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, 2023
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, 2023 (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 $12,073,654. The calculation excludes 116,936 shares of the registrant's common stock held by current executive officers and directors 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 February 29, 2024, the number of outstanding shares of the registrant's common stock was 16,969,103.

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, 2023 (the "2024 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:

- 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.
- 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 initiate, 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 our 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.
- Sales of our divested product, DSUVIA, may fail to attain the threshold revenue levels required for us to share in future revenues from those sales.
- 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.
- If we cannot maintain compliance with Nasdaq's listing requirements, Nasdaq may delist our common stock from trading, which could limit investors' ability to make transactions in our common stock and subject us to additional trading restrictions.
- 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.

2023 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.

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 injection 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.

Nafamostat Product Candidates

Product/Product Candidate	Description	Target Use	Status
Niyad	Lyophilized vial containing nafamostat for injection	Regional anticoagulant for injection 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. Plan to begin enrollment in a registrational trial in the first quarter of 2024 and submit a Premarket Approval, or PMA, application to the FDA by the end of 2024.
LTX-608	Lyophilized vial containing nafamostat for injection	IV infusion for disseminated intravascular coagulation, or DIC, acute respiratory distress syndrome, or ARDS, acute pancreatitis, or as an anti-viral treatment	IND to be submitted following toxicology evaluation to enable Phase 2 study.

Niyad

We are developing Niyad to become the first and currently only FDA-approved regional anticoagulant for injection 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, and for chronic kidney disease patients undergoing intermittent hemodialysis, or IHD, in dialysis centers. Niyad is expected to be used during renal replacement therapy for AKI patients in the hospital and for end-stage renal disease, or ESRD, patients receiving dialysis in outpatient clinics. 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 in Japan and South Korea 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. 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 10 U.S. hospital intensive care units. NEPHRO CRRT stands for **N**afamostat **E**fficacy in **Ph**ase 3 **R**egistrati**o**nal **C**ontinuous **R**enal **R**eplacement **T**herapy Study. The NEPHRO study is set to begin enrolling patients in the first quarter of 2024, with top-line data expected by the third quarter of 2024 and submission of an application for PMA planned by the end of 2024. The study will enroll and evaluate 166 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 nafamostat studies on anticoagulation of the extracorporeal circuit can help guide and support our Niyad development efforts.

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.

Pre-filled Syringe (PFS) Product Candidates

Product/Product Candidate	Description	Target Use	Status
Fedsyra™	Ephedrine pre-filled syringe for injection	Clinically important hypotension occurring in the setting of anesthesia	Product candidate licensed from Laboratoire Aguettant, or Aguettant; evaluating timing of New Drug Application, or NDA, for submission to FDA. Approved in the European Union; owned and marketed by Aguettant.
Phenylephrine	Phenylephrine pre-filled syringe for injection	Clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia	Product candidate licensed from Aguettant; evaluating timing of NDA for submission to FDA. Approved in the European Union; owned and marketed by Aguettant.

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 have been two recently FDA-approved pre-filled ephedrine syringe products made available on the market. 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 evaluating the timing of submitting the NDA for our ephedrine pre-filled syringe given the two other FDA-approved products recently made available on the market.

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. Regiocit, which is the 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 in 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 currently 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. We have pending patent applications directed to the use of nafamostat in DIC, acute pancreatitis, as an antiviral agent, in ARDS and other conditions. Our estimate of the number of DIC patients annually is over 250,000.

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 currently purchase non-FDA approved ready-to-use, pre-filled syringe products mainly from compounding facilities, or manually dilute the products in-house. 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. We believe our two pre-filled syringe product candidates could have a peak sales potential of over $100 million. We are evaluating the timing of an NDA submission for our ephedrine pre-filled syringe product candidate given two other ephedrine pre-filled syringe products have recently been FDA-approved and are being marketed.

Our Strategy

Our strategy is focused on developing, obtaining approval, and commercializing our product candidates, first and foremost, Niyad. Accordingly, we divested DSUVIA to Alora Pharmaceuticals, LLC, or Alora, in April 2023, who will continue to commercialize the product and pay us royalties, sales-based milestone and other payments, as defined in the DSUVIA Agreement (see below). Further, we will continue marketing DSUVIA to the Department of Defense, or DoD. We believe

this will maximize the value of DSUVIA as Alora has more available resources to invest on DSUVIA commercialization and as a result can execute a more robust commercial plan to support DSUVIA sales expansion. We have no plans to further develop or commercialize any of our other sufentanil sublingual products that were previously our product candidates. As described below, we entered into an agreement with XOMA (US) LLC, or XOMA, whereby we have sold our rights to all royalties, milestones and other payments until XOMA receives a certain specified return on its investment, after which we will share equally in the royalties earned on sales to the DoD, milestones and other payments from Alora. This transaction was consummated to provide further funding for the development of our lead product candidate, Niyad. We are focused on submitting our PMA application for Niyad by the end of 2024 and expect to enroll the first patient in our Niyad registrational study in the first quarter of 2024.

In April 2023, Vertical Pharmaceuticals, LLC, a wholly owned subsidiary of Alora acquired certain assets and assumed certain liabilities of Talphera relating to our 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, pursuant to that certain Asset Purchase Agreement, or the DSUVIA Agreement. Under the DSUVIA Agreement, we are entitled to receive quarterly payments in an amount equal to 15% of net Product sales to all customers excluding net sales to the DoD, and sales by or on behalf of Aguettant, and quarterly payments in an amount equal to 75% of net Product sales to the DoD. We are also entitled to receive sales milestones up to $116.5 million based on the achievement of Alora attaining certain levels of annual sales. In January 2024, we entered into an agreement to monetize these payments from Alora under the XOMA Agreement (as defined below) until the XOMA Threshold (as defined below) has been achieved. Refer to 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 do not have plans to further develop any sufentanil sublingual product candidates.

In July 2021, we entered into a License and Commercialization Agreement, or the DZUVEO Agreement, with Aguettant, pursuant to which Aguettant obtained the exclusive right to develop and commercialize DZUVEO in the European Union, Norway, Iceland, Liechtenstein, Andorra, Vatican City, Monaco, Switzerland and the United Kingdom, or the DZUVEO Territory, for the management of acute moderate to severe pain in adults in medically monitored settings. We supplied Aguettant with primary packaged product and Aguettant then completed secondary packaging of the finished product. Pursuant to the DSUVIA Agreement, we and Aguettant entered into an amendment to the DZUVEO Agreement, or the Amended DZUVEO Agreement, and an amendment and restatement to the supply agreement with respect to the manufacture and supply of DZUVEO, or the Amended and Restated Supply Agreement. The rights and obligations under the Amended DZUVEO Agreement and the Amended and Restated Supply Agreement were assumed by Alora, as part of the DSUVIA asset divestment agreement. We received €2.5 million, or approximately $2.9 million, in 2021 under the DZUVEO Agreement. Refer to Note 3, “Discontinued Operations” to the consolidated financial statements in this Annual Report on Form 10-K for additional information.

In July 2021, we entered into a License and Commercialization Agreement, or the PFS Agreement, with Aguettant, pursuant to which we 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 us with the products for use in commercialization and, if they are approved in the U.S., Aguettant was originally entitled to receive up to $24 million in sales-based milestone payments. In connection with our and Aguettant’s agreement to enter into the Amended DZUVEO Agreement (as defined below) and the Amended and Restated Supply Agreement, we entered into an amendment to the PFS Agreement with Aguettant pursuant to which, effective on April 3, 2023, (a) Aguettant paid us a complementary payment in the amount of €1.5 million, and (b) the maximum amount in sales-based milestone payments that Aguettant is entitled to receive reduced to $21 million. Refer to Note 5, “In-License Agreement” to the consolidated financial statements to this Annual Report on Form 10-K for additional information.

In January 2024, we entered into a Payment Interest Purchase Agreement, or the XOMA Agreement, with XOMA, pursuant to which we sold to XOMA our right amounts payable to us by Alora under the DSUVIA Agreement in exchange for $8.0 million in order to monetize certain future royalties and potential sales-based milestone payments, retaining the right, after XOMA has received a certain minimum amount of payments in respect of such royalties and potential sales-based milestone payments, or the XOMA Threshold, to 50% of the royalties in respect of net sales of DSUVIA to the DoD, 50% of potential sales-based milestones in respect of net sales of DSUVIA and 50% of certain associated license and acquisition payments relating to DSUVIA. Refer to Note 16, “Subsequent Events” to the consolidated financial statements in this Annual Report on Form 10-K for additional information.

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. 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.

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 2040, 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.

Competition

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 an anticoagulant in the extracorporeal circuit. Niyad would be the first and only product approved for this indication, if approved. 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 market 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. We have pending patent applications directed to the use of nafamostat in DIC, acute pancreatitis, as an antiviral agent, in ARDS and other conditions.

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, a recently FDA-approved pre-filled syringe with a different formulation and concentration than our product candidate.

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.

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.

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 injection 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 approved products 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 approved products 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 approved product 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 judicial, executive branch and Congressional challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the Affordable Care Act. For example, President Biden signed the Inflation Reduction Act of 2022, or the IRA, 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, President Biden signed the American Rescue Plan Act of 2021 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, at the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services , or HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. 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, 2023, we employed 15 full-time employees, approximately 90% 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, and as of December 31, 2023, we had an accumulated deficit of $444.2 million. In addition, we have generated negative cash flows from operations and we expect to incur significant losses in 2024 and may incur significant losses and negative cash flows from operations in the 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, payments from Grünenthal GmbH, or Grünenthal, the monetization of certain future royalties and commercial sales milestones from the European sales of Zalviso by Grünenthal, funding from the Department of Defense, or DoD, with revenues from sales of DSUVIA, and payments under the Amended DZUVEO Agreement with Aguettant. On January 12, 2024, we entered into the XOMA Agreement to monetize future royalties and potential sales-based milestone payments arising under the DSUVIA Agreement, retaining the right, after XOMA has received a certain minimum amount of payments in respect of such royalties and potential sales-based milestone payments, or the XOMA Threshold, to 50% of the royalties in respect of net sales of DSUVIA to the DoD, 50% of potential sales-based milestones in respect of net sales of DSUVIA and 50% of certain associated license and acquisition payments relating to DSUVIA. 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, including under the Controlled Equity Offering^{SM} Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, 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, 2023 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, including under the ATM Agreement with Cantor. 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.

There can be no assurance that Alora will successfully commercialize DSUVIA pursuant to the DSUVIA Agreement. 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.

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. Refer to Note 3, “Discontinued Operations” to the consolidated financial statements in 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 XOMA receives the minimum amount of certain royalties and potential sales-based payments 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.

Whether we receive royalties from DSUVIA sales to the DoD after the XOMA Threshold is reached is dependent on the ability of Alora to successfully commercialize DSUVIA.

We have divested DSUVIA to Alora, who will continue to commercialize the product and we may in the future share in certain royalties and other payments including sales milestone payments from Alora pursuant to the XOMA Agreement. In particular, we divested to XOMA our rights to payments from Alora, subject to our retained interest in certain future payments in the event the XOMA Threshold is met. The commercial success of DSUVIA will depend heavily on numerous factors, including:

- Alora's ability to market, sell, and distribute DSUVIA;
- Alora's ability to establish and maintain commercial manufacturing relationships with third-party service providers;
- acceptance by the medical community, including physicians, nurses, patients and pharmacy and therapeutics committees;
- acceptance of pricing and placement on payers' formularies;
- Alora's ability to effectively compete with other medications for the treatment of moderate-to-severe acute pain in medically supervised settings, including IV-opioids and any subsequently approved products;
- effective management of, and compliance with, the DSUVIA Risk Evaluation and Mitigation Strategy, or REMS, program;
- continued demonstration of an acceptable safety profile of DSUVIA; and
- Alora's ability to obtain, maintain, enforce, and defend the intellectual property rights and claims for DSUVIA.

