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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 31, 2023

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	**001-35068**	**41-2193603**
(State of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

25821 Industrial Blvd., Suite 400
Hayward, CA 94545
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(650) 216-3500**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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	ACRX	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 8.01 Other Events.

On March 12, 2023, AcelRx Pharmaceuticals, Inc., or AcelRx, entered into an Asset Purchase Agreement, or the Purchase Agreement, with Vertical Pharmaceuticals, LLC, a wholly owned subsidiary of Alora Pharmaceuticals, LLC, or the Buyer, pursuant to which Buyer agreed to acquire certain assets and assume certain liabilities of AcelRx relating to its sufentanil sublingual tablet product referred to as DSUVIA or DZUVEO, or any other single-dose pharmaceutical product for use in medically supervised settings containing a sublingual tablet that includes sufentanil as the sole active ingredient, as a 30 mcg tablet or other dosage form or strength as reasonably necessary for lifecycle management, or the Product. The Product expressly excludes the pharmaceutical product referred to as Zalviso (sufentanil sublingual tablets, each 15 mcg), any other multi-dose administration system containing sufentanil sublingual tablets (whether as the sole active ingredient or in combination with other active ingredients), and any single-dose formulation of sufentanil for use outside of a medically supervised setting.

The Company's DSUVIA business met the definition of a discontinued operation as of March 31, 2023. Accordingly, the assets and liabilities associated with these operations were classified as assets and liabilities of discontinued operations as of and for the three-month period ended March 31, 2023, and the year ended December 31, 2022, and the operations and cash flows of the DSUVIA business were presented as discontinued for all periods presented within the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 (the "First Quarter Form 10-Q"), filed with the U.S. Securities and Exchange Commission (the "SEC") on May 10, 2023.

The Company has revised the following sections of its Annual Report on Form 10-K for the year ended December 31, 2022 (the "2022 Annual Report") to reflect the DSUVIA business as discontinued operations. This update is consistent with the presentation of continuing and discontinued operations included in the Company's First Quarter Form 10-Q.

- Exhibit 99.1: Item 7. Management's Discussion and Analysis of Results of Operations and Financial Condition; and
- Exhibit 99.2: Item 8. Financial Statements and Supplementary Data.

The information included in Exhibits 99.1 and 99.2 to this Current Report is presented in connection with the reporting change described above and does not otherwise amend or restate any other portions of the 2022 Annual Report. Except for the matter noted above, Exhibits 99.1 and 99.2 to this Current Report do not reflect events occurring after the Company filed its 2022 Annual Report. Information contained in Exhibits 99.1 and 99.2 should be read in conjunction with and as a supplement to information contained in the 2022 Annual Report. For information on events occurring since the filing of the 2022 Annual Report, please refer to the Company's subsequent filings with the Securities and Exchange Commission.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that involve risks and uncertainties. Such forward-looking statements, including statements relating to the clinical development of the Company's product candidates, reflect the Company's expectations about its future performance and opportunities that involve substantial risks and uncertainties. When used herein, the words "potential," "believe," "expect," "expects," "expected," "anticipate," "may," "will," "enable," "should," "seek," "approximately," "intends," "intended," "plans," "planned," "planning," "estimates," "benefits," or the negative of these words or other comparable terminology and similar expressions, as they relate to the Company or its management, are intended to identify such forward-looking statements. These forward-looking statements are based on information available to the Company as of the date of this Current Report on Form 8-K and are subject to a number of risks, uncertainties, and other factors that could cause the Company's performance to differ materially from those expressed in, or implied by, these forward-looking statements. These risks and uncertainties include, among other things, risks related to the Company's product development activities and ongoing commercial business operations; risks related to the Company's ability and that of its business partners to implement development plans, launch plans, forecasts and other business expectations; risks related to unexpected variations in market growth and demand for the Company's commercial and developmental products and technologies; risks related to the Company's liquidity and its ability to maintain capital resources sufficient to conduct required clinical studies; the Company's ability to retain its listing on the Nasdaq exchange; and risks relating to the Company's ability to obtain regulatory approvals for its developmental product candidates. These forward-looking statements should be considered together with the risks and uncertainties that may affect the Company's business and future results included in the Company's filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are based on information currently available to the Company, and the Company assumes no obligation to update any forward-looking statements except as required by applicable law.

Item 9.01 Financial Statements and Exhibits.

(b) The information set forth in Item 8.01 of this Current Report is incorporated herein by reference in its entirety.

(d) Exhibits.

Exhibit No.	Document
23	Consent of WithumSmith+Brown, PC, independent registered public accounting firm.
99.1	Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.
99.2	Item 8. Financial Statements and Supplementary Data
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
104	Cover Page Interactive Data file (embedded within the Inline XBRL document).

SIGNATURE

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

Date: July 31, 2023

ACELRX PHARMACEUTICALS, INC.

By: /s/ Raffi Asadorian
Name: Raffi Asadorian
Title: Chief Financial Officer

Exhibit 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-268396, 333-264326, and 333-239156) and Form S-8 (Nos. 333-258896, 333-239213, 333-230139, 333-223535, 333-216492, 333-202709, 333-194634, 333-187206, 333-237195, 333-209998, 333-180334, and 333-172409) of AcelRx Pharmaceuticals, Inc. of our report dated March 31, 2023, except for the effects of the discontinued operations disclosed in Note 3, as to which the date is July 31, 2023, which includes an explanatory paragraph relating to AcelRx Pharmaceuticals, Inc.'s ability to continue as a going concern, relating to the consolidated financial statements and schedule II, which appears in this Current Report on Form 8-K.

/s/ WithumSmith+Brown, PC

San Francisco, California
July 31, 2023

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing elsewhere in this Current Report on Form 8-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions and other factors that could cause actual results to differ materially from those made, projected or implied in the forward-looking statements. Our actual results may differ materially from those discussed below. Please see "Forward-Looking Statements" and "Risk Factors" included in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 for factors that could cause or contribute to such differences. As used in this Exhibit 99.1, unless the context suggests otherwise, "we," "us," "our," the "Company" or "AcelRx" refer to AcelRx Pharmaceuticals, Inc. and its consolidated subsidiaries.

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. Our portfolio consists of nafamostat product candidates and pre-filled syringe product candidates, as further described in "Item 1. Business." in Part I of the Annual Report on Form 10-K for the year ended December 31, 2022 that was previously filed with the SEC on March 31, 2023, or the 2022 Annual Report. We have signed an agreement with Alora to divest our sufentanil sublingual products (DSUVIA and DZUVEO) with the right to receive sales-based milestone and other payments, which closed in April 2023. We do not have plans to further develop any sufentanil sublingual product candidates.

