, the FDA may be required to change its interpretation, which could delay or prevent the approval of such an NDA. Any significant delay in the acceptance, review or approval of an NDA or PMA that we have submitted would have a material adverse effect on our business and financial condition and would require us to obtain significant additional funding.

Our expectations for FDA approvability of our product candidates may be inaccurate, and we may be required to conduct additional manufacturing, nonclinical or clinical development work in order to obtain FDA approval for these products, which would add to our expenses and delay any associated revenue.

Nafamostat is being developed for use in both medical devices and drug indications. Although nafamostat is approved for certain uses in Japan, our ability to leverage that for an expedited development and approval pathway with the FDA may be limited, and we may be required to conduct additional unanticipated nonclinical studies and clinical trials in order to seek approval in the U.S. We are studying Niyad™ in the NEPHRO CRRT study under an investigational device exemption, or IDE. Niyad has received Breakthrough Device Designation from the FDA for regional anticoagulant for infusion into the extracorporeal circuit and is expected to be used during renal replacement therapy for acute kidney injury patients in the hospital and for end-stage renal disease patients receiving dialysis in outpatient clinics. We expect that Niyad will require approval of a PMA application for commercialization in the U.S., and as a company we have never submitted nor received approval for a PMA.

The active drug component of Niyad, nafamostat, is also being developed for drug indications as LTX-608, for which we expect to submit Investigational New Drug applications once IND-enabling studies have been completed. We may be delayed in the submission of our planned INDs if there are unexpected findings in our nonclinical studies, which could also adversely impact our ongoing NEPHRO CRRT study and planned PMA submission.

A key part of our business strategy is to establish collaborative relationships to commercialize and fund development and approval of our products, particularly outside of the United States. We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our products successfully, if at all.

We will need to establish and maintain successful collaborative relationships to obtain international sales, marketing and distribution capabilities for our products. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty. For example:

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical or regulatory results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- our contracts for collaborative arrangements are or may be terminable at will on written notice and may otherwise expire or terminate, and we may not have alternatives available to achieve the potential for our products in those territories or markets;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration, including in connection with any contractual breach notice;

- we have limited control over the decisions of our partners, and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delays to the partnered program;

- our ability to generate future payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drugs and devices, maintain regulatory approvals and our ability to successfully manufacture and achieve market acceptance of our products;

- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;

- our partners may not devote sufficient capital or resources towards our products; and

- our partners may not comply with applicable government regulatory requirements necessary to successfully market and sell our products.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, any research, clinical development, manufacturing or commercialization efforts pursuant to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms, we may have to undertake development and commercialization activities at our own expense.

We may experience difficulties in retaining our existing employees and managing our operations.

We need to retain and maintain our existing managerial, operational, regulatory, developmental, finance and other personnel and resources in order to develop our product candidates and manage our operations. Our current infrastructure may be inadequate to support our strategy and any future workforce reduction may be disruptive to our operations, may negatively affect our productivity, and may constrain our commercialization activities. For example, a workforce reduction could yield unanticipated consequences, such as attrition beyond planned staff reductions, negatively impacting employee morale and our corporate culture, or increased difficulties in our day-to-day operations, and prevent us from developing our product candidates as rapidly as planned. If we encounter such unanticipated consequences, we may have difficulty retaining and attracting personnel. In addition, the implementation of any additional workforce or expense reduction programs may divert the efforts of our management team and other key employees, which could adversely affect our business. Furthermore, we may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our cost reduction plan, due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the cost reduction plan, our operating results and financial condition would be adversely affected.

If we, or current and potential partners, are unable to compete effectively, our products may not reach their commercial potential.

The U.S. biotechnology and pharmaceutical industries are characterized by intense competition and cost pressure. Our Niyad product candidate, if approved in the U.S., may compete with currently available anticoagulants such as heparin and citrate. The LTX-608 nafamostat product candidates, if approved in the U.S., may compete with existing or emerging third party products. The PFS product candidates, if approved in the U.S., may compete with other ready-to-use formulations of ephedrine and phenylephrine.

Key competitive factors affecting the commercial success of our approved products are likely to be efficacy, safety profile, reliability, convenience of dosing, price and reimbursement. Many of our competitors and potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of drug candidates, obtaining FDA and other regulatory approval of products, and the commercialization of those products. Accordingly, our competitors may be more successful than we are in obtaining FDA approval for drugs and devices and achieving widespread market acceptance. Our competitors' drugs, devices or drug delivery systems may be more effective, have fewer adverse effects, be less expensive to develop and manufacture, or be more effectively marketed and sold than any product we may seek to commercialize. This may render our products obsolete or non-competitive. We anticipate that we will face intense and increasing competition as new drugs and devices enter the market, additional technologies become available, and competitors establish collaborative or licensing relationships, which may adversely affect our competitive position. These and other competitive risks may materially adversely affect our ability to attain or sustain profitable operations.

Coverage and adequate reimbursement may not be available for our product candidates, if approved, in the United States and in Europe, which could make it difficult for us, or our partners, to sell our products profitably.

Our and our partners' ability to commercialize our product candidates in the future, if approved, in the United States will depend, in part, on the extent to which coverage and adequate reimbursement will be available from government payer programs at the federal and state levels, authorities, including Medicare and Medicaid, private health insurers, managed care plans and other third-party payers.

No uniform policy requirement for coverage and reimbursement for drug products exists among third-party payers in the United States or Europe. Therefore, coverage and reimbursement can differ significantly from payer to payer. As a result, the coverage determination process is often a time-consuming and costly process that will require us or our partners to provide scientific and clinical support for the use of the approved products to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such products. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact utilization. Our or our partners' inability to promptly obtain and sufficiently maintain coverage and adequate reimbursement rates from third party payers could significantly harm our operating results, our ability to raise capital needed to commercialize our approved drugs and our overall financial condition.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. There have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our or our partners' ability to sell the products profitably. These legislative and/or regulatory changes may negatively impact the reimbursement for our products, following approval. The availability of numerous generic pain medications may also substantially reduce the likelihood of reimbursement for approved products in Europe and elsewhere. The application of user fees to generic drug products may expedite the approval of additional pain medication generic drugs. We would expect that our product candidates will experience pricing pressures in connection with the product sale due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. If we or our partners fail to successfully secure and maintain reimbursement coverage for our products or are significantly delayed in doing so, there may be difficulty achieving market acceptance of our products and our business will be harmed.

Furthermore, market acceptance and sales of our products will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payers, such as private health insurers, hospitals and health maintenance organizations, decide which drugs and devices they will pay for and establish reimbursement levels. We cannot be sure that reimbursement will be available for our product candidates, if approved, in the United States or in Europe. Also, reimbursement amounts may reduce the demand for, or the price of, our products. For example, additional studies in Europe may be needed to ensure premium reimbursement in certain countries. If reimbursement is not available, or is available only to limited levels, we, or our partners, may not be able to successfully commercialize our product candidates, if approved, in the United States or in Europe. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Additionally, the regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs and devices vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. 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 in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues able to be generated from the sale of the product in that country.

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

If we are found to have improperly promoted off-label uses of our products in the United States, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription drug and medical device products. 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 the FDA determines that our or our partners' public disclosures, promotional materials or training constitutes promotion of non-approved or off-label use, it could request modifications to disclosure policies, training or promotional materials or subject us or our partners to regulatory or enforcement actions, including the issuance of an untitled letter, a Warning Letter, injunction, seizure, civil fine or criminal penalties and a requirement for corrective advertising, including Dear Doctor letters. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our or our partners' promotional or training materials to constitute promotion of non-approved or off-label use, which could result in significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, increased losses and diminished profits and the curtailment or restructuring of operations, any of which could adversely affect our or our partners' ability to operate and, thus, adversely impact our business and our financial results. The FDA or other enforcement authorities could also request that we enter into a consent decree or a corporate integrity agreement or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, in the United States, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we or our partners are unable to establish and maintain relationships with group purchasing organizations any future revenues or future profitability could be jeopardized.

Many end-users of pharmaceutical and medical device products have relationships with group purchasing organizations, or GPOs, whereby such GPOs provide such end-users access to a broad range of pharmaceutical and medical device products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug and device purchasing decisions of such end-users. Hospitals and other end-users contract with the GPO of their choice for their purchasing needs. We expect to derive revenue from end-user customers that are members of GPOs for our product candidates, if approved. Establishing and maintaining strong relationships with these GPOs will require us to be a reliable supplier, remain price competitive and comply with FDA regulations. We currently do not have any commercial products that we can distribute through our existing GPO partners. In addition, the GPOs with whom we do have relationships may have relationships with manufacturers that sell competing products, and such GPOs may earn higher margins from these products or combinations of competing products or may prefer products other than ours for other reasons. If we, or our partners, are unable to establish or maintain our GPO relationships, sales of our product candidates, if approved, and related revenues could be negatively impacted.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

Existing and future legislation may increase the difficulty and cost for us to commercialize our products and affect the prices we may obtain.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, was enacted in an effort to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, impose new taxes and fees on the health industry and impose additional health policy reforms.

The Affordable Care Act continues to substantially change health care financing and delivery by both governmental and private insurers, which may increase our regulatory burdens and operating costs.

There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or 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 and creating a new manufacturer discount program. It is possible that there will be additional health reform measures. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is also unclear how any such challenges and the healthcare reform measures of the second Trump administration will impact the Affordable Care Act. We expect that the

Affordable Care Act and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to successfully commercialize our products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our products may lose regulatory approval and we may not achieve or sustain profitability, which would adversely affect our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. Aggregate reductions of Medicare payments to providers went into effect on April 1, 2013, and due to subsequent legislative amendments to the statute will stay in effect until 2032, unless Congressional action is taken. The American Taxpayer Relief Act further reduced Medicare payments to several providers, including hospitals. Additionally, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, which began on January 1, 2024.

In the United States, there has been increasing legislative and enforcement interest with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing and reform government program reimbursement methodologies for drugs. At the federal level, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs that have been on the market for at least 7 years covered under Medicare, or the Medicare Drug Price Negotiation Program, and (ii) 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 reimbursement 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, 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 are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. Furthermore, even after initial price and reimbursement approvals, reductions in prices and changes in reimbursement levels can be triggered by multiple factors, including reference pricing systems and publication of discounts by third party payers or authorities in other countries. In Europe, prices can be reduced further by parallel distribution and parallel trade (i.e., arbitrage between low-priced and high-priced countries). If any of these events occur, revenue from sales of our products in Europe would be negatively affected.

Legislative and regulatory proposals have been made to expand post-approval requirements and further restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our products, if any, may be.

We expect that additional healthcare reform measures will be adopted within and outside the United States in the future, any of which could negatively impact our business. The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect the demand for any drug or device products for which we have obtained or may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability, and the level of taxes that we are required to pay.

Risks Related to Our Reliance on Third Parties

We will rely on third party manufacturers to produce clinical supplies of our product candidates. The failure of third-party manufacturers to provide us with adequate clinical supplies, and if approved, commercial supplies, could result in a material adverse effect on our business.

We currently use third party manufacturers to produce clinical supplies of our product candidates. Reliance on third party manufacturers entails many risks including:

- the inability to meet our product specifications and quality requirements consistently;
- the inability to procure raw materials in a timely fashion due to ongoing challenges in the global supply chain;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to maintain in good order our production and manufacturing equipment for our products;
- a failure to comply with cGMP and similar foreign standards;
- the inability to negotiate manufacturing or supply agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing or supply agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for essential product components or finished goods, such that if we are unable to secure a sufficient supply of these product components or finished goods, we will be unable to manufacture, supply and sell our products in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified secondary or backup suppliers for those essential components or finished goods that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, economic sanctions, or government orders related to pandemics;
- carrier disruptions due to international conflicts and/or increased costs that are beyond our control; and
- the failure to deliver our products under specified storage conditions and in a timely manner.

Any of these events could lead to stock outs, inability to successfully commercialize our products, if approved, clinical trial delays, or failure to obtain regulatory approval. Some of these events could be the basis for FDA action, including injunction, recall, seizure, or total or partial suspension of production. If any of these events were to occur, our business would be materially adversely affected.

We rely on limited sources of supply for the active pharmaceutical ingredient, or API, and finished product of our nafamostat-based product candidates and any disruption in the chain of supply may cause a delay in developing our product candidates.

We currently have a single source of supply of API and finished product for our nafamostat-based product candidates. If supply from those vendors is interrupted or discontinued, or if we are unable to negotiate supply agreements with them, there could be a significant impact on our development activities for those product candidates.

In addition, our contract development and manufacturing organization, or CDMO, our sole-source for the finished goods of our nafamostat-based product candidates, is located in China, and we expect to rely on this supplier for the foreseeable future. Chinese biotechnology companies and CDMOs may become subject to trade restrictions, sanctions, and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of finished goods to us. In addition, in March 2025, the U.S. government imposed tariffs on biopharmaceutical products imported from China, which will increase our cost of doing business until we are able to source such products outside of China and any other jurisdiction subject to such tariffs. We have contracted with, or are in the process of pursuing contracts with, alternative suppliers or manufacturers outside of China for our finished goods for our nafamostat-based product candidates. While we believe that our current manufacturing plan will provide us with alternative sources for such supplies, if supplies are interrupted, or the quality of finished goods provided by such alternative sources is not to our specification, it could cause delays in our supply chain and increase the cost of manufacturing our nafamostat-based product candidates, which could harm our business.

Manufacturing issues may arise that could delay or increase costs related to product development and regulatory approval.

We have relied, and will continue to rely, on contract manufacturers, fabricators and third-party service providers to produce the necessary Niyad product for clinical and non-clinical development and eventually for commercial sales. We currently outsource manufacturing and packaging of Niyad to third parties and intend to continue to do so. These purchases were made and will continue to be made utilizing short-term purchase order agreements and we may not be able to enter into long-term agreements for commercial supply with these third-party manufacturers or may be unable to do so on acceptable terms. In addition, we may encounter production issues with our current or future contract manufacturers and other third-party service providers, including the reliability of the production equipment, quality of the finished goods produced, their inability to meet demand or other unanticipated delays.

As we scale up manufacturing of Niyad in the future to support commercial demand, and conduct required production and stability testing, these processes may require refinement or resolution. For example, as we scale up, we may identify significant issues which could result in failure to maintain regulatory approval of Niyad, increased scrutiny by regulatory agencies, delays in clinical development and regulatory approval, increases in our operating expenses, or failure to obtain approval for our product candidates in the United States.

The facilities of any of our future manufacturers of Niyad must be approved by the FDA before commercial distribution from such manufacturers occurs. We do not fully control the manufacturing process and are completely dependent on these third-party manufacturing partners for compliance with the FDA or other foreign regulatory agency's requirements for manufacture. In addition, although our third-party manufacturers are well-established manufacturers, we are dependent on their continued adherence to cGMP manufacturing and acceptable changes to their processes. If our manufacturers do not meet the FDA or other foreign regulatory agency's strict regulatory requirements, they will not be able to secure FDA or other foreign regulatory agency approval for their manufacturing facilities. If the FDA or the relevant foreign regulatory agency does not approve these facilities for the commercial manufacture of Niyad, we will need to find alternative suppliers, which would result in significant delays in obtaining regulatory agency approval. These challenges may have a material adverse impact on our business, results of operations, financial condition and prospects.

We may not be able to establish additional sources of supply for Niyad. Such suppliers are subject to FDA and other foreign regulatory agency's regulations requiring that materials be produced under cGMPs or Quality System Regulations, or QSR. Failure by any of our suppliers to comply with applicable regulations may result in delays.

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

We will utilize CROs for the development of our product candidates. We will rely on such CROs, as well as clinical trial sites, to ensure the proper and timely conduct of our clinical trials and document preparation. While we have agreements or will enter into such agreements governing their activities, we have limited influence over their actual performance. We have plans to rely upon CROs to monitor and manage data for post-approval clinical programs or any FDA-required clinical programs for our product candidates, as well as the execution of nonclinical and clinical trials. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA's current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA for all product candidates in clinical development. The FDA enforces these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. Upon inspection, the FDA may determine that our clinical trials do not comply with cGCPs. Accordingly, if our CROs or clinical trial sites fail to comply with these regulations, we may be required to repeat clinical trials, which would delay the regulatory process.

Our CROs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug or medical device development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may allow our potential competitors to access our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates, if approved, would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Risks Related to Our Business Operations and Industry

Our relationships with clinical investigators, health care professionals, consultants, commercial partners, third-party payers, hospitals, and other customers are subject to applicable anti-kickback, fraud and abuse and other healthcare laws, which could expose us to significant penalties.

Healthcare providers, including physicians, and others play a primary role in the recommendation and prescribing of any products for which we may obtain marketing approval. Our business operations and arrangements with investigators, healthcare professionals, consultants, commercial partners, hospitals, third-party payers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws. These laws may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute the products for which we obtain marketing approval. Applicable federal and state healthcare laws include, but are not limited to, the following:

- the federal healthcare Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or rebate), 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, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly or willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which impose certain obligations, including mandatory contractual terms, on covered healthcare providers, health plans and clearinghouses, and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- foreign laws, regulations, standards and regulatory guidance which govern the collection, use, disclosure, retention, security and transfer of personal data, including the European Union General Data Privacy Regulation, or GDPR, which introduces strict requirements for processing personal data of individuals within the European Union;

- the federal Physician Payment Sunshine Act, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies to report annually to the Centers for Medicare & Medicare Services, or 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, as well as ownership and investment interests held by physicians and their immediate family members;

- analogous state laws that may apply to our business practices, including but not limited to, state laws that require pharmaceutical companies to implement compliance programs and/or comply with the pharmaceutical industry's voluntary compliance guidelines; state laws that impose restrictions on pharmaceutical companies' marketing practices and require manufacturers to track and file reports relating to pricing and marketing information, which requires tracking and reporting gifts, compensation and other remuneration and items of value provided to healthcare professionals and entities, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects; and

- the federal Foreign Corrupt Practices Act of 1977, United Kingdom Bribery Act 2010 and other similar anti-bribery laws in other jurisdictions which generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage.

A determination that our operations or activities are not, or were not, in compliance with United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws involve substantial costs. It is possible that governmental authorities will conclude that our or our partners' business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these or any other healthcare regulatory laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, increased losses and diminished profits, additional oversight and reporting obligations 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 adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses or divert our management's attention from the operation of our business.

Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious internal and external attacks on our technology environment. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors,

business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

Significant disruptions of our third-party vendors' and/or business partners' information technology systems or other similar data security incidents could adversely affect our business operations and result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, sensitive information, which could result in financial, legal, regulatory, business and reputational harm to us. In addition, information technology system disruptions, whether from attacks on our technology environment or from computer viruses, natural disasters, terrorism, war and telecommunication and electrical failures, could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

There is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including but not limited to personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply with applicable federal and state breach notification laws and foreign law equivalents, subject us to time consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us, and result in significant legal and financial exposure and/or reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security-related legal or other obligations to third parties, or any further security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, which could include personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations, which could materially and adversely affect our business and prospects. Moreover, data security incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures and obtained and maintain cybersecurity insurance intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents, or adequately protect us against any such occurrences.

Business interruptions could delay our operations and sales efforts.

Our headquarters is located in the San Francisco Bay Area, near known earthquake fault zones and is vulnerable to significant damage from earthquakes. Our contract manufacturers, suppliers, clinical trial sites and local and national transportation vendors are all subject to business interruptions due to weather, outbreaks of pandemic diseases, natural disasters, or man-made incidents. We are also vulnerable to other types of natural disasters and other events that could disrupt our operations. If any of these events occurred and prevented us or third parties on which we rely from using all or a significant portion of our or their facilities, it may be difficult or, in certain cases, impossible for us to continue our business and operations for a substantial period of time.

We do not carry insurance for earthquakes or other natural disasters, and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are "at will" employees. Recruiting and retaining qualified scientific, manufacturing, and commercial personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. In addition, failure to succeed in clinical trials, or delays in the regulatory approval process, may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive or key employee might impede the progress of our research, development and commercialization objectives.

We may acquire companies, product candidates or products or engage in strategic transactions, which could divert our management's attention and cause us to incur various costs and expenses.

We may acquire or invest in companies, product candidates or products that we believe could complement or expand our business or otherwise offer growth opportunities. The pursuit of potential acquisitions or investments may divert the attention of management and has caused, and in the future may cause, us to incur various costs and expenses in identifying, investigating, and pursuing them, whether or not they are consummated. We may not be able to identify desirable acquisitions or investments or be successful in completing or realizing anticipated benefits from such transactions. In addition, the acquisition of product candidates and products is a highly competitive area, and many other companies are pursuing the same or similar product candidates to those that we may consider attractive. Larger companies with more well-established and diverse revenue streams may have a competitive advantage over us due to their size, financial resources and more extensive clinical development and commercialization capabilities.

In addition, we receive inquiries relating to potential strategic transactions, including collaborations, licenses, and acquisitions. Such potential transactions may divert the attention of management and may cause us to incur various costs and expenses in investigating and evaluating such transactions, whether or not they are consummated.

We face potential product liability claims, and, if such claims are successful, we may incur substantial liability.