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. 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 our 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 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 both medical device and drug indications for use. 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 injection 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.

On July 14, 2021, we entered into the PFS Agreement with Aguettant pursuant to which we 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 us with the products for use in commercialization, if they are approved in the U.S. Our current expectation based on our communication with the FDA is that Fedsyra, the PFS ephedrine product candidate, will be approvable by the FDA without additional manufacturing changes or clinical development. We have not yet received all the available data to support the planned NDA submission for the PFS phenylephrine product. If we or the FDA determine that additional development work will be needed for U.S. approval of either of the PFS product candidates, we would incur additional expense and be delayed in obtaining any revenue from that product.

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, such as the reduction that eliminated approximately 40% of our workforce in May 2022 and subsequent related workforce reductions, may be disruptive to our operations, may negatively affect our productivity, and may constrain our commercialization activities. For example, a further 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 June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the Affordable Care Act . For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, 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 Biden 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, President Biden signed the American Rescue Plan Act of 2021 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, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. 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.

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. In addition, due to the recent strains on the global supply chain, the lead times for many items used in our production are getting longer and may impact our ability to manufacture our products in a timely manner.

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.

Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the SEC. 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 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 need 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 know-how 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 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. For example, the closing price of our common stock ranged between $0.46 and $2.59 during the year ended December 31, 2023, and $1.78 and $12.10 during the year ended December 31, 2022. 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 future 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.

If we cannot maintain compliance with Nasdaq's continued listing requirements, our common stock may be delisted from The Nasdaq Global Market.

In order to maintain our listing on Nasdaq, we are required to comply with the Nasdaq requirements, which includes maintaining a minimum bid price and a minimum public float.

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 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.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, evaluating the effectiveness of our internal controls and disclosing any changes or material weaknesses identified through such evaluation. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

During the preparation of our consolidated financial statements for the year ended December 31, 2022, we identified an error within our earnings per share calculation for the three and six months ended June 30, 2022, and the nine months ended September 30, 2022, whereby we did not properly apply the two-class method of calculating earnings per share with respect to the warrants issued in November 2021. Our management subsequently concluded that a material weakness existed and our internal control over financial reporting was not effective.

As a result, we determined that there were material errors in the financial statements that required a restatement of the unaudited condensed consolidated financial statements included in our Forms 10-Q for the quarterly periods ended June 30, 2022 and September 30, 2022. This was due to the inadequate design and implementation of controls related to the technical accounting review and analysis over earnings per share calculations which were insufficient to prevent or detect errors in the calculation. Specifically, the error was due to management's failure to identify warrants issued in November 2021 as participating securities and consequently attribute earnings to these securities as part of a two-class EPS calculation.

While we believe we have fully remediated the material weakness related to the technical accounting review and analysis over earnings per share calculations as reflected in our June 30, 2023 Form 10-Q filing, any failure to maintain effective internal control over financial reporting in the future, or failure to remediate any future material weakness, could adversely impact our ability to report our financial position and results of operations on a timely and accurate basis.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. If we are not able to comply with the requirements of the Sarbanes-Oxley Act or if we are unable to maintain effective internal control over financial reporting, we may not be able to produce timely and accurate financial statements or guarantee that information required to be disclosed by us in the reports that we file with the SEC, is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms. Any failure of our internal control over financial reporting or disclosure controls and procedures could cause our investors to lose confidence in our publicly reported information, cause the market price of our stock to decline, expose us to sanctions or investigations by the SEC or other regulatory authorities, or impact our results of operations.

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 awards 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. On September 28, 2022, the Court issued a formal written opinion, or the First Opinion, dismissing all of the plaintiff's claims against the Company and the named defendants with leave for plaintiffs to amend their complaint. On November 28, 2022 the plaintiffs filed their second amended complaint. On July 7, 2023, the Court issued a formal written opinion, or the Second Opinion, dismissing all of the plaintiff's claims against the Company and the named defendants with leave for plaintiffs to amend their complaint in part and without leave to amend in part. On September 5, 2023, the plaintiffs filed a third amended complaint. Defendants' motion to dismiss the third amended complaint is fully briefed and a hearing is scheduled for April 4, 2024. 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. The complaint names nine of the Company's officers and directors and asserts the same claims as those in the previously filed derivative actions. The Company has not yet been served in this new complaint. 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 often is 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.

As of December 31, 2023, we had federal net operating loss carryforwards of $377.7 million, of which $114.9 million federal net operating losses generated before January 1, 2018 will begin to expire in 2029. $262.8 million of such federal net operating losses were generated after December 31, 2017. As of December 31, 2023, we had state net operating loss carryforwards of $137.4 million, which begin to expire in 2028. 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 information technology manager help identify, assess and manage the Company's cybersecurity threats and risks. Our chief financial officer and information technology manager 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 information technology manager.

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 information technology manager 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 February 29, 2024, there were 46 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, 2023, including year-over-year comparisons versus the year ended December 31, 2022, as reported in our Annual Report on Form 10-K for the year ended December 31, 2022, which consolidated financial statements were recast to reflect discontinued operations and filed with our Current Report on Form 8-K on August 1, 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), two ready-to-use pre-filled syringe product candidates (Fedsyra and phenylephrine), and 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.

Our strategy is focused on developing, obtaining approval, and commercializing our product candidates, first and foremost, Niyad. Accordingly, we divested DSUVIA to Alora in April 2023, who will continue to commercialize the product and pay us sales-based milestone and other payments, as defined in the DSUVIA Agreement. Further, we will continue marketing DSUVIA to the Department of Defense. We believe this will maximize the value of DSUVIA as Alora has more available resources to invest on DSUVIA commercialization and as a result can execute a more robust commercial plan to support DSUVIA sales expansion. We have no plans on further developing or commercializing any of our other sufentanil sublingual products that were previously our product candidates. As described below, in January 2024, we entered into an agreement with XOMA whereby we have sold our rights to all royalties, milestones and other payments until XOMA receives a certain specified return on its investment, after which we will share equally in the royalties earned on sales to the Department of Defense, milestones and other payments from Alora. This transaction was consummated to provide further funding for the development of our lead product candidate, Niyad. We are focused on beginning enrollment in the Niyad registrational trial in the first quarter of 2024 and anticipate submitting a PMA application for Niyad to the FDA by the end of 2024.

In January 2024, we entered into the XOMA Agreement pursuant to which we sold to XOMA our right to amounts payable to us by Alora under the DSUVIA Agreement in exchange for $8.0 million in order to monetize certain future royalties and potential sales-based milestone payments, retaining the right, after XOMA has received a certain minimum amount of payments in respect of such royalties and potential sales-based milestone payments, or the XOMA Threshold, to 50% of the royalties in respect of net sales of DSUVIA to the DoD, 50% of potential sales-based milestones in respect of net sales of DSUVIA and 50% of certain associated license and acquisition payments relating to DSUVIA. Refer to Note 16, "Subsequent Events" to the consolidated financial statements in this Annual Report on Form 10-K for additional information.

General Trends and Outlook

Global Supply Chain

We continue to engage with various elements of our supply chain and distribution channel, including our customers, contract manufacturers, and logistics and transportation providers, to supply our product candidates for development purposes and to remain informed of any challenges within our supply chain. We intend to adapt our plans as needed to continue to drive our product development programs. However, global events have impacted our global supply chain and we may face further disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products. Such supply disruptions may adversely impact our ability to continue development of our product candidates and ultimately generate sales of and revenues from any approved products, and our business, financial condition, results of operations and growth prospects could be adversely affected.

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 in the future adversely affect our operating results. 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.

Financial Overview

We have incurred net losses and generated negative cash flows from operations (although the termination of the royalty monetization for Zalviso resulted in net income for 2022) 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 2023 was $18.4 million, and our net income was $47.8 million for 2022. As of December 31, 2023, we had an accumulated deficit of $444.2 million. As of December 31, 2023, we had cash, cash equivalents, short-term investments and restricted cash totaling $9.4 million compared to $20.8 million as of December 31, 2022.

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.

Revenue from Contracts with Customers

We follow the provisions of Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*. This guidance provides a unified model to determine how revenue is recognized. We recognize revenue upon transfer of control of promised products or services to customers in an amount that reflects the consideration we expect to receive in exchange for those products or services. Prior to the divestment of DSUVIA to Alora, we sold our products primarily through wholesale and specialty distributors.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under our agreements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) we satisfy each performance obligation.

Our revenue relates to our services performed to support sales of DSUVIA to the DoD by Alora under the Marketing Agreement. Our performance obligation is to serve as the exclusive sales agent for selling DSUVIA to the DoD through the term of the Marketing Agreement. The non-creditable and non-refundable revenues are variable consideration based on 75% of net sales of DSUVIA to the DoD during the period subject to certain adjustments. We evaluate if we are a principal or an agent in a transaction to determine whether revenue should be recorded on a gross or net basis depending on if we obtain control over the goods and services before they are transferred to customers. We are acting as an agent in relation to DSUVIA sales to the DoD.

The consideration in the Marketing Agreement reflects a variable amount, for which we estimate the amount of consideration to which we will be entitled by using the expected value method. We include in the transaction price the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. Revenues are recognized when the DoD obtains control of the product, at which time we have an unconditional right to receive payment for such revenue earned.

In January 2024, we entered into an agreement to monetize these and other payments from Alora under the XOMA Agreement until the XOMA Threshold is attained. See Note 16, “Subsequent Events” to the consolidated financial statements in this Annual Report on Form 10-K for additional information.

Non-Cash Interest Income on Liability Related to Sale of Future Royalties

In September 2015, we sold certain royalty and milestone payment rights from the sales of Zalviso in the European Union by our former commercial partner, Grünenthal GmbH, or Grünenthal, pursuant to the Collaboration and License Agreement, dated as of December 16, 2013, as amended, to PDL BioPharma, Inc., or PDL, for an upfront cash purchase price of $65.0 million, or the Zalviso Royalty Monetization. Under the relevant accounting guidance, because of our significant continuing involvement, the Zalviso Royalty Monetization was accounted for as a liability that was amortized using the effective interest method over the life of the arrangement. In order to determine the amortization of the liability, we were required to estimate the total amount of future royalty and milestone payments to be received by us and paid to PDL, up to a capped amount of $195.0 million, over the life of the arrangement. The aggregate future estimated royalty and milestone payments (subject to the capped amount), less the $61.2 million of net proceeds we received, were to be recorded as interest expense over the life of the liability. Consequently, we imputed interest on the unamortized portion of the liability and recorded interest expense related to the Zalviso Royalty Monetization accordingly.

During the three months ended June 30, 2020, Grünenthal notified us that it was terminating the Amended License Agreement, effective November 13, 2020. The terms of the Grünenthal Agreements were extended to May 2021 to enable Grünenthal to sell down its Zalviso inventory, a right it had under the Grünenthal Agreements. The rights to market and sell Zalviso in the Territory reverted back to us in May 2021.

There was a continuing obligation on our part, through the term of the Zalviso Royalty Monetization, to use commercially reasonable efforts to negotiate a replacement license agreement, or New Arrangement. However, without a New Arrangement to commercialize Zalviso in Europe, we were unable to reliably estimate the future payments to SWK Funding LLC, or SWK, (assignee of PDL) over the remaining life of the Zalviso Royalty Monetization. Due to the significant judgments and factors related to the estimates of future payments under the Zalviso Royalty Monetization, there were significant uncertainties surrounding the amount and timing of future payments and the probability of realization of any estimated contingent gain. While the expected payments under the Zalviso Royalty Monetization were lower than the gross proceeds of $65.0 million received, we deferred recognition of any probable contingent gain until the Zalviso Royalty Monetization liability expired.