On January 7, 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 AcelRx's 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 Exhibit 99.2 to this Current Report on Form 8-K for additional information.

On July 14, 2021, we entered into a License and Commercialization Agreement, or the PFS Agreement, with Laboratoire Aguettant, or 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 containing 10 ml of a solution of 3 mg/ml ephedrine hydrochloride for injection and (ii) a phenylephrine pre-filled syringe containing 10 ml of a solution of 50 mcg/ml phenylephrine hydrochloride for injection. Aguettant will supply us with the products for use in commercialization and, if they are approved in the U.S., Aguettant is 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 (as defined below), we entered into an amendment to the PFS Agreement with Aguettant pursuant to which, effective on the closing of the DSUVIA Agreement (as defined below), (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 was reduced to $21 million.

On July 14, 2021, we also 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 supply Aguettant with primary packaged product and Aguettant then completes secondary packaging of the finished product. Pursuant to the DSUVIA Agreement (as defined below), as a condition of the transaction contemplated thereunder, we and Aguettant will enter 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, in each case, in a form reasonably acceptable to Alora. The rights and obligations under the Amended DZUVEO Agreement and the Amended and Restated Supply Agreement will be 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 6, "In-License Agreement" and Note 20, "Subsequent Events" to the consolidated financial statements in Exhibit 99.2 to this Current Report on Form 8-K for additional information.

On March 12, 2023, we entered into an asset purchase agreement, or the DSUVIA Agreement, with Alora pursuant to which Alora will acquire certain assets and assume certain liabilities relating to 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 Zalviso, 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. Subject to closing of the transaction contemplated under the DSUVIA Agreement, we will be entitled to receive quarterly payments in an amount equal to 15% of net Product sales to all customers excluding net sales to the Department of Defense and sales by or on behalf of Aguettant, and quarterly payments in an amount equal to 75% of net Product sales to the Department of Defense. Subject to closing of the transaction contemplated under the DSUVIA Agreement, we will also be entitled to receive sales milestones up to $116.5 million based on the achievement of Alora attaining certain levels of annual sales and 20% of any consideration, other than royalty payments, received by Alora and its affiliates in connection with a grant to any third party of a license related to any Product, or by Alora and its affiliates and equityholders 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. We expect the transaction to close in April 2023 and we expect to support the transition to Alora under a Transition Services Agreement signed at or prior to the closing of the transaction contemplated under the DSUVIA Agreement. In addition, at or prior to the closing, we and Alora will enter into an intellectual property agreement pursuant to which Alora will grant 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. Refer to Note 20, "Subsequent Events" to the consolidated financial statements in Exhibit 99.2 to this Current Report on Form 8-K for additional information.

Our strategy is focused on developing, obtaining approval, and commercializing our product candidates, Niyad and the pre-filled syringes. 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. 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, while we further reduce our operating costs. We have no plans on further developing or commercializing any of our other sufentanil sublingual products that were previously our product candidates. We are focused on achieving an Emergency Use Authorization, or EUA, for Niyad in 2023, and if successful, we expect to begin commercialization, while also initiating the clinical study for full regulatory approval.

On October 25, 2022, we filed a certificate of amendment to our amended and restated certificate of incorporation to effect a 1-for-20 reverse stock split of our outstanding common stock, effective as of 5:01 p.m. Eastern Time on October 25, 2022, or the Reverse Stock Split. Unless expressly stated herein, all share amounts of our common stock presented in this Annual Report have been adjusted to reflect the Reverse Stock Split. See Note 1, "Organization and Summary of Significant Accounting Policies" to the consolidated financial statements in Exhibit 99.2 to this Current Report on Form 8-K for additional information.

Product Development Programs

Our product development portfolio features Niyad (a regional anticoagulant for the dialysis circuit), two innovative therapies for the treatment of acute pain, two ready-to-use pre-filled syringe product candidates (Fedsyra and phenylephrine), and LTX-608 (a proprietary nafamostat formulation for direct IV infusion for disseminated intravascular coagulation, or DIC, for acute respiratory distress syndrome, or ARDS, as an anti-viral treatment for COVID-19, and for acute pancreatitis). Please refer to "Part I. Item 1. Business—Our Portfolio" in the 2022 Annual Report for a detailed discussion of our approved products and product candidates.

General Trends and Outlook

COVID-19-related

Government-mandated orders and related safety policies on account of the COVID-19 pandemic have prevented us from operating our business in the normal course. We continue to adhere to the various and diverse orders issued by government officials in the jurisdictions in which we operate. In addition, some hospitals, ambulatory surgery centers and other healthcare facilities have barred visitors that are not caregivers or mission-critical and otherwise restricted access to such facilities. As a result, the educational and promotional efforts of our commercial and medical affairs personnel have been substantially reduced, and in some cases, stopped. Cancellation or delays of formulary committee meetings and delays of elective surgeries have also affected the pace of formulary approvals and, consequently, the rate of adoption and use of DSUVIA.

As a result of COVID-19 and related international travel restrictions, in addition to the testing requirements of our vendor, the timing for testing and acceptance of the installed DSUVIA automated packaging line, and subsequent FDA approval, was delayed. Refer to Note 20, “Subsequent Events” to the consolidated financial statements in Exhibit 99.2 to this Current Report on Form 8-K for additional information.

We will continue to engage with various elements of our supply chain and distribution channel, including our customers, contract manufacturers, and logistics and transportation providers, to meet demand for products and to remain informed of any challenges within our supply chain. We continue to monitor demand and intend to adapt our plans as needed to continue to drive our business and meet our obligations during the evolving COVID-19 pandemic. However, if the COVID-19 pandemic continues and persists for an extended period of time, we may face 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 generate sales of and revenues from our products and our business, financial condition, results of operations and growth prospects could be adversely affected.

As the global pandemic of COVID-19 continues to rapidly evolve, it could result in a significant long-term disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. The extent to which the COVID-19 pandemic continues to impact our business, our ability to generate sales of and revenues from our approved products, and our future clinical development and regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions, quarantines and social distancing requirements in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the virus.

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 and the broader availability of COVID-19 vaccines, 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.