Our past sales of DSUVIA/DZUVEO expose us to the risk of product liability claims. Product liability claims might be brought against us by patients, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our products; and
- decreased demand for our products.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. In addition, our current product liability insurance contains an exclusion related to any claims related to our products from a governmental body, or payer, or those claims arising from a multi-plaintiff action for bodily injury or property damage. Multi-plaintiff claims caused by product defects are covered. This exclusion does not apply to any bodily injury claim related to our products made by an individual. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim, or series of claims, brought against us could cause our stock price to decline and, if judgments are excluded from our insurance coverage or

exceed our insurance coverage, could adversely affect our results of operations and business. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. There can be no assurance that such coverage will be adequate to protect us against any future losses due to liability.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors 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 that our employees, independent contractors, investigators, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates (1) regulations implemented by the FDA and similar foreign regulatory bodies; (2) laws requiring the reporting of true, complete and accurate information to such regulatory bodies; (3) healthcare fraud and abuse laws of the United States and similar foreign fraudulent misconduct laws; and (4) laws requiring the reporting of financial information or data accurately. The promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry are subject to extensive laws designed to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. It is not always possible to identify and deter employee and other third-party misconduct. The precautions we take to detect and prevent inappropriate conduct 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. If any such actions are instituted against us, and we are not successful in defending ourselves, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar agreements to resolve allegations of non-compliance with these laws, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Our Intellectual Property

If we cannot defend our issued patents from third party claims or if our pending patent applications fail to issue, our business could be adversely affected.

To protect our proprietary technology, we rely on patents as well as other intellectual property protections including trade secrets, nondisclosure agreements, and confidentiality provisions. We are pursuing a number of U.S. patent applications and foreign national applications directed to our product candidates. The patent applications that we have filed and have not yet been granted may fail to result in issued patents in the United States or in foreign countries. Even if the patents do successfully issue, third parties may challenge the patents. We have entered into the DSUVIA Agreement with Alora pursuant to which Alora acquired all patents and trademarks related to DSUVIA and DZUVEO. In addition, we and Alora entered into an intellectual property agreement pursuant to which Alora granted fully-paid, royalty-free and perpetual licenses to us under certain specified intellectual property rights acquired by Alora under the DSUVIA Agreement for, among other things, the development, manufacture, commercialization and exploitation of certain products, including Zalviso.

As we continue to develop our product candidates, we generally expect to pursue 505(b)(2) NDA application pathways with the exception of the first LTX-608 application which we expect to be treated as a new chemical entity. As a result of these filing avenues, we will need to include patent certifications regarding the reference listed drugs that our 505(b)(2) applications are based upon. These patent certifications could trigger patent litigation by the patent holders that we have certified against.

Our commercial success will depend in part on successfully defending our current patents against third party challenges and expanding our existing patent portfolio to provide additional layers of patent protection, as well as extending patent protection. There can be no assurance that we will be successful in defending our existing and future patents against third party challenges, or that our pending patent applications will result in additional issued patents.

The patent positions of pharmaceutical companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States. Legal developments may preclude or limit the scope of available patent protection.

There is also no assurance that any patents issued to us will not become the subject of adversarial or post-issuance proceedings such as opposition, *inter partes* review, post-grant review, *ex parte* re-examination or other post-issuance proceedings. In addition, there is no assurance that the relevant patent office court or agency in such adversarial proceedings would not make unfavorable decisions, such as reducing the scope of a patent of ours, invalidating issued claims or determining that a patent of ours is invalid or unenforceable. There is also no assurance that any patents issued to us will provide us with competitive advantages, will not be challenged by any third parties, or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, there can be no guarantee that others will not independently develop similar products, duplicate any of our products, or design around our patents.

Litigation involving patents, patent applications and other proprietary rights is expensive and time consuming. If we are involved in such litigation, it could cause delays in bringing our products to market and interfere with our business.

Our commercial success depends in part on our not infringing patents or misappropriating trademarks or other third-party intellectual property rights. Although we are not currently aware of litigation or other proceedings or third-party claims of intellectual property infringement or misappropriation related to our product candidates, the pharmaceutical industry is especially prone to extensive litigation proceedings between competitors regarding their patents and other intellectual property rights.

As we enter our target markets, it is possible that competitors or other third parties will claim that our products and/or processes infringe or misappropriate their intellectual property rights. These third parties may have obtained and may in the future obtain patents covering products or processes that are similar to our products, or may include composition or method claims that encompass our technology, allowing them to assert that our continued use of our own technologies infringes such newly emerging patent rights.

In the event that a patent infringement claim is asserted against us, we may counter, as an affirmative defense, that we do not infringe the relevant patent claims, that the patent is invalid or otherwise unenforceable or any combination thereof. The strength of our defenses will depend on the patents asserted, the interpretation of those patents, and our ability to establish the invalidity of the asserted patents. However, we could be unsuccessful in advancing non-infringement, invalidity or unenforceability arguments in our defense. In the United States, issued patents enjoy a presumption of validity, and the party challenging the validity of a patent claim must present clear and convincing evidence of invalidity, which is a high burden of proof. Conversely, the patent owner needs only prove infringement by a preponderance of the evidence, which is a lower burden of proof.

If a court in a final and non-appealable decision were to hold that we have infringed someone else's valid patent claim, we could be prevented from using that third-party patented technology and may also be required to pay the owner of the patent for damages for past sales and need to seek license access to the patented technology for future sales. If we decide to pursue such a license to one or more of these patents, we may not be able to obtain a license on commercially reasonable terms, if at all, or the license we obtain may require us to pay substantial royalties or grant cross licenses to our patent rights. For example, if the relevant patent is owned by a competitor, that competitor may choose not to license patent rights to us. If we decide to develop alternative technology to avoid such third-party patent claims, we may not be able to do so in a timely or cost-effective manner, if at all.

In addition, because patent applications remain unpublished for 18 months from their initial filing date and some applications may be afforded confidentiality during prosecution that can take years to issue, there may currently be pending applications that are unknown to us and that may later result in issued patents that could cover one or more of our products.

It is possible that we may in the future receive communications from competitors and other companies alleging that we may be infringing their patents, misappropriating their trade secrets or otherwise violating their intellectual property rights, where they may offer license access to such intellectual property or threaten litigation. In addition to patent infringement claims, third parties may assert copyright, trademark or other intellectual property rights against us. We may need to expend considerable resources to counter such claims and may not be successful in our defense. Our business may suffer if a finding of infringement or misappropriation is established.

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

The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States. The pharmaceutical patent situation outside the United States is just as uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property estate.

We cannot predict the breadth of claims that may be allowed or enforced in the patents that may issue from the applications that we currently have pending or may in the future file ourselves or acquire or license from third parties. Claims could be brought regarding the validity of our patents by third parties. Further, if any patent right that we obtain is deemed invalid and/or unenforceable, it could impact our ability to commercialize or partner our technology.

Competitors or third parties may infringe our patents. We may decide it is necessary to assert patent infringement claims against such entities, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or that the third party's technology does not in fact infringe upon our patents. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our related pending patent applications at risk of not issuing. Litigation may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able to prevent misappropriation of our intellectual property rights, particularly in countries outside the United States where national laws and court systems are less robust, making patent rights more difficult to enforce, and very expensive to pursue. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. 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.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we were the first to make the inventions covered by each of our pending patent applications or issued patents;
- our patent applications were filed before the inventions covered by each patent or patent application was published by a third-party;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents issued to us or our collaborators will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties; or
- the patents of others will not have an adverse effect on our business.

If we do not adequately protect our intellectual property rights, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize any of our product opportunities, if approved, and delay or render impossible our achievement of profitability.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary knowledge and technological advances, 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 business partners, employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. 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 without misappropriating our rights. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable

competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be paid to the United States Patent and Trademark Office and various foreign governmental patent agencies in several stages over the lifetime of the patents and/or applications.

We have systems in place, including the use of third-party vendors, to manage payment of periodic maintenance fees, renewal fees, annuity fees and various other patent and application fees. The United States Patent and Trademark Office, or 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 application process. 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. If this occurs, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit.

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. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Additionally, claims may be brought regarding the validity of our patents by third parties in the United States and foreign countries. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property rights.

We have not yet registered our trademarks in all our potential markets, and failure to secure those registrations could adversely affect our business.

We have filed a trademark application for TALPHERA in the United States and will file related trademark applications in other major foreign pharmaceutical jurisdictions of interest. In addition, we have obtained approval of our Niyad and Fedsyra marks in the United States and are awaiting our first use of those marks in commerce in order to secure our federal registrations. Although we are not currently aware of any oppositions to or cancellations of our registered trademarks or pending applications, it is possible that one or more of the applications and/or registrations could be subject to rejection, opposition or cancellation. In addition, we will need to seek FDA approval to use Niyad and other potential product trademarks as part of future potential applications for marketing approval of the relevant developmental products. The registrations will be subject to use and maintenance requirements. It is also possible that we have not yet registered all of our trademarks in all of our potential markets, and that there are names or symbols that may be protectable marks for which we have not sought registration, and failure to secure those registrations could adversely affect our business. Opposition or cancellation proceedings may be filed against our trademarks and our trademarks may not survive such proceedings.

Risks Related to Ownership of Our Common Stock

The market price of our common stock has historically been and may continue to be highly volatile.

The trading price of our common stock has experienced significant volatility and is likely to be volatile in the future. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- failure to successfully develop and commercialize our product candidates in the United States;
- inability to obtain additional funding needed to conduct our planned business operations;

- the integration and performance of any assets or businesses we acquire;
- our inability to develop and commercialize products and product candidates that we in-license;
- the perception of limited market sizes or pricing for our products;
- safety issues;
- adverse results or delays in clinical trials;
- changes in laws or regulations applicable to our products;
- inability to obtain adequate product supply for our products, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- changes in the structure of the healthcare payment systems;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- decisions by our collaboration partners regarding market access, pricing, and commercialization efforts in countries where they have the right to commercialize our products;
- failure to maintain our existing collaborations or enter into new collaborations;
- the perception of the pharmaceutical industry generally, and of opioid manufacturers more specifically, by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or other significant transactions, including disposition transactions, or capital commitments by us or our competitors;
- disputes or other developments relating to employment matters, business development efforts, proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key management or scientific personnel;
- costs associated with potential governmental investigations, inquiries, regulatory actions or lawsuits that may be brought against us as a result of us being an opioid manufacturer;
- other types of significant lawsuits, including patent, stockholder, securities class action and derivative litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future;
- our ability to maintain compliance with Nasdaq listing requirements;
- liquidity of our common stock; and
- trading volume of our common stock.

In addition, the stock market in general, and The Nasdaq Global Market, or Nasdaq, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

Our common stock may be delisted from The Nasdaq Global Market if we cannot regain compliance with Nasdaq's continued listing requirements.

In order to maintain our listing on Nasdaq, we are required to comply with the Nasdaq requirements, which includes maintaining a minimum bid price of $1.00, a minimum public float and a minimum stockholders' equity. In particular, we are required to maintain a minimum stockholders' equity of at least $10 million or meet the alternative compliance standards relating to the market value of the listed securities or our total assets and revenue. On November 27, 2024, we received a notice from Nasdaq stating that we were not in compliance with Nasdaq Listing Rule 5450(b)(1)(A) based on our stockholders' equity of $9.6 million as of September 30, 2024, as reported in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 (the "Minimum Stockholder Equity Requirement"), and on December 6, 2024, we received a notice from Nasdaq stating that we were not in compliance with Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Price Rule") because our common stock failed to maintain a minimum closing bid price of $1.00 for 30 consecutive business days. These notices had no immediate effect on the Nasdaq listing or trading of our common stock.

We submitted a compliance plan to Nasdaq to regain compliance with the Minimum Stockholder Equity Requirement which Nasdaq accepted. Accordingly, we have a compliance period for the Minimum Stockholder Equity Requirement of 180 calendar days, or until May 26, 2025, in which to regain compliance. In addition, we have a compliance period for the Minimum Bid Price Rule of 180 calendar days, or until June 4, 2025, in which to regain compliance, pursuant to Nasdaq Marketplace Rule 5810(c)(3)(A). If, at any time before that date the bid price of our common stock closes at $1.00 per share or more for a minimum of 10 consecutive business days, Nasdaq will notify us that we have achieved compliance with the Minimum Bid Price Rule.

If we do not achieve compliance with the Minimum Bid Price Rule during the initial 180 calendar day period, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would need to transfer the listing of our common stock to the Nasdaq Capital Market, provided that it meets the continued listing requirement for market value of publicly held shares and all other initial listing standards of the Nasdaq Capital Market, with the exception of the Minimum Bid Price Rule. In addition, we would also be required to notify Nasdaq of our intent to cure the minimum bid price deficiency, which may include, if necessary, implementing a reverse stock split. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we do not meet the other listing standards, Nasdaq could provide notice that the common stock will become subject to delisting. In the event we receive notice that our common stock is being delisted, Nasdaq rules permit us to appeal any delisting determination by Nasdaq to a Hearings Panel, or the Panel. We expect that our common stock would remain listed pending the Panel's decision. However, there can be no assurance that, if we do appeal the delisting determination by Nasdaq to the Panel, that such appeal would be successful, or that we will be able to regain compliance with the Minimum Bid Price Rule or maintain compliance with the other listing requirements.

If we fail to effect a reverse stock split, thus regaining compliance with the Minimum Bid Price Rule, or we fail to regain compliance with the Minimum Stockholders Equity Requirement, our common stock may be delisted. Delisting from the Nasdaq Global Market or any Nasdaq market could make trading our common stock more difficult for investors, potentially leading to declines in our share price and liquidity. In addition, without a Nasdaq market listing, stockholders may have a difficult time getting a quote for the sale or purchase of our common stock, the sale or purchase of our common stock would likely be made more difficult and the trading volume and liquidity of our common stock could decline. Delisting from Nasdaq could also result in negative publicity and could also make it more difficult for us to raise additional capital. The absence of such a listing may adversely affect the acceptance of our common stock as currency or the value accorded by other parties. Further, if we are delisted, we would also incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our stockholders to sell our common stock in the secondary market. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over-the-counter quotation system, such as the OTCQB market, where an investor may find it more difficult to sell our common stock or obtain accurate quotations as to the market value of our common stock. We cannot assure you that our common stock, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over-the counter quotation system. If our common stock is delisted, it may come within the definition of "penny stock" as defined in the Exchange Act and would be covered by Rule 15g-9 of the Exchange Act. That Rule imposes additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors. For transactions covered by Rule 15g-9, the broker-dealer must make a special suitability determination for the purchaser and receive the purchaser's written agreement to the transaction prior to the sale. Consequently, Rule 15g-9, if it were to become applicable, would affect the ability or willingness of broker-dealers

to sell our securities, and accordingly would affect the ability of stockholders to sell their securities in the public market. These additional procedures could also limit our ability to raise additional capital in the future.

Sales of a substantial number of shares of our common stock in the public market by us or our stockholders could cause our stock price to fall.

Because we will continue to need additional capital in the future to continue to expand our business and our research and development activities, among other things, we may conduct additional equity offerings. Sales of a substantial number of shares of our common stock in the public market or our issuance of common stock warrants, or the perception that these sales or issuances might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants under our equity incentive plans. Grants under our equity incentive plans may also cause our stockholders to experience additional dilution, which could cause our stock price to fall. We may in the future issue additional shares of our common stock as consideration in mergers, acquisitions and other business development transactions. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. All of our shares of common stock outstanding are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements of Rule 144 under the Securities Act. Sales of stock by our stockholders could have a material adverse effect on the trading price of our common stock.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our capital stock, and we are prohibited from doing so under the terms of the Loan Agreement. Regardless of the restrictions in the Loan Agreement or the terms of any potential future indebtedness, we anticipate that we will retain all available funds and any future earnings to support our operations and finance the growth and development of our business and, therefore, we do not expect to pay cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our Board of Directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our Board of Directors may deem relevant.

Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- a staggered Board of Directors;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to our Board of Directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our Board of Directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Risks of a General Nature

Litigation may substantially increase our costs and harm our business.

We have been, are, and may in the future become, party to lawsuits including, without limitation, actions and proceedings in the ordinary course of business relating to our directors, officers, stockholders, intellectual property rights, employment matters and the safety or efficacy of our products, which will cause us to incur legal fees and other costs related thereto, including potential expenses for the reimbursement of legal fees of officers and directors under indemnification obligations. The expense of defending against such litigation may be significant and there can be no assurance that we will be successful in any defense. Further, the amount of time that may be required to resolve such lawsuits is unpredictable, and these actions may divert management's attention from the day-to-day operations of our business, which could adversely affect our business, results of operations, and cash flows. Our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such award could have a material adverse effect on our consolidated operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. Litigation is subject to inherent uncertainties, and an adverse result in such matters that may arise from time to time could have a material adverse effect on our business, results of operations, and financial condition. Please see "Part II.—Item 8. Financial Statements and Supplementary Data—Note 8, Commitments and Contingencies—Litigation" in this Annual Report on Form 10-K for additional information about pending legal proceedings.

Our involvement in securities-related class action litigation could divert our resources and management's attention and harm our business.

The stock markets have from time-to-time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In addition, the market price of our common stock may vary significantly based on Talphera-specific events, such as receipt of Complete Response Letters, Warnings Letters, such as the Warning Letter we received from the FDA on February 11, 2021, negative clinical results, a negative vote or decision by an FDA advisory committee, or other negative feedback from the FDA, EMA, or other regulatory agencies. In the past, securities-related class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their investigational drug or medical device product candidate development programs and the FDA's review of their NDAs. Following receipt of the FDA's Warning Letter, a securities class action complaint was filed against us and two of our officers on June 8, 2021, in the United States District Court for the Northern District of California. The amended securities class action complaint, which was filed on March 7, 2022, named a third officer as a defendant. The Court granted three motions to dismiss plaintiffs' complaint: the first on September 28, 2022, the second on November 28, 2022, and the third, with prejudice, on May 7, 2024. Judgment was entered for defendants on plaintiffs' claims on May 7, 2024. On June 5, 2024, plaintiffs filed a notice of appeal in the United States Court of Appeals for the Ninth Circuit. Briefing on the appeal was complete on January 21, 2025. The Court has not yet scheduled a hearing on the appeal.

On July 6, 2021, September 30, 2021, October 26, 2021, and November 17, 2021, four purported shareholder derivative complaints were filed in the United States District Court for the Northern District of California asserting state and federal claims based on the same alleged misstatements as the securities class action complaint. On December 6, 2021, the Court entered an order consolidating all four actions and staying the consolidated action pending the outcome of any motion to dismiss the securities class action. On February 16, 2024, another purported shareholder derivative complaint was filed in the Court of Chancery of the State of Delaware, asserting the same claims as those in the previously filed derivative actions. The case has been stayed pending the outcome of any motion to dismiss the securities class action. Please refer to "Part II.—Item 8. Financial Statements and Supplementary Data—Note 8, Commitments and Contingencies—Litigation" in this Annual Report on Form 10-K for additional information about these pending legal proceedings. Securities-related class action litigation is often expensive and diverts management's attention and our financial resources, which could harm our business. Additional lawsuits related to the pending litigation may follow. Moreover, if Talphera experiences a decline in its stock price, we could face additional securities class action lawsuits.

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

Under current law, federal net operating losses generated in tax years beginning prior to January 1, 2018 generally will expire 20 years after they were generated if not used prior thereto; federal net operating losses generated in tax years beginning after December 31, 2017, will carryforward indefinitely, but the deductibility of such federal net operating losses generally is limited to 80% of current year taxable income. Many states have similar laws. Our ability to use our federal and state net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the net operating losses, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses. Accordingly, our federal and state net operating losses could expire unused and be unavailable to offset future income tax liabilities. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. The completion of the July 2013 public equity offering, together with our public equity offering in December 2012, our initial public offering, private placements and other transactions that have occurred, have triggered such an ownership change. We may experience additional ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. Furthermore, our ability to utilize net operating losses of companies that we have acquired or may acquire in the future may be subject to limitations. In the future, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards or other tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us and could adversely affect our business, results of operations, and cash flows.

Our effective tax rate may fluctuate, we may be adversely affected by changes in tax laws and regulations, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. federal, state, and local jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various jurisdictions that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each jurisdiction. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including changes in the mix of our profitability among the jurisdiction in which we operate, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and enactment of new tax laws. Or changes in the interpretation and application of existing tax laws. New income, sales, use or other tax laws, rules, regulations, or ordinances could be enacted at any time. For example, recent legislation commonly referred to as the Inflation Reduction Act imposes a one percent excise tax on share buybacks imposed on the corporation repurchasing such stock, effective for tax years beginning after December 31, 2022. Also, the Tax Act eliminated the option to currently deduct research and development expenditures in the year incurred, and instead requires taxpayers to capitalize and amortize U.S.-based and non-U.S.-based research and development expenditures over five and fifteen years, respectively. Although there has been proposed legislation that would defer the capitalization requirement to later years, we have no assurance that the provision will be repealed, deferred, or otherwise modified. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk management and strategy

We have implemented and maintain various 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 ("Information Systems and Data").

Our chief financial officer and our third-party information technology provider help identify, assess and manage the Company's cybersecurity threats and risks. Our chief financial officer and our third-party information technology provider identify and assess risks from cybersecurity threats by monitoring and evaluating our threat environment using various methods including, for example, the use of manual and automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and actors, evaluating our industry's risk profile, evaluating threats reported to us, and conducting external audits and vulnerability assessments to identify vulnerabilities.

Depending on the environment, 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: incident detection and response, incident response plan, risk assessments, encryption of data, network security controls, data segregation, access controls, physical security, asset management, tracking and disposal, systems monitoring, employee training, penetration testing, and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's risk management processes. For example, our chief financial officer evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including, for example, professional services firms, including legal counsel, cybersecurity consultants, cybersecurity software providers, penetration testing firms and forensic investigators.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, contract research organizations and contract manufacturing organizations. 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 process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider.

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 "Risks Related to Our Business Operations and Industry — Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us".

Governance

Our board of directors' audit committee 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 financial officer and our third-party information technology provider.

Our chief financial officer is responsible for hiring appropriate personnel, helping to manage the Company's risk, and communicating key priorities to relevant personnel. Our chief financial officer and our third-party information technology provider are responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response processes are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances. Our chief financial officer works with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified. In addition, the Company's incident response processes include reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The audit committee receives periodic updates from our chief financial officer concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The audit committee also receives summaries or presentations related to cybersecurity threats, risk and mitigation.