On May 31, 2022, we entered into a Termination Agreement with SWK to fully terminate the Zalviso Royalty Monetization for which we paid cash consideration of $0.1 million, and neither PDL nor SWK retained any further interest in the Zalviso Royalty Monetization. Accordingly, effective May 31, 2022, the Zalviso Royalty Monetization was no longer reflected on our financial statements or other records as a sale of assets to PDL or SWK and all security interests and other liens of every type held by the parties to the Zalviso Royalty Monetization have been terminated and automatically released without further action by any party. The $84.1 million gain on extinguishment of the liability related to the sale of future royalties was recognized in the consolidated statements of operations as other income.

We recorded non-cash royalty revenues and non-cash interest (income) expense within our consolidated statements of operations over the term of the Zalviso Royalty Monetization.

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.

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 Redeemable Convertible Preferred Stock, and 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 Income (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 June 2016, the FASB issued Accounting Standards Update, or ASU, 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The measurement of expected credit losses is based on historical experience, current conditions, and reasonable and supportable forecasts that affect collectability. ASU 2016-13 also eliminates the concept of "other-than-temporary" impairment when evaluating available-for-sale debt securities and instead focuses on determining whether any impairment is a result of a credit loss or other factors. An entity will recognize an allowance for credit losses on available-for-sale debt securities rather than an other-than-temporary impairment that reduces the cost basis of the investment. We adopted ASU 2016-13 on January 1, 2023, using the modified retrospective approach, and no cumulative effect adjustment to accumulated deficit was needed as of the adoption date. Additionally, no prior period amounts were adjusted. The adoption of ASU 2016-13 did not have a material impact on our consolidated financial statements.

Recently Issued Accounting Pronouncements

On December 14, 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 an 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 results of operations have fluctuated from period to period and may continue to fluctuate in the future, based upon our research and development efforts, variations in the level of expenditures related to development efforts and debt service obligations during any given period. 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, 2023 and 2022

Revenue

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 the DoD and for which Alora pays us 75% of net sales of DSUVIA sold to the DoD. In January 2024, we entered into the XOMA Agreement pursuant to which we sold to XOMA our right to future royalties and potential sales-based milestone amounts payable to us by Alora under the DSUVIA Agreement in exchange for $8.0 million until the XOMA Threshold is attained, after which time we may share in certain future payments from Alora. Refer to Note 16, "Subsequent Events" to the consolidated financial statements in this Annual Report on Form 10-K for additional information.

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;
- depreciation and 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 2023 and 2022 (in thousands, except percentages):

	Years Ended December 31,		$ Change	% Change
	2023	2022	2023 vs. 2022	2023 vs. 2022
Niyad	$ 2,103	$ 405	$ 1,698	419%
PFS	4	313	(309)	(99)%
Overhead	3,439	2,623	816	31%
Total research and development expenses	$ 5,546	$ 3,341	$ 2,205	66%

Research and development expenses during 2023 increased as compared to 2022, primarily due to increased spending on Niyad.

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 2023 and 2022 were as follows (in thousands, except percentages):

	Years Ended December 31,		$ Change	% Change
	2023	2022	2023 vs. 2022	2023 vs. 2023
Selling, general and administrative expenses	$ 11,994	$ 17,011	$ (5,017)	(29)%

Selling, general and administrative expenses decreased for 2023 as compared to 2022, primarily due to a $2.8 million reduction in employee compensation and related expenses as a result of lower headcount, a $2.0 million reduction in consulting and legal fees, and a net reduction in other selling, general and administrative expenses of $0.2 million in the year ended December 31, 2023.

Impairment of Property and Equipment

We do not have plans to further develop any sufentanil sublingual product candidates. Accordingly, in 2022 we determined that it is no longer probable that we will realize the future economic benefit associated with the costs of the Zalviso-related purchased equipment and manufacturing-related facility improvements we have made at our contract manufacturer and, therefore, recorded a non-cash impairment charge of $4.9 million to the Zalviso-related assets for the year ended December 31, 2022.

Other Income

Total other income for 2023 and 2022 was as follows (in thousands, except percentages):

	Years Ended December 31,		$ Change	% Change
	2023	2022	2023 vs. 2022	2023 vs. 2022
Interest expense	$ (134)	$ (1,116)	$ 982	(88)%
Interest income and other income, net	6,736	366	6,370	1,740%
Non-cash interest income on liability related to sale of future royalties	—	1,136	(1,136)	(100)%
Gain on extinguishment of liability related to sale of future royalties	—	84,052	(84,052)	(100)%
Total other income	$ 6,602	$ 84,438	$ (77,836)	(92)%

Interest expense consisted primarily of interest accrued or paid on our debt obligation agreements and amortization of debt discounts. Interest expense decreased for 2023 as compared to 2022, primarily as a result of a lower average outstanding loan balance. In April 2023, in connection with the closing of the DSUVIA Agreement, we fully repaid the Loan Agreement with Oxford. Refer to 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 2023 and 2022 primarily consisted of changes in the fair value of our warrant liability, the Lowell holdback shares and interest earned on our investments. The increase in interest income and other income, net for 2023 as compared to 2022, was primarily due to the $5.3 million decrease in the fair value of our warrant liability and a $0.7 million gain on the satisfaction of the contingency related to the liability for the Lowell holdback shares issued in June 2023.

The non-cash interest income on the liability related to the sale of future royalties is attributable to the Zalviso Royalty Monetization which was fully terminated in May 2022. In May 2022, we entered into a Termination Agreement with SWK Funding LLC, or SWK, (assignee of PDL BioPharma, Inc., or PDL) to fully terminate the Zalviso Royalty Monetization for which we paid cash consideration of $0.1 million, and neither PDL nor SWK retains any further interest in the Zalviso Royalty Monetization. Accordingly, effective May 31, 2022, the Zalviso Royalty Monetization is no longer reflected on our financial statements or other records as a sale of assets to PDL or SWK and all security interests and other liens of every type held by the parties to the Zalviso Royalty Monetization have been terminated and automatically released without further action by any party. The $84.1 million gain on extinguishment of the liability related to the sale of future royalties is recognized in the consolidated statements of operations as other income.

Liquidity and Capital Resources

Liquidity and Going Concern

As of December 31, 2023, we had cash, cash equivalents and investments totaling $9.4 million, compared to $20.8 million as of December 31, 2022. Our cash and investment balances are held in a variety of interest-bearing instruments, including obligations of commercial paper, corporate debt securities, 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 (although the termination of the Zalviso Royalty Monetization resulted in net income for 2022) and we expect to incur significant losses in 2024 and may incur significant losses and negative cash flows from operations in the future. Although we raised additional capital in January 2024 as discussed below, 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, 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 16, "Subsequent Events" 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 to the purchasers in a two-tranche private placement to purchase shares of common stock at a purchase price of $0.769 per share and an exercise price of $0.001 per share. The pre-funded warrants are exercisable immediately and have an unlimited term. The terms of the private placement included:

- the first tranche of the private placement, which closed in January 2024, resulted in the aggregate gross proceeds of approximately $6.0 million excluding the proceeds, if any, from the exercise of the pre-funded warrants issued in such tranche.

- the second tranche of the private placement, which is a conditional purchase by the purchasers subject to either (a) the satisfaction or waiver of achieving a pivotal trial milestone event, or the Pivotal Trial Milestone, or (b) the satisfaction or waiver of the volume-weighted average price of the 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, or the Price Milestone, which will result in additional aggregate gross proceeds to us of approximately $10.0 million with respect to the Pivotal Trial Milestone and $2.0 million with respect to the Price Milestone, excluding the proceeds, if any, from the exercise of the pre-funded warrants issued in such closing.

In the first tranche of the private placement, we issued pre-funded warrants to purchase up to 7,792,208 shares of common stock. In the second tranche of the private placement, we expect to issue (i) in connection with achieving the Pivotal Trial Milestone, pre-funded warrants to purchase up to 12,987,013 shares of common stock, and (ii) in connection with achieving the Price Milestone, pre-funded warrants to purchase up to 2,597,402 shares of common stock. Any of the conditions in the second tranche can be waived by each purchaser.

July 2023 Private Placement

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

- 5,340,591 shares of common stock;

- pre-funded warrants to purchase up to 2,012,356 shares of common stock with an exercise price of $0.001 per share;

- Series A common stock warrants to purchase up to an aggregate of 7,352,947 shares of 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 common stock with an exercise price of $1.11 per share.

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

December 2022 Registered Direct Offering

In December 2022, we issued and sold in a registered direct offering to institutional investors:

- 748,744 shares of common stock;

- pre-funded warrants exercisable for an aggregate of 2,632,898 shares of common stock with an exercise price of $0.0001 per share; and

- common stock warrants exercisable for an aggregate of 4,227,052 shares of common stock with an exercise price of $2.07 per share.

The shares of common stock and accompanying common stock warrants were sold at a combined offering price of $2.22625 per share and accompanying common stock warrant, and the pre-funded warrants and accompanying common stock warrants were sold at a combined offering price of $2.22615 per pre-funded warrant and accompanying warrant. The pre-funded warrants were immediately exercisable following the closing of the offering and have an unlimited term. The common stock warrants will not be exercisable until after the six-month anniversary of the closing of the offering and will expire on December 29, 2028. Total net proceeds from the offering were approximately $6.6 million, after deducting fees payable to the placement agent and other estimated offering expenses payable by us, excluding the proceeds, if any, from the exercise of the pre-funded warrants and the common stock warrants. Refer to Note 9, "Stockholders' Equity" and Note 10, "Warrants" to the consolidated financial statements in this Annual Report on Form 10-K for additional information.

August 2022 Private Placement

On August 3, 2022, we issued and sold to Lincoln Park Capital Fund, LLC, in a private placement, 3,000 shares of Series A redeemable convertible preferred stock, par value $0.001 per share, with $100 per share stated value, together with a warrant to purchase up to an aggregate of 81,150 shares of common stock for a purchase price of $0.3 million. The warrant had an exercise price of $4.07 per share, was immediately exercisable and has a term ending on February 3, 2028. In 2022, we redeemed the 3,000 shares of Series A redeemable convertible preferred stock for $0.3 million, and retired such shares. Upon the closing of the December 2022 registered direct offering, we modified the previously issued warrant to reduce the exercise price to $2.07 per share in accordance with the warrant terms. Refer to 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.

Cantor Controlled Equity Offering℠ Sales Agreement

In June 2016, we entered into a Controlled Equity Offering℠ Sales Agreement, as amended, the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, as agent, pursuant to which we may offer and sell, from time to time through Cantor, shares of our common stock. During 2023, there were no sales under the ATM Agreement. During 2022, we issued and sold approximately 0.1 million shares of common stock pursuant to the ATM Agreement and received net proceeds of $0.5 million, after deducting fees and expenses. As of December 31, 2023, we had the ability to sell approximately $35.6 million of our common stock under the ATM Agreement, subject to the filing of a prospectus supplement with the SEC to our registration statement on Form S-3. Our ability to sell such shares 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. Under the loan agreement, we borrowed an aggregate principal amount of $25.0 million under a term loan. After deducting all loan initiation costs and outstanding interest on the prior loan agreement with Hercules Capital Funding Trust 2014-1 and Hercules Technology II, L.P, we received $15.9 million in net proceeds. 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,	
	2023	**2022**
Net cash used in operating activities	$ (17,492)	$ (28,331)
Net cash (used in)/provided by investing activities	(528)	36,450
Net cash provided by/(used in) financing activities	3,466	(507)

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 income related to the sale of future royalties and interest expense related to our debt financings.

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 used in operating activities of $28.3 million during 2022 reflected net income of $47.8 million, offset by aggregate non-cash items of $74.7 million and an approximate $1.4 million net change in our operating assets and liabilities. Non-cash inflows included an $84.2 million gain on the termination of the Zalviso Royalty Monetization, partially offset by a $4.9 million charge for the impairment of Zalviso-related property and equipment, $2.9 million in stock-based compensation expense and $1.7 million in depreciation and amortization expense. The net change in our operating assets and liabilities included a $1.6 million decrease in accrued liabilities.