Department of Defense

In April 2020, DSUVIA achieved Milestone C approval by the Department of Defense, or DoD, a decision that clears the path for the DoD to begin placing orders for DSUVIA for inclusion in all Army Sets, Kits, and Outfits, or SKOs, for deployed/deploying troops. This SKO fulfillment is dependent on the Army’s completion of their product information package including instructions on fulfillment and training which remains in process. In September 2020, we announced that DSUVIA was added to the DoD Joint Deployment Formulary, a core list of pharmaceutical products that are designated for deploying military units across all service branches. Also in September 2020, the U.S. Army awarded AcelRx with an initial contract of up to $3.6 million over four years for the purchase of DSUVIA to support a DoD-sponsored study, which is currently underway, to aid the development of clinical practice guidelines. Since the fourth quarter of 2020, DSUVIA orders are being fulfilled for the Army Prepositioned Stock Program, or APS. The aforementioned clinical and APS orders are separate from the planned SKO fulfillment. Upon closing of the transaction contemplated under the DSUVIA Agreement, Alora will be responsible for commercializing DSUVIA except that we will retain the responsibility for driving the demand within the Department of Defense, and we will receive quarterly payments in an amount equal to 75% of net Product sales to the Department of Defense. Refer to Note 20, “Subsequent Events” to the consolidated financial statements in Exhibit 99.2 to this Current Report on Form 8-K for additional information.

Financial Overview

Although the termination of the Royalty Monetization resulted in net income for the year ended December 31, 2022, we have incurred net losses and generated negative cash flows from operations since inception and expect to incur losses in the future as we continue commercialization activities to support the U.S. launch of DSUVIA, support European sales of DZUVEO by Aguettant, and fund any future research and development activities needed to support the FDA regulatory review of our product candidates.

Our net income was $47.8 million for the year ended December 31, 2022, and our net loss was $35.1 million for the year ended December 31, 2021. As of December 31, 2022, we had an accumulated deficit of $425.8 million. As of December 31, 2022, we had cash, cash equivalents, short-term investments and restricted cash totaling $20.8 million compared to $51.6 million as of December 31, 2021.

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 to the consolidated financial statements in Exhibit 99.2 to this Current Report on Form 8-K. 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 Exhibit 99.2 to this Current Report on Form 8-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*. The 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. We sell 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.

Product sales revenue

We sell our product primarily through distributors. Revenues from product sales are recognized when distributors obtain control of our product, which occurs at a point in time, upon delivery to such distributors. These distributors subsequently resell the product to certified medically supervised healthcare settings. In addition to distribution agreements with these customers, we enter into arrangements with group purchasing organizations, or GPOs, and other certified medically supervised healthcare settings that provide for privately negotiated discounts with respect to the purchase of our products. For revenue recognition under bill-and-hold arrangements, wherein the customer agrees to buy product from us but requests delivery at a later date, we deem that control passes to the customer when the product is ready for delivery. We recognize revenue under these types of arrangements when a signed agreement is in place, the transaction is billable, the customer has significant risk and rewards for the product and the ability to direct the asset, the product has been set aside specifically for the customer, and the product cannot be redirected to another customer. Revenue from product sales is recorded at the transaction price, net of estimates for variable consideration consisting of chargebacks, government rebates, returns, distribution fees and GPO fees. Variable consideration is recorded at the time product sales are recognized resulting in a reduction in product revenue. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Variable consideration is estimated using the most-likely amount method, which is the single-most likely outcome under a contract and is typically at the stated contractual rate. Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted in accordance with the expected value method under ASC Topic 606 for relevant factors. These factors include current contractual and statutory requirements, specific known market events and trends, industry data, and/or forecasted customer buying and payment patterns. Actual amounts of consideration ultimately received may differ from our estimates. If actual results vary materially from our estimates, we will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted. These estimates include:

Chargebacks – Our customers subsequently resell our product to qualified healthcare providers. In addition to distribution agreements with customers, we enter into arrangements with qualified healthcare providers that provide discounts with respect to the purchase of our product. Chargebacks represent the estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers at prices lower than the list prices charged to customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue-related accrued liabilities on the consolidated balance sheets. Chargeback amounts are determined at the time of resale to the qualified healthcare providers by customers, and we issue credits for such amounts generally within a few weeks of the customer's notification to us of the resale. Reserves for chargebacks consists of credits that we expect to issue for units that remain in the distribution channel inventories at each reporting period end that we expect will be sold to the qualified healthcare providers, and chargebacks for units that our customers have sold to the qualified healthcare providers, but for which credits have not been issued.

Government Rebates – We are subject to discount obligations under state Medicaid programs. We estimate our Medicaid rebates and record them in the same period the related product revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in accrued liabilities on the consolidated balance sheets.

Returns – We allow our distributors to return product for credit 6 months prior to, and up to 12 months after, the product expiration date. As such, there may be a significant period of time between the time the product is shipped and the time the credit is issued on returned product.

Distribution Fees - Distribution fees include fees paid to certain customers for sales order management, data and distribution services. Distribution fees are recorded as a reduction of revenue in the period the related product revenue is recognized.

GPO Fees – We pay administrative fees to GPOs for services and access to data. These fees are based on contracted terms and are paid after the quarter in which the product was purchased by the GPOs' members.

Trade Discounts and Allowances - We provide our customers with discounts which include early payment incentives that are explicitly stated in our contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized.

We believe our estimated allowances for chargebacks, government rebates and product returns require a high degree of judgment and are subject to change based on our limited experience and certain quantitative and qualitative factors. We believe our estimated allowances for distribution fees, GPO fees and trade discounts and allowances do not require a high degree of judgment because the amounts are settled within a relatively short period of time. We will continue to assess our estimates of variable consideration as we accumulate additional historical data and will adjust these estimates accordingly. Changes in product revenue allowance estimates could materially affect our results of operations and financial position.

Contract and other collaboration revenue

We generate revenue from collaboration agreements. These agreements typically include payments for upfront signing or license fees, cost reimbursements for development and manufacturing services, milestone payments, product sales, and royalties on licensee's future product sales. Product sales related revenue under these collaboration agreements is classified as product sales revenue, while other revenue generated from collaboration agreements is classified as contract and other collaboration revenue.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC Topic 606. Our performance obligations include delivering product to our distributors, commercialization license rights, development services, services associated with the regulatory approval process, joint steering committee services, demonstration devices, manufacturing services, material rights for discounts on manufacturing services, and product supply.

We have optional additional items in contracts, which are considered marketing offers and are accounted for as separate contracts when the customer elects such options. Arrangements that include a promise for future commercial product supply and optional research and development services at the customer's or our discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, such material rights are accounted for as separate performance obligations. If we are entitled to additional payments when the customer exercises these options, any additional payments are recorded in revenue when the customer obtains control of the goods or services.