Item 2. Properties

We lease approximately 4,012 square feet of office space in San Mateo, California under a sublease agreement that expires on August 31, 2025. We believe that our facilities are adequate to meet our current needs.

Item 3. Legal Proceedings

From time to time, we may be involved in legal proceedings relating to intellectual property, commercial, employment and other matters arising in the ordinary course of business. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position or cash flows. Please see the matters under the caption "Part II.—Item 8. Financial Statements and Supplementary Data—Note 8, Commitments and Contingencies—Litigation."

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 has been traded on The Nasdaq Global Market since January 2024 under the symbol "TLPH" and prior to that had been traded on The Nasdaq Global Market since February 2011 under the symbol "ACRX". As of March 17, 2025, there were 42 holders of record of our common stock. This number does not include "street name" or beneficial holders, whose shares are held of record by banks, brokers, financial institutions and other nominees.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We anticipate that we will retain all available funds and any future earnings to support our operations and finance the growth and development of our business and, therefore, we do not expect to pay cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Recent Sales of Unregistered Securities

None.

Item 6. Reserved

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

The following discussion and analysis should be read in conjunction with our audited financial statements and the related notes that appear elsewhere in this Annual Report on Form 10-K.

The following discussion and analysis covers our financial condition and results of operations for the year ended December 31, 2024, including year-over-year comparisons versus the year ended December 31, 2023, as reported in our Annual Report on Form 10-K for the year ended December 31, 2023. This discussion and analysis as well as other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions, and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in "Part I, Item 1A – Risk Factors" of this Annual Report on Form 10-K.

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. Our product development portfolio features Niyad (a regional anticoagulant for the dialysis circuit), LTX-608 (a nafamostat formulation for direct IV infusion) that we intend to develop for one or more of the following indications: disseminated intravascular coagulation, or DIC, acute respiratory distress syndrome, or ARDS, acute pancreatitis, or as an anti-viral treatment, and two ready-to-use pre-filled syringe product candidates (Fedsyra and phenylephrine).

Our strategy is focused on developing, obtaining approval, and commercializing Niyad. We intend to expand our portfolio to include additional acute care therapies for use in medically supervised settings.

General Trends and Outlook

Inflation

We do not believe that inflation has had a material impact on our business or operating results during the periods presented. However, inflation, led by supply chain constraints, federal stimulus funding, increases to household savings, and the sudden macroeconomic shift in activity levels arising from the loosening or removal of many government restrictions, has had, and may continue to have, an impact on overhead costs and transportation costs and may adversely affect our operating results in the future. In addition, increased inflation has had, and may continue to have, an effect on interest rates. Increased interest rates may adversely affect our borrowing rate and our ability to obtain, or the terms under which we can obtain, any potential additional funding. In addition, in March 2025, the U.S. government imposed tariffs on biopharmaceutical products imported from China, which will increase our cost of doing business until we are able to source such products outside of China and any other jurisdiction subject to such tariffs.

DSUVIA Divestment

We divested DSUVIA to Alora in April 2023, who agreed to continue to commercialize the product and pay us royalties, sales-based milestone and other payments, as defined in the DSUVIA Agreement (see Note 3, "Discontinued Operations" to the consolidated financial statements to this Annual Report on Form 10-K for additional information regarding the DSUVIA Agreement). We will continue marketing DSUVIA to the Department of Defense, or DoD. We have no plans to further develop or commercialize any of our other sufentanil sublingual products that were previously our product candidates.

In January 2024, we entered into an agreement with XOMA (US) LLC, or XOMA, whereby we have sold our rights to all payments for services performed to support sales of DSUVIA to the DoD by Alora under the Marketing Agreement, and sales milestones we are entitled to under the DSUVIA Agreement with Alora, until XOMA receives a certain specified return on its investment, after which we will share equally in the payments earned on sales to the Department of Defense, milestones and other payments from Alora (see Note 7, "Sale of Future Payments" to the consolidated financial statements to this Annual Report on Form 10-K for additional information). This transaction was consummated to provide further funding for the development of our lead product candidate, Niyad. In October 2024, Alora notified us that they are discontinuing their DSUVIA sales efforts to non-DoD customers. At this time, we are uncertain as to the impact of this decision on sales of DSUVIA to the DoD, but we expect to be able to continue to market DSUVIA to the DoD until all inventory is sold or Alora makes the decision to no longer provide the supply of DSUVIA to the DoD. We are working to attempt to facilitate a longer-term supply arrangement for DSUVIA, but there are no assurances we will be successful.

Financial Overview

We have incurred net losses and generated negative cash flows from operations and expect to continue to incur losses in the future as we continue to fund any future research and development activities needed to support the FDA regulatory review of our product candidates.

Our net loss for 2024 was $13.0 million and for 2023 it was $18.4 million. As of December 31, 2024, we had an accumulated deficit of $457.2 million. As of December 31, 2024, we had cash, cash equivalents and short-term investments totaling $8.9 million compared to $9.4 million as of December 31, 2023.

Critical Accounting Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. Note 1, "Organization and Summary of Significant Accounting Policies" to the consolidated financial statements in this Annual Report on Form 10-K describes the significant accounting policies used in the preparation of the financial statements. Certain of these significant accounting policies are considered to be critical accounting policies, as defined below.

A critical accounting policy is defined as one that is both material to the presentation of our financial statements and requires management to make difficult, subjective or complex judgments that could have a material effect on our financial condition and results of operations. Specifically, critical accounting estimates have the following attributes: (i) we are required to make assumptions about matters that are highly uncertain at the time of the estimate; and (ii) different estimates we could reasonably have used, or changes in the estimate that are reasonably likely to occur, would have a material effect on our financial condition or results of operations.

We believe the following policies to be the most critical to an understanding of our financial condition and results of operations because they require us to make estimates, assumptions and judgments about matters that are inherently uncertain. Management has discussed the development, selection and disclosure of the following estimates with the Audit Committee.

Sale of Future Payments

On January 12, 2024, we entered into the Purchase Agreement with XOMA to monetize a portion of our future payments for services performed to support sales of DSUVIA to the DoD by Alora under the Marketing Agreement, and sales milestones under the DSUVIA Agreement. Refer to Note 7, "Sale of Future Payments" to the consolidated financial statements in this Annual Report on Form 10-K for further details on the Purchase Agreement and to Note 3, "Discontinued Operations" for further details on the Marketing Agreement.

The liability related to the sale of future payments is recorded as debt and will be amortized under the effective interest rate method over the estimated life of the Purchase Agreement. The amortization of the liability related to the sale of future payments is based on our current estimate of future payments under the Marketing Agreement. The estimate of future payments include payments related to estimated future DoD sales and the probability of meeting and the potential timing of milestone payments are derived using internal management estimates and reflect management's judgements, current market conditions, and internal forecasts. A significant change in these inputs could result in a material increase or decrease to the effective interest rate of the liability for the sale of future payments.

We will periodically assess the amount and timing of expected payments using a combination of internal projections and historical data. To the extent our future estimates of future payments are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, we will adjust the amortization of the Sale of Future Payment Liability and prospectively recognize the related non-cash interest expense. In October 2024, Alora notified us that they are discontinuing their DSUVIA sales efforts to non-DoD customers. At this time, we are uncertain as to the impact of this decision on sales of DSUVIA to the DoD. As a result, we estimate that future payments under the Purchase Agreement will be less than the proceeds from the sale of such future payments.

Non-Cash Interest Expense on Liability Related to the Sale of Future Payments

Under the relevant accounting guidance, because of our significant continuing involvement, the XOMA Agreement is accounted for as a liability that is amortized using the effective interest method over the life of the arrangement. In order to determine the amortization of the liability related to the sale of future payments, we are required to estimate the total amount of future payments to XOMA over the life of the Purchase Agreement. As mentioned above, in October 2024, Alora notified us that they are discontinuing their DSUVIA sales efforts to non-DoD customers. Accordingly, we estimate that future payments under the Purchase Agreement will be less than the proceeds from the sale of such future payments and we will not recognize any further related non-cash interest expense. When the expected payments under the sale of future payments are lower than the gross proceeds received, we defer recognition of any probable contingent gain until we have met our obligations under the liability related to the sale of future payments.

Acquisitions

We evaluate acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If so, the transaction is accounted for as an asset acquisition. If not, further determination is required as to whether or not we have acquired inputs and processes that have the ability to create outputs, which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

Acquisitions meeting the definition of business combinations are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated to the net assets acquired at their respective fair values. In a business combination, any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

For asset acquisitions, a cost accumulation model is used to determine the cost of an asset acquisition. Direct transaction costs are recognized as part of the cost of an asset acquisition. We also evaluate which elements of a transaction should be accounted for as a part of an asset acquisition and which should be accounted for separately. The cost of an asset acquisition, including transaction costs, is allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis. Goodwill is not recognized in an asset acquisition. Any difference between the cost of an asset acquisition and the fair value of the net assets acquired is allocated to the non-monetary identifiable assets based on their relative fair values. When a transaction accounted for as an asset acquisition includes an in-process research and development, or IPR&D, asset, the IPR&D asset is only capitalized if it has an alternative future use other than in a particular research and development project. For an IPR&D asset to have an alternative future use: (a) we must reasonably expect that we will use the asset acquired in the alternative manner and anticipate economic benefit from that alternative use, and (b) our use of the asset acquired must not be contingent on further development of the asset subsequent to the acquisition date (that is, the asset can be used in the alternative manner in the condition in which it existed at the acquisition date). Otherwise, amounts allocated to IPR&D that have no alternative use are expensed. Our asset acquisitions typically include contingent consideration arrangements that encompass obligations to make future payments to sellers contingent upon the achievement of future financial targets. Contingent consideration is not recognized until all contingencies are resolved and the consideration is paid or probable of payment, at which point the consideration is allocated to the assets acquired on a relative fair value basis.

In-Process Research and Development

In accordance with ASC Topic 350, *Intangibles - Goodwill and Other*, the acquired IPR&D has initially been accounted for as an indefinite-lived intangible asset and, therefore, not amortized. If the IPR&D asset achieves regulatory approval and the asset life is determined to be finite, the asset's useful life will be estimated, and the asset will be amortized over its remaining useful life.

The IPR&D asset is reviewed for impairment annually or whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. These events and changes can include significant current period operating losses or negative cash flows associated with the use of the IPR&D asset, such as the result of unfavorable data from any ongoing or future clinical trial, changes in assumptions that negatively impact projected cash flows, or because of any other information regarding the prospects of successfully developing or commercializing our programs. When impairment indicators are present, we compare undiscounted future cash flows to the asset's carrying value to determine if the asset is recoverable. If the carrying values are in excess of undiscounted expected future cash flows, we measure any impairment by comparing the fair value of the asset to its carrying value.

No impairment losses were recorded on the IPR&D asset during the years ended December 31, 2024 or 2023.

Warrants Issued in Connection with Financings

We account for issued warrants as either liability or equity in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, or ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. Under ASC 480-10, warrants are considered liability if they are mandatorily redeemable and they require settlement in cash or other assets, or a variable number of shares. If warrants do not meet liability classification under ASC 480-10, we consider the requirements of ASC 815-40 to determine whether the warrants should be classified as liability or equity. Under ASC 815-40, contracts that may require settlement for cash are liabilities, regardless of the probability of the occurrence of the triggering event. Liability-classified warrants are measured at fair value on the issuance date and at the end of each reporting period. Any change in the fair value of the warrants after the issuance date is recorded in the consolidated statements of operations. If warrants do not require liability classification under ASC 815-40, in order to conclude warrants should be classified as equity, we assess whether the warrants are indexed to our common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP. Equity-classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date.

Net Income (Loss) per Share of Common Stock

Basic and diluted net income (loss) per common share, or EPS, are calculated in accordance with the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 260*, Earnings per Share*.

We apply the two-class method to compute both basic and diluted net income or loss per share. The two-class method is an earnings allocation formula that treats participating securities as having rights to earnings that would otherwise have been available to common stockholders (including pre-funded warrants). Shares of common stock into which the pre-funded warrants may be exercised are considered outstanding for the purposes of computing net loss per share because the shares may be issued for little or no consideration and are exercisable after the original issuance date. In addition, we are required to calculate diluted net income or loss per share under the two-class method if the effect is more dilutive than the application of another dilutive method of calculating diluted EPS (i.e., the treasury stock, if-converted, or contingently issuable share method). In periods where there is a net loss, no allocation of undistributed net loss to the participating securities is performed if the holders of these securities are not contractually obligated to participate in our losses. Our participating securities include the November 2021 Financing Warrants, December 2022 Common Stock Warrants, the Series A and Series B common stock warrants, the placement agent Series A and Series B common stock warrants (see Note 9, "Stockholders' Equity" and Note 10, "Warrants" to the consolidated financial statements in this Annual Report on Form 10-K for additional information).

For additional information regarding the net income (loss) per share, see Note 12, "Net Loss per Share of Common Stock" to the consolidated financial statements in this Annual Report on Form 10-K.

Discontinued Operations

In accordance with ASC 205-20, *Presentation of Financial Statements: Discontinued Operations*, a disposal of a component of an entity or a group of components of an entity is required to be reported as discontinued operations if the disposal represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results. In the period in which the component meets held-for-sale or discontinued operations criteria the major current assets, non-current assets, current liabilities, and non-current liabilities shall be reported as components of total assets and liabilities separate from those balances of the continuing operations. At the same time, the results of all discontinued operations, less applicable income taxes, shall be reported as components of net loss separate from the net income (loss) of continuing operations.

Our DSUVIA business met the definition of a discontinued operation as of March 31, 2023. Accordingly, we have classified the results of the DSUVIA business as discontinued operations in our consolidated statements of operations for all periods presented. All assets and liabilities associated with the DSUVIA business were classified as assets and liabilities of discontinued operations in the consolidated balance sheets for the periods presented. All amounts included in the notes to the consolidated financial statements relate to continuing operations unless otherwise noted. For additional information, see Note 3, "Discontinued Operations" to the consolidated financial statements in this Annual Report on Form 10-K.

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, or ASU 2023-07, which requires all public entities, including public entities with a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. Additionally, the standard requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. We adopted annual requirements under ASU 2023-07 on January 1, 2024, and plan to adopt interim requirements under ASU 2023-07 on January 1, 2025, on a retrospective basis. ASU 2023-07 only impacted the disclosures and did not impact the consolidated financial statements. See Note 16, "Segment Information" to the consolidated financial statements in this Annual Report on Form 10-K for disclosures related to the adoption of ASU 2023-07.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which is intended to enhance transparency into the nature and function of expenses, primarily through additional disclosures on certain cost and expenses. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted, and the amendments may be applied prospectively to reporting periods after the effective date or retrospectively to all periods presented in the financial statements. We are in the process of evaluating the impact of this new guidance on our disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires companies to disclose, on an annual basis, specific categories in the effective tax rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. In addition, ASU 2023-09 requires companies to disclose additional information about income taxes paid. ASU 2023-09 will be effective for annual periods beginning January 1, 2025, and will be applied on a prospective basis with the option to apply the standard retrospectively. We are evaluating the disclosure impact of ASU 2023-09; however, the adoption of ASU 2023-09 will not have a material impact on our consolidated financial statements.

We do not believe other recently issued but not yet effective accounting standards, if currently adopted, would have a material effect on our consolidated financial statements.

Results of Operations

Our consolidated results of operations are presented for the years ended December 31, 2024 and 2023. Certain financial results (revenues and expenses) relating to the divestment of our DSUVIA/DZUVEO business are reflected in discontinued operations. See Note 3, "Discontinued Operations" to the consolidated financial statements in this Annual Report on Form 10-K for additional information. Unless otherwise noted, the discussion below, and the revenue and expense amounts discussed below, are based on and relate to our continuing operations.

Results of operations for any period may be unrelated to results of operations for any other period. In addition, historical results should not be viewed as indicative of future operating results.

Years Ended December 31, 2024 and 2023

Revenue

There was no revenue recognized in 2024. For 2023, we recognized $0.7 million in revenue related to the DSUVIA Agreement with Alora under the Marketing Agreement executed in April 2023, pursuant to which Talphera has the exclusive right to market and offer DSUVIA for sale to DoD and for which Alora pays us 75% of net sales of DSUVIA sold to DoD.

Research and Development Expenses

Research and development expenses included the following:

- expenses incurred under agreements with contract research organizations and clinical trial sites;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- payments to third party pharmaceutical and engineering development contractors;
- payments to third party manufacturers;
- other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and equipment and laboratory and other supply costs; and
- costs for equipment and laboratory and other supplies.

We expect to incur future research and development expenditures to support the FDA regulatory review of our product candidates and anticipated activities required for the development of our nafamostat product candidates.

We track external development expenses on a program-by-program basis. Our development resources are shared among all our programs. Compensation and benefits, facilities, depreciation, stock-based compensation, and development support services are not allocated specifically to projects and are considered research and development overhead.

Below is a summary of our research and development expenses for 2024 and 2023 (in thousands, except percentages):

	Years Ended December 31,		$ Change	% Change
	2024	2023	2024 vs. 2023	2024 vs. 2023
Total research and development expenses	$ 6,718	$ 5,546	$ 1,172	21%

Research and development expenses during 2024 increased as compared to 2023, primarily due to an increase in costs associated with Niyad development.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, benefits and stock-based compensation for personnel engaged in commercialization, administration, finance and business development activities. Other significant expenses included allocated facility costs and professional fees for general legal, audit and consulting services.

Total selling, general and administrative expenses for 2024 and 2023 were as follows (in thousands, except percentages):

	Years Ended December 31,		$ Change	% Change
	2024	2023	2024 vs. 2023	2024 vs. 2023
Selling, general and administrative expenses	$ 8,534	$ 11,994	$ (3,460)	(29)%

Selling, general and administrative expenses decreased for 2024 as compared to 2023, primarily due to the divestment of DSUVIA. More specifically, the decrease for 2024 compared to 2023 was attributed to a $1.2 million reduction in employee compensation and related expenses due to a reduction in headcount, a $0.7 million reduction in legal fees, a $0.6 million decrease in stock-based compensation expense, a $0.4 million decrease in audit and consulting services, and a net decrease in other selling, general and administrative expenses of $0.6 million.

Other Income

Total other income for 2024 and 2023 was as follows (in thousands, except percentages):

	Years Ended December 31,		$ Change	% Change
	2024	2023	2024 vs. 2023	2024 vs. 2023
Interest expense	$ —	$ (134)	$ 134	(100)%
Interest income and other income, net	679	1,416	(737)	(52)%
Gain on sale of future payments	1,246	—	1,246	100%
Change in fair value of warrant liability	717	5,320	(4,603)	(87)%
Non-cash interest expense on liability related to sale of future payments	(394)	—	(394)	100%
Total other income	$ 2,248	$ 6,602	$ (4,354)	(66)%

Interest expense consisted primarily of interest accrued or paid on our debt obligation agreements and amortization of debt discounts. In April 2023, in connection with the closing of the DSUVIA Agreement, we fully repaid the Loan Agreement with Oxford. See Note 6, "Long-Term Debt" to the consolidated financial statements in this Annual Report on Form 10-K for additional information.

Interest income and other income, net, for 2024 and 2023, consisted of interest earned on our investments and included a $0.7 million gain on the satisfaction of the contingency related to the liability for the Lowell holdback shares issued in June 2023.

Gain on sale of future payments for 2024 consisted of $1.2 million in other income related to the XOMA Purchase Agreement (see Note 7, "Sale of Future Payments" to the consolidated financial statements in this Annual Report on Form 10-K for additional information).

Change in fair value of warrant liability for 2024 included a $0.7 million decrease in the fair value of our warrant liability as compared to a $5.3 million decrease in the fair value of our warrant liability for 2023 (see Note 2, "Investments and Fair Value Measurements" to the consolidated financial statements in this Annual Report on Form 10-K for additional information).

The non-cash interest expense on the liability related to the sale of future payments is attributable to the XOMA Purchase Agreement (see Note 7, "Sale of Future Payments" to the consolidated financial statements in this Annual Report on Form 10-K for additional information).

Discontinued Operations

For 2024, there were no activities for discontinued operations. For 2023, we recognized a net loss from discontinued operations $8.1 million (see Note 3, "Discontinued Operations" to the consolidated financial statements in this Annual Report on Form 10-K for additional information).

Liquidity and Capital Resources

Liquidity and Going Concern

As of December 31, 2024, we had cash, cash equivalents and short-term investments totaling $8.9 million, compared to $9.4 million as of December 31, 2023. Our cash and investment balances are held in a variety of interest-bearing instruments, including obligations of commercial paper, U.S. government sponsored enterprise debt securities and money market funds. Cash in excess of immediate requirements is invested with a view toward capital preservation and liquidity.

To date, we have incurred losses and generated negative cash flows from operations and we expect to incur significant losses in 2025 and may incur significant losses and negative cash flows from operations in the future. Although we raised additional capital in March 2025 (see Note 17, "Subsequent Event" to the consolidated financial statements in this Annual Report on Form 10-K for additional information), considering our current cash resources and current and expected levels of operating expenses for the next twelve months, we expect to need additional capital to fund our planned operations prior to the twelve-month anniversary of the filing date of this Annual Report on Form 10-K.

We may seek to raise such additional capital through public or private equity offerings, the issuance of debt securities, a new debt facility, or entering into product development, license or distribution agreements with third parties. Our existing capital resources will not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to sustain our operations.

While we believe our plans to raise additional funds will alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, these plans are not entirely within our control and cannot be assessed as being probable of occurring. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to further reduce our workforce, delay, reduce the scope of, or cease, the development of our product candidates in advance of the date on which our cash resources are exhausted to ensure that we have sufficient capital to meet our obligations and continue on a path designed to preserve stockholder value. In addition, if we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish rights to our technologies, future revenue streams or product candidates, or to grant licenses on terms that may not be favorable to us.