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

During 2022, cash provided by investing activities of $36.5 million was primarily the net result $46.4 million in proceeds from maturity of investments partially offset by $7.9 million for purchases of investments and $1.7 million in cash paid for the Lowell asset acquisition, net of cash acquired.

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 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.

During 2022, cash used in financing activities of $0.5 million was primarily due to $8.4 million in long-term debt payments, including $8.3 million under the Loan Agreement with Oxford, partially offset by $7.9 million in net proceeds received in connection with equity financings.

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 successfully initiate and 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, including our two in-licensed product candidates from Aguettant, 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;
- milestone and royalty revenue we receive under our collaborative development and commercialization arrangements;
- 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 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 Securities Exchange Act of 1934, as amended, or 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, 2023, our chief executive officer and chief financial officer have concluded that, subject to the limitations described below, our disclosure controls and procedures were effective as of December 31, 2023.

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, 2023 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, 2023 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 2024 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 2024 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 2024 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 2024 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 2024 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 2024 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 2024 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 2024 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 2024 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

		Incorporation By Reference			
Exhibit Number	Exhibit Description	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
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Registrant.	8-K	001-35068	3.1	08/04/2022
3.6	Certificate of Elimination of Series A Convertible Preferred Stock of the Registrant.	8-K	001-35068	3.2	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 Warrant to Purchase Common Stock of the Registrant, dated as of May 30, 2019.	8-K	001-35068	4.1	06/03/2019
4.5	Form of Warrant to Purchase Common Stock of the Registrant, dated as of November 15, 2021.	8-K	001-35068	4.1	11/15/2021

4.6	Warrant to Purchase Common Stock of the Registrant, dated as of August 3, 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
10.5+	Amended and Restated 2020 Equity Incentive Plan.	8-K	001-350683	10.1	06/17/2021
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	06/16/2020
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 Vincent J. Angotti, effective as of March 6, 2017.	10-Q	001-35068	10.4	05/08/2017
10.12+	Offer Letter between the Registrant and Raffi Asadorian, dated July 18, 2017.	8-K	001-35068	10.1	07/19/2017
10.13+	Amended and Restated Severance Benefit Plan effective as of February 7, 2017.	8-K	001-35068	10.2	02/09/2017
10.14§#	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
10.15§#	License and Commercialization Agreement (DZUVEO), dated July 14, 2021, between the Registrant and Laboratoire Aguettant.	10-Q	001-35068	10.1	11/15/2021
10.16§#	License and Commercialization Agreement (PFS), dated July 14, 2021, between the Registrant and Laboratoire Aguettant.	10-Q	001-35068	10.2	11/15/2021

10.17	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
10.18	Controlled Equity Offering[SM] Sales Agreement between the Registrant and Cantor Fitzgerald & Co., dated as of June 21, 2016.	8-K	001-35068	10.1	06/21/2016
10.19	Amendment No. 1 to the Controlled Equity Offering[SM] Sales Agreement between the Registrant and Cantor Fitzgerald & Co., dated as of August 29, 2020.	S-3	333-239156	1.3	06/12/2020
10.20	Loan and Security Agreement between the Registrant and Oxford Finance, LLC, dated as of May 30, 2019.	8-K	001-35068	10.1	06/03/2019
10.21	First Amendment to Loan and Security Agreement between the Registrant and Oxford Finance, LLC, dated as of May 5, 2021.	10-Q	001-35068	10.4	11/15/2021
10.22	Second Amendment to Loan and Security Agreement between the Registrant and Oxford Finance, LLC, dated as of November 14, 2021.	10-K	001-35068	10.31	03/10/2022
10.23	Registration Rights Agreement, between the Registrant and Lincoln Park Capital Fund, LLC, dated as of August 3, 2022.	8-K	001-35068	10.2	08/04/2022
10.24	Form of Securities Purchase Agreement, by and among the Registrant and the Purchasers, dated as of July 17, 2023.	8-K	001-35068	10.1	07/21/2023
10.25	Form of Registration Rights Agreement, by and among the Registrant and the Purchasers, dated as of July 17, 2023.	8-K	001-35068	10.2	07/21/2023
10.26	Form of Series A common stock warrant (July 2023).	8-K	001-35068	10.3	07/21/2023
10.27	Form of Series B common stock warrant (July 2023).	8-K	001-35068	10.4	07/21/2023
10.28	Form of Pre-Funded Warrant (July 2023).	8-K	001-35068	10.5	07/21/2023
10.29	Form of placement agent Series A common stock warrant.	8-K	001-35068	10.6	07/21/2023
10.30	Form of placement agent Series B common stock warrant.	8-K	001-35068	10.7	07/21/2023
10.31	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
10.32	Form of Securities Purchase Agreement, by and among the Registrant and Investor Company ITF Rosalind Master Fund L.P., dated as of January 17, 2024.	8-K	001-35068	10.2	01/22/2024
10.33	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
10.34	Form of Pre-Funded Warrant (January 2024).	8-K	001-35068	10.4	01/22/2024

23.1	Consent of BPM LLP, Independent Registered Public Accounting Firm.
23.2	Consent of Withum Smith & Brown 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.
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
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).

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§ 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 6, 2024

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 6, 2024
/s/ Raffi Asadorian **Raffi Asadorian**	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 6, 2024
/s/ Adrian Adams **Adrian Adams**	Chairman	March 6, 2024
/s/ Marina Bozilenko **Marina Bozilenko**	Director	March 6, 2024
/s/ Jill Broadfoot **Jill Broadfoot**	Director	March 6, 2024
/s/ Stephen J. Hoffman, Ph.D., M.D. **Stephen J. Hoffman, Ph.D., M.D.**	Director	March 6, 2024
/s/ Abhinav Jain **Abhinav Jain**	Director	March 6, 2024
/s/ Mark Wan **Mark Wan**	Director	March 6, 2024

TALPHERA, INC.

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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 sheet of Talphera, Inc. (the "Company") as of December 31, 2023, and the related consolidated statement of operations, changes in redeemable convertible preferred stock and stockholders' equity (deficit), and cash flow for the year ended December 31, 2023 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and the results of its operations and its cash flows for the year ended December 31, 2023 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 entity's internal control over financial reporting. Accordingly, we express no such opinion.[4]

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 6, 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

AcelRx Pharmaceuticals, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of AcelRx Pharmaceuticals, Inc. (the "Company") as of December 31, 2022, the related consolidated statement of operations, changes in redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for the year ended December 31, 2022, 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, 2022, and the results of its operations and its cash flows for the year ended December 31, 2022, 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 incurring 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 audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures 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 audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below 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. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Product Revenue Allowances for Chargebacks, Government Rebates and Product Returns

Description of the Matter

As described in Note 1 to the consolidated financial statements, revenue from product sales is recognized net of estimates for variable consideration consisting of chargebacks, government rebates, returns, distribution fees, GPO fees and product returns. This variable consideration is recorded in the same period that the related revenue is recognized and creates variability for the consideration that the Company expects to receive. Liabilities related to government rebates and rebate programs of managed healthcare organizations involve the use of significant assumptions and judgments that include consideration of legal interpretations of applicable laws and regulations, historical claims experience, the payer channel mix, current contract prices, unbilled claims, claims submission time lags, and inventory levels in the distribution channel. Estimates for product returns consider existing return policies with customers, historical sales and return rates, inventory levels in the distribution channel, and product shelf lives.

Management's estimated allowance for chargebacks, government rebates, and product returns requires a high degree of judgment and is subject to change based on various quantitative and qualitative factors. Accordingly, extensive audit effort and a high degree of auditor judgment were needed to evaluate management's estimates and assumptions used in the determination of chargebacks, government rebates, and product returns.

How We Addressed the Matter in Our Audit

We obtained an understanding of and evaluated the design of controls relating to the Company's processes for estimating chargebacks, government rebates, and product returns.

We evaluated the significant accounting policies relating to chargebacks, government rebates, and product returns, as well as management's application of the policies, for appropriateness and reasonableness.

To test management's estimates of chargebacks, rebates and returns, we obtained management's calculations for the respective estimates and performed one or more of the following procedures: clerically tested the calculation, agreed relevant inputs to the terms of relevant contracts, performed retrospective reviews, performed a sensitivity analysis on the inputs and assumptions used in the estimates and assessed subsequent events, evaluated the methodologies and assumptions used and the underlying data used by the Company, evaluated the assumptions used by management against historical trends, evaluated the change in estimated accruals from the prior periods, and assessed the historical accuracy of the Company's estimates against actual results.

/s/ WithumSmith+Brown, PC

We began serving as the Company's auditor in 2015. We became the predecessor auditor in 2023.
San Francisco, California
March 31, 2023, except for the effects of the discontinued operations disclosed in Note 3, as to which the date is July 31, 2023
PCAOB ID Number 100

Talphera, Inc.
Consolidated Balance Sheets
(in thousands, except share data)

	December 31, 2023	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	$ 5,721	$ 15,275
Restricted cash	—	5,000
Short-term investments	3,660	495
Prepaid expenses and other current assets	2,175	1,865
Assets of discontinued operations	—	1,931
Total current assets	11,556	24,566
In-process research and development asset	8,819	8,819
Other assets	20	166
Assets of discontinued operations	—	13,936
Total assets	$ 20,395	$ 47,487
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,336	$ 1,256
Accrued and other liabilities	2,445	2,531
Long-term debt, current portion	—	5,363
Liabilities of discontinued operations, current portion	731	4,620
Total current liabilities	4,512	13,770
Warrant liability	1,778	7,098
Other long-term liabilities	—	810
Liabilities of discontinued operations	—	3,995
Total liabilities	6,290	25,673
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.001 par value—200,000,000 shares authorized as of December 31, 2023 and 2022; 16,952,519 and 8,243,680 shares issued and outstanding as of December 31, 2023 and 2022, respectively	17	8
Additional paid-in capital	458,314	447,635
Accumulated deficit	(444,226)	(425,829)
Total stockholders' equity	14,105	21,814
Total Liabilities and Stockholders' Equity	$ 20,395	$ 47,487

See notes to consolidated financial statements.

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

	Year Ended December 31,	
	2023	**2022**
Revenue	$ 651	$ —
Operating costs and expenses:		
Research and development	5,546	3,341
Selling, general and administrative	11,994	17,011
Impairment of property and equipment	—	4,948
Total operating costs and expenses	17,540	25,300
Loss from operations	(16,889)	(25,300)
Other income (expense):		
Interest expense	(134)	(1,116)
Interest income and other income, net	6,736	366
Non-cash interest income on liability related to the sale of future royalties	—	1,136
Non-cash gain on extinguishment of liability related to the sale of future royalties	—	84,052
Total other income, net	6,602	84,438
Net (loss) income before income taxes	(10,287)	59,138
Provision for income taxes	—	(13)
Net (loss) income from continuing operations	(10,287)	59,125
Net loss from discontinued operations – See Note 3	(8,110)	(11,370)
Net (loss) income	(18,397)	47,755
Deemed dividends related to Series A Redeemable Convertible Preferred Stock	—	(186)
Income allocated to participating securities	—	(5,240)
Net (loss) income attributable to Common Shareholders, basic	$ (18,397)	$ 42,329
Net (loss) income attributable to Common Shareholders, diluted	$ (18,397)	$ 42,342
Net (loss) income per share attributable to stockholders:		
Basic (loss) earnings per share		
(Loss) income from continuing operations	$ (0.72)	$ 7.27
Loss from discontinued operations	$ (0.57)	$ (1.54)
Net (loss) income per share	$ (1.29)	$ 5.73
Diluted (loss) earnings per share		
(Loss) income from continuing operations	$ (0.72)	$ 7.25
Loss from discontinued operations	$ (0.57)	$ (1.53)
Net (loss) income per share	$ (1.29)	$ 5.72
Shares used in computing net (loss) income per share of common stock, basic – See Note 12	14,263,744	7,385,348
Shares used in computing net (loss) income per share of common stock, diluted – See Note 12	14,263,744	7,406,986

See notes to consolidated financial statements.