Transaction Price

We have both fixed and variable consideration. Non-refundable upfront fees and product supply selling prices are considered fixed, while milestone payments are identified as variable consideration when determining the transaction price. Funding of research and development activities is considered variable until such costs are reimbursed at which point, they are considered fixed. We allocate the total transaction price to each performance obligation based on the relative estimated standalone selling prices of the promised goods or services for each performance obligation.

At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone (such as a regulatory submission by us) is included in the transaction price. Milestone payments that are not within our control, such as approvals from regulators, are not considered probable of being achieved until those approvals are received.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Allocation of Consideration

As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. Estimated selling prices for license rights and material rights for discounts on manufacturing services are calculated using an income approach model and can include the following key assumptions: the development timeline, sales forecasts, costs of product sales, commercialization expenses, discount rate, the time which the manufacturing services are expected to be performed, and probabilities of technical and regulatory success. For all other performance obligations, we use a cost-plus margin approach.

Timing of Recognition

Significant management judgment is required to determine the level of effort required under an arrangement and the period over which we expect to complete our performance obligations under the arrangement. We estimate the performance period or measure of progress at the inception of the arrangement and re-evaluate it each reporting period. This re-evaluation may shorten or lengthen the period over which revenue is recognized. Changes to these estimates are recorded on a cumulative catch-up basis. If we cannot reasonably estimate when our performance obligations either are completed or become inconsequential, then revenue recognition is deferred until we can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method. Revenue is recognized for products at a point in time when control of the product is transferred to the customer in an amount that reflects the consideration we expect to be entitled to in exchange for those product sales, which is typically once the product physically arrives at the customer, and for licenses of functional intellectual property at the point in time the customer can use and benefit from the license. For performance obligations that are services, revenue is recognized over time proportionate to the costs that we have incurred to perform the services using the cost-to-cost input method.

Non-Cash Interest Expense 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. Under the relevant accounting guidance, because of our significant continuing involvement, the 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 ARPI LLC 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 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 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 Royalty Monetization. Due to the significant judgments and factors related to the estimates of future payments under the 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 Royalty Monetization were lower than the gross proceeds of $65.0 million received, we deferred recognition of any probable contingent gain until the Royalty Monetization liability expired.

On May 31, 2022, we entered into a Termination Agreement with SWK to fully terminate the Royalty Monetization for which we paid cash consideration of $0.1 million, and neither PDL nor SWK retains any further interest in the Royalty Monetization. Accordingly, effective May 31, 2022, the 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 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.

We recorded non-cash royalty revenues and non-cash interest (income) expense within our consolidated statements of operations over the term of the 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 FASB 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 and 2022 Warrants and the Series A Redeemable Convertible Preferred Stock.

For additional information regarding the net income (loss) per share, see Note 16, "Net Income (Loss) per Share of Common Stock" to the consolidated financial statements in Exhibit 99.2 to this Current Report on Form 8-K.

Results of Operations

We have realigned our cost structure from a focus on commercialization to a focus on advancing our recently acquired late-stage development pipeline. In 2022, we reduced our headcount-related expenses, primarily within the commercial organization. In the beginning of 2022, we employed 43 full-time employees. As of December 31, 2022, we employed 19 full-time employees. These reductions have resulted in, and will continue to result in, decreased operating expenses in 2022 and beyond. 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, and the uncertainty as to the extent and magnitude of the impact from the COVID-19 pandemic. 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.

Our consolidated results of operations are presented for the years ended December 31, 2022 and 2021. Certain financial results (revenues and expenses) relating to the divestment of our DSUVIA/DZUVEO business are reflected in Note 3, “Discontinued Operations” to the consolidated financial statements in Exhibit 99.2 to this Current Report on Form 8-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.

Years Ended December 31, 2022 and 2021

Revenue

As a result of the divestiture, all DSUVIA/DSUVEO-related revenues have been reclassified under discontinued operations.

Product Sales Revenue

Product sales revenue of $0.3 million for the year ended December 31, 2021 consisted of sales of Zalviso in Europe by Grünenthal. In May 2020, Grünenthal terminated the Collaboration and License Agreement and the Manufacture and Supply Agreement, or together, the Grünenthal Agreements, accordingly the rights to market and sell Zalviso in Europe reverted back to us on May 12, 2021. In July 2022, the European Marketing Authorization for Zalviso was withdrawn.

Contract and Other Collaboration Revenue

Contract and other collaboration revenue of $0.1 million for the year ended December 31, 2021 consisted of revenue under the Grünenthal Agreements related to research and development services, non-cash royalty revenue related to the Royalty Monetization and royalty revenue for sales of Zalviso in Europe.

Cost of goods sold

As a result of the divestiture, all DSUVIA/DSUVEO-related costs of goods sold have been reclassified under discontinued operations.

Total costs of goods sold for the year ended December 31, 2021 was $0.6 million. Direct costs from contract manufacturers for Zalviso totaled $0.3 million in the year ended December 31, 2021. Direct cost of goods sold for Zalviso includes the inventory costs of the active pharmaceutical ingredient, or API, third-party contract manufacturing costs, estimated warranty costs, packaging and distribution costs, shipping, handling and storage costs.

We periodically evaluate the carrying value of inventory on hand for potential excess amounts over demand using the same lower of cost or net realizable value approach as that used to value the inventory. During the year ended December 31, 2021, we recorded Zalviso inventory impairment charges of $0.1 million, included in direct costs of goods sold.

The indirect costs to manufacture Zalviso in the year ended December 31, 2021 totaled $0.3 million. Indirect costs include internal personnel and related costs for purchasing, supply chain, quality assurance, depreciation and related expenses.

Research and Development Expenses

As a result of the divestiture, all DSUVIA/DSUVEO-related research and development expenses have been reclassified under discontinued operations.

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, and the preparation and submission of the NDAs for our two in-licensed pre-filled syringe, or PFS, product candidates from Aguettant.

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 the years ended December 31, 2022 and 2021 (in thousands, except percentages):

	Years Ended December 31,		$ Change	% Change
	2022	2021	2022 vs. 2021	2022 vs. 2021
Niyad	$ 405	$ —	$ 405	100%
PFS	313	50	263	526%
Zalviso	58	49	9	18%
Overhead	2,565	2,336	229	10%
Total research and development expenses	$ 3,341	$ 2,435	$ 906	37%

Research and development expenses during the year ended December 31, 2022, as compared to the year ended December 31, 2021, increased by $0.9 million primarily due to PFS and Niyad development activities and compensation costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consisted 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 the years ended December 31, 2022 and 2021, were as follows (in thousands, except percentages):

	Years Ended December 31,		$ Change	% Change
	2022	2021	2022 vs. 2021	2022 vs. 2021
Selling, general and administrative expenses	$ 17,011	$ 15,488	$ 1,523	10%

Selling, general and administrative expenses increased by $1.5 million during the year ended December 31, 2022, as compared to the year ended December 31, 2021. The increase is primarily due to $1.6 million in financing transaction related costs, $0.8 million of which were cash transaction costs, with the remaining $0.8 million attributed to the accounting for the warrant issued in the December 2022 financing.