XOMA Purchase Agreement

In January 2024, we entered into the Purchase Agreement with XOMA in exchange for $8.0 million for the sale of our right, title and interest in and to amounts payable to us pursuant to the DSUVIA Agreement with Alora until the XOMA Threshold is attained, after which time we may share in certain future payments from Alora (see Note 7, “Sale of Future Payments” to the consolidated financial statements in this Annual Report on Form 10-K for additional information).

January 2024 Private Placement

In January 2024, we entered into securities purchase agreements with institutional investors, relating to the issuance and sale of pre-funded warrants, or the January 2024 Pre-Funded Warrants, to the purchasers in a two-tranche private placement to purchase shares of our common stock at a purchase price of $0.769 per share and an exercise price of $0.001 per share, or the January 2024 Private Placement. The January 2024 Pre-Funded Warrants are exercisable immediately and have an unlimited term. The terms of the January 2024 Private Placement included:

- the first tranche of the January 2024 Private Placement, which closed on January 22, 2024, resulted in the aggregate gross proceeds of approximately $6.0 million excluding the proceeds, if any, from the exercise of the January 2024 Pre-Funded Warrants issued in such tranche. In the first tranche of the January 2024 Private Placement, we issued January 2024 Pre-Funded Warrants to purchase up to 7,792,208 shares of our common stock.

- the second tranche of the January 2024 Private Placement, was a conditional purchase by the purchasers subject to either (a) the satisfaction or waiver of achieving, by September 30, 2024, the NEPHRO CRRT primary and one of the secondary clinical trial endpoints, resulting in our issuing January 2024 Pre-Funded Warrants to purchase up to 12,987,013 shares of our common stock, and receiving additional aggregate gross proceeds of approximately $10.0 million, and/or (b) the satisfaction or waiver of the volume-weighted average price of our common stock for each of the immediately subsequent five trading days following our announcement of our pivotal trial data being at least $0.92 per share, resulting in our issuing January 2024 Pre-Funded Warrants to purchase up to 2,597,402 shares of our common stock and receiving additional aggregate gross proceeds of approximately $2.0 million.

On September 30, 2024, we amended our securities purchase agreements, dated January 17, 2024, with entities affiliated with Nantahala Management, LLC, or the Nantahala Agreements, to extend to June 30, 2025 the date by which we must achieve the precedent conditions to the second closing thereunder, or the Nantahala Amendments. If prior to the second closing, we consummate an equity financing, then the purchasers shall be released from their obligation to purchase additional shares of our common stock and/or pre-funded warrants pursuant to the Nantahala Agreements, as amended.

In connection with the January 2024 Private Placement, we agreed to amend and restate a portion of the outstanding warrants issued in connection with the July 2023 Private Placement (see below), representing (i) Series A common stock warrants to purchase up to 2,941,178 shares of our common stock and (ii) Series B common stock warrants to purchase up to 2,941,178 shares of our common stock, to reduce the exercise price thereunder to $0.77 per share.

See Note 9, “Stockholders’ Equity” and Note 10, “Warrants” to the consolidated financial statements in this Annual Report on Form 10-K for additional information).

July 2023 Private Placement

In July 2023, we entered into securities purchase agreements with institutional investors and issued and sold in a private placement, or the July 2023 Private Placement:

- 5,340,591 shares of our common stock;
- pre-funded warrants to purchase up to 2,012,356 shares of our common stock with an exercise price of $0.001 per share, or the July 2023 Pre-Funded Warrants;
- Series A common stock warrants to purchase up to an aggregate of 7,352,947 shares of our common stock with an exercise price of $1.11 per share; and
- Series B common stock warrants to purchase up to an aggregate of 7,352,947 shares of our common stock with an exercise price of $1.11 per share.

As mentioned above, in connection with the January 2024 Private Placement, we agreed to amend and restate a portion of the outstanding Series A and Series B common stock warrants issued under the July 2023 Private Placement to reduce the exercise price thereunder to $0.77 per share.

See Note 9, "Stockholders' Equity" and Note 10, "Warrants" to the consolidated financial statements in this Annual Report on Form 10-K for additional information.

Registration Statement on Form S-3

In November 2023, we filed, and the SEC subsequently declared effective, a registration statement on Form S-3 pursuant to which we may offer shares of our common stock and preferred stock, various series of debt securities and/or warrants to purchase any of such securities, either individually or in combination, up to a total dollar amount of $150 million, from time to time at prices and on terms to be determined by market conditions at the time of any offering. Our ability to sell such securities will be limited until we are no longer subject to the SEC's "baby shelf" limitations.

Oxford Loan Agreement

In May 2019, we entered into a loan agreement with Oxford Finance, LLC, or Oxford. In April 2023, in connection with the closing of the divestment of DSUVIA to Alora, we paid Oxford the remaining amount due of approximately $3.4 million including accrued interest and fees under the loan, and the loan agreement was terminated with no further obligations by either party. For more information, see Note 6, "Long-Term Debt" to the consolidated financial statements in this Annual Report on Form 10-K.

Cash Flows

	Years Ended December 31,	
	2024	**2023**
Net cash used in operating activities	$ (12,683)	$ (17,492)
Net cash provided by/(used in) investing activities	3,781	(528)
Net cash provided by financing activities	12,044	3,466

The discussion of our cash flows that follows includes the impact of discontinued operations. For additional information, see Note 3, "Discontinued Operations" to the consolidated financial statements in this Annual Report on Form 10-K.

Cash Flows from Operating Activities

The primary use of cash for our continuing operating activities during these periods was to support our product development efforts for our product candidates while the primary use of cash for discontinued operations was to fund commercial activities for DSUVIA. Our cash used in operating activities also reflected changes in our working capital, net of adjustments for non-cash charges, such as stock-based compensation, depreciation and amortization of our fixed assets, non-cash interest expense related to the sale of future payments and interest expense related to our debt financings.

Cash used in operating activities of $12.7 million during 2024, reflected a net loss of $13.0 million, partially offset by aggregate non-cash charges of $0.5 million and included an approximate $0.2 million net change in our operating assets and liabilities. Significant non-cash adjustments included $1.0 million in stock-based compensation expense, $0.4 million in interest expense related to the sale of future payments and a $0.7 million decrease in the fair value of our warrant liability. The net change in our operating assets and liabilities was primarily due to a $1.6 million decrease in prepaid expenses and other current assets, a $0.7 million decrease in accounts payable and a $1.2 million decrease in accrued liabilities.

Cash used in operating activities of $17.5 million during 2023 reflected a net loss of $18.4 million, partially offset by aggregate non-cash charges of approximately $2.4 million and included an approximate $1.5 million net change in our operating assets and liabilities. Non-cash adjustments included an impairment charge of $6.9 million on our net assets held for sale in connection with our divestment of DSUVIA, an impairment charge of $1.1 million on fixed assets, a gain of $1.1 million related to the termination of lease liabilities, a $5.3 million decrease in the fair value of our warrant liability, $1.7 million in stock-based compensation expense, $0.7 million related to the issuance of the Lowell holdback shares, a $0.4 million gain on extinguishment of debt, and $0.3 million in depreciation and amortization expense. The net change in our operating assets and liabilities included a $0.2 million decrease in prepaid expenses and other assets, a $1.1 million decrease in accrued liabilities, and a $0.6 million decrease in accounts payable.

Cash Flows from Investing Activities

Our investing activities have consisted primarily of our capital expenditures and purchases and sales and maturities of our available-for-sale investments.

During 2024, cash provided by investing activities of $3.8 million was primarily the net result of $8.8 million in proceeds from maturity of investments and $5.0 million in purchases of investments.

During 2023, cash used in investing activities of $0.5 million was primarily the net result of by $3.7 million for purchases of investments, partially offset by $2.7 million in cash proceeds on the sale of DSUVIA to Alora and $0.5 million in proceeds from the maturities of investments.

Cash Flows from Financing Activities

Cash flows from financing activities primarily reflect proceeds from the sale of our securities and payments made on debt financings.

During 2024, cash provided by financing activities of $12.0 million was primarily due to net proceeds from the XOMA Purchase Agreement of $6.1 million, and $5.9 million in net proceeds from the January 2024 private placement.

During 2023, cash provided by financing activities of $3.5 million was primarily due to $8.9 million in net proceeds from the July 2023 private placement, partially offset by $5.4 million in long-term debt payments under the loan agreement with Oxford.

Capital Commitments and Capital Resources

Our current operating plan includes expenditures related to the development of our product candidates. Our operating plan includes anticipated activities required for the development and supply of our nafamostat product candidates. These assumptions may change as a result of many factors. We will continue to evaluate the work necessary to gain approval of our product candidates in the United States and intend to update our cash forecasts accordingly. Considering our current cash resources and current and expected levels of operating expenses for the next twelve months, we expect to need additional capital to fund our planned operations for at least the next twelve months.

Our future capital requirements may vary materially from our expectations based on numerous factors, including, but not limited to, the following:

- the ability to timely and successfully complete our clinical trial for the Niyad product candidate;
- the outcome, timing and cost of the development of our other nafamostat product candidates;

- expenditures related to drafting and submission of new drug or device regulatory applications with the FDA for our developmental product candidates and payment of statutory filing fees and related application prosecution costs arising from such submissions;
- costs associated with business development activities and licensing transactions;
- the outcome and timing of the regulatory submissions for our product candidates and any approvals for our product candidates;
- expenditures related to the potential commercialization of our product candidates, if approved;
- the initiation, progress, timing and completion of any post-approval clinical trials for our product candidates, if approved;
- the ability to retain the listing of our common stock on Nasdaq;
- changes in the focus and direction of our business strategy and/or research and development programs;
- delays that may be caused by changing regulatory requirements;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of future in-licensing and out-licensing transactions;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
- the potential impact of trade laws and regulations of the United States associated with the use of our contract development and manufacturing organization, or CDMO, for nafamostat-based finished goods located in China;
- the cost of procuring clinical supplies of our product candidates, and commercial supplies, if approved;
- the cost of establishing new supply chains and related third party logistics to support our developmental product candidates;
- the extent to which we acquire or invest in businesses, products and product candidates or technologies; and
- the expenses associated with litigation.

In the long term, our existing capital resources will not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to sustain our operations. We will have to raise additional funds through the sale of our equity securities, monetization of current and future assets, issuance of debt or debt-like securities or from development and licensing arrangements to sustain our operations and continue our development programs.

Please see “Part I., Item 1A. Risk Factors—Risks Related to Our Financial Condition and Need for Additional Capital.”

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information specified under this item.

Item 8. Financial Statements and Supplementary Data

The financial statements required by this item are attached to this Form 10-K beginning with page F-1.

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

None.

Item 9A. Controls and Procedures

We maintain disclosure controls and procedures (as defined in Exchange Act Rule 13a–15(e) and 15d-15(e)) that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, and the rules and regulations thereunder, 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, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Evaluation of Disclosure Controls and Procedures

We have carried out an evaluation, under the supervision, and with the participation, of management including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e)) of the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Annual Report on Form 10–K. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2024.

Management's Annual Report on Internal Control over Financial Reporting

The following report is provided by management in respect of Talphera's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act):

1. Talphera's management is responsible for establishing and maintaining adequate internal control over financial reporting.

2. Talphera's management has used the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, framework (2013 framework) to evaluate the effectiveness of internal control over financial reporting. Management believes that the COSO framework is a suitable framework for its evaluation of financial reporting because it is free from bias, permits reasonably consistent qualitative and quantitative measurements of Talphera's internal control over financial reporting, is sufficiently complete so that those relevant factors that would alter a conclusion about the effectiveness of Talphera's internal control over financial reporting are not omitted and is relevant to an evaluation of internal control over financial reporting.

3. Management has assessed the effectiveness of Talphera's internal control over financial reporting as of December 31, 2024, and has concluded that such internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to the rules of the Securities and Exchange Commission applicable to smaller reporting companies that permit us to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) that occurred during the quarter ended December 31, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures and our internal control over financial reporting are designed to provide reasonable, not absolute, assurance that the objectives of the control system are met. We continue to implement, improve and refine our disclosure controls and procedures and our internal control over financial reporting.

Item 9B. Other Information

None.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information regarding our directors and executive officers set forth under the headings "Proposal No.1—Election of Directors," "Information Regarding the Board of Directors and Corporate Governance," and "Executive Officers of the Registrant" of the 2025 Proxy Statement is incorporated herein by reference.

Information regarding our Audit Committee, including the members of our Audit Committee, set forth under the heading "Information Regarding the Board of Directors and Corporate Governance—Audit Committee" of the 2025 Proxy Statement is incorporated herein by reference.

Information regarding the procedures by which our shareholders may recommend nominees to our Board of Directors set forth under the heading "Information Regarding the Board of Directors and Corporate Governance—Nominating and Corporate Governance Committee" of the 2025 Proxy Statement is incorporated herein by reference.

Information regarding our Code of Business Conduct and Ethics set forth under the heading "Information Regarding the Board of Directors and Corporate Governance—Code of Business Conduct and Ethics" of the 2025 Proxy Statement is incorporated herein by reference.

Information regarding our insider trading policy is set forth under the heading "Information Regarding the Board of Directors and Corporate Governance – Insider Trading Policy" of the 2025 Proxy Statement is incorporated herein by reference.

Item 11. Executive Compensation

Information regarding executive compensation and director compensation set forth under the headings "Executive Compensation" and "Director Compensation," respectively, of the 2025 Proxy Statement is incorporated herein by reference.

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

Information contained in the sections captioned "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" of the 2025 Proxy Statement is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions and Director Independence

Information contained in the section captioned "Related Person Transactions and Indemnification" of the 2025 Proxy Statement is incorporated herein by reference.

Information regarding director independence set forth under the heading "Information Regarding the Board of Directors and Corporate Governance" of the 2025 Proxy Statement is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

Information regarding our independent auditor fees and services in the section captioned "Proposal No. 2—Ratification of Selection of Independent Registered Public Accounting Firm" of the 2025 Proxy Statement is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Form 10-K:

1. Financial Statements:

See Index to Financial Statements in Item 8 of this Form 10-K.

2. Financial Statement Schedules:

Reference is made to the financial statement schedules included under Item 8 of Part II hereof. All other schedules are omitted because they are not applicable, not required or the information is shown in the financial statements or the notes thereto.

(b) Exhibits

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
2.1§#	Asset Purchase Agreement, between the Registrant and Vertical Pharmaceuticals, LLC, dated March 12, 2023.	10-Q	001-35068	2.1	11/14/2023
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	02/18/2011
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation, dated January 9, 2024	8-K	001-35068	3.1	01/09/2024
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	06/25/2019
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	10/25/2022
3.7	Amended and Restated Bylaws of the Registrant.	8-K	001-35068	3.1	01/09/2024
4.1	Description of Capital Stock.	10-K	001-35068	4.1	03/15/2021
4.2	Reference is made to Exhibits 3.1 through 3.4.				
4.3	Specimen Common Stock Certificate of the Registrant.	S-1	333-170594	4.2	01/31/2011
4.4	Form of Common Warrant(May 2019).	8-K	001-35068	4.1	06/03/2019
4.5	Form of Common Warrant(November 2021).	8-K	001-35068	4.1	11/15/2021
4.6	Common Stock Purchase Warrant (August 2022).	8-K	001-35068	4.1	08/04/2022
4.7	Form of Common Warrant (December 2022).	8-K	001-35068	4.1	12/28/2022
4.8	Form of Pre-Funded Warrant (December 2022).	8-K	001-35068	4.2	12/28/2022
4.9	Form of Common Warrant, as amended (November 2022).	8-K	001-35068	4.3	12/28/2022
10.1+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1	333-170594	10.1	01/07/2011
10.2+	2011 Equity Incentive Plan.	S-8	333-172409	99.3	02/24/2011
10.3+	Forms of Stock Option Grant Notice, Notice of Exercise and Option Agreement under 2011 Equity Incentive Plan.	10-K	001-35068	10.5	03/30/2011
10.4+	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement under 2011 Equity Incentive Plan.	10-K	001-35068	10.6	03/30/2011

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.5+	Amended and Restated 2020 Equity Incentive Plan.	8-K	001-350683	10.1	06/24/2024
10.6+	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Amended and Restated 2020 Equity Incentive Plan.	S-8	333-239213	99.2	06/16/2020
10.7+	Forms of RSU Award Grant Notice and Award Agreement (RSU Award) under the Amended and Restated 2020 Equity Incentive Plan.	S-8	333-239213	99.3	06/16/2020
10.8+	Amended and Restated 2011 Employee Stock Purchase Plan.	S-8	333-239213	99.4	06/24/2024
10.9+	Amended and Restated Offer Letter between the Registrant and Badri (Anil) Dasu, dated December 30, 2010.	S-1	333-170594	10.15	01/07/2011
10.10+	Amended and Restated Offer Letter between the Registrant and Pamela Palmer, dated December 29, 2010.	S-1	333-170594	10.16	01/07/2011
10.11+	Offer Letter between the Registrant and Shakil Aslam, dated May 13, 2024.				
10.12+	Offer Letter between the Registrant and Vincent J. Angotti, effective as of March 6, 2017.	10-Q	001-35068	10.4	05/08/2017
10.13+	Offer Letter between the Registrant and Raffi Asadorian, dated July 18, 2017.	8-K	001-35068	10.1	07/19/2017
10.14+	Amended and Restated Severance Benefit Plan effective as of February 7, 2017.	8-K	001-35068	10.2	02/09/2017
10.15§#	Commercial Supply Agreement, effective March 31, 2021 by and between the Registrant and Catalent Pharma Solutions, LLC.	10-Q	001-35068	10.1	08/16/2021
10.16§#	License and Commercialization Agreement (DZUVEO), dated July 14, 2021, between the Registrant and Laboratoire Aguettant.	10-Q	001-35068	10.1	11/15/2021
10.17§#	License and Commercialization Agreement (PFS), dated July 14, 2021, between the Registrant and Laboratoire Aguettant.	10-Q	001-35068	10.2	11/15/2021
10.18	Contingent Value Rights Agreement, dated as of January 7, 2022, by and among the Registrant, James Wilkie, solely in his capacity as the representative of the Lowell stockholders and option holders, and Computershare Inc., and its wholly-owned subsidiary, Computershare Trust Company, N.A., a federally chartered trust company, collectively as Rights Agent.	8-K	001-35068	10.1	01/12/2022
10.19	Form of Series A common stock warrant (July 2023).	8-K	001-35068	10.3	07/21/2023
10.20	Form of Series B common stock warrant (July 2023).	8-K	001-35068	10.4	07/21/2023
10.21	Form of Pre-Funded Warrant (July 2023).	8-K	001-35068	10.5	07/21/2023
10.22	Form of placement agent Series A common stock warrant (July 2023).	8-K	001-35068	10.6	07/21/2023
10.23	Form of placement agent Series B common stock warrant (July 2023).	8-K	001-35068	10.7	07/21/2023

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.24	Form of Securities Purchase Agreement, by and among the Registrant and entities affiliated with Nantahala Management, LLC, dated as of January 17, 2024.	8-K	001-35068	10.1	01/22/2024
10.25	Form of Registration Rights Agreement, between the Registrant and the Purchasers, dated as of January 17, 2024.	8-K	001-35068	10.3	01/22/2024
10.26	Form of Pre-Funded Warrant (January 2024).	8-K	001-35068	10.4	01/22/2024
10.27	Form of Amendment No. 1 to Securities Purchase Agreement, dated September 30, 2024, by and among Talphera, Inc. and entities affiliated with Nantahala Management, LLC.	8-K	001-35068	10.1	10/01/2024
19	Talphera, Inc. Insider Trading Policy.				
23.1	Consent of BPM LLP, Independent Registered Public Accounting Firm.				
24.1	Power of Attorney (included in signature page).				
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.				
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.				
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
97+	Talphera, Inc. Incentive Compensation Recoupment Policy.	10-K	001-35068	97	3/6/2024
101.INS	XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Schema Document				
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document				
101.LAB	Inline XBRL Taxonomy Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document				

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.INS, 101.SCH, 101.CAL, 101.DEF, 101.LAB, and 101.PRE).				

§ Schedules omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of any omitted schedule upon request by the SEC.

+ Indicates management contract or compensatory plan.

Material in the exhibit marked with an "[*]" has been omitted because it is confidential, not material, and would be competitively harmful if publicly disclosed.

The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 31, 2025

Talphera, Inc.
(Registrant)

/s/ Vincent J. Angotti
Vincent J. Angotti
Chief Executive Officer and Director
(Principal Executive Officer)

/s/ Raffi Asadorian
Raffi Asadorian
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Vincent J. Angotti and Raffi Asadorian, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution for him or her, and in his or her name 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 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 therewith, 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, and any of them, his or her 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, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Vincent J. Angotti **Vincent J. Angotti**	Chief Executive Officer and Director *(Principal Executive Officer)*	March 31, 2025
/s/ Raffi Asadorian **Raffi Asadorian**	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 31, 2025
/s/ Adrian Adams **Adrian Adams**	Chairman	March 31, 2025
/s/ Marina Bozilenko **Marina Bozilenko**	Director	March 31, 2025
/s/ Jill Broadfoot **Jill Broadfoot**	Director	March 31, 2025
/s/ Stephen J. Hoffman, Ph.D., M.D. **Stephen J. Hoffman, Ph.D., M.D.**	Director	March 31, 2025
/s/ Abhinav Jain **Abhinav Jain**	Director	March 31, 2025
/s/ Mark Wan **Mark Wan**	Director	March 31, 2025

TALPHERA, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Talphera, Inc. (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2024, 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 as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring operating losses and negative cash flows from operating activities since inception and expects to continue to incur operating losses and negative cash flows in the future. These matters raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ BPM LLP

We have served as the Company's auditor since 2023.
Walnut Creek, California
March 31, 2025

Talphera, Inc.