Talphera, Inc.
Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)

	Series A Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance as of December 31, 2021	—	$ —	6,840,967	$ 7	$ 437,684	$ (473,584)	$ (35,893)
Issuance of Series A Redeemable Convertible Preferred Stock and Warrants	3,000	129	—	—	110	—	110
Deemed dividends related to Series A Redeemable Convertible Preferred Stock		186			(186)		(186)
Redemption of Series A Redeemable Convertible Preferred Stock and Warrants	(3,000)	(315)	—	—	—	—	—
Stock-based compensation	—	—	—	—	2,889	—	2,889
Issuance of common stock in connection with asset purchase	—	—	481,026	—	5,511	—	5,511
Net proceeds from issuance of common stock and pre-funded warrants in connection with equity financings	—	—	873,074	1	789	—	790
Modification of equity-classified warrants	—	—	—	—	822	—	822
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	—	—	37,672	—	(58)	—	(58)
Issuance of common stock upon ESPP purchase	—	—	10,941	—	74	—	74
Net income	—	—	—	—	—	47,755	47,755
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 and warrants in connection with equity financings	—	—	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

See notes to consolidated financial statements.

Talphera, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net (loss) income	$ (18,397)	$ 47,755
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Non-cash interest income on liability related to the sale of future royalties	—	(1,136)
Depreciation and amortization	311	1,647
Non-cash interest expense related to debt financing	53	393
Non-cash issuance costs for warrant liability	—	775
Revaluation of liability for Lowell holdback shares	(723)	—
Stock-based compensation	1,729	2,889
Non-cash gain on extinguishment of liability related to the sale of future royalties	—	(84,152)
Impairment of property and equipment	—	4,948
Revaluation of warrant liability	(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)	—
Other	(24)	(60)
Changes in operating assets and liabilities:		
Accounts receivable	(189)	(149)
Inventories	61	(107)
Prepaid expenses and other assets	244	299
Other assets	226	—
Accounts payable	(575)	551
Accrued liabilities	(1,132)	(1,613)
Operating lease liabilities	(147)	(285)
Deferred revenue	(29)	(86)
Net cash used in operating activities	(17,492)	(28,331)
Cash flows from investing activities:		
Purchase of property and equipment	(100)	(364)
Purchase of investments	(3,651)	(7,861)
Sale of the DSUVIA assets	2,723	—
Cash paid for asset acquisition, net of cash acquired	—	(1,687)
Proceeds from maturities of investments	500	46,362
Net cash (used in) provided by investing activities	(528)	36,450
Cash flows from financing activities:		
Payment of long-term debt	(5,416)	(8,433)
Net proceeds from issuance of Issuance of Series A Redeemable Convertible Preferred Stock and Warrants	—	239
Redemption of Series A Redeemable Convertible Preferred Stock	—	(315)
Proceeds from issuance of common stock, accompanying warrants and pre-funded warrants in July 2023 private placement offering	8,856	—
Proceeds from issuance of common stock, accompanying warrants and pre-funded warrants in December 2022 registered direct offering	—	7,528
Net proceeds from issuance of common stock in connection with exercise of pre-funded warrants	3	—
Net proceeds from issuance of common stock in connection with at-the-market sales agreement	—	458
Net proceeds from issuance of common stock through equity plans	45	74
Payment of employee tax obligations related to vesting of restricted stock units	(22)	(58)
Net cash provided by (used in) financing activities	3,466	(507)
Net change in cash, cash equivalents and restricted cash	(14,554)	7,612
Cash, cash equivalents and restricted cash—Beginning of period	20,275	12,663
Cash, cash equivalents and restricted cash—End of period	$ 5,721	$ 20,275
Supplemental Disclosures of Cash Flow Information:		
Cash paid for interest	$ 119	$ 824
Income taxes paid	$ —	$ 13
Noncash Investing and Financing Activities:		
Purchase of property and equipment in accounts payable and accrued expenses	$ —	$ 825
Equity issuance costs from modification of November 2021 Financing Warrants	$ —	$ 47
Equity issuance costs in accounts payable and accrued expenses	$ —	$ 51
(Settlement)/liability for held back shares issued in connection with asset acquisition	$ (77)	$ 800
Issuance of common stock in connection with asset acquisition	$ —	$ 5,511
Establishment of right-of-use asset and lease liability	$ —	$ 127
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), two ready-to-use pre-filled syringe, or PFS, product candidates (Fedsyra and phenylephrine), 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.

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" below) 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 plans to study under an investigational device exemption, or IDE, and which 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, that it intends to develop for the treatment of one or more of the following indications: ARDS, DIC, acute pancreatitis or as an anti-viral agent.

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, 2023 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 termination of the Zalviso Royalty Monetization resulted in net income for the year ended December 31, 2022; however, prior to this, the Company had 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. Although, the Company raised additional capital in January 2024 (see Note 16, "Subsequent Events"), 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, including under the Controlled Equity Offering[SM] Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, 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 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 preparation of financial statements in conformity with accounting principles generally accepted in the United States, or GAAP, requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and the accompanying notes. Actual results could differ from those estimates.

The Company's audited financial statements as of December 31, 2022, included in the Company's Annual Report on Form 10-K filed with the SEC on March 31, 2023, were recast to reflect discontinued operations and filed with the Company's Current Report on Form 8-K on August 1, 2023. See Note 3, "Discontinued operations" below.

Reclassifications

Certain prior year amounts in the consolidated financial statements have been reclassified to conform to the current year's presentation. In particular, property and equipment, net and restricted cash, net of current portion have been reclassified as other assets, and operating lease liabilities, current portion, has been reclassified as accrued and other liabilities in the consolidated balance sheets.

Principles of Consolidation

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.

Use of Estimates

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, impairment of long-lived assets, management's assessment of going concern, revenue recognition, liability for royalty monetization and accrued clinical trial liabilities. 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.

Cash, Cash Equivalents and Restricted Cash

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.

On May 30, 2019, the Company entered into a Loan Agreement with Oxford Finance LLC, or Oxford, or the Lender. The Loan Agreement requires that the Company always maintain unrestricted cash of not less than $5.0 million in accounts subject to control agreements in favor of the Lender, tested monthly as of the last day of the month. The Company has classified these unrestricted funds as restricted cash on the consolidated balance sheets. On April 3, 2023, the Company repaid Oxford the full amount due under the loan, and the Loan Agreement was terminated with no further obligations by either party.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same such amounts in the consolidated statements of cash flows:

	Balance as of	
	December 31, 2023	December 31, 2021
Cash and cash equivalents	$ 5,721	$ 15,275
Restricted cash	—	5,000
Total cash, cash equivalents, and restricted cash	$ 5,721	$ 20,275

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.

Segment Information

The Company operates in a single segment, the development and commercialization of innovative therapies for use in medically supervised settings. The Company's revenue relates to the Company's services performed to support sales of DSUVIA to the Department of Defense, or DoD, by Alora under the Marketing Agreement (as defined in Note 3, "Discontinued Operations" below).

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.

Impairment of Long-Lived Assets

The Company periodically assesses the impairment of long-lived assets and, if indicators of asset impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through an analysis of the undiscounted future expected operating cash flows. If impairment is indicated, the Company records the amount of such impairment for the excess of the carrying value of the asset over its estimated fair value.

The Company realigned its cost structure from a focus on commercialization to a focus on advancing its late-stage development pipeline, namely the Niyad product candidates and the pre-filled syringes. As a result, the Company decided to not focus any development resources on Zalviso in the United States. In addition, due to the termination of the agreements with Grünenthal for Zalviso in Europe and the related withdrawal of the Marketing Authorization in Europe in July 2022, the Company did not expect any revenues from Zalviso in Europe in the foreseeable future. Accordingly, the Company determined that it was no longer probable that it would realize the future economic benefit associated with the costs of the Zalviso-related purchased equipment and manufacturing-related facility improvements the Company had made at its contract manufacturer and, therefore, recorded a non-cash impairment charge of $4.9 million to the Zalviso-related assets for the year ended December 31, 2022. The impairment charge was recorded as operating expense in the consolidated statement of operations. Depreciation and amortization expense was immaterial for the year ended December 31, 2022.

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.

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").

Revenue from Contracts with Customers

The Company follows the provisions of Accounting Standards Codification, or ASC, Topic 606, *Revenue from Contracts with Customers*. This guidance provides a unified model to determine how revenue is recognized. The Company recognizes revenue upon transfer of control of promised products or services to customers in an amount that reflects the consideration the Company expects to receive in exchange for those products or services. Prior to the divestment of DSUVIA to Alora, the Company sold its products primarily through wholesale and specialty distributors.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company's revenue relates to the Company's services performed to support sales of DSUVIA to the Department of Defense, or DoD, by Alora under the Marketing Agreement (as defined in Note 3, "Discontinued Operations" below). The Company's performance obligation is to serve as the exclusive sales agent for selling DSUVIA to the DoD through the term of the Marketing Agreement. The non-creditable and non-refundable revenues are variable consideration based on 75% of net sales of DSUVIA to the DoD during the period subject to certain adjustments. The Company evaluates if it is a principal or an agent in a transaction to determine whether revenue should be recorded on a gross or net basis depending on if it obtains control over the goods and services before they are transferred to customers. The Company is acting as an agent in relation to DSUVIA sales to the DoD.

The consideration in the Marketing Agreement reflects a variable amount, for which the Company estimates the amount of consideration to which it will be entitled by using the expected value method. The Company includes in the transaction price the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. Revenues are recognized when the DoD obtains control of the product, at which time the Company has an unconditional right to receive payment for such revenue earned.

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.

Restructuring Costs

The Company's restructuring costs consist of employee termination benefit costs. Liabilities for costs associated with the cost reduction plan are recognized when the liability is incurred and are measured at fair value. One-time termination benefits are expensed at the date the Company notifies the employee, unless the employee must provide future service, in which case the benefits are expensed ratably over the future service period.

In May 2022, the Company initiated a reorganization that eliminated approximately 40% of its employees, primarily within the commercial organization. For the year ended December 31, 2022, the Company incurred approximately $0.5 million in employee termination benefits related to this restructuring, all of which has been paid. This headcount reduction was completed in the second quarter of 2022. No additional expenses were incurred in connection with this cost reduction plan.

Non-Cash Interest Income on Liability Related to Sale of Future Royalties

In September 2015, the Company sold certain royalty and milestone payment rights from the sales of Zalviso in the European Union by Grünenthal to PDL for gross proceeds of $65.0 million, or the Zalviso Royalty Monetization. Grünenthal terminated the Grünenthal Agreements effective November 13, 2020. The terms of the Grünenthal Agreements were extended to May 2021 to enable Grünenthal to sell down its Zalviso inventory. The rights to market and sell Zalviso in the Territory reverted back to the Company in May 2021.

Under the Zalviso Royalty Monetization, the Company had a continuing obligation to use commercially reasonable efforts to negotiate a replacement license agreement, or New Arrangement. Under the relevant accounting guidance, because of the Company's significant continuing involvement, the Zalviso Royalty Monetization was accounted for as a liability that is being amortized using the effective interest method over the life of the arrangement. In order to determine the amortization of the liability, the Company was required to estimate the total amount of future royalty and milestone payments to be received by the Company and payments made to PDL, up to a capped amount of $195.0 million, over the life of the arrangement. The aggregate future estimated royalty and milestone payments (subject to the capped amount), less the $61.2 million of net proceeds the Company received, was to be amortized as interest expense over the life of the liability. Consequently, the Company imputed interest on the unamortized portion of the liability and recorded interest expense, or interest income, as these estimates were updated and recorded non-cash royalty revenues and non-cash interest income (expense), net, within its consolidated statements of operations over the term of the Zalviso Royalty Monetization.

When the expected payments under the Zalviso Royalty Monetization were lower than the gross proceeds of $65.0 million received, the Company deferred recognition of any probable contingent gain until the Zalviso Royalty Monetization liability expired. See Note 7, "Liability Related to Sale of Future Royalties".