Impairment of Property and Equipment

We have decided to not focus any development resources on Zalviso in the United States and do not expect to resubmit the Zalviso NDA in the foreseeable future. In addition, we do not expect any revenues from Zalviso in Europe in the foreseeable future. Accordingly, 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 the years ended December 31, 2022 and 2021, was as follows (in thousands, except percentages):

	Years Ended December 31,		$ Change	% Change
	2022	2021	2022 vs. 2021	2022 vs. 2021
Interest expense	$ (1,116)	$ (2,193)	$ 1,077	(49)%
Interest income and other income, net	366	124	242	195%
Non-cash interest income on liability related to sale of future royalties	1,136	3,038	(1,902)	(63)%
Gain on extinguishment of liability related to sale of future royalties	84,052	—	(84,052)	(100)%
Total other income	$ 84,438	$ 969	$ 83,469	8,614%

Interest expense consisted primarily of interest accrued or paid on our debt obligation agreements and amortization of debt discounts. Interest expense decreased for the year ended December 31, 2022, as compared to the year ended December 31, 2021, primarily as a result of a lower average outstanding loan balance. As of December 31, 2022, the outstanding balance due under the Loan Agreement with Oxford was $5.4 million. Refer to Note 9, “Long-Term Debt” to the consolidated financial statements in in Exhibit 99.2 to this Current Report on Form 8-K for additional information.

Interest income and other income for the years ended December 31, 2022 and 2021 primarily consisted of interest earned on our investments and the change in the fair value of our contingent put option. The increase in interest income and other income in the year ended December 31, 2022, compared to the year ended December 31, 2021, was primarily due to higher yields on our investments and the change in the fair value of our contingent put option.

The non-cash interest income on the liability related to the sale of future royalties is attributable to the Royalty Monetization that we completed in September 2015. As described in Note 11, “Liability Related to Sale of Future Royalties” to the consolidated financial statements in in Exhibit 99.2 to this Current Report on Form 8-K, the Royalty Monetization has been recorded as debt under the applicable accounting guidance. The effective interest income rate for the years ended December 31, 2022 and 2021, was approximately 3.2% and 3.5%, respectively.

On May 31, 2022, we entered into a Termination Agreement with SWK to fully terminate the Royalty Monetization and we recognized an $84.1 million gain on extinguishment of the liability related to the sale of future royalties.

Liquidity and Capital Resources

Liquidity and Going Concern

The termination of the Royalty Monetization resulted in net income for the year ended December 31, 2022; however, before this, we had incurred losses and generated negative cash flows from operations since inception and we expect to continue to incur operating losses and negative cash flows in the future. These conditions raise substantial doubt about our ability to continue as a going concern. 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 the 2022 Annual Report. 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, monetize or securitize certain assets, refinance our loan agreement, enter into product development, license or distribution agreements with third parties, or divest any of our product candidates. 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 its 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.

We have funded our operations primarily through issuance of equity securities, borrowings, payments from Grünenthal, monetization of certain future royalties and commercial sales milestones from the European sales of Zalviso by Grünenthal, funding of approximately $22.6 million from the DoD, and more recently with revenues from sales of DSUVIA since the commercial launch in the first quarter of 2019 and the upfront payment under the DZUVEO Agreement with Aguettant.

As of December 31, 2022, we had cash, cash equivalents and investments totaling $20.8 million, compared to $51.6 million as of December 31, 2021. The decrease was primarily due to cash required to fund our continuing and discontinued operations, including debt service, development activities for our newly acquired late-stage pipeline product candidates, commercialization activities for DSUVIA, including installation of the automated packaging line for DSUVIA, and business development activities. 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.

On December 29, 2022, we completed a registered direct offering with an institutional investor, or the Purchaser, in which we issued and sold 748,744 shares of our common stock, pre-funded warrants exercisable for an aggregate of 2,632,898 shares of common stock, and common warrants exercisable for an aggregate of 4,227,052 shares of common stock. The shares of common stock and accompanying common warrants were sold at a combined offering price of $2.22625 per share and accompanying common warrant, and the pre-funded warrants and accompanying common warrants were sold at a combined offering price of $2.22615 per pre-funded warrant and accompanying common warrant. The pre-funded warrants were immediately exercisable following closing of the offering, have an unlimited term, and have an exercise price of $0.0001 per share. The common warrants will not be exercisable until after the six-month anniversary of the closing of the offering, will have an exercise price of $2.07 per share 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 warrants. As of December 31, 2022, the 2,632,898 pre-funded warrants and the 4,227,052 common warrants remain outstanding.

On August 3, 2022, we entered into a securities purchase agreement with Lincoln Park Capital Fund, LLC, or LPC, pursuant to which we 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 (subject to adjustment for stock splits, reverse stock splits and similar recapitalization events), for $0.3 million, and became immediately exercisable and has a term ending on February 3, 2028. Upon the closing of the December 29, 2022 registered direct offering, we modified the previously issued warrant to LPC to reduce the exercise price to $2.07 per share in accordance with the warrant’s down round feature. As of December 31, 2022, this warrant had not been exercised and was still outstanding.

On November 17, 2021, we completed a registered direct offering in which we issued and sold 875,000 shares of our common stock at a price of $16.00 per share and warrants exercisable for an aggregate of 875,000 shares of our common stock at a price of $20.00 per share. The total net proceeds from this offering were approximately $13.9 million. Upon the closing of the December 29, 2022 registered direct offering, we agreed to amend a previously issued warrant held by the Purchaser to purchase up to 750,000 shares of common stock in this November 17, 2021 registered direct offering to reduce the exercise price to $2.07 per share and to extend the expiration date to December 29, 2028. The remaining warrants issued in the November 17, 2021 registered direct offering for 125,000 shares of our common stock are currently exercisable at a price of $20.00 per share and expire on November 15, 2026. All of the warrants exercisable for a total of 875,000 shares of our common stock issued in connection with this registered direct offering remain outstanding at December 31, 2022.