Consolidated Balance Sheets
(in thousands, except share data)

	December 31, 2024	December 31, 2023
Assets		
Current Assets:		
Cash and cash equivalents	$ 8,863	$ 5,721
Short-term investments	—	3,660
Prepaid expenses and other current assets	554	2,195
Total current assets	9,417	11,576
In-process research and development asset	8,819	8,819
Total assets	$ 18,236	$ 20,395
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 670	$ 1,336
Accrued and other liabilities	1,254	2,445
Liabilities of discontinued operations, current portion	723	731
Total current liabilities	2,647	4,512
Warrant liability	1,061	1,778
Liability related the sale of future payments	6,527	—
Total liabilities	10,235	6,290
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.001 par value—200,000,000 shares authorized as of December 31, 2024 and 2023; 17,029,469 and 16,952,519 shares issued and outstanding as of December 31, 2024 and 2023, respectively	17	17
Additional paid-in capital	465,214	458,314
Accumulated deficit	(457,230)	(444,226)
Total stockholders' equity	8,001	14,105
Total Liabilities and Stockholders' Equity	$ 18,236	$ 20,395

See notes to consolidated financial statements.

Talphera, Inc.

Consolidated Statements of Operations
(in thousands, except share and per share data)

	Year Ended December 31,	
	2024	**2023**
Revenue	$ —	$ 651
Operating costs and expenses:		
Research and development	6,718	5,546
Selling, general and administrative	8,534	11,994
Total operating costs and expenses	15,252	17,540
Loss from operations	(15,252)	(16,889)
Other income (expense):		
Interest expense	—	(134)
Interest income and other income, net	679	1,416
Gain on sale of future payments	1,246	—
Gain on change in fair value of warrant liability	717	5,320
Non-cash interest expense on liability related to the sale of future payments	(394)	—
Total other income, net	2,248	6,602
Net loss from continuing operations	(13,004)	(10,287)
Net loss from discontinued operations – See Note 3	—	(8,110)
Net loss	$ (13,004)	$ (18,397)
Net loss per share attributable to stockholders:		
Basic and diluted, continuing operations	$ (0.50)	$ (0.72)
Basic and diluted, discontinued operations	$ 0.00	$ (0.57)
Basic and diluted loss per share	$ (0.50)	$ (1.29)
Shares used in computing net loss per share of common stock, basic and diluted – See Note 12	25,845,639	14,263,744

See notes to consolidated financial statements.

Talphera, Inc.

Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of December 31, 2022	8,243,680	$ 8	$ 447,635	$ (425,829)	$ 21,814
Stock-based compensation	—	—	1,729	—	1,729
Issuance of common stock in connection with asset purchase	69,808	—	77	—	77
Net proceeds from issuance of common stock, accompanying warrants and pre-funded warrants in July 2023 private placement offering	5,340,591	5	8,851	—	8,856
Exercise of pre-funded warrants	3,228,781	3	—	—	3
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	27,450	—	(22)	—	(22)
Issuance of common stock upon ESPP purchase	42,209	1	44	—	45
Net loss	—	—	—	(18,397)	(18,397)
Balance as of December 31, 2023	16,952,519	17	458,314	(444,226)	14,105
Stock-based compensation	—	—	989	—	989
Net proceeds from issuance of pre-funded warrants in January 2024 private placement offering	—	—	5,884	—	5,884
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	27,435	—	(17)	—	(17)
Issuance of common stock upon ESPP purchase	49,515	—	44	—	44
Net loss	—	—	—	(13,004)	(13,004)
Balance as of December 31, 2024	17,029,469	$ 17	$ 465,214	$ (457,230)	$ 8,001

See notes to consolidated financial statements.

Talphera, Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (13,004)	$ (18,397)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest expense on liability related to the sale of future payments	394	—
Depreciation and amortization	—	311
Net amortization of discount on short-term investments	(121)	(24)
Non-cash interest expense related to debt financing	—	53
Revaluation of liability for Lowell holdback shares	—	(723)
Stock-based compensation	989	1,729
Gain on change in fair value of warrant liability	(717)	(5,320)
Impairment of net assets held for sale	—	6,853
Impairment of fixed assets	—	1,065
Gain on termination of lease liabilities	—	(1,098)
Gain on extinguishment of debt liability	—	(400)
Changes in operating assets and liabilities:		
Inventories	—	61
Prepaid expenses and other current assets	1,641	281
Accounts payable	(671)	(575)
Accrued liabilities	(1,194)	(1,132)
Operating lease liabilities	—	(147)
Deferred revenue	—	(29)
Net cash used in operating activities	(12,683)	(17,492)
Cash flows from investing activities:		
Purchase of property and equipment	—	(100)
Sale of the DSUVIA assets	—	2,723
Purchase of investments	(4,979)	(3,651)
Proceeds from maturities of investments	8,760	500
Net cash provided by (used in) investing activities	3,781	(528)
Cash flows from financing activities:		
Payment of long-term debt	—	(5,416)
Gross proceeds from sale of future payments	6,654	—
Issuance costs related to sale of future payments	(521)	—
Net proceeds from issuance of common stock, accompanying warrants and pre-funded warrants in July 2023 private placement offering	—	8,856
Net proceeds from issuance of common stock in connection with exercise of pre-funded warrants	—	3
Net proceeds from issuance of pre-funded warrants in January 2024 private placement offering	5,884	—
Net proceeds from issuance of common stock through equity plans	27	23
Net cash provided by financing activities	12,044	3,466
Net change in cash and cash equivalents	3,142	(14,554)
Cash and cash equivalents—Beginning of period	5,721	20,275
Cash and cash equivalents—End of period	$ 8,863	$ 5,721
Supplemental Disclosures of Cash Flow Information:		
Cash paid for interest	$ —	$ 119
Income taxes paid	$ —	$ —
Noncash Investing and Financing Activities:		
Equity issuance costs from warrant modification	$ 251	$ —
Settlement of held back shares issued in connection with asset acquisition	$ —	$ (77)
Offering costs in accounts payable	$ —	$ 72
Fair value of warrants issued to placement agent	$ —	$ 263

See notes to consolidated financial statements.

1. Organization and Summary of Significant Accounting Policies

The Company

Talphera, Inc., or the Company, or Talphera, was incorporated in Delaware on July 13, 2005, as SuRx, Inc. The Company subsequently changed its name to AcelRx Pharmaceuticals, Inc. and, on January 9, 2024, to Talphera, Inc. The Company's operations are based in San Mateo, California.

Talphera is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. The Company's product development portfolio features Niyad™ (a regional anticoagulant for the dialysis circuit), and LTX-608 (a nafamostat formulation for direct IV infusion) that the Company intends to develop for one or more of the following indications: disseminated intravascular coagulation, or DIC, acute respiratory distress syndrome, or ARDS, acute pancreatitis, or as an anti-viral treatment, and two ready-to-use pre-filled syringe, or PFS, product candidates (Fedsyra and phenylephrine).

On March 12, 2023, the Company entered into an Asset Purchase Agreement, or the DSUVIA Agreement, with Vertical Pharmaceuticals, LLC, a wholly owned subsidiary of Alora Pharmaceuticals, LLC, or Alora, pursuant to which Alora agreed to acquire certain assets and assume certain liabilities of the Company relating to its sufentanil sublingual tablet product referred to as DSUVIA or DZUVEO, or any other single-dose pharmaceutical product for use in medically supervised settings containing a sublingual tablet that includes sufentanil as the sole active ingredient, as a 30 mcg tablet or other dosage form or strength as reasonably necessary for lifecycle management, or the Product. The closing of the DSUVIA Agreement occurred on April 3, 2023 (see Note 3, "Discontinued Operations").

On January 7, 2022, the Company acquired Lowell Therapeutics, Inc., or Lowell, a privately held company (see Note 4, "Asset Acquisition") and, as a result acquired the Niyad developmental product, a regional anticoagulant for the dialysis circuit during continuous renal replacement therapy for acute kidney injury patients in the hospital, that the Company is studying under an investigational device exemption, or IDE, and for which it has received Breakthrough Device Designation status from the FDA. While not approved for commercial use in the United States, the active drug component of Niyad, nafamostat, has been approved in Japan and South Korea as a regional anticoagulant for the dialysis circuit, disseminated intravascular coagulation, and acute pancreatitis. Niyad is a lyophilized formulation of nafamostat, a broad-spectrum, synthetic serine protease inhibitor, with anticoagulant, anti-inflammatory, and potential anti-viral activities. The second intended indication for Niyad is as a regional anticoagulant for the dialysis circuit for chronic kidney disease patients undergoing intermittent hemodialysis in dialysis centers. In addition, the Company acquired LTX-608, a nafamostat formulation for direct IV infusion.

On July 14, 2021, the Company entered into a License and Commercialization Agreement, or the PFS Agreement, with Laboratoire Aguettant, or Aguettant, pursuant to which the Company obtained the exclusive right to develop and, subject to FDA approval, commercialize in the United States an ephedrine pre-filled syringe for injection, and (ii) a phenylephrine PFS for injection. Aguettant will supply the Company with the products for use in commercialization, if they are approved in the U.S.

Liquidity and Going Concern

The consolidated financial statements for the year ended December 31, 2024, were prepared on the basis of a going concern, which contemplates that the Company will be able to realize assets and discharge liabilities in the normal course of business. The Company has incurred recurring operating losses and negative cash flows from operating activities since inception and expects to continue to incur operating losses and negative cash flows in the future. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Considering the Company's current cash resources and its current and expected levels of operating expenses for the next twelve months, management expects to need additional capital to fund its planned operations prior to the 12-month anniversary of the date this Annual Report on Form 10-K is filed with the United States Securities and Exchange Commission, or the SEC.

Management may seek to raise such additional capital through public or private equity offerings, debt securities, a new debt facility, monetizing or securitizing certain assets, entering into product development, license or distribution agreements with third parties, or divesting any of the Company's remaining product candidates. While management believes its plans to raise additional funds will alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern, these plans are not entirely within the Company's control and cannot be assessed as being probable of occurring.

Additional funds may not be available when the Company needs them on terms that are acceptable to the Company, or at all. If adequate funds are not available, the Company may be required to further reduce its workforce, delay the ongoing clinical trial for Niyad, or delay the development of its regulatory filing plans for its product candidates in advance of the date on which the Company's cash resources are exhausted to ensure that the Company has sufficient capital to meet its obligations and continue on a path designed to preserve stockholder value. In addition, if additional funds are raised through collaborations, strategic alliances or licensing arrangements with third parties, the Company may have to relinquish rights to its technologies, future revenue streams or product candidates, or to grant licenses on terms that may not be favorable to the Company.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, or GAAP, and with the rules and regulations of the U.S. Securities and Exchange Commission, or SEC.

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Management believes its most significant accounting estimates relate to fair value of warrants, liability related to the sale of future payments, accrued clinical trial liabilities and management's assessment of going concern. Management evaluates its estimates on an ongoing basis including critical accounting policies. Estimates are based on historical experience and on various other market-specific and other relevant assumptions that the Company believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Reclassifications

Certain prior year amounts in the consolidated financial statements have been reclassified to conform to the current year's presentation. In particular, other assets has been reclassified as prepaid expenses and other current assets in the consolidated balance sheets, other has been reclassified as net amortization of discount on short-term investments, accounts receivable and other assets have been reclassified as prepaid expenses and other current assets, and payment of employee tax obligations related to vesting of restricted stock units has been reclassified to net proceeds from issuance of common stock through equity plans in the consolidated statement of cash flows and the portion of interest income and other income, net related to the revaluation of liability-classified warrants has been reclassified to change in fair value of warrants in the consolidated statements of operations. The Company has adopted Accounting Standards Update, or ASU, 2023-07, *Improvements to Reportable Segment Disclosures*, which requires the prior period to reflect the change in presentation. See Note 16, "Segment Reporting". These reclassifications did not affect the prior period's total assets, total liabilities, stockholders' equity, net loss or net cash used in operating activities.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity (at date of purchase) of three months or less to be cash equivalents. Cash and cash equivalents consist of cash on deposit with banks.

Short-Term Investments

All marketable securities are classified as available for sale and consist of commercial paper and U.S. government sponsored enterprise debt securities. These securities are carried at estimated fair value, which is based on quoted market prices or observable market inputs of almost identical assets, with unrealized gains and losses included in accumulated other comprehensive income (loss). The amortized cost of securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in interest income or expense. The cost of securities sold is based on specific identification. When the fair value of an available-for-sale security falls below the amortized cost basis, it is evaluated to determine if any of the decline in value is attributable to credit loss. Decreases in fair value attributable to credit loss are recorded directly to the consolidated statement of operations with a corresponding allowance for credit losses, limited to the amount that the fair value is less than the amortized cost basis. If the credit quality subsequently improves, the allowance is reversed up to a maximum of the previously recorded credit losses. When the Company intends to sell an impaired available-for-sale security, or if it is more likely than not that the Company will be required to sell the security prior to recovering the amortized cost basis, the entire fair value adjustment will immediately be recognized in the consolidated statement of operations with no corresponding allowance for credit losses.

Fair Value of Financial Instruments

The Company measures and reports its cash equivalents, investments and financial liabilities at fair value. Fair value is defined as the exchange price that would be received for an asset or an exit price paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy defines a three-level valuation hierarchy for disclosure of fair value measurements as follows:

Level I—Unadjusted quoted prices in active markets for identical assets or liabilities;

Level II—Inputs other than quoted prices included within Level I that are observable, unadjusted quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities; and

Level III—Unobservable inputs that are supported by little or no market activity for the related assets or liabilities.

The categorization of a financial instrument within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Concentration of Risk

The Company invests cash that is currently not being used for operational purposes in accordance with its investment policy in debt securities of U.S. government sponsored agencies, commercial paper and overnight deposits. The Company is exposed to credit risk in the event of default by the institutions holding the cash equivalents and available-for-sale securities to the extent recorded on the consolidated balance sheets. The Company has significant cash balances at financial institutions which throughout the year regularly exceed the federally insured limit of $250,000. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations, and cash flows.

The Company relies on a single contract manufacturer, or CMO, for the active pharmaceutical ingredient, or API, for Niyad™ and a second single contract manufacturer for the finished Niyad product.

All revenue relates to the Company’s services for fees earned on the sales of DSUVIA to the DoD by Alora.

Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If so, the transaction is accounted for as an asset acquisition. If not, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

Acquisitions meeting the definition of business combinations are accounted for using the acquisition method of accounting, which requires that the purchase price be allocated to the net assets acquired at their respective fair values. In a business combination, any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

For asset acquisitions, a cost accumulation model is used to determine the cost of an asset acquisition. Direct transaction costs are recognized as part of the cost of an asset acquisition. The Company also evaluates which elements of a transaction should be accounted for as a part of an asset acquisition and which should be accounted for separately. The cost of an asset acquisition, including transaction costs, is allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis. Goodwill is not recognized in an asset acquisition. Any difference between the cost of an asset acquisition and the fair value of the net assets acquired is allocated to the non-monetary identifiable assets based on their relative fair values. When a transaction accounted for as an asset acquisition includes an in-process research and development, or IPR&D, asset, the IPR&D asset is only capitalized if it has an alternative future use other than in a particular research and development project. For an IPR&D asset to have an alternative future use (a) the Company must reasonably expect that it will use the asset acquired in the alternative manner and anticipate economic benefit from that alternative use, and (b) the Company's use of the asset acquired is not contingent on further development of the asset subsequent to the acquisition date (that is, the asset can be used in the alternative manner in the condition in which it existed at the acquisition date). Otherwise, amounts allocated to IPR&D that have no alternative use are expensed. Asset acquisitions may include contingent consideration arrangements that encompass obligations to make future payments to sellers contingent upon the achievement of future financial targets. Contingent consideration is not recognized until all contingencies are resolved and the consideration is paid or probable of payment, at which point the consideration is allocated to the assets acquired on a relative fair value basis.

In-Process Research and Development

In accordance with ASC Topic 350, *Intangibles - Goodwill and Other*, the acquired IPR&D has initially been accounted for as an indefinite-lived intangible asset and, therefore, not amortized. If the IPR&D asset achieves regulatory approval and the asset life is determined to be finite, the asset's useful life will be estimated, and the asset will be amortized over its remaining useful life.

The IPR&D asset is reviewed for impairment annually or whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. These events and changes can include significant current period operating losses or negative cash flows associated with the use of the IPR&D asset, such as the result of unfavorable data from any ongoing or future clinical trial, changes in assumptions that negatively impact projected cash flows, or because of any other information regarding the prospects of successfully developing or commercializing the Company's programs. When impairment indicators are present, the Company compares undiscounted future cash flows to the asset's carrying value to determine if the asset is recoverable. If the carrying values are in excess of undiscounted expected future cash flows, the Company measures any impairment by comparing the fair value of the asset to its carrying value.

No impairment losses were recorded on the IPR&D asset during the years ended December 31, 2024 or 2023.

Discontinued Operations

In accordance with ASC 205-20 *Presentation of Financial Statements: Discontinued Operations*, a disposal of a component of an entity or a group of components of an entity is required to be reported as discontinued operations if the disposal represents a strategic shift that has (or will have) a major effect on an entity's operations and financial results. In the period in which the component meets held-for-sale or discontinued operations criteria the major current assets, non-current assets, current liabilities, and non-current liabilities shall be reported as components of total assets and liabilities separate from those balances of the continuing operations. At the same time, the results of all discontinued operations, less applicable income taxes, shall be reported as components of net loss separate from the net income (loss) of continuing operations.

The Company's DSUVIA business met the definition of a discontinued operation as of March 31, 2023. Accordingly, the Company has classified the results of the DSUVIA business as discontinued operations in its consolidated statements of operations for all periods presented. All assets and liabilities associated with the DSUVIA business were classified as assets and liabilities of discontinued operations in the consolidated balance sheets for the periods presented. All amounts included in the notes to the consolidated financial statements relate to continuing operations unless otherwise noted. (See Note 3, "Discontinued Operations").

Research and Development Expenses

Research and development costs are charged to expense when incurred. Research and development expenses include salaries, employee benefits, including stock-based compensation, consultant fees, laboratory supplies, costs associated with clinical trials and manufacturing, including contract research organization fees, other professional services and allocations of corporate costs. The Company reviews and accrues clinical trial expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of patient studies and other events.

Stock-Based Compensation

Compensation expense for all stock-based payment awards made to employees and directors, including employee stock options and restricted stock units related to the 2020 Equity Incentive Plan, or 2020 EIP, the 2011 Equity Incentive Plan, or 2011 EIP, and employee share purchases related to the Amended and Restated 2011 Employee Stock Purchase Plan, or ESPP, is based on estimated fair values at grant date. The Company determines the grant date fair value of the awards using the Black-Scholes option-pricing model and generally recognizes the fair value as stock-based compensation expense on a straight-line basis over the vesting period of the respective awards. The Company applies the graded-vesting attribution method to awards with market conditions that include graded-vesting features. Additionally, the Company uses the Monte Carlo Simulation model to evaluate the derived service period and fair value of awards with market conditions, including assumptions of historical volatility and risk-free interest rate commensurate with the vesting term.

The Black-Scholes option pricing model requires inputs such as expected term, expected volatility and risk-free interest rate. These inputs are subjective and generally require significant analysis and judgment to develop. The expected term, which represents the period of time that options granted are expected to be outstanding, is derived by analyzing the historical experience of similar awards, giving consideration to the contractual terms of the stock-based awards, vesting schedules and expectations of future employee behavior. Expected volatilities are estimated using the historical stock price performance over the expected term of the option, which are adjusted as necessary for any other factors which may reasonably affect the volatility of the Company's stock in the future. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for the expected term of the award. The Company recognizes forfeitures when they occur and does not anticipate paying dividends in the near future.

Warrants Issued in Connection with Financings

The Company accounts for issued warrants as either liability or equity in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, or ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. Under ASC 480-10, warrants are considered liability if they are mandatorily redeemable and they require settlement in cash or other assets, or a variable number of shares. If warrants do not meet liability classification under ASC 480-10, the Company considers the requirements of ASC 815-40 to determine whether the warrants should be classified as liability or equity. Under ASC 815-40, contracts that may require settlement for cash are liabilities, regardless of the probability of the occurrence of the triggering event. Liability classified warrants are measured at fair value on the issuance date and at the end of each reporting period. Any change in the fair value of the warrants after the issuance date is recorded in the consolidated statements of operations. If warrants do not require liability classification under ASC 815-40, in order to conclude warrants should be classified as equity, the Company assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP. Equity classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date.

Sale of Future Payments

On January 12, 2024, the Company entered into the Purchase Agreement with XOMA to monetize a portion of its future payments for commercial sales of DSUVIA and services performed by the Company to support sales of DSUVIA to the Department of Defense, or DoD, by Alora under the Marketing Agreement, and sales milestones under the DSUVIA Agreement. Refer to Note 7, "Sale of Future Payments" for further details on the Purchase Agreement.

The Company recorded approximately $6.1 million, net of $0.5 million in issuance costs, of the $8.0 million proceeds as a liability, as this portion of the proceeds represents a sale of future revenues under ASC 470 for which the Company has continuing involvement in the generation of cash flows. The Company recorded approximately $1.2 million, net of $0.2 million in issuance costs, of the $8.0 million proceeds as other income, as this portion of proceeds represents the sale of all of the Company's interest in future payments related to commercial sales of DSUVIA for which the Company is no longer entitled to receive such payments and has no further continuing involvement. The Company utilized internal estimates to develop a cash flow model based on business assumptions to determine the allocation of the proceeds.

The liability related to the sale of future payments is recorded as debt and will be amortized under the effective interest rate method over the estimated life of the Purchase Agreement. The Company estimates the effective interest rate based on its estimate of total payments to be received by XOMA under the Purchase Agreement. The Company reassesses these estimates at each reporting date and adjusts the effective interest rate and amortization of the liability on a prospective basis, as necessary. The Company records the payments to XOMA as a reduction of the liability when paid. As such payments are made to XOMA, the balance of the liability will be effectively repaid over the life of the Purchase Agreement.