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 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*.

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 Series A Redeemable Convertible Preferred Stock, and 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 Income (Loss) per Share of Common Stock".

Recently Adopted Accounting Pronouncements

In June 2016, the FASB, issued Accounting Standards Update, or ASU, 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. The measurement of expected credit losses is based on historical experience, current conditions, and reasonable and supportable forecasts that affect collectability. ASU 2016-13 also eliminates the concept of "other-than-temporary" impairment when evaluating available-for-sale debt securities and instead focuses on determining whether any impairment is a result of a credit loss or other factors. An entity will recognize an allowance for credit losses on available-for-sale debt securities rather than an other-than-temporary impairment that reduces the cost basis of the investment. The Company adopted ASU 2016-13 on January 1, 2023, using the modified retrospective approach, and no cumulative effect adjustment to accumulated deficit was needed as of the adoption date. Additionally, no prior period amounts were adjusted. The adoption of ASU 2016-13 did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

On December 14, 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 an 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, 2023 and 2022, the contractual maturity of all investments held was less than one year.

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

	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

	As of December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, cash equivalents and restricted cash:				
Cash	$ 13,275	$ —	$ —	$ 13,275
Money market funds	321	—	—	321
U.S. government agency securities	2,444	—	—	2,444
Commercial paper	4,235	—	—	4,235
Total cash, cash equivalents and restricted cash	20,275	—	—	20,275
Short-term investments:				
Commercial paper	495	—	—	495
Total short-term investments	495	—	—	495
Total cash, cash equivalents, restricted cash and short-term investments	$ 20,770	$ —	$ —	$ 20,770

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, 2023 or 2022. As such, we did not record a credit allowance for the year ended December 31, 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, 2023 and December 31, 2022, 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 (see Note 10, "Warrants" below). 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 interest income and other income, net 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, 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

	As of December 31, 2022			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 321	312	—	—
U.S. government agency securities	2,444	—	2,444	—
Commercial paper	4,730	—	4,730	—
Total assets measured at fair value	$ 7,495	$ 321	$ 7,174	$ —
Liabilities				
Warrant liability	$ 7,098	$ —	$ —	$ 7,098
Total liabilities measured at fair value	$ 7,098	$ —	$ —	$ 7,098

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, 2023 and 2022 (in thousands):

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

There were no transfers between Level I, Level II or Level III of the fair value hierarchy during the years ended December 31, 2023 or 2022.

3. Discontinued Operations

Asset Purchase 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. With the closing of the transaction, 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 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 assets and liabilities associated with these operations have been classified as assets and liabilities of discontinued operations in the consolidated balance sheets at December 31, 2023 and 2022. 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,	
	2023	2022
Total revenues	$ 501	$ 1,771
Cost of goods sold	711	1,508
Selling, general and administrative expense	731	9,744
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	1,852
Loss from discontinued operations	(8,110)	(11,333)
Interest expense	—	37
Net loss from discontinued operations	$ (8,110)	$ (11,370)

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

	December 31, 2023	December 31, 2022
Accounts receivable, net	$ —	$ 309
Inventories	—	1,178
Prepaid expenses and other current assets	—	444
Total current assets of discontinued operations	—	1,931
Property, plant and equipment, net	—	10,261
Operating lease right-of-use assets	—	3,499
Other assets	—	176
Total non-current assets of discontinued operations	—	13,936
Total assets of discontinued operations	$ —	$ 15,867
Accounts payable	$ 10	$ 784
Accrued liabilities	721	1,720
Operating lease liabilities, current portion	—	1,601
Note payable, current portion	—	400
Deferred revenue, current portion	—	115
Total current liabilities of discontinued operations	731	4,620
Operating lease liabilities, net of current portion	—	2,959
Deferred revenue, net of current portion	—	1,036
Total non-current liabilities of discontinued operations	—	3,995
Total liabilities of discontinued operations	731	8,615
Net assets (liabilities) of discontinued operations	$ (731)	$ 7,252

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,	
	2023	2022
Cash flows from operating activities:		
Depreciation and amortization	$ 215	$ 1,465
Stock-based compensation	19	250
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)	(364)

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)

4. Asset Acquisition

On January 7, 2022, the Company closed its acquisition of Lowell and acquired the product nafamostat, and the associated patents and historical know-how. The acquisition was valued at approximately $32.5 million plus cash acquired of $3.5 million and certain other adjustments. All options to purchase capital stock and all shares of Lowell capital stock issued and outstanding immediately before the effective time of the merger were cancelled in exchange for the right to receive (i) 450,477 shares of the Company's common stock issued at a five day daily volume weighted average price of $11.46 per share as of January 7, 2022, or the Acquisition Date, valued at $5.2 million on closing, (ii) cash in the amount of $3.5 million, (iii) 69,808 shares of the Company's common stock to be held back to satisfy any potential indemnification and other obligations of Lowell and its securityholders valued at $0.8 million, (iv) $0.5 million cash and stock paid for sellers' transaction costs and (v) up to $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.

The shares issued in the merger were issued in a private placement pursuant to the exemption from registration under Section 4(a)(2) of the Securities Act of 1933, as amended, or the Securities Act, including Rule 506 of Regulation D promulgated under the Securities Act, or Regulation D, without general solicitation as a transaction not involving any public offering.

The merger has been accounted for as an asset acquisition of a single IPR&D asset that has an alternative future use. The initial measurement of the asset purchased of $8.8 million was based on the purchase cost of $12.4 million including (i) $6.0 million common stock fair value on the closing date (issued and held back on the acquisition date), (ii) $0.5 million seller's costs paid by the Company, (iii) $3.5 million cash and (iv) approximately $2.5 million of transaction costs less purchase price allocated to cash acquired of $3.5 million. Due to the nature of regulatory and sales-based milestones, the contingent consideration of up to $26.0 million was not included in the initial cost of the assets purchased as they are contingent upon events that are outside the Company's control, such as regulatory approvals and issuance of patents, and 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, 2023, none of the contingent events have occurred.

The following table summarizes the total consideration for the acquisition and the value of the IPR&D asset acquired (in thousands):

Consideration		
Cash	$	3,536
Issuance of common stock to Lowell security holders in connection with asset acquisition		5,161
Issuance of common stock to settle Lowell's transaction costs in connection with asset acquisition		350
Liability for issuance of 69,808 hold back shares to Lowell securityholders[(1)]		800
Transaction costs		2,521
Total consideration	$	12,368
IPR&D Asset Acquired		
Purchase price	$	12,368
Cash acquired		(3,549)
Total IPR&D asset acquired[(2)]	$	8,819

(1) Recorded as Other long-term liabilities in the consolidated balance sheets at December 31, 2022. Shares were issued in the year ended December 31, 2023 and, accordingly, the related liability was extinguished.

(2) Recorded as In-process research and development asset in the consolidated balance sheets.

The IPR&D asset has initially been accounted for as an indefinite-lived asset, and as a long-lived asset, it is reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. 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. No impairment losses were recorded on the IPR&D asset during the years ended December 31, 2023 or 2022.

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, 2023, 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.

As of December 31, 2022, the accrued balance due under the Loan Agreement with Oxford was $5.4 million. Interest expense related to the Loan Agreement was $0.1 million for the year ended December 31, 2023, $0.1 million of which represented amortization of the debt discount. Interest expense related to the Loan Agreement was $1.1 million, of which $0.4 million represented amortization of the debt discount, and $2.2 million for the year ended December 31, 2022 and the effective interest rate was approximately 13.6%.

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.

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 Warrants. The 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. For further discussion, see Note 10, "Warrants".

7. Liability Related to Sale of Future Royalties

On September 18, 2015, the Company entered into the Zalviso Royalty Monetization with PDL for which it received gross proceeds of $65.0 million. Under the Zalviso Royalty Monetization, PDL was to receive 75% of the European royalties under the Amended License Agreement with Grünenthal, as well as 80% of the first four commercial milestones worth $35.6 million (or 80% of $44.5 million), up to a capped amount of $195.0 million over the life of the arrangement.

The Company periodically assessed the expected royalty and milestone payments using a combination of historical results, internal projections and forecasts from external sources. To the extent such payments were greater or less than the Company's initial estimates or the timing of such payments is materially different than its original estimates, the Company prospectively adjusted the amortization of the liability and the effective interest rate. Grünenthal notified the Company that it was terminating the Amended License Agreement effective November 13, 2020. On August 31, 2020, PDL sold its royalty interest for Zalviso to SWK Funding, LLC, or SWK, under the Zalviso Royalty Monetization. The terms of the Grünenthal Agreements were extended to May 12, 2021 to enable Grünenthal to sell down its Zalviso inventory. The rights to market and sell Zalviso in Europe reverted back to the Company on May 12, 2021.

On May 31, 2022, the Company entered into a Termination Agreement with SWK to fully terminate the Zalviso Royalty Monetization for which the Company paid cash consideration of $0.1 million, and neither PDL nor SWK retains any further interest in the Zalviso Royalty Monetization. Accordingly, effective May 31, 2022, the Zalviso Royalty Monetization is no longer reflected on the Company's consolidated financial statements or other records as a sale of assets to PDL or SWK and all security interests and other liens of every type held by the parties to the Zalviso Royalty Monetization have been terminated and automatically released without further action by any party. The $84.1 million gain on extinguishment of the liability related to the sale of future royalties is recognized in the consolidated statements of operations as other income.

The effective interest income rate for the year ended December 31, 2022 was approximately 3.2%.

The following table shows the activity within the liability account during the year ended December 31, 2022 (in thousands):

	Year ended December 31, 2022	Period from inception to December 31, 2022
Liability related to sale of future royalties — beginning balance	$ 85,288	$ —
Proceeds from sale of future royalties	—	61,184
Non-cash royalty revenue	—	(1,083)
Non-cash interest (income) expense recognized	(1,136)	24,051
Consideration paid for termination of Royalty Monetization	(100)	(100)
Gain on extinguishment of liability related to sale of future royalties	(84,052)	(84,052)
Liability related to sale of future royalties as of December 31, 2022	$ —	$ —

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. On September 1, 2022, the Court held oral hearings on the Company's motion to dismiss the amended complaint with prejudice that was filed on July 21, 2022. On September 28, 2022, the Court issued a formal written opinion, or the First Opinion, dismissing all of the plaintiff's claims against the Company and the named defendants with leave for plaintiffs to amend their complaint. On November 28, 2022 the plaintiffs filed their second amended complaint. On July 7, 2023, the Court issued a formal written opinion, or the Second Opinion, dismissing all of the plaintiff's claims against the Company and the named defendants with leave for plaintiffs to amend their complaint in part and without leave to amend in part. On September 5, 2023, the plaintiffs filed a third amended complaint. Defendants' motion to dismiss the third amended complaint is fully briefed and a hearing is scheduled for April 4, 2024.

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. The complaint names nine of the Company's officers and directors and asserts the same claims as those in the previously filed derivative actions. The Company has not yet been served.

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, 2023, 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.

Preferred Stock

On August 3, 2022, the Company entered into a securities purchase agreement with LPC, or the Purchaser, pursuant to which the Company issued, in a private placement transaction, 3,000 shares of Series A Redeemable Convertible Preferred Stock, par value $0.001 per share, with $100 per share stated value, together with a warrant to purchase up to an aggregate of 81,150 shares of common stock at an exercise price of $4.07 per share, for $0.3 million (see Note 10, "Warrants"). The transaction price of $0.3 million was allocated to the Series A Redeemable Convertible Preferred Stock and warrants based on their relative fair values. The Series A Redeemable Convertible Preferred Stock was initially recorded at $0.1 million separately from stockholders' equity in the Company's consolidated balance sheets due to the shares being redeemable based on contingent events outside of the Company's control.