On January 22, 2021, we completed an underwritten public offering in which we issued and sold 725,000 shares of our common stock to the underwriter at a price of $35.25 per share. On January 27, 2021, the underwriters exercised their option in full and purchased an additional 108,750 shares at a price of $35.25 per share. The total net proceeds from this offering of an aggregate 833,750 shares were approximately $28.9 million.

We entered into a Controlled Equity Offering℠ Sales Agreement, or, 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 the year ended December 31, 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. During the year ended December 31, 2021, we had issued and sold an aggregate of approximately 0.2 million shares of common stock pursuant to the ATM Agreement, for which we had received net proceeds of approximately $7.5 million, after deducting fees and expenses. As of December 31, 2022, we had the ability to sell approximately $35.6 million of our common stock under the ATM Agreement.

On May 30, 2019, we entered into the Loan Agreement with 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, we received $15.9 million in net proceeds. As of December 31, 2022, the outstanding balance under the Loan Agreement was $5.4 million. For more information, see Note 9, “Long-Term Debt” to the consolidated financial statements in Exhibit 99.2 to this Current Report on Form 8-K for additional information.

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. We do not expect COVID-19 to have a material impact on our high quality, short-dated investments.

Cash Flows

	Years Ended December 31,	
	2022	**2021**
Net cash used in operating activities	$ (28,331)	$ (30,002)
Net cash provided by/(used in) investing activities	36,450	(26,123)
Net cash (used in)/provided by financing activities	(507)	41,514

Cash Flows from Operating Activities

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

Cash used in operating activities of $28.3 million during the year ended December 31, 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 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 used in operating activities of $30.0 million during the year ended December 31, 2021, reflected a net loss of $35.1 million, partially offset by aggregate non-cash charges of $4.9 million and included an approximate $0.2 million net change in our operating assets and liabilities. Non-cash charges included $4.6 million for stock-based compensation expense, $3.0 million in non-cash interest income on the liability related to the Royalty Monetization, and $2.0 million in depreciation and amortization expense. The net change in our operating assets and liabilities included a $1.2 million increase in deferred revenue and a $0.9 million increase in prepaid expenses and other assets.

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 the year ended December 31, 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.

During the year ended December 31, 2021, cash used in investing activities of $26.1 million was primarily the net result of $70.5 million for purchases of investments, $1.8 million for purchases of property and equipment, and $0.8 million in asset acquisition costs related to our acquisition of Lowell, partially offset by $47.0 million in proceeds from the sale and maturity of investments.

Cash Flows from Financing Activities

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

During the year ended December 31, 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.

During the year ended December 31, 2021, cash provided by financing activities of $41.5 million was primarily due to $50.3 million in net proceeds received in connection with equity financings, including the issuance of warrants and shares sold under our ATM Agreement, partially offset by $8.8 million used for payment of long-term debt.

Capital Commitments and Capital Resources

Our current operating plan includes expenditures related to the development of our product candidates. In addition, on January 7, 2022, we acquired Lowell in a transaction for consideration of approximately $32.5 million plus net cash acquired and certain other adjustments, inclusive of approximately $26.0 million of contingent consideration payable in cash or stock at AcelRx's option, upon the achievement of regulatory and sales-based milestones. For additional information regarding the acquisition of Lowell, see Note 4, "Asset Acquisition" to the consolidated financial statements in Exhibit 99.2 to this Current Report on Form 8-K for additional information. Our operating plan includes anticipated activities required for the development and supply of our nafamostat product candidates, and the preparation and submission of the NDAs for our two in-licensed PFS product candidates from Aguettant. 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 retain the listing of our common stock on the Nasdaq exchange;
- expenditures related to the potential commercialization of our product candidates, if approved;
- expenditures related to drafting and submission of new drug or device regulatory applications with the U.S. Food and Drug Administration, or 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;
- the outcome, timing and cost of the development of our nafamostat product candidates;
- the initiation, progress, timing and completion of any post-approval clinical trials for our product candidates, if approved;
- 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 II., Item 1A. Risk Factors—Risks Related to Our Financial Condition and Need for Additional Capital” in our 2022 Annual Report.

We have material cash requirements and other contractual obligations related to our Loan Agreement with Oxford (as described in Note 9, “Long-Term Debt”), and office rent (as described in Note 10, “Leases” to the consolidated financial statements in Exhibit 99.2 to this Current Report on Form 8-K).

Exhibit 99.2

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of
AcelRx Pharmaceuticals, Inc.:
Hayward, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of AcelRx Pharmaceuticals, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, changes in redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2022, and the related notes and schedule II (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 2021, and the results of its operations and its cash flows for each of the two years in the period 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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

Emphasis of the Matter – Restatement of Unaudited Interim Financial Statements

As disclosed in Note 21 of the consolidated financial statements, the unaudited interim financial statements as of and for the periods ended June 30, 2022 and September 30, 2022 have been restated to correct an error within the earnings per share calculation.

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 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 have served as the Company's auditor since 2015.

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

AcelRx Pharmaceuticals, Inc.

Consolidated Balance Sheets
(in thousands, except share data)

	December 31, 2022	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	$ 15,275	$ 7,663
Restricted cash	5,000	—
Short-term investments	495	38,967
Prepaid expenses and other current assets	1,865	2,011
Assets of discontinued operations	1,931	1,848
Total current assets	24,566	50,489
Operating lease right-of-use assets	96	271
Property and equipment, net	—	4,907
In-process research and development asset	8,819	—
Other assets	70	1,978
Restricted cash, net of current portion	—	5,000
Assets of discontinued operations	13,936	15,248
Total assets	$ 47,487	$ 77,893
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities:		
Accounts payable	$ 1,256	$ 917
Accrued and other liabilities	2,431	3,429
Long-term debt, current portion	5,363	8,333
Operating lease liabilities, current portion	100	182
Liabilities of discontinued operations	4,620	5,648
Total current liabilities	13,770	18,509
Long-term debt, net of current portion	—	5,007
Operating lease liabilities, net of current portion	—	101
Warrant liability	7,098	—
Liability related to the sale of future royalties	—	85,288
Other long-term liabilities	810	81
Liabilities of discontinued operations	3,995	4,800
Total liabilities	25,673	113,786
Commitments and Contingencies		
Stockholders' Equity (Deficit)*:		
Common stock, $0.001 par value—200,000,000 shares authorized as of December 31, 2022 and 2021; 8,243,680 and 6,840,967 shares issued and outstanding as of December 31, 2022 and 2021, respectively	8	7
Additional paid-in capital	447,635	437,684
Accumulated deficit	(425,829)	(473,584)
Total stockholders' equity (deficit)	21,814	(35,893)
Total Liabilities and Stockholders' Equity (Deficit)	$ 47,487	$ 77,893

* Adjusted to give retroactive effect to a 1-for-20 reverse stock split effective as of 5:01 p.m. Eastern Time on October 25, 2022.