Income Taxes

Deferred tax assets and liabilities are measured based on differences between the financial reporting and tax basis of assets and liabilities using enacted rates and laws that are expected to be in effect when the differences are expected to reverse. The Company records a valuation allowance for the full amount of deferred assets, which would otherwise be recorded for tax benefits relating to operating loss and tax credit carryforwards, as realization of such deferred tax assets cannot be determined to be more likely than not.

Net Loss per Share of Common Stock

Basic and diluted net income (loss) per common share, or EPS, are calculated in accordance with the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic *260, Earnings per Share*.

The Company applies the two-class method to compute basic and, if more dilutive than other methods, diluted net income or loss per share. The two-class method is an earnings allocation formula that treats participating securities as having rights to earnings that would otherwise have been available to common stockholders (including pre-funded warrants). Shares of common stock into which the pre-funded warrants may be exercised are considered outstanding for the purposes of computing net loss per share because the shares may be issued for little or no consideration and are exercisable after the original issuance date. In addition, the Company is required to calculate diluted net income or loss per share under the two-class method if the effect is more dilutive than the application of another dilutive method of calculating diluted EPS (i.e., the treasury stock, if-converted, or contingently issuable share method). In periods where there is a net loss, no allocation of undistributed net loss to participating securities is performed if the holders of these securities are not contractually obligated to participate in the Company's losses. The Company's participating securities include the November 2021 Financing Warrants, December 2022 Common Stock Warrants, the July 2023 Series A and Series B common stock warrants, and the placement agent July 2023 Series A and Series B common stock warrants (see Note 9, "Stockholders' Equity" and Note 10, "Warrants").

For additional information regarding the net loss per share, see Note 12, "Net Loss per Share of Common Stock".

Recently Adopted Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, or ASU 2023-07, which requires all public entities, including public entities with a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. Additionally, the standard requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. The Company adopted annual requirements under ASU 2023-07 on January 1, 2024, and plans to adopt interim requirements under ASU 2023-07 on January 1, 2025, on a retrospective basis. ASU 2023-07 only impacted the disclosures and did not impact the consolidated financial statements. See Note 16, "Segment Information" for disclosures related to the adoption of ASU 2023-07.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, or ASU 2024-03, which is intended to enhance transparency into the nature and function of expenses, primarily through additional disclosures on certain cost and expenses. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted, and the amendments may be applied prospectively to reporting periods after the effective date or retrospectively to all periods presented in the financial statements. The Company is in the process of evaluating the impact of this new guidance on its disclosures.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires companies to disclose, on an annual basis, specific categories in the effective tax rate reconciliation and provide additional information for reconciling items that meet a quantitative threshold. In addition, ASU 2023-09 requires companies to disclose additional information about income taxes paid. ASU 2023-09 will be effective for annual periods beginning January 1, 2025, and will be applied on a prospective basis with the option to apply the standard retrospectively. The Company is evaluating the disclosure impact of ASU 2023-09; however, the adoption of ASU 2023-09 will not have a material impact on the Company's consolidated financial statements.

The Company does not believe other recently issued but not yet effective accounting standards, if currently adopted, would have a material effect on the consolidated financial statements.

2. Investments and Fair Value Measurement

Investments

The Company classifies its marketable securities as available for sale and records its investments at fair value. Available-for-sale securities are carried at estimated fair value based on quoted market prices or observable market inputs of almost identical assets, with the unrealized holding gains and losses included in accumulated other comprehensive income (loss).

As of December 31, 2024 and 2023, the contractual maturity of all investments held was less than one year.

The tables below summarize the Company's cash, cash equivalents and short-term investments (in thousands):

	As of December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 364	$ —	$ —	$ 364
Money market funds	2,632	—	—	2,632
U.S. government agency securities	5,867	—	—	5,867
Total cash and cash equivalents	$ 8,863	$ —	$ —	$ 8,863

	As of December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 1,342	$ —	$ —	$ 1,342
Money market funds	90	—	—	90
U.S. government agency securities	1,896	—	—	1,896
Commercial paper	2,393	—	—	2,393
Total cash and cash equivalents	5,721	—	—	5,721
Short-term investments:				
U.S. government agency securities	3,362	—	—	3,362
Commercial paper	298	—	—	298
Total short-term investments	3,660	—	—	3,660
Total cash, cash equivalents, and short-term investments	$ 9,381	$ —	$ —	$ 9,381

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. Impairment is assessed at the individual security level. Factors considered in determining whether a loss resulted from a credit loss or other factors include the Company's intent and ability to hold the investment until the recovery of its amortized cost basis, the extent to which the fair value is less than the amortized cost basis, the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, any historical failure of the issuer to make scheduled interest or principal payments, any changes to the rating of the security by a rating agency, any adverse legal or regulatory events affecting the issuer or issuer's industry, any significant deterioration in economic conditions. There were no material realized or unrealized gains or losses on marketable securities for the years ended December 31, 2024 or 2023. As such, we did not record a credit allowance for the year ended December 31, 2024 or 2023.

Fair Value Measurement

The Company's financial instruments consist of Level I and II assets. Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments is readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy. For Level II instruments, the Company estimates fair value by utilizing third-party pricing services in developing fair value measurements where fair value is based on valuation methodologies such as models using observable market inputs, including benchmark yields, reported trades, broker/dealer quotes, bids, offers and other reference data. Such Level II instruments typically include U.S. Treasury, U.S. government agency securities and commercial paper. As of December 31, 2024 and December 31, 2023, the Company held, in addition to Level II assets, a warrant liability related to the December 2022 Common Stock Warrants (see Note 10, "Warrants" below for further description). The fair value of the warrant liability was estimated using the Black Scholes Model which uses as inputs the following weighted average assumptions: dividend yield, expected term in years; equity volatility; and risk-free interest rate. The Company follows the guidance in ASC 820 for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period. The estimated fair value of the warrant liability represents a Level III measurement. Changes to the estimated fair value of these liabilities are recorded in change in fair value of warrant liability in the consolidated statements of operations.

The following tables set forth the fair value of the Company's financial assets by level within the fair value hierarchy (in thousands):

	As of December 31, 2024			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 2,632	$ 2,632	$ —	$ —
U.S. government agency securities	5,867	—	5,867	—
Total assets measured at fair value	$ 8,499	$ 2,632	$ 5,867	$ —
Liabilities				
Warrant liability	$ 1,061	$ —	$ —	$ 1,061
Total liabilities measured at fair value	$ 1,061	$ —	$ —	$ 1,061

	As of December 31, 2023			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 90	$ 90	$ —	$ —
U.S. government agency securities	5,258	—	5,258	—
Commercial paper	2,691	—	2,691	—
Total assets measured at fair value	$ 8,039	$ 90	$ 7,949	$ —
Liabilities				
Warrant liability	$ 1,778	$ —	$ —	$ 1,778
Total liabilities measured at fair value	$ 1,778	$ —	$ —	$ 1,778

The following table sets forth a summary of the changes in the fair value of the Company's Level III warrant liability for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31, 2024	Year Ended December 31, 2023
Fair value—beginning of period	$ 1,778	$ 7,098
Change in fair value of December 2022 Common Stock Warrants	(717)	(5,320)
Fair value—end of period	$ 1,061	$ 1,778

At December 31, 2024, the December 2022 Common Stock Warrants were valued at approximately $1.1 million, using the Black-Scholes option pricing model as follows: exercise price of $2.07 per share, stock price of $0.5241 per share, expected life of 4 years, volatility of 100.81%, a risk-free rate of 4.33% and 0% expected dividend yield.

At December 31, 2023, the December 2022 Common Stock Warrants were valued at approximately $1.8 million, using the Black-Scholes option pricing model as follows: exercise price of $2.07 per share, stock price of $0.74 per share, expected life of 5 years, volatility of 94.05%, a risk-free rate of 3.84% and 0% expected dividend yield.

There were no transfers between Level I, Level II or Level III of the fair value hierarchy during the years ended December 31, 2024 or 2023.

3. Discontinued Operations

DSUVIA Agreement

On April 3, 2023, the Company, closed the transactions contemplated by the DSUVIA Agreement entered into on March 12, 2023, with Alora, pursuant to which Alora agreed to acquire certain assets and assume certain liabilities of the Company relating to its sufentanil sublingual tablet product referred to as DSUVIA or DZUVEO, or any other single-dose pharmaceutical product for use in medically supervised settings containing a sublingual tablet that includes sufentanil as the sole active ingredient, as a 30 mcg tablet or other dosage form or strength as reasonably necessary for lifecycle management, or the Product. The Product expressly excludes the pharmaceutical product referred to as Zalviso (sufentanil sublingual tablets, each 15 mcg), any other multi-dose administration system containing sufentanil sublingual tablets (whether as the sole active ingredient or in combination with other active ingredients), and any single-dose formulation of sufentanil for use outside of a medically supervised setting. The Company is entitled to receive (a) up to $116.5 million in sales-based milestones, (b) quarterly payments in an amount equal to 15% of net sales based on sales of the Product to all customers, other than sales to the United States DoD under the Marketing Agreement (as defined below), pursuant to which Alora will pay the Company 75% of Product net sales to the DoD, and sales by or on behalf of Laboratoire Aguettant, or Aguettant, and (c) 20% of any consideration, excluding royalty payments based on sales of the Product and subject to customary exclusions, received by Alora or its affiliates in connection with a grant to any third party of a license related to the Product, or by Alora or its affiliates or equity holders in connection with a sale or transfer to any third party of an ownership interest in any assets acquired by Alora under the DSUVIA Agreement.

The DSUVIA Agreement contains customary representations, warranties, and covenants by each party. Alora agreed not to practice, license or otherwise exploit any of the intellectual property rights acquired by it under the DSUVIA Agreement to manufacture, develop or commercialize any product (other than the Product) that is or has been commercialized by the Company or its affiliate as of the date of the DSUVIA Agreement, or any product that is competitive with any such product. In addition, Alora will use commercially reasonable efforts to maintain regulatory approvals for and commercialize the Product in the United States. The DSUVIA Agreement also contains indemnification rights for each of the Company and Alora for breaches of representations, warranties, and covenants, as well as certain other matters, subject to certain specified limitations.

The closing of the DSUVIA Agreement included the execution of the Amended DZUVEO Agreement (as defined below) and the Amended and Restated Supply Agreement (as defined below) between the Company and Aguettant, as well as certain ancillary agreements between the Company and Alora. Such ancillary agreements include (a) an intellectual property agreement, pursuant to which Alora granted fully-paid, royalty-free and perpetual licenses to the Company under certain specified intellectual property rights acquired by Alora under the DSUVIA Agreement for, among other things, the development, manufacture, commercialization and exploitation of certain products, including Zalviso, (b) a transition services agreement, pursuant to which, during the period specified therein, the Company will be paid to provide certain

services (including, manufacturing technology transfer, supply chain, regulatory, and medical affairs services) to Alora, and distribute, on behalf of Alora, certain inventory of the Product transferred to Alora under the DSUVIA Agreement, and (c) an ongoing marketing agreement, or the Marketing Agreement, pursuant to which the Company will have the exclusive right to market and offer the Product for sale to the DoD and Alora will pay to the Company 75% of net sales of the Product sold to the DoD, subject to adjustment in certain circumstances.

Amendments to Certain Agreements Between the Company and Aguettant

The Company and Aguettant are parties to (a) the License and Commercialization Agreement, dated July 14, 2021, pursuant to which Aguettant obtained the exclusive right to develop and commercialize DZUVEO in certain European countries for the management of acute moderate to severe pain in adults in medically monitored settings, or the DZUVEO Agreement, and (b) the supply agreement, dated December 6, 2021, with respect to the manufacture and supply of DZUVEO in form of bulk product by the Company to Aguettant, or the Supply Agreement. Pursuant to the DSUVIA Agreement, the Company and Aguettant entered into an amendment to the DZUVEO Agreement, or the Amended DZUVEO Agreement, and an amendment and restatement to the Supply Agreement, or the Amended and Restated Supply Agreement.

Pursuant to the Amended DZUVEO Agreement, (a) Aguettant's obligations to make sales-based milestone payments and to achieve certain levels of minimum sales terminated, (b) the Company agreed to manufacture and supply DZUVEO in the form of bulk products (i.e., products that are pre-packaged in labeled pouches and packed in bright stock cartons for shipment) to Aguettant or its affiliates or sublicensees, and Aguettant will be responsible for manufacturing finished products from bulk products, before Aguettant establishes a semi-automated packaging line for the Product, and (c) after Aguettant has established such semi-automated packaging line, the Company will cause DZUVEO to be manufactured and supplied in the form of bulk tablets (i.e., products in tablet forms supplied in bulk (not packaged) quantities) to Aguettant or its affiliates or sublicensees, and Aguettant will be responsible for manufacturing finished products from bulk tablets. The Amended and Restated Supply Agreement will govern the manufacture and supply of DZUVEO in the form of bulk products or bulk tablets, and contain customary terms, including those with respect to manufacturing requirements, forecast, delivery, and post-delivery inspection.

Pursuant to the DSUVIA Agreement, the Company assigned the Amended DZUVEO Agreement and the Amended and Restated Supply Agreement to Alora.

In addition, the Company and Aguettant amended the License and Commercialization Agreement, dated July 14, 2021, pursuant to which the Company obtained exclusive rights to develop and commercialize certain ephedrine pre-filled syringe and certain phenylephrine prefilled syringe in the United States, or the PFS Agreement (see Note 5, "In-License Agreement" below).

The Company's DSUVIA business met the definition of a discontinued operation as of March 31, 2023. Accordingly, the liabilities associated with these operations have been classified as liabilities of discontinued operations in the consolidated balance sheets at December 31, 2024 and 2023. There were no assets of discontinued operations at December 31, 2024 or 2023. The operations and cash flows of the DSUVIA business are presented as discontinued for all periods presented.

The following table presents the results of the discontinued operations (in thousands):

	Year ended December 31,	
	2024	2023
Total revenues	$ —	$ 501
Cost of goods sold	—	711
Selling, general and administrative expense	—	731
Impairment of net assets held for sale	—	6,853
Impairment of fixed assets	—	1,065
Gain on termination of lease liabilities	—	(1,098)
Research and development expenses	—	349
Net loss from discontinued operations	$ —	$ (8,110)

The following table summarizes the carrying amounts of major classes of liabilities of discontinued operations for each of the periods presented (in thousands).

	December 31, 2024	December 31, 2023
Accrued liabilities	$ 723	$ 731
Total current liabilities of discontinued operations	723	731
Net liabilities of discontinued operations	$ (723)	$ (731)

The following table presents the significant non-cash items and purchases of property and equipment for the discontinued operations that are included in the consolidated statements of cash flows (in thousands):

	Year Ended December 31,	
	2024	2023
Cash flows from operating activities:		
Depreciation and amortization	$ —	$ 215
Stock-based compensation	—	19
Impairment of net assets held for sale	—	6,853
Impairment of fixed assets	—	1,065
Gain on termination of lease liabilities	—	(1,098)
Gain on extinguishment of debt	—	(400)
Purchases of property and equipment	—	(100)

The following table represents the loss on sale of discontinued operations for the year ended December 31, 2023:

	Year Ended December 31, 2023
Cash proceeds	$ 2,723
Less: net assets transferred	(8,723)
Less: disposal costs	(853)
Loss on sale of discontinued operations, before income taxes	(6,853)
Income tax expense	—
Loss on sale of discontinued operations	$ (6,853)

In October 2024, Alora notified the Company that they are discontinuing their DSUVIA sales efforts on behalf of non-DoD customers. At this time, the Company is uncertain as to the impact of this decision on sales of DSUVIA to the DoD, but it expects to be able to continue to market DSUVIA to the DoD until all inventory is sold or Alora makes the decision to no longer provide the supply of DSUVIA to the DoD.

4. Asset Acquisition

In January 2022, the Company acquired Lowell pursuant to the Merger Agreement, in a transaction which includes up to approximately $26.0 million of contingent consideration payable in cash or stock at the Company's option, upon the achievement of regulatory and sales-based milestones. In connection with the Merger Agreement, the Company acquired Niyad and LTX-608, an IPR&D asset.

The carrying value of the IPR&D asset is $8.8 million at December 31, 2024 and 2023. Contingent consideration of up to $26.0 million associated with the Merger Agreement, payable in cash or stock at the Company's option, was not included in the initial cost of the assets purchased as the contingent consideration is contingent upon events that are outside the Company's control, such as regulatory approvals and issuance of patents, which are not considered probable until notification is received. However, upon achievement or anticipated achievement of each milestone, the Company shall recognize the related, appropriate payment as an additional cost of the acquired IPR&D asset. As of December 31, 2024, none of the contingent events have occurred.

5. In-License Agreement

On July 14, 2021, the Company entered into a License and Commercialization Agreement, or the PFS Agreement, with Aguettant pursuant to which the Company obtained the exclusive right to develop and, subject to FDA approval, commercialize in the United States (i) an ephedrine pre-filled syringe for injection, and (ii) a phenylephrine pre-filled syringe for injection. Aguettant will supply the Company with the products for use in commercialization if they are approved in the United States.

The PFS Agreement has an initial term of ten (10) marketing years, with the first marketing year ending on December 31 of the calendar year after the first launch of a product (or December 31 of the same calendar year if the first launch of a product occurs between January 1 and April 30 of a calendar year). The term will automatically renew for successive five marketing year periods unless a party notifies the other party of its intention not to renew at least six (6) months prior to the expiration of the then-current term.

The Company will purchase each product from Aguettant at an agreed price, or the PFS Purchase Price, subject to adjustment. The Company will also make revenue share payments that, combined with the PFS Purchase Price, will range from 40% to 45% of net sales in the United States.

The Company and Aguettant will agree on minimum sales obligations twelve (12) months prior to the launch of each product.

The Company has the right to grant sublicenses to its affiliates or, with the prior approval of Aguettant, third parties, subject to certain limitations.

In connection with the Company's and Aguettant's agreement to enter into the Amended DZUVEO Agreement and the Amended and Restated Supply Agreement, the parties entered into an amendment to the PFS Agreement, or the Amended PFS Agreement, pursuant to which, effective April 3, 2023, (a) Aguettant paid the Company a complementary payment in the amount of EUR 1,500,000, and (b) the Company's obligation to make a certain specified sales-milestone payment terminated such that the maximum amount in sales-based milestone payments that Aguettant is entitled to receive has been reduced from $24.0 million to $21.0 million.

As of December 31, 2024, there have been no payments by the Company to Aguettant under the PFS Agreement.

6. Long-Term Debt

Loan Agreement with Oxford

On May 30, 2019, the Company entered into the Loan Agreement with Oxford Finance LLC, or Oxford, as the Lender. Under the Loan Agreement, the Lender made a term loan to the Company in an aggregate principal amount of $25.0 million, or the Loan, which was funded on May 30, 2019.

In connection with the closing of the divestment of DSUVIA to Alora, on April 3, 2023, the Company paid Oxford the remaining amount due of approximately $3.4 million including accrued interest and fees under the Loan, and the Loan Agreement was terminated with no further obligations by either party. Interest expense related to the Loan Agreement was $0.1 million, which represented amortization of the debt discount, for the year ended December 31, 2023.

In connection with the Loan Agreement, on May 30, 2019, the Company issued warrants to the Lender and its affiliates, which are exercisable for an aggregate of 8,833 shares of the Company's common stock with a per share exercise price of $56.60, or the Loan Agreement Warrants (see Note 10, "Warrants").

7. Sale of Future Payments

In January 2024, the Company and XOMA entered into the Purchase Agreement for the sale by the Company to XOMA, in exchange for $8.0 million, of the Company's right, title and interest in and to certain amounts payable to the Company, or collectively, the Purchased Receivables, pursuant to the DSUVIA Agreement in respect of net sales of the Product, excluding sales of the Product by Aguettant.

The Purchased Receivables include:

(i) 100% of certain payments based on net sales of the Product and potential sales-based milestone payments of up to $116.5 million in respect of net sales of the Product, in each case made on and after January 1, 2024 and excluding sales of the Product by Aguettant, and of certain associated license and acquisition payments relating to the Product, until XOMA has received $20.0 million of payments in respect of the foregoing, or the XOMA Threshold, or the Stepdown Date; and

(ii) following the Stepdown Date, (A) 100% of payments based on net sales of the Product other than net sales to the United States Department of Defense, or DoD and (B) 50% of each of the following: (a) payments based on net sales of the Product to the DoD, (b) potential sales-based milestone payments in respect of net sales of the Product, and (c) certain associated license and acquisition payments relating to the Product.

The Company has retained its right, title and interest in and to, following the Stepdown Date, 50% of each of the following: (a) payments based on net sales of the Product to the DoD, (b) potential sales-based milestone payments in respect of net sales of the Product, and (c) of certain associated license and acquisition payments relating to the Product.

The Purchase Agreement contains customary representations, warranties and agreements by the Company and XOMA, indemnification obligations of the parties and other obligations of the parties.

The allocation of the consideration for the Purchase Agreement resulted in proceeds of $1.4 million reduced by $0.2 million of transaction costs being allocated to the sale of all future interest in payments related to commercial sales of DSUVIA representing its fair value. As a result of the Company's loss of control, no further continuing involvement in, or rights to future payments related to commercial sales of DSUVIA, the Company recognized other income of $1.2 million in January 2024.

The Company evaluated the terms of the Purchase Agreement and concluded that the features of the Purchased Receivables are similar to those of a debt instrument. Accordingly, the Company recorded the allocated proceeds of approximately $6.6 million reduced by approximately $0.5 million of transaction costs, as a liability. The Company accounts for the value of the debt at amortized cost. The amounts received by the Company will be accreted to the total estimated amount of the payments necessary to extinguish the Company's obligation under the Purchase Agreement, which will be recognized as interest expense. The carrying value of the debt will decrease for payments made to XOMA.