The Series A Redeemable Convertible Preferred Stock was convertible, at the option of the holders, into shares of common stock at a conversion price of approximately $3.70 per share, subject to adjustment and beneficial ownership limitations set forth in the Certificate of Designation. The Company had the option to redeem the Series A Redeemable Convertible Preferred Stock for cash at 105% of the Stated Value on the date of and for 15 days following the Reverse Stock Split, subject to the Purchaser's right to convert the shares prior to such redemption. The Purchaser had the right to require the Company to redeem the shares of Series A Redeemable Convertible Preferred Stock for cash at 110% of the Stated Value of such shares commencing after the Company's right to redeem expired. The Series A Redeemable Convertible Preferred Stock was required to redeemed for cash at 110% of the Stated Value upon a delisting event. As a result, the Series A Redeemable Convertible Preferred Stock was recorded separately from stockholders' equity because it was redeemable upon the occurrence of redemption events that were considered not solely withing the Company's control. As such, during the year ended December 31, 2022, the Company recognized approximately $0.2 million in deemed dividends related to the Series A Redeemable Convertible Preferred Stock in the consolidated statements of operations and the consolidated statements of changes in redeemable convertible preferred stock and stockholders' equity.

The holders of the Series A Redeemable Convertible Preferred Stock were entitled to certain registration rights, rights for approval of increases in the authorized shares of such series, and to dividends paid on common stock on an as-if converted basis. The Series A Redeemable Convertible Preferred stock had no voting rights, other than the right to (i) vote exclusively on the Reverse Stock Split and any proposal to adjourn any meeting of stockholders called for the purpose of voting on the Reverse Stock Split and (ii) to 1,000,000 votes per each share of Series A Redeemable Convertible Preferred Stock, to vote together with the common stock, as a single class; to the extent cast on the Reverse Stock Split in the same proportion as

shares of common stock. In addition, in the event of any liquidation, dissolution, or winding-up of the Company, the holders of the Series A Redeemable Convertible Preferred Stock were entitled to receive 110% the preferred stock's Stated Value plus any declared but unpaid dividends before any payment was made to holders of common stock.

On October 11, 2022, the Company and LPC entered into the Securities Redemption Agreement whereby on October 12, 2022, the Company redeemed for cash at a price equal to 105% of the Stated Value per share all 3,000 outstanding shares of Series A Redeemable Convertible Preferred Stock for $0.3 million. As a result, all shares of such series were retired and are no longer outstanding. On October 25, 2022, the Company filed a certificate of elimination to its amended and restated certificate of incorporation which (i) eliminated the previous designation of 3,000 shares of Series A Redeemable Convertible Preferred Stock from the Company's amended and restated certificate of incorporation and (ii) caused such shares of Series A Redeemable Convertible Preferred Stock to resume their status as authorized but unissued and non-designated shares of preferred stock.

Common Stock

July 2023 Private Placement

On July 17, 2023, the Company entered into a securities purchase agreement, or the Purchase Agreement, with several institutional investors, or the Purchasers, relating to the issuance and sale to the Purchasers in a private placement of 5,340,591 shares of common stock, par value $0.001 per share, 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. See Note 10, "Warrants" for additional information regarding the July 2023 Pre-Funded Warrants, and July 2023 Series A and Series B common stock warrants. The private placement closed on July 20, 2023.

The combined offering price 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 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 private placement. The potential gross proceeds from the July 2023 Series A common stock warrants and July 2023 Series B common stock warrants, if fully exercised for cash, is approximately $16.3 million.

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 resulting in cumulative aggregate gross proceeds to the Company of at least $9.5 million in cash. As of December 31, 2023, none of the July 2023 Series A or Series B common stock warrants were exercised. 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 placement agent July 2023 Series A and Series B common stock warrants.

December 2022 Registered Direct Offering

On December 29, 2022, the Company completed the December 2022 Financing in which it issued (i) 748,744 shares of its common stock, par value $0.001 per share, (ii) the December 2022 Pre-Funded Warrants to purchase 2,632,898 shares of common stock, and (iii) the December 2022 Common Stock Warrants, which accompany the common stock and December 2022 Pre-Funded Warrants, to purchase an aggregate of 4,227,052 shares of common stock (see Note 10, "Warrants"). The shares of common stock and accompanying December 2022 Warrants were sold at a combined offering price of $2.22625 per share and accompanying common warrant, and the December 2022 Pre-Funded Warrants and accompanying December 2022 Common Stock Warrants were sold at a combined offering price of $2.22615 per December 2022 Pre-Funded Warrant and accompanying December 2022 Common Stock Warrant. The December 2022 Financing resulted in aggregate gross proceeds of $7.5 million, before $1.7 million of transaction costs, $0.8 million of which were non-cash issuance costs,

excluding the proceeds, if any, from the exercise of the December 2022 Pre-Funded Warrants and the December 2022 Common Stock Warrants. The common stock was allocated $0.1 million of the gross proceeds received based on its relative fair value to the other instruments issued (see Note 10, “Warrants”).

January 2024 Private Placement

On January 17, 2024, the Company entered into a private placement with certain institutional investors 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 study of Niyad, and an additional $2.0 million if Talphera stock trades above a specified price following the NEPHRO registration trial announcement, before deducting offering expenses payable by us (see Note 16, “Subsequent Events” below for additional information).

ATM Agreement

On June 21, 2016, the Company entered into a Controlled Equity Offering℠ Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, as agent, pursuant to which the Company may offer and sell, from time to time through Cantor, shares of the Company’s common stock, or the Common Stock having an aggregate offering price of up to $40.0 million, or the Shares. On May 9, 2019, the Company increased the aggregate offering price of shares of the Company’s common stock which may be offered and sold under the ATM Agreement by $40.0 million, for a total of $80.0 million, or the Shares. The offering of Shares pursuant to the ATM Agreement will terminate upon the earlier of (a) the sale of all of the Shares subject to the ATM Agreement or (b) the termination of the ATM Agreement by Cantor or the Company, as permitted therein. The Company will pay Cantor a commission rate in the low single digits on the aggregate gross proceeds from each sale of Shares and has agreed to provide Cantor with customary indemnification and contribution rights.

The Company issued and sold 124,330 shares of common stock pursuant to the ATM Agreement and received net proceeds of $0.5 million, after deducting fees and expenses, during the year ended December 31, 2022. No shares were sold under the ATM Agreement in the year ended December 31, 2023.

As of December 31, 2023, the Company had the ability to offer and sell shares of the Company’s common stock having an aggregate offering price of up to $35.6 million under the ATM Agreement. The Company’s ability to sell shares under the ATM Agreement will be limited until the Company is no longer subject to the SEC’s “baby shelf” limitations.

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 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 October 10, 2023, at the 2023 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 1,500,000 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 be issued under the Amended 2020 Plan will not exceed the sum of: (i) 1,990,000 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.

Amended and Restated 2011 Employee Stock Purchase Plan

Additionally, 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.

In the year ended December 31, 2023, there were 42,209 shares issued under the Amended ESPP. The weighted average fair value of shares issued under the Amended ESPP in 2023 and 2022 was $1.08 and $6.82 per share, respectively. As of December 31, 2023, there were 169,667 shares available for future grant under the Amended ESPP.

10. Warrants

The activity related to warrants during the years ended December 31, 2023 and 2022, is summarized as follows:

	Common Stock from Warrants	Weighted-average Exercise Price (per share)
Outstanding at December 31, 2021	883,833	$ 5.15
Granted	6,941,100	$ 1.27
Outstanding at December 31, 2022	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
Exercisable at December 31, 2023	21,682,049	$ 1.40

At December 31, 2023, 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	1,416,473	Unlimited	1,416,473	$ 0.001
$ 1.11	14,787,044	4.62	14,787,044	$ 1.11
$ 1.70	367,647	4.62	367,647	$ 1.70
$ 2.07	4,977,052	5.07	4,977,052	$ 2.07
$ 20.00	125,000	2.92	125,000	$ 20.00
$ 56.60	8,833	5.49	8,833	$ 56.60
Total	21,682,049	5.06	21,682,049	$ 1.40

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 and an exercise price of $0.001 per share.

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 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.

The placement agent July 2023 Series A and Series B Common Stock Warrants have the same terms as the July 2023 Series A and Series B Common Stock Warrants to be issued to the purchasers, 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, 2023, all of 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 had not been exercised and 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, 2023.

On January 17, 2024, certain of these July 2023 Series A and Series B Common Stock Warrants were amended to reduce the exercise price to $0.77 per share in connection with the January 2024 Private Placement (see Note 16, "Subsequent Events" below for additional information).

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. The December 2022 Common Stock Warrants were valued upon issuance at approximately $7.1 million, using the Black-Scholes option pricing model as follows: exercise price of $2.07 per share, stock price of $2.13 per share, expected life of 6 years, volatility of 95.44%, a risk-free rate of 3.93% and 0% expected dividend yield. Accordingly, the Company allocated the fair value of $7.1 million of the gross proceeds received to Warrant liability on it consolidated balance sheets. The aggregate remaining gross proceeds of $0.4 million were allocated to the two remaining securities using the relative fair value method, resulting in the common stock and the December 2022 Pre-Funded Warrants being allocated values of $0.1 million and $0.3 million, respectively, and such amount being recorded to stockholders' equity.

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. See Note 2, "Investments and Fair Value Measurement" above.

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

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.

The August 2022 LPC Warrant was originally valued at approximately $0.3 million using the Black-Scholes option pricing model as follows: exercise price of $4.07 per share, stock price of $4.44 per share, expected life of 5.5 years, volatility of 89.94%, a risk-free rate of 2.86% and 0% expected dividend yield. The Series A Redeemable Convertible Preferred Stock and the August 2022 LPC Warrant were issued in a unit structure with the August 2022 LPC Warrant eligible to be classified in stockholders' equity, therefore the aggregate net proceeds of $0.2 million were allocated to the two securities using the relative fair value method, resulting in the Series A Redeemable Convertible Preferred Stock and the August 2022 LPC Warrant being allocated values of $0.1 million and $0.1 million, respectively, and recorded to stockholders' equity.

As of December 31, 2023, 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.

The November 2021 Financing warrants were valued at approximately $8.6 million using the Black-Scholes option pricing model as follows: exercise price of $20.00 per share, stock price of $14.92 per share, expected life of five years, volatility of 91.77%, a risk-free rate of 1.26% and 0% expected dividend yield. The common stock and warrants were issued in a unit structure; therefore, in accordance with ASC Topic 815, the aggregate gross proceeds of $14.0 million were allocated to the two securities using the relative fair value method, resulting in the common stock and warrants being allocated values of $8.4 million and $5.6 million, respectively, and recorded to stockholders' equity.

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 modification of these November 2021 Financing Warrants lowered the exercise price to the price per share in the December 2022 Financing. These November 2021 Financing Warrants remained a freestanding equity-classified instrument following the modification. The Company concluded that the modification of these November 2021 Financing Warrants provided more favorable terms to the Purchaser with the purpose of inducing the Purchaser to complete the December 2022 Financing. Pursuant to ASU 2021-04, the Company remeasured the fair value of the November 2021 Financing Warrants as of the modification date based on the modified terms and recorded the increase in fair value of $0.8 million as equity issuance costs, $0.7 million of which was allocated to selling, general and administrative expenses and $0.1 million of which was allocated to additional paid in capital, based on the relative fair values of the 2022 Warrants, classified as liabilities, and the Common Stock and Pre-funded Warrants, classified in equity, respectively. The fair value assumptions related to the modification of these 750,000 November 2021 Financing Warrants as of December 29, 2022 were as follows: exercise price of $2.07 per share, stock price of $2.13 per share, expected life of six years, volatility of 95.44%, a risk-free rate of 3.93% and 0% expected dividend yield.

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, 2023, all of the November 2021 Financing Warrants had not been exercised and were still 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.

As of December 31, 2023, Loan Agreement Warrants to purchase 8,833 shares of common stock issued to the Lender and its affiliates had not been exercised and were still outstanding. These warrants expire in May 2029.