See notes to consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

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

	Year Ended December 31,	
	2022	**2021**
Revenue:		
Product sales	$ —	$ 270
Contract and other collaboration	—	108
Total revenue	—	378
Operating costs and expenses:		
Cost of goods sold	—	571
Research and development	3,341	2,435
Selling, general and administrative	17,011	15,488
Impairment of property and equipment	4,948	—
Total operating costs and expenses	25,300	18,494
Loss from operations	(25,300)	(18,116)
Other income:		
Interest expense	(1,116)	(2,193)
Interest income and other income, net	366	124
Non-cash interest income on liability related to sale of future royalties	1,136	3,038
Gain on extinguishment of liability related to the sale of future royalties	84,052	—
Total other income	84,438	969
Net income (loss) from continuing operations before provision for income taxes	59,138	(17,147)
Provision for income taxes	(13)	(5)
Net income (loss) from continuing operations	59,125	(17,152)
Net loss from discontinued operations –(Note 3)	(11,370)	(17,947)
Net income (loss)	47,755	(35,099)
Deemed dividend related to Series A Redeemable Convertible Preferred Stock	(186)	—
Income allocated to participating securities	(5,240)	—
Net income (loss) attributable to Common Shareholders, basic	$ 42,329	$ (35,099)
Net income (loss) attributable to Common Shareholders, diluted	$ 42,342	$ (35,099)
Net income (loss) per share attributable to stockholders:		
Basic earnings (loss) per share		
Income (loss) from continuing operations	$ 7.27	$ (2.86)
Income (loss) from discontinued operations	$ (1.54)	$ (3.00)
Net income (loss)	$ 5.73	$ (5.86)
Diluted earnings (loss) per share		
Income (loss) from continuing operations	$ 7.25	$ (2.86)
Income (loss) from discontinued operations	$ (1.53)	$ (3.00)
Net income (loss)	$ 5.72	$ (5.86)
Shares used in computing net income (loss) per share of common stock, basic –(Note 16)	7,385,348	5,993,013
Shares used in computing net income (loss) per share of common stock, diluted –(Note 16)	7,406,986	5,993,013

See notes to consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share data)
1-for-20 reverse stock split reflected for all years presented

	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, 2020	—	$ —	4,940,590	$ 5	$ 382,730	$ (438,485)	$ (55,750)
Stock-based compensation	—	—	—	—	4,609	—	4,609
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	—	—	24,433	—	(249)	—	(249)
Net proceeds from issuance of common stock in connection with equity financings	—	—	1,860,078	2	44,714	—	44,716
Net proceeds from issuance of warrants in connection with equity financings	—	—	—	—	5,562	—	5,562
Issuance of common stock upon exercise of stock options	—	—	969	—	17	—	17
Issuance of common stock upon ESPP purchase	—	—	14,897	—	301	—	301
Net loss	—	—	—	—	—	(35,099)	(35,099)
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

See notes to consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 47,755	$ (35,099)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Non-cash royalty revenue related to royalty monetization	—	(83)
Non-cash interest income on liability related to royalty monetization	(1,136)	(3,038)
Depreciation and amortization	1,647	1,973
Non-cash interest expense related to debt financing	393	761
Non-cash issuance costs for warrant liability	775	—
Stock-based compensation	2,889	4,609
Non-cash gain on termination of liability related to royalty monetization	(84,152)	—
Impairment of property and equipment	4,948	—
Inventory impairment charge	—	810
Other	(60)	(138)
Changes in operating assets and liabilities:		
Accounts receivable	(149)	475
Inventories	(107)	(295)
Prepaid expenses and other assets	299	(908)
Accounts payable	551	111
Accrued liabilities	(1,613)	79
Operating lease liabilities	(285)	(447)
Deferred revenue	(86)	1,188
Net cash used in operating activities	(28,331)	(30,002)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(364)	(1,827)
Purchase of investments	(7,861)	(70,459)
Cash paid for asset acquisition, net of cash acquired	(1,687)	(821)
Proceeds from sale of investments	—	2,996
Proceeds from maturities of investments	46,362	43,988
Net cash provided by (used in) investing activities	36,450	(26,123)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of long-term debt	(8,433)	(8,833)
Net proceeds from 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 December 2022 registered direct offering	7,528	—
Net proceeds from issuance of common stock and warrants in connection with November 2021 registered direct offering	—	13,918
Net proceeds from issuance of common stock and warrants in connection with 2021 underwritten public offering	—	28,886
Net proceeds from issuance of common stock in connection with at-the-market sales agreement.	458	7,474
Net proceeds from issuance of common stock through equity plans	74	318
Tax payments related to shares withheld for restricted stock units vested	(58)	(249)
Net cash (used in) provided by financing activities	(507)	41,514
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	7,612	(14,611)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH —Beginning of year	12,663	27,274
CASH, CASH EQUIVALENTS AND RESTRICTED CASH —End of year	$ 20,275	$ 12,663
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for interest	$ 824	$ 1,595
Income taxes paid	$ 13	$ 5
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Purchases of property and equipment in accounts payable and accrued expenses	$ 825	$ 1,095
Equity issuance costs from modification of November 2021 Financing Warrants	$ 47	$ —
Equity issuance costs in accounts payable and accrued expenses	$ 51	$ —
Liability for held back shares in connection with asset acquisition in other long-term liabilities	$ 800	$ —
Issuance of common stock in connection with asset acquisition	$ 5,511	$ —
Asset acquisition costs in accounts payable and accrued expenses	$ —	$ 1,087
Establishment of right-of-use asset and lease liability	$ 127	$ 4,669
Write-off of right-of-use asset and lease liability	$ —	$ (3,128)
Gain on termination of sublease	$ —	$ 522

See notes to consolidated financial statements.

1. Organization and Summary of Significant Accounting Policies

The Company

AcelRx Pharmaceuticals, Inc., or the Company, or AcelRx, was incorporated in Delaware on July 13, 2005 as SuRx, Inc. The Company subsequently changed its name to AcelRx Pharmaceuticals, Inc. The Company's operations are based in Hayward, California.