The Company periodically assesses the expected payments for services performed to support sales of DSUVIA to the DoD by Alora under the Marketing Agreement and milestone payments under the DSUVIA Agreement using a combination of historical results, internal projections, and forecasts from external sources. To the extent such payments are greater or less than the Company's initial estimates or the timing of such payments is materially different than its original estimates, the Company will prospectively adjust the amortization of the liability and the effective interest rate. Due to the significant judgments and factors related to the estimates of future payments under the Purchase Agreement, there are significant uncertainties surrounding the amount and timing of future payments.

As the payments are remitted to XOMA, the liability will be effectively repaid over the life of the agreement. In order to determine the amortization of the liability related to the sale of future payments, the Company is required to estimate the total amount of future payments to XOMA over the life of the Purchase Agreement. In October 2024, Alora notified the Company that they are discontinuing their DSUVIA sales efforts to non-DoD customers. At this time, the Company is uncertain as to the impact of this decision on sales of DSUVIA to the DoD. As a result, the Company estimates that future payments under the Purchase Agreement will be less than the proceeds from the sale of such future payments. Accordingly, the Company will not recognize any related non-cash interest expense. When the expected payments under the sale of future payments are lower than the gross proceeds of $6.6 million received, the Company defers recognition of any probable contingent gain until the Company has met its obligations under the liability related to the sale of future payments. For the year ended December 31, 2024, the estimated effective interest rate under the agreement was approximately 0%.

The Company did not recognize any non-cash revenue and recognized non-cash interest expense of approximately $0.4 million for the year ended December 31, 2024. The interest and amortization of issuance costs are reflected as non-cash interest expense for the sale of future payments in the consolidated statements of operations.

The following table shows the activity within the liability account during the year ended December 31, 2024, and the period from inception to December 31, 2024 (in thousands):

	Year ended December 31, 2024	Period from inception to December 31, 2024
Liability related to sale of future payments — beginning balance	$ —	$ —
Proceeds from sale of future payments, net of issuance costs	6,133	6,133
Payments to XOMA	—	—
Non-cash interest expense recognized	394	394
Liability related to sale of future payments as of December 31, 2024	$ 6,527	$ 6,527

8. Commitments and Contingencies

Litigation

On June 8, 2021, a securities class action complaint was filed in the U.S. District Court for the Northern District of California against the Company and two of its officers. The plaintiff is a purported stockholder of the Company. The complaint alleged that defendants violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by making false and misleading statements and omissions of material fact about the Company's disclosure controls and procedures with respect to its marketing of DSUVIA. The complaint sought unspecified damages, interest, attorneys' fees, and other costs. On December 16, 2021, the Court appointed co-lead plaintiffs. Plaintiffs' amended complaint was filed on March 7, 2022. The amended complaint named the Company and three of its officers and continued to allege that defendants violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by making false and misleading statements and omissions of material fact about the Company's disclosure controls and procedures with respect to its marketing of DSUVIA. The amended complaint also asserted a violation of Section 20A of the Exchange Act against the individual defendants for alleged insider trading. The amended complaint sought unspecified damages, interest, attorneys' fees, and other costs. The Court granted three motions to dismiss plaintiffs' complaint: the first on September 28, 2022, the second on November 28, 2022, and the third, with prejudice on May 7, 2024. Judgment was entered for defendants on plaintiffs' claims on May 7, 2024. On June 5, 2024, plaintiffs filed a notice of appeal in the United States Court of Appeals for the Ninth Circuit. Briefing on the appeal was complete on January 21, 2025. The Court has not yet scheduled a hearing on the appeal.

On July 6, 2021, a purported shareholder derivative complaint was filed in the U.S. District Court for the Northern District of California. The complaint names ten of the Company's officers and directors and asserts state and federal claims based on the same alleged misstatements as the securities class action complaint. On September 30, 2021, October 26, 2021, and November 17, 2021, three additional purported shareholder derivative complaints were filed in the U.S. District Court for the Northern District of California. The complaints name nine of the Company's officers and directors and also assert state and federal claims based on the same alleged misstatements as the securities class action complaint. All four complaints seek unspecified damages, attorneys' fees, and other costs. On December 6, 2021, the Court entered an order consolidating all four actions and staying the consolidated action pending the outcome of any motion to dismiss the securities class action.

On February 16, 2024, another purported shareholder derivative complaint was filed in the Court of Chancery of the State of Delaware, asserting the same claims as those in the previously filed derivative actions. The case has been stayed pending the outcome of any motion to dismiss the securities class action.

Please see "Part I., Item 1A. Risk Factors—Risks of a General Nature—Litigation may substantially increase our costs and harm our business."

The Company believes that these lawsuits are without merit and intends to vigorously defend against them. Given the uncertainty of litigation, the preliminary stage of the cases, and the legal standards that must be met for, among other things, class certification and success on the merits, the Company cannot estimate the reasonably possible loss or range of loss that may result from these actions. It is reasonably possible that this estimate may change in the near term. An adverse outcome regarding these matters could materially adversely affect the Company's financial condition, results of operations, and cash flows.

Termination Agreement and Mutual Release Between the Company and Catalent

On March 12, 2023, the Company and Catalent Pharma Solutions, LCC, or Catalent, entered into a termination agreement and mutual release, or the Termination Agreement, to terminate the Site Readiness Agreement with an effective date of August 15, 2019 and as amended on September 24, 2020, the SRA Agreement, and the commercial supply agreement with an effective date of March 31, 2021, the CSA Agreement. Pursuant to the Termination Agreement, as of the date on which the Company has removed and transported certain equipment from Catalent's site, the SRA Agreement and the CSA Agreement will terminate except with respect to certain specified provisions of such agreements.

9. Stockholders' Equity

The Company is authorized to issue two classes of stock to be designated, respectively, as "Common Stock" and "Preferred Stock." The total number of shares which the Company is authorized to issue is 210,000,000 shares, and includes 200,000,000 shares of Common Stock, each having a par value of $0.001, and 10,000,000 shares of Preferred Stock, each having a par value of $0.001. Each outstanding share of Common Stock entitles the holder thereof to one vote on each matter properly submitted to the stockholders of the Company for their vote. The rights, preferences and privileges of the holders of Common Stock are subject to and may be adversely affected by the rights of the holders of shares of any series of Preferred Stock that we may designate in the future. As of December 31, 2024, there are no shares of Preferred Stock issued and outstanding.

Subject to the preferences that may be applicable to any outstanding shares of Preferred Stock, the holders of Common Stock are entitled to receive ratably such dividends, if any, as may be declared by the Company's board of directors. No dividends have been declared to date.

Common Stock

January 2024 Private Placement

On January 17, 2024, the Company entered into a private placement with certain institutional investors, or the January 2024 Purchasers, for aggregate gross proceeds of $6.0 million upfront, an additional $10.0 million committed upon the announcement of positive clinical trial results for the Company's NEPHRO CRRT study of Niyad, and an additional $2.0 million if Talphera stock trades above a specified price following the NEPHRO CRRT registration trial announcement, before deducting offering expenses payable by the Company, or the January 2024 Private Placement.

The terms of the January 2024 Private Placement include:

(i) the first tranche of the January 2024 Private Placement, which closed on January 22, 2024, resulted in the aggregate gross proceeds to the Company of approximately $6.0 million for pre-funded warrants to purchase up to 7,792,208 shares of Common Stock, excluding the proceeds, if any, from the exercise of the pre-funded warrants issued in such tranche, or the January 2024 Pre-Funded Warrants (see Note 10, "Warrants").

(ii) the second tranche of the January 2024 Private Placement, which is a conditional purchase by the January 2024 Purchasers subject to either (a) the satisfaction or waiver of achieving, by September 30, 2024, the NEPHRO CRRT primary and one of the secondary clinical trial endpoints, resulting in the Company issuing pre-funded warrants to purchase up to 12,987,013 shares of Common Stock, and receiving additional aggregate gross proceeds of approximately $10.0 million, and/or (b) the satisfaction or waiver of the volume-weighted average price of the Common Stock for each of the immediately subsequent five (5) trading days following the Company's announcement of its NEPHRO CRRT trial data being at least $0.92 per share, resulting in the Company issuing pre-funded warrants to purchase up to 2,597,402 shares of Common Stock and receiving additional aggregate gross proceeds of approximately $2.0 million.

Any of the conditions in the second tranche can be waived by each of the January 2024 Purchasers. The Company determined that the conditional tranche right is equity classified as it is indexed to the Company's own shares and meets all other conditions for equity classification and that the fair value of the right was immaterial at issuance.

In connection with the January 2024 Private Placement, the Company and the January 2024 Purchasers agreed to amend and restate a portion of the July 2023 Series A common stock warrants and July 2023 Series B common stock warrants outstanding by reducing the exercise price thereunder from $1.11 to $0.77 per share (see Note 10, "Warrants").

On September 30, 2024, the Company amended the securities purchase agreements of the January 2024 Private Placement, dated January 17, 2024, with entities affiliated with Nantahala Management, LLC, or the Nantahala Agreements, to extend to June 30, 2025 the date by which the Company must achieve the precedent conditions to the second closing thereunder, or the Nantahala Amendments. If prior to the second closing, the Company consummates an equity financing, then the January 2024 Purchasers shall be released from their obligation to purchase additional shares of Common Stock and/or pre-funded warrants to purchase Common Stock pursuant to the Nantahala Agreements, as amended. The Company determined that the Nantahala Amendments represented a modification but that no financial impact would be recorded as the difference between the fair values of the Nantahala Agreements immediately before and after the Nantahala Amendments was insignificant.

The January 2024 Private Placement contains customary representations, warranties and agreements by the Company and the Purchasers, indemnification rights and other obligations of the parties.

July 2023 Private Placement

On July 17, 2023, the Company entered into a securities purchase agreement, or the July 2023 Purchase Agreement, with several institutional investors, or the July 2023 Purchasers, relating to the issuance and sale to the July 2023 Purchasers in a private placement, or the July 2023 Private Placement, of 5,340,591 shares of Common Stock, pre-funded warrants to purchase up to an aggregate of 2,012,356 shares of Common Stock at an exercise price of $0.001 per share, or the July 2023 Pre-Funded Warrants; July 2023 Series A common stock warrants to purchase up to an aggregate of 7,352,947 shares of Common Stock at an exercise price of $1.11 per share; and July 2023 Series B common stock warrants to purchase up to an aggregate of 7,352,947 shares of Common Stock at an exercise price of $1.11 per share. In connection with the January 2024 Private Placement, a portion of these July 2023 Series A common stock warrants and July 2023 Series B common stock warrants were restated and amended to reduce the exercise price thereunder from $1.11 to $0.77 per share (see Note 10, “Warrants”).

The combined offering price of the July 2023 Private Placement was $1.36 per share of Common Stock and accompanying July 2023 Series A common stock warrant and July 2023 Series B common stock warrant, or in the case of July 2023 Pre-Funded Warrants, $1.359 per pre-funded warrant and accompanying July 2023 Series A common stock warrant and July 2023 Series B common stock warrant (which is the purchase price per share of common stock and accompanying warrants less $0.001). The aggregate gross proceeds to the Company from the July 2023 Private Placement were approximately $10.0 million, before deducting placement agent fees and other expenses payable by the Company of approximately $1.1 million, and excluding the proceeds, if any, from the exercise of the July 2023 Pre-Funded Warrants and July 2023 Series A and July 2023 Series B common stock warrants issued in the July 2023 Private Placement.

In May 2023, the Company engaged H.C. Wainwright & Co., LLC to act as placement agent in the private placement. As compensation, the Company paid the placement agent a cash fee equal to 5.25% of the aggregate gross proceeds generated from the private placement and reimbursed certain expenses of the placement agent in connection with the private placement totaling $0.1 million. The placement agent will be entitled to an additional one-time payment of $200,000 upon the exercise of the July 2023 Series A and Series B common stock warrants. In addition, the Company issued to the placement agent fully vested July 2023 Series A common stock warrants, or placement agent July 2023 Series A common stock warrants, to purchase 183,824 shares of common stock and fully vested July 2023 Series B common stock warrants, or placement agent July 2023 Series B common stock warrants, to purchase 183,823 shares of common stock.

See Note 10, “Warrants” for additional information regarding the July 2023 Series A and B warrants and the placement agent July 2023 Series A and Series B common stock warrants.

Stock Plans

2011 Equity Incentive Plan

In January 2011, the Board of Directors adopted, and the Company’s stockholders approved, the 2011 Equity Incentive Plan, or 2011 EIP. The initial aggregate number of shares of the Company’s common stock that were issuable pursuant to stock awards under the 2011 EIP was approximately 93,750 shares. The number of shares of Common Stock reserved for issuance under the 2011 EIP automatically increased on January 1 of each year, starting on January 1, 2012 and continuing through January 1, 2020, by 4% of the total number of shares of the Company’s common stock outstanding on December 31 of the preceding calendar year, or such lesser number of shares of Common Stock as determined by the Board of Directors.

As of June 16, 2020, no more awards may be granted under the 2011 Equity Incentive Plan, or the 2011 EIP, although all outstanding stock options and other stock awards previously granted under the 2011 EIP will continue to remain subject to the terms of the 2011 EIP.

Amended and Restated 2020 Equity Incentive Plan

On June 16, 2020, at the 2020 Annual Meeting of Stockholders of the Company, the Company's stockholders, upon the recommendation of the Company's Board of Directors, approved the Company's 2020 Equity Incentive Plan, or the 2020 EIP.

The initial aggregate number of shares of the Company's common stock issuable pursuant to stock awards under the 2020 EIP was 275,000 shares. In addition, the share reserve will be increased by the number of returning shares, if any, as such shares become available from time to time under the 2011 EIP, for an additional number of shares not to exceed 744,608 shares. The term of any option granted under the 2020 EIP is determined on the date of grant but shall not be longer than 10 years. The Company issues new shares for settlement of vested restricted stock units and exercises of stock options. The Company does not have a policy of purchasing its shares relating to its stock-based programs.

On June 24, 2024, at the 2024 Annual Meeting of Stockholders of the Company, upon the recommendation of the Company's Board of Directors, the Company's stockholders approved an amendment and restatement of the Company's 2020 Equity Incentive Plan, or the Amended 2020 Plan, to increase the number of authorized shares reserved for issuance thereunder by 1,171,395 shares, subject to adjustment for certain changes in the Company's capitalization. The aggregate number of shares of the Company's common stock that may be issued under the Amended 2020 Plan will not exceed the sum of: (i) 3,161,395 shares, and (ii) up to 744,608 shares subject to outstanding awards granted under the 2011 Equity Incentive Plan that may become available for issuance under the Amended 2020 Plan, as such shares become available from time to time.

Inducement Grant

In May 2024, the Company granted stock-based awards outside of the existing stock plans to one new employee, or the Inducement Grant. These awards were granted as a material inducement for accepting employment with the Company, in accordance with Nasdaq Listing Rule 5635(c)(4). The inducement awards consisted of a total of 217,000 shares of the Company's common stock, which includes an aggregate of 185,000 shares of Common Stock issuable upon the exercise of inducement stock option grants and 32,000 shares of Common Stock issuable upon the vesting of restricted stock unit awards generally subject to the same terms and conditions as grants that are made under the Company's Amended 2020 Plan.

Amended and Restated 2011 Employee Stock Purchase Plan

On June 16, 2020, the Company's stockholders, upon the recommendation of the Company's Board of Directors, approved the Amended and Restated 2011 Employee Stock Purchase Plan, or the Amended ESPP, which increased the aggregate number of shares of the Company's common stock reserved for issuance under the 2011 Employee Stock Purchase Plan, or ESPP, to 245,000 shares, subject to adjustment for certain changes in the Company's capitalization, and removed the "evergreen" provision from the ESPP.

On June 24, 2024, at the 2024 Annual Meeting of Stockholders of the Company, upon the recommendation of the Company's Board of Directors, the Company's stockholders approved an amendment and restatement of the Company's 2011 Employee Stock Purchase Plan, or the Amended 2011 ESPP, to increase the number of authorized shares reserved for issuance thereunder by 100,000 shares, subject to adjustment for certain changes in the Company's capitalization. The aggregate number of shares of the Company's common stock that may now be issued under the Amended 2011 ESPP is 345,000.

10. Warrants

The activity related to warrants during the years ended December 31, 2024 and 2023, is summarized as follows:

	Common Stock from Warrants	Weighted-average Exercise Price (per share)
Outstanding at January 1, 2023	7,824,933	$ 1.71
Granted	17,085,897	$ 0.99
Exercised	(3,228,781)	$ (0.0003)
Outstanding at December 31, 2023	21,682,049	$ 1.40
Granted	7,792,208	$ 0.001
Outstanding at December 31, 2024	29,474,257	$ 0.96
Exercisable at December 31, 2024	29,474,257	$ 0.96

At December 31, 2024, the range of exercise prices for shares under warrants and the weighted-average remaining contractual life is as follows:

	Warrants Outstanding			Warrants Exercisable	
Warrant Exercise Price	Number of Warrants	Weighted-Average Remaining Contractual Life (Years)	Number of Warrants	Weighted-Average Exercise Price
$ 0.001	9,208,681	Unlimited	9,208,681	$ 0.001
$ 0.77	5,882,356	3.55	5,882,356	$ 0.77
$ 1.11	8,904,688	3.55	8,904,688	$ 1.11
$ 1.70	367,647	3.55	367,647	$ 1.70
$ 2.07	4,977,052	4.00	4,977,052	$ 2.07
$ 20.00	125,000	1.87	125,000	$ 20.00
$ 56.60	8,833	4.41	8,833	$ 56.60
Total	29,474,257	3.65	29,474,257	$ 0.96

January 2024 Pre-Funded Warrants and Amendment of Prior Warrants

On January 17, 2024, the Company issued the January 2024 Pre-Funded Warrants to purchase up to an aggregate of 7,792,208 shares of Common Stock in the first tranche of the two-tranche January 2024 Private Placement (see Note 9, “Stockholders’ Equity”). The January 2024 Pre-Funded Warrants were exercisable immediately following the closing date of the first tranche of the January 2024 Private Placement, or January 22, 2024, and have an unlimited term and an exercise price of $0.001 per share.

The January 2024 Pre-Funded Warrants were classified as a component of permanent equity in the Company's consolidated balance sheet as they are freestanding financial instruments that are immediately exercisable, do not embody an obligation for the Company to repurchase its own shares and permit the holders to receive a fixed number of shares of Common Stock upon exercise. All of the shares underlying the January 2024 Pre-Funded Warrants have been included in the weighted-average number of shares of Common Stock used to calculate net loss per share attributable to common stockholders because the shares may be issued for little or no consideration and are fully vested and are exercisable after their original issuance date. The January 2024 Pre-Funded Warrants may participate with common shareholders in dividends or other distributions.

In July 2023, in connection with the July 2023 Private Placement Warrants (see below), the Company issued to certain of the July 2023 Purchasers (i) Series A common stock warrants to purchase up to 3,676,473 shares of Common Stock and (ii) Series B common stock warrants to purchase up to 3,676,473 shares of Common Stock, or collectively, the Prior Warrants. In connection with the January 2024 Private Placement, the Company and the January 2024 Purchasers agreed to amend and restate 2,941,178 of each the Series A common stock warrants and Series B common stock warrants outstanding, by reducing the exercise price thereunder from $1.11 to $0.77 per share. Pursuant to ASU 2021-04, the Company remeasured the fair value of the amended and restated Prior Warrants as of the modification date based on the modified terms and recorded the increase in fair value of $0.3 million as equity issuance costs, all of which was allocated to additional paid in capital. The fair value assumptions related to the modification of these 5,882,356 amended and restated Prior Warrants as of January 17, 2024 were as follows: exercise price of $0.77 per share, stock price of $0.769 per share, expected life of 4.5 years, volatility of 96.91%, a risk-free rate of 4.02% and 0% expected dividend yield.

July 2023 Private Placement Warrants

On July 20, 2023, the Company issued pre-funded warrants to purchase up to an aggregate of 2,012,356 shares of Common Stock at an exercise price of $0.001 per share, or the July 2023 Pre-Funded Warrants, the July 2023 Series A common stock warrants to purchase up to an aggregate of 7,352,947 shares of Common Stock at an exercise price of $1.11 per share, and the July 2023 Series B common stock warrants to purchase up to an aggregate of 7,352,947 shares of Common Stock at an exercise price of $1.11 per share.

The July 2023 Pre-Funded Warrants were exercisable immediately following the closing date of the July 2023 Private Placement, or July 20, 2023, and have an unlimited term.

The July 2023 Series A and Series B common stock warrants were exercisable immediately following the closing date of July 20, 2023, and have a five-year term, unless certain milestone events are met which accelerate the expiration date to 45 days following such announcement. The July 2023 Series A and Series B common stock warrants also include certain rights upon “fundamental transactions” as described in such warrants, including the right of the holders thereof to receive from the Company or a successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of Common Stock in such fundamental transaction in the amount of the Black Scholes value (as described in such warrants) of the unexercised portion of the applicable warrants on the date of the consummation of such fundamental transaction.

The Company evaluated the July 2023 Pre-Funded Warrants, and the July 2023 Series A and Series B common stock warrants under ASC 815-40 and determined that they did not require liability classification and met the requirements for instruments that are both indexed to an entity’s own stock and classified in stockholders’ equity. Accordingly, the proceeds were allocated between Common Stock and the July 2023 Pre-Funded Warrants, Series A and Series B common stock warrants at their respective relative fair value basis to stockholders’ equity and as a component of additional paid-in capital on the consolidated balance sheets. The fair value of the July 2023 Series A and Series B common stock warrants was determined using a Black-Scholes option pricing model and the Common Stock based on the closing date share price and were recorded in additional paid-in capital within stockholders' equity on the consolidated balance sheets.