January 2024 Private Placement

On January 17, 2024, the Company entered into a private placement with certain institutional investors 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 study of Niyad, and an additional $2.0 million if Talphera stock trades above a specified price following the NEPHRO registration trial announcement, before deducting offering expenses payable by us (see Note 16, "Subsequent Events" below for additional information).

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):

	December 31, 2023	December 31, 2022
Research and development	$ 498	$ 570
Selling, general and administrative	1,212	2,069
Discontinued operations	19	250
Total	$ 1,729	$ 2,889

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, 2022	88,711	$ 34.16
Granted	58,502	7.75
Vested	(44,744)	35.46
Forfeited	(19,691)	25.00
Restricted stock units outstanding, December 31, 2022	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

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)
December 31, 2022	725,623	$ 52.98		
Granted	288,929	1.67		
Forfeited	(14,673)	9.72		
Expired	(106,558)	83.88		
Exercised	—	—		
December 31, 2023	893,321	$ 33.41	6.3	$ 1
Vested and exercisable options—December 31, 2023	488,725	$ 53.69	4.3	$ —
Vested and expected to vest—December 31, 2023	893,321	$ 33.41	6.3	$ 1

As of December 31, 2023, there were 1,631,319 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, 2023 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 - $1.76	281,505	9.2	$ 1.67	—	$ —
$4.62 - $6.93	15,350	8.5	$ 5.21	12,818	$ 4.93
$8.03 - $12.045	86,817	8.1	$ 8.08	40,123	$ 8.09
$14.40 - $21.60	14,633	5.9	$ 16.55	13,418	$ 16.61
$22.40 - $33.60	11,700	7.1	$ 28.62	11,386	$ 28.68
$34,40 - $51.60	280,662	5.4	$ 41.01	208,326	$ 42.23
$57.40 - $86.10	169,213	2.7	$ 64.86	169,213	$ 64.86
$94.60 - $141.90	17,371	1.0	$ 127.59	17,371	$ 127.59
$204.40 - $306.60	16,070	0.2	$ 206.24	16,070	$ 206.24
	893,321	6.3	$ 33.41	488,725	$ 53.69

The weighted average grant-date fair value of options granted during the years ended December 31, 2023 and 2022 was $1.32 and $5.80 per share, respectively. As of December 31, 2023, total stock-based compensation expense related to unvested options to be recognized in future periods was $0.9 million which is expected to be recognized over a weighted-average period of 2.1 years. The grant date fair value of options vested during the years ended December 31, 2023 and 2022 was $0.9 million and $1.7 million, respectively. The total intrinsic value of options exercised during the years ended December 31, 2023 and 2022 was $0 and $0, respectively.

The Company has granted performance-based stock options to certain of its executive officers, which are included in the stock option tables and associated disclosures above. 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 performance-based stock options are eligible to vest subject to the satisfaction of the service-based vesting requirements and attainment of share price target goals, a market-based condition. No performance-based stock options vested during the years ended December 31, 2023 and 2022.

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

	Year Ended December 31,	
	2023	2022
Expected term (in years)	6.3	6.3
Risk-free interest rate	3.9% - 4.6%	1.6% - 3.0%
Expected volatility	94%	88%
Expected dividend rate	0%	0%

12. Net Income (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, the Series A Redeemable Convertible Preferred Stock 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 year ended December 31, 2023 was attributed entirely to common stockholders. For the year ended December 31, 2022, the Company presented diluted EPS using the two-class method as it was more dilutive. 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 July 2023 and December 2022 Pre-Funded Warrants issued with a de minimis exercise price of $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 table sets forth the computation of the Company's basic and diluted net income (loss) per share of common stock during the years ended December 31, 2023 and 2022 (in thousands, except for share and per share amounts):

	Year Ended December 31,	
	2023	2022
	(in thousands, except share and per share amounts)	
Basic net income (loss) per common share:		
Net income (loss) from continuing operations	$ (10,287)	$ 59,125
Less: deemed dividends related to Series A Redeemable Convertible Preferred Stock	—	(186)
Less: income allocated to participating securities	—	(5,240)
Net income (loss) from continuing operations attributable to common shareholders, basic	(10,287)	53,699
Net loss from discontinued operations attributable to common shareholders, basic	(8,110)	(11,370)
Net income (loss) attributable to common shareholders, basic	$ (18,397)	$ 42,329
Weighted average shares outstanding — basic	14,263,744	7,385,348
Income (loss) from continuing operations, basic	$ (0.72)	$ 7.27
Loss from discontinued operations, basic	$ (0.57)	$ (1.54)
Net income (loss) per share, basic	$ (1.29)	$ 5.73
Diluted net income (loss) per common share:		
Net income (loss) from continuing operations	$ (10,287)	$ 59,125
Less: deemed dividends related to Series A Redeemable Convertible Preferred Stock	—	(186)
Less: income allocated to participating securities	—	(5,227)
Net income (loss) from continuing operations attributable to common shareholders, diluted	(10,287)	$ 53,712
Net loss from discontinued operations attributable to common shareholders, diluted	(8,110)	$ (11,370)
Net income (loss) attributable to common shareholders, diluted	$ (18,397)	$ 42,342
Weighted average shares outstanding — basic	14,263,744	7,385,348
Dilutive effect of warrants	—	20,285
Dilutive effect of RSUs	—	1,353
Weighted average shares outstanding — diluted	14,263,744	7,406,986
Income (loss) from continuing operations, diluted	$ (0.72)	$ 7.25
Loss from discontinued operations, diluted	$ (0.57)	$ (1.53)
Net income (loss) per share, diluted	$ (1.29)	$ 5.72

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,	
	2023	2022
ESPP, RSUs and stock options to purchase common stock	979,553	815,710
Common stock warrants	20,265,576	133,833

13. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2023	2022
Accrued compensation and employee benefits	$ 2,005	$ 1,732
Accrued professional services	121	456
Other accrued liabilities	319	343
Total accrued liabilities	$ 2,445	$ 2,531

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 and $0.3 million for the years ended December 31, 2023 and 2022, respectively.

15. Income Taxes

The Company recorded a provision for income taxes of $0 thousand and $13 thousand for the years ended December 31, 2023 and 2022, respectively.

Net deferred tax assets as of December 31, 2023 and 2022 consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Deferred tax assets:		
Accruals and other	$ 1,717	$ 3,790
Research credits	7,839	7,392
Net operating loss carryforward	88,839	84,325
Section 59(e) R&D expenditures	1,937	3,496
Section 174 R&D expenditures	1,651	981
Total deferred tax assets	101,983	99,984
Deferred tax liabilities:		
IP from Acquisition	(1,874)	(2,052)
Total deferred tax liabilities	(1,874)	(2,052)
Valuation allowance	(100,109)	(97,932)
Net deferred tax assets	$ —	$ —

Reconciliations of the statutory federal income tax to the Company's effective tax during the years ended December 31, 2023 and 2022 are as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Tax at statutory federal rate	$ (3,862)	$ 10,031
State tax—net of federal benefit	2,495	823
Acquired assets	—	1,728
Stock options	738	611
Other	(431)	355
Change in valuation allowance	2,177	(13,520)
Revaluation of Put Option Liability	(1,117)	(15)
Provision for income taxes	$ —	$ 13

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 $2.2 million and decreased by $13.5 million during the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, the Company had federal net operating loss carryforwards of $377.7 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 $262.8 million generated from 2018 to 2023 will carryforward indefinitely but are subject to the 80% taxable income limitation. As of December 31, 2023, the Company had state net operating loss carryforwards of $137.4 million, which begin to expire in 2028.

As of December 31, 2023, the Company had federal research credit carryovers of $7.0 million, which begin to expire in 2026. As of December 31, 2023, the Company had state research credit carryovers of $4.4 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, 2023 and 2022 is as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Unrecognized benefit—beginning of period	$ 2,678	$ 2,635
Gross increases—prior period tax positions	—	—
Gross increases—current period tax positions	157	43
Unrecognized benefit—end of period	$ 2,835	$ 2,678

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, 2023 and 2022. The Company files income tax returns in the United States, California, and other states. The tax years 2005 through 2014, and 2016 through 2023, 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, 2022 or 2023. 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. Subsequent Events

Purchase Agreement with XOMA

On January 12, 2024, the Company and XOMA (US) LLC, or XOMA, entered into a Payment Interest Purchase Agreement, or 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 royalty 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 a certain minimum amount of payments in respect of the foregoing, or the XOMA Threshold, or the Stepdown Date; and

(ii) following the Stepdown Date, (A) 100% of royalty 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.

Securities Purchase Agreements

On January 17, 2024, the Company entered into Securities Purchase Agreements, or the Securities Purchase Agreements, with certain institutional investors, or the Purchasers, relating to the issuance and sale of pre-funded warrants to the Purchasers in a two-tranche private placement, or the Private Placement, to purchase shares of the Company’s common stock, par value $0.001 per share, or the Common Stock, at a purchase price of $0.769 per share and an exercise price of $0.001 per share, or the Pre-Funded Warrants. The Pre-Funded Warrants are exercisable immediately following each closing date of the Private Placement and have an unlimited term.

The terms of the Private Placement include:

(i) the first tranche of the Private Placement, which closed on January 22, 2024, resulted in the aggregate gross proceeds to the Company of approximately $6.0 million excluding the proceeds, if any, from the exercise of the Pre-Funded Warrants issued in such tranche.

(ii) the second tranche of the Private Placement, which is a conditional purchase by the Purchasers subject to either (a) the satisfaction or waiver of achieving a pivotal trial milestone event, or the Pivotal Trial Milestone, 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 pivotal trial data being at least $0.92 per share, or the Price Milestone, which will result in additional aggregate gross proceeds to the Company of approximately $10.0 million with respect to the Pivotal Trial Milestone and $2.0 million with respect to the Price Milestone, excluding the proceeds, if any, from the exercise of the Pre-Funded Warrants issued in such closing.

In the first tranche of the Private Placement, the Company issued Pre-Funded Warrants to purchase up to 7,792,208 shares of Common Stock. In the second tranche of the Private Placement, the Company is expected to issue (i) in connection with achieving the Pivotal Trial Milestone, Pre-Funded Warrants to purchase up to 12,987,013 shares of Common Stock, and (ii) in connection with achieving the Price Milestone, Pre-Funded Warrants to purchase up to 2,597,402 shares of Common Stock.

Any of the conditions in the second tranche can be waived by each Purchaser.

The Securities Purchase Agreements contain customary representations, warranties and agreements by the Company and the Purchasers, indemnification rights and other obligations of the parties.

Registration Rights Agreement

In connection with the Private Placement, the Company entered into a registration rights agreement, dated January 17, 2024, with the Purchasers, or the Registration Rights Agreement, pursuant to which the Company has agreed to file one or more registration statements under the Securities Act of 1933, as amended, or the Securities Act with the Securities and Exchange Commission, or the SEC, covering the resale of the shares of Common Stock underlying the Pre-Funded Warrants no later than 15 days following the date of each applicable closing of the Private Placement, and to use reasonable best efforts to have the registration statements declared effective as promptly as practical thereafter, and in any event no later than 90 days following the applicable closing date in the event of a "full review" by the SEC.

Amendment of Prior Warrants

On July 20, 2023, in connection with a prior private placement, the Company issued to certain of the Purchasers (i) Series A common stock purchase warrants to purchase up to 3,676,473 shares of Common Stock and (ii) Series B common stock purchase warrants to purchase up to 3,676,473 shares of Common Stock, or the Prior Warrants. In connection with the current Private Placement, the Company and the Purchasers agreed to amend and restate, a portion of the outstanding Prior Warrants, representing (i) Series A common stock purchase warrants to purchase up to 2,941,178 shares of Common Stock and (ii) Series B common stock purchase warrants to purchase up to 2,941,178 shares of Common Stock, to reduce the exercise price thereunder to $0.77 per share.