In connection with the January 2024 Private Placement, the Company and the purchasers agreed to amend and restate the Prior Warrants by reducing their exercise price from $1.11 to $0.77 per share (see “January 2024 Pre-Funded Warrants and Amendment of Prior Warrants” above).

The placement agent July 2023 Series A and Series B Common Stock Warrants (see Note 9, “Stockholders’ Equity”) have the same terms as the July 2023 Series A and Series B Common Stock Warrants, except such warrants do not have a Black Scholes provision in the event of a fundamental transaction and the exercise price of such warrants is $1.70 per share, which is 125% of the combined offering price per share. The Company concluded that the placement agent July 2023 Series A and Series B Common Stock Warrants are freestanding equity-linked derivative instruments that met the criteria for equity classification. The placement agent July 2023 Series A and Series B Common Stock Warrants were valued at approximately $0.3 million, using the Black-Scholes option pricing model as follows: exercise price of $1.70 per share, stock price of $1.07 per share, expected life of 5 years, volatility of 94.3%, a risk-free rate of 4.08% and 0% expected dividend yield.

As of December 31, 2024, none of the July 2023 Series A and Series B common stock warrants nor the placement agent July 2023 Series A and Series B common stock warrants had been exercised and all were still outstanding, while 595,883 of the July 2023 Pre-Funded Warrants were exercised in the year ended December 31, 2023, and 1,416,473 remained outstanding as of December 31, 2024.

December 2022 Registered Direct Offering Warrants

On December 29, 2022, the Company issued pre-funded warrants to purchase 2,632,898 shares of Common Stock, or the December 2022 Pre-Funded Warrants, and common warrants to purchase an aggregate of 4,227,052 shares of Common Stock, or the December 2022 Common Stock Warrants.

The December 2022 Pre-Funded Warrants were exercisable immediately following the closing date of the December 2022 Registered Direct Offering, or December 29, 2022, had an unlimited term and an exercise price of $0.0001 per share.

The December 2022 Common Stock Warrants were exercisable following the six-month anniversary of the closing date of December 29, 2022, have a six-year term and an exercise price of $2.07 per share. The 2022 Warrants included full ratchet anti-dilutive adjustment rights in the event the Company issued shares of Common Stock or common stock equivalents in the future with a value less than the then effective exercise price of such common warrants subject to certain customary exceptions, and further subject to a minimum exercise price of $1.00 per share. On April 25, 2023, the December 2022 Common Stock Warrants were amended to remove these full ratchet anti-dilutive adjustment rights.

In the event of certain fundamental transactions involving the Company, the holder of the December 2022 Common Stock Warrants may require the Company to make a payment based on a Black-Scholes valuation, using specified inputs. The December 2022 Pre-Funded Warrants did not provide similar rights to the Purchaser. Therefore, the Company accounted for the December 2022 Common Stock Warrants as a liability, while the December 2022 Pre-Funded Warrants met the permanent equity criteria classification. The December 2022 Pre-Funded Warrants were classified as a component of permanent equity, or APIC, because they were freestanding financial instruments that are legally detachable and separately exercisable from the shares of Common Stock with which they were issued, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of shares of Common Stock upon exercise. In addition, the December 2022 Pre-Funded Warrants did not provide any guarantee of value or return.

As of December 31, 2024, none of the 4,227,052 December 2022 Common Stock Warrants had been exercised and all remained outstanding, while all the 2,632,898 December 2022 Pre-Funded Warrants were exercised in full in the year ended December 31, 2023 and none remained outstanding at December 31, 2024.

August 2022 LPC Warrant

The August 2022 LPC Warrant had an original exercise price of $4.07 per share (subject to adjustment for stock splits, reverse stock splits and similar recapitalization events), became immediately exercisable and has a term ending on February 3, 2028. In addition, through August 3, 2023, if the Company issued or sold (or is deemed to have issued or sold) any Common Stock, convertible securities or options (as defined in the August 2022 LPC Warrant), for a consideration per share, or the New Issuance Price, less than a price equal to the exercise price in effect immediately prior to such issue or sale or deemed issuance or sale, each of the foregoing, a dilutive issuance, then immediately after such dilutive issuance, the exercise price then in effect for the August 2022 LPC Warrant shall be reduced to an amount equal to the New Issuance Price, or the Down Round Feature.

In December 2022, the Down Round Feature was triggered due to the price per share received from the issuance of Common Stock and warrants in connection with the December 2022 Financing. In July 2023, the Down Round Feature was again triggered due to the price per share received from the issuance of Common Stock and warrants in connection with the in connection with the July 2023 Private Placement. In each instance, the Company calculated the value of the effect of the Down Round Feature measured as the difference between the warrants' fair value, using the Black-Scholes option-pricing model, before and after the Down Round Feature was triggered using the then current exercise price and the new exercise price. The difference in fair value of the effect of the Down Round Feature was immaterial in both instances and had no impact on net loss per share in the periods presented. This down round feature expired on August 3, 2023.

As of December 31, 2024, the August 2022 LPC Warrant had not been exercised and was still outstanding.

November 2021 Financing Warrants

On November 15, 2021, the Company entered into a securities purchase agreement with certain investors pursuant to which the Company, in a registered direct offering, sold (i) an aggregate of 875,000 shares of the Company's common stock, and (ii) warrants to purchase up to an aggregate of 875,000 shares of Common Stock, for an aggregate purchase price of $14.0 million.

The November 2021 Financing Warrants had an original exercise price of $20.00 per share and became exercisable, if the holder's post-exercise beneficial ownership is less than or equal to 9.99%, 6 months after their issuance date and had a five-year term through November 15, 2026.

Upon the closing of the December 2022 Financing, 750,000 of the 875,000 November 2021 Financing Warrants were modified, to reduce the exercise price of the warrants from $20.00 per share to $2.07 per share and to extend the expiration date to December 29, 2028.

The remaining warrants issued in the November 17, 2021, registered direct offering for 125,000 shares of the Company's common stock are currently exercisable at a price of $20.00 per share and expire on November 15, 2026.

As of December 31, 2024, none the November 2021 Financing Warrants had been exercised and all remained outstanding.

Loan Agreement Warrants

In connection with the Loan Agreement, on May 30, 2019, the Company issued warrants to the Lender and its affiliates, which are exercisable for an aggregate of 8,833 shares of the Company's common stock with a per share exercise price of $56.60, or the Loan Agreement Warrants. The Loan Agreement Warrants may be exercised on a cashless basis. The Loan Agreement Warrants are exercisable for a term beginning on the date of issuance and ending on the earlier to occur of ten years from the date of issuance or the consummation of certain acquisitions of the Company as set forth in the Loan Agreement Warrants. The number of shares for which the Loan Agreement Warrants are exercisable and the associated exercise price are subject to certain proportional adjustments as set forth in the Loan Agreement Warrants. The Loan Agreement Warrants have been classified within stockholders' equity and accounted for as a discount to the loan by allocating the gross proceeds on a relative fair value basis.

As of December 31, 2024, none of the Loan Agreement Warrants had been exercised and all remained outstanding.

11. Stock-Based Compensation

The Company recorded total stock-based compensation expense for stock options, stock awards and the Amended ESPP as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development	$ 375	$ 498
Selling, general and administrative	614	1,212
Discontinued operations	—	19
Total	$ 989	$ 1,729

In the year ended December 31, 2024, there were 49,515 shares issued under the Amended ESPP. The weighted average fair value of shares issued under the Amended ESPP in 2024 and 2023 was $0.88 and $1.08 per share, respectively. As of December 31, 2024, there were 165,897 shares available for future grant under the Amended ESPP.

The following table summarizes restricted stock unit activity under the Company's Equity Incentive Plans:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Restricted stock units outstanding, January 1, 2023	82,778	$ 16.97
Granted	48,158	1.67
Vested	(40,356)	19.28
Forfeited	(4,348)	12.56
Restricted stock units outstanding, December 31, 2023	86,232	$ 7.57
Granted	176,768	1.03
Vested	(42,525)	11.31
Forfeited	(7,552)	2.03
Restricted stock units outstanding, December 31, 2024	212,923	$ 1.59

The following table summarizes stock option activity under the Company's Equity Incentive Plans:

	Number of Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
January 1, 2023	725,623	$ 52.98		
Granted	288,929	1.67		
Forfeited	(14,673)	9.72		
Expired	(106,558)	83.88		
January 1, 2024	893,321	$ 33.41		
Granted	1,053,612	1.03		
Forfeited	(41,156)	1.75		
Expired	(118,877)	71.96		
December 31, 2024	1,786,900	$ 12.48	7.6	$ —
Vested and exercisable options—December 31, 2024	605,249	$ 34.28	4.8	$ —
Vested and expected to vest—December 31, 2024	1,786,900	$ 12.48	7.6	$ —

As of December 31, 2024, there were 1,956,919 shares available for future grant under the 2020 EIP.

Additional information regarding the Company's stock options outstanding and vested and exercisable as of December 31, 2024, is summarized below:

	Options Outstanding			Options Vested and Exercisable	
Exercise Prices	Number of Stock Options Outstanding	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price per Share	Shares Subject to Stock Options	Weighted-Average Exercise Price per Share
$0.684 - $1.03	859,701	9.2	$ 1.01	24,409	$ 0.68
$1.08 - $1.62	185,000	9.4	$ 1.08	—	$ —
$1.76 - $2.64	249,184	8.1	$ 1.76	114,204	$ 1.76
$4.62 - $6.93	10,850	7.5	$ 4.62	10,850	$ 4.62
$8.03 - $12.045	84,703	7.1	$ 8.08	60,199	$ 8.08
$14.40 - $21.60	12,033	5.0	$ 16.50	12,033	$ 16.50
$22.40 - $33.60	11,700	6.1	$ 28.62	11,625	$ 28.66
$34,40 - $51.60	208,405	4.1	$ 41.92	206,605	$ 41.96
$57.40 - $86.10	163,274	1.7	$ 64.92	163,274	$ 64.92
$94.60 - $141.90	2,050	0.9	$ 94.60	2,050	$ 94.60
	1,786,900	7.6	$ 12.48	605,249	$ 34.28

The weighted average grant-date fair value of options granted during the years ended December 31, 2024 and 2023, was $0.84 and $1.32 per share, respectively. As of December 31, 2024, total stock-based compensation expense related to unvested options to be recognized in future periods was $1.0 million which is expected to be recognized over a weighted-average period of 2.5 years. The grant date fair value of options vested during the years ended December 31, 2024 and 2023, was $2.0 million and $0.9 million, respectively. There were no options exercised during the years ended December 31, 2024 and 2023. In addition, the performance-based stock options granted in March 2021 to certain of the Company's executive officers remained unvested and expired during the year ended December 31, 2024.

The Company used the following assumptions to calculate the fair value of each time-based stock option:

	Year Ended December 31,	
	2024	2023
Expected term (in years)	6.5	6.3
Risk-free interest rate	4.1% - 4.5%	3.9% - 4.6%
Expected volatility	98%	94%
Expected dividend rate	0%	0%

12. Net Loss per Share of Common Stock

The Company applies the two-class method to compute basic net income (loss) per share by dividing the net income (loss) attributable to common shareholders by the weighted average number of shares of common stock outstanding for the period. The diluted net income (loss) per share of common stock is computed by giving effect to all potential common stock equivalents outstanding for the period determined 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 purposes of this calculation, options to purchase common stock, RSUs, and warrants to purchase common stock were considered to be common stock equivalents.

The July 2023 Series A and Series B common stock warrants, the placement agent July 2023 Series A and Series B common stock warrants, the December 2022 Common Stock Warrants, and the November 2021 Financing Warrants are all participating securities which, by definition, entitle the holders thereof to participate in dividends and other distributions of assets by the Company to its holders of common shares as though the holder then held common shares; however, there is no contractual obligation on the part of the warrantholders to participate in the Company's losses.

Given that the Company's participating securities do not have a contractual obligation to share in the Company's losses, net loss for the years ended December 31, 2024 and 2023, was attributed entirely to common stockholders. In periods with a reported net loss, common stock equivalents are excluded from the calculation of diluted net loss per share of common stock if their effect is antidilutive. Potential common shares that are issuable for little or no cash consideration, such as the Company's January 2024, July 2023 and December 2022 Pre-Funded Warrants issued with de minimis exercise prices of $0.001, $0.001 and $0.0001 per share, respectively, are considered outstanding common shares which are included in the calculation of basic and diluted net income (loss) per share in all circumstances.

The following outstanding shares of common stock equivalents were excluded from the computation of diluted net income (loss) per share of common stock for the periods presented because including them would have been antidilutive:

	Year Ended December 31,	
	2024	2023
ESPP, RSUs and stock options to purchase common stock	1,999,823	979,553
Common stock warrants	20,265,576	20,265,576

In addition, the shares contingently issuable in connection with the Merger Agreement, as described in Note 4, "Asset Acquisition", have also been excluded from the computation of diluted net loss per share of common stock for the periods presented because the contingencies for issuance of these shares have not been met.

13. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2024	2023
Accrued compensation and employee benefits	$ 880	$ 2,005
Accrued professional services	84	121
Other accrued liabilities	290	319
Total accrued liabilities	$ 1,254	$ 2,445

14. 401(k) Plan

The Company sponsors a 401(k) plan that stipulates that eligible employees can elect to contribute to the 401(k) plan, subject to certain limitations. Pursuant to the 401(k) plan, the Company makes a matching contribution of up to 4% of the related compensation. Under the vesting schedule, employees have ownership in the matching employer contributions based on the number of years of vesting service completed. Company contributions were $0.2 million for each of the years ended December 31, 2024 and 2023.

15. Income Taxes

Net deferred tax assets as of December 31, 2024 and 2023, consist of the following (in thousands):

	December 31, 2024	December 31, 2023
Deferred tax assets:		
Accruals and other	$ 1,347	$ 1,717
Research credits	8,379	7,839
Net operating loss carryforward	90,142	88,839
Section 59(e) R&D expenditures	1,136	1,937
Section 174 R&D expenditures	2,446	1,651
XOMA royalty	1,371	—
Total deferred tax assets	104,821	101,983
Deferred tax liabilities:		
IP from Acquisition	(1,852)	(1,874)
Total deferred tax liabilities	(1,852)	(1,874)
Valuation allowance	(102,969)	(100,109)
Net deferred tax assets	$ —	$ —

Reconciliations of the statutory federal income tax to the Company's effective tax during the years ended December 31, 2024 and 2023 are as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Tax at statutory federal rate	$ (2,731)	$ (3,862)
State tax—net of federal benefit	55	2,495
Research credits	(363)	(292)
Stock options	319	738
Other	10	(139)
Change in valuation allowance	2,860	2,177
Revaluation of Put Option Liability	(150)	(1,117)
Provision for income taxes	$ —	$ —

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of deferred tax assets is dependent on future taxable income, if any, the timing and the amount of which are uncertain. Accordingly, the deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by $2.9 million and $2.2 million during the years ended December 31, 2024 and 2023, respectively.

As of December 31, 2024, the Company had federal net operating loss carryforwards of $384.8 million, of which $114.9 million federal net operating losses generated before January 1, 2018, will begin to expire in 2029. Federal net operating losses of $270.0 million generated from 2018 to 2023, will carryforward indefinitely but are subject to the 80% taxable income limitation. As of December 31, 2024, the Company had state net operating loss carryforwards of $134.7million, which begin to expire in 2028.

As of December 31, 2024, the Company had federal research credit carryovers of $7.5 million, which begin to expire in 2026. As of December 31, 2024, the Company had state research credit carryovers of $4.7 million, which will carryforward indefinitely.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research credits, to offset its post-change income may be limited. Based on an analysis performed by the Company as of December 31, 2013, it was determined that two ownership changes have occurred since inception of the Company. The first ownership change occurred in 2006 at the time of the Series A financing and, as a result of the change, $1.4 million in federal and state net operating loss carryforwards will expire unutilized. In addition, $26 thousand in federal and state research and development credits will expire unutilized. The second ownership change occurred in July 2013 at the time of

the underwritten public offering; however, the Company believes the resulting annual imposed limitation on use of pre-change tax attributes is sufficiently high that the limit itself will not result in unutilized pre-change tax attributes.

Uncertain Tax Positions

A reconciliation of the beginning and ending balances of the unrecognized tax benefits during the years ended December 31, 2024 and 2023, is as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Unrecognized benefit—beginning of period	$ 2,835	$ 2,678
Gross increases—prior period tax positions	—	—
Gross increases—current period tax positions	196	157
Unrecognized benefit—end of period	$ 3,031	$ 2,835

The entire amount of the unrecognized tax benefits would not impact the Company's effective tax rate if recognized.

There were no accrued interest or penalties related to unrecognized tax benefits in the years ended December 31, 2024 or 2023. The Company files income tax returns in the United States, California, and other states. The tax years 2005 through 2014, and 2016 through 2024, remain open in all jurisdictions. The Company is not currently under examination by income tax authorities in U.S. federal, state or foreign jurisdictions. The Company does not anticipate any significant changes within 12 months of this reporting date of its uncertain tax positions.

In March 2020, the Coronavirus Aid, Relief and Economic Security, or CARES, Act was signed into law. The CARES Act included several tax changes as part of its economic package. These changes principally related to expanded net operating loss carryback periods, increases to interest deductibility limitations, and accelerated alternative minimum tax refunds. The Company has evaluated these items and determined that the items do not have a material effect on the Company's financial statements as of December 31, 2023 or 2024. Additionally, the CARES Act enacted the Employee Retention Credit, or ERC, to incentivize companies to retain employees, which was subsequently modified by extension of the CARES Act. Under the provisions of the CARES Act and its subsequent extension, the Company was eligible for ERCs, subject to certain criteria. Accordingly, the Company recorded a reduction in payroll taxes related to ERCs claimed for $1.4 million in the year ended December 31, 2021. These credits were recorded in the consolidated statements of operations as an offset to the related payroll expenses in the respective operating costs and expenses line item and are disclosed within prepaid expenses and other current assets on the Company's consolidated balance sheets at December 31, 2023.

16. Segment Information

The Company reports segment information based on how it internally evaluates the operating performance of its business units, or segments. The Company has one reportable segment, which is the development and commercialization of innovative therapies for use in medically supervised settings.

The Company's chief operating decision maker, or CODM, which consists of its Chief Executive Officer and the Chief Financial Officer, reviews the Company's operating results on an aggregate basis and manages the Company's operations. The CODM assesses performance for the segment and decides how to allocate resources based on consolidated net loss that is also reported on the consolidated statements of operations. The CODM uses consolidated net loss to evaluate the Company's spend and monitor budget versus actual results. The monitoring of budgeted versus actual results is used in assessing performance of the segment and in establishing resource allocation across the organization.

The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets.

Factors used in determining the reportable segment include the nature of the Company's operating activities, the organizational and reporting structure and the type of information reviewed by the CODM to allocate resources and evaluate financial performance. The accounting policies of the segment are the same as those described in the summary of significant accounting policies.

The segment derives its revenues in the United States pursuant to the Marketing Agreement with Alora. All long-lived assets are maintained in the United States.

The table below is a summary of the segment loss, including significant segment expenses (in thousands):

	Year ended December 31,	
	2024	2023
Revenue	$ —	$ 651
Less:		
Employee expense (not including stock-based compensation)	6,212	6,974
Development and clinical trial expense	3,385	2,501
Other general and administrative expense[(a)]	4,376	5,917
Other segment income, net[(b)]	(969)	(4,454)
Discontinued operations	—	8,110
Segment and consolidated net loss	$ (13,004)	$ (18,397)

(a) Other general and administrative expense includes consulting and professional services fees, insurance, facilities and other corporate expenses.

(b) Other segment income, net includes gain on sale of future payments, fair value adjustments to warrant liability, interest income and expense, and stock-based compensation expense and marketing support.

17. Subsequent Events

On March 31, 2025, the Company entered into a securities purchase agreement and registration rights agreement with several institutional investors and a member of management (collectively, the "Purchasers"), relating to the issuance and sale in a private placement in three separate tranches of: (i) shares of its common stock, par value $0.001 per share, and (ii) pre-funded warrants to purchase shares of common stock. The pre-funded warrants will be exercisable immediately following the applicable closing and have an unlimited term and an exercise price of $0.001 per share.

At the first closing of the private placement, the Company will issue and sell to the Purchasers: (i) 3,405,118 shares of common stock, and (ii) pre-funded warrants to purchase up to an aggregate of 4,999,316 shares of common stock. The aggregate gross proceeds to the Company from the first closing of the private placement will be approximately $4.9 million, before deducting placement agent fees and other estimated expenses payable by the Company, and excluding the proceeds, if any, from the exercise of the pre-funded warrants.

The second and third closings of the private placement will occur if the Company announces the enrollment of at least 17 and 35 patients, respectively, in its Niyad NEPHRO CRRT study and following such announcements the average volume weighted average price of its common stock for each of the immediately subsequent five (5) trading days is at least $0.7325 per share. At each of the second and third closings, the Company expects to issue and sell to the Purchasers: (i) 3,405,118 shares of common stock, and (ii) pre-funded warrants to purchase up to an aggregate of 4,999,316 shares of common stock. The gross proceeds to the Company from the second and third closings of the private placement are expected to be approximately $4.9 million each (approximately $9.8 million in the aggregate), before deducting placement agent fees and other estimated expenses payable by the Company, and excluding the proceeds, if any, from the exercise of the pre-funded warrants.

Pursuant to the registration rights agreement, the Company agreed to file registration statements under the Securities Act of 1933, as amended, with the Securities and Exchange Commission following the applicable closings covering the resale of the shares of common stock to be issued in the private placement and the shares of common stock underlying the pre-funded warrants.

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