AcelRx is a specialty pharmaceutical company focused on the development and commercialization of innovative therapies for use in medically supervised settings. DSUVIA® (known as DZUVEO® in Europe) is focused on the treatment of acute pain, and utilizes sufentanil, delivered via a non-invasive route of sublingual administration, exclusively for use in medically supervised settings. On November 2, 2018, the U.S. Food and Drug Administration, or FDA, approved DSUVIA for use in adults in a certified medically supervised healthcare setting, such as hospitals, surgical centers, and emergency departments, for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. The commercial launch of DSUVIA in the United States occurred in the first quarter of 2019. In June 2018, the European Commission, or EC, granted marketing approval of DZUVEO for the management of acute moderate to severe pain in adults in medically monitored settings. Zalviso was approved in Europe and was commercialized by Grünenthal GmbH, or Grünenthal, through May 12, 2021 (see *Termination of Grünenthal Agreements* below). In July 2022, the European Marketing Authorization for Zalviso was withdrawn.

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 together Alora, pursuant to which Alora will acquire certain assets and assume certain liabilities relating to 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 Purchase Agreement occurred on April 3, 2023 (see Note 3, "Discontinued Operations" and Note 20, "Subsequent Events" below.

In July 2021, the Company entered into a License and Commercialization Agreement with Laboratoire Aguettant, or Aguettant, for Aguettant to commercialize DZUVEO in the European Union, Norway, Iceland, Liechtenstein, Andorra, Vatican City, Monaco, Switzerland and the United Kingdom, or the DZUVEO Agreement. See Note 20, "Subsequent Events" below.

In July 2021, the Company also entered into a separate License and Commercialization Agreement with Aguettant, or the PFS Agreement, 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 containing 10 ml of a solution of 3 mg/ml ephedrine hydrochloride for injection, and (ii) a phenylephrine pre-filled syringe containing 10 ml of a solution of 50 mcg/ml phenylephrine hydrochloride for injection. Aguettant will supply the Company with the products for use in commercialization and, if they are approved in the U.S., Aguettant is entitled to receive up to $24 million in sales-based milestone payments. See Note 20, "Subsequent Events" below.

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 Niyad™, a regional anticoagulant for 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. The Company plans to study Niyad, which has received Breakthrough Device Designation status from the FDA and an ICD-10 procedural code from the U.S. Centers for Medicare & Medicaid Services, under an investigational device exemption. 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, which has a half-life of 8 minutes, with anticoagulant, anti-inflammatory and potential anti-viral activities. In addition, the Company acquired LTX-608, a proprietary nafamostat formulation for direct IV infusion that it intends to develop for the treatment of acute respiratory distress syndrome, or ARDS, and disseminated intravascular coagulation, or DIC.

Termination of Grünenthal Agreements

On December 16, 2013, AcelRx and Grünenthal entered into a Collaboration and License Agreement, or the License Agreement, which was amended effective July 17, 2015, and September 20, 2016, or the Amended License Agreement, which granted Grünenthal rights to commercialize Zalviso in Europe. In September 2015, the European Commission granted marketing approval for the marketing authorization application, or MAA, for Zalviso for the management of acute moderate-to-severe post-operative pain in adult patients. On December 16, 2013, AcelRx and Grünenthal entered into a Manufacture and Supply Agreement, or the MSA, which was amended effective July 15, 2015, or the Amended MSA, and together with the Amended License Agreement, the Grünenthal Agreements. Under the Amended MSA, the Company exclusively manufactured and supplied Zalviso for Grünenthal's European sales.

On May 18, 2020, the Company received a notice from Grünenthal that it had exercised its right to terminate the Grünenthal Agreements, effective November 13, 2020. The terms of the Grünenthal Agreements were extended to May 12, 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 Zalviso Territory reverted back to the Company on May 12, 2021. In July 2022, the European Marketing Authorization for Zalviso was withdrawn.

Termination of Royalty Monetization

On September 18, 2015, the Company sold the majority of the royalty rights and certain commercial sales milestones it was entitled to receive under the Amended License Agreement with Grünenthal to PDL BioPharma, Inc., or PDL, in a transaction referred to as the Royalty Monetization. On August 31, 2020, PDL announced it sold its royalty interest for Zalviso to SWK Funding, LLC, or SWK. On May 31, 2022, the Company entered into a Termination Agreement with SWK to fully terminate the Royalty Monetization for which the Company paid cash consideration of $0.1 million. Neither PDL nor SWK retains any further interest in the Royalty Monetization. Accordingly, effective May 31, 2022, the 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 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 Going Concern

The consolidated financial statements for the year ended December 31, 2022 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 Royalty Monetization resulted in net income for the year ended December 31, 2022; however, before 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. 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2022 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℠ 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.

Reverse Stock Split

On September 23, 2022, at a special meeting of stockholders, the Company's stockholders authorized the Company's Board of Directors to effect a reverse stock split of all outstanding shares of common stock in a range of 1-for-10 to 1-for-30. The Board of Directors subsequently approved a reverse stock split with a ratio of 1-for-20, or the Reverse Stock Split. On October 25, 2022, following the filing of a certificate of amendment to the Company's amended and restated certificate of incorporation, every 20 shares of the Company's common stock that were issued and outstanding automatically converted into one outstanding share of common stock. The Reverse Stock Split affected all shares of common stock outstanding immediately prior to the effective time of the Reverse Stock Split, as well as the number of shares of common stock available for issuance under the Company's equity incentive and employee stock purchase plans. Outstanding stock options, restricted stock units and warrants were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased. The Reverse Stock Split affected all holders of common stock uniformly and did not affect any stockholder's percentage of ownership interest. The par value of the Company's common stock remained unchanged at $0.001 per share and the number of authorized shares of common stock remained the same after the Reverse Stock Split.

As the par value per share of the Company's common stock remained unchanged at $0.001 per share, the change in the common stock recorded at par value has been reclassified to additional paid-in capital on a retroactive basis. All references to shares of common stock, stock options, restricted stock units and warrants and per share data for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted to reflect the Reverse Stock Split on a retroactive basis.

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.

Reclassifications

Certain prior year amounts in the consolidated financial statements have been reclassified to conform to the current year's presentation. In particular, the restricted cash classified as "Cash and cash equivalents" has been reclassified to "Restricted cash, net of current portion" in the consolidated balance sheets as of December 31, 2021 and in the consolidated statement of cash flows as of December 31, 2022 and December 31, 2021. See "—Cash, Cash Equivalents and Restricted Cash" below.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. 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 revenue recognition, inventory valuation and the liability related to the sale of future royalties. 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, Restricted Cash and Short-Term Investments

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.

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, 2022	**December 31, 2021**
Cash and cash equivalents	$ 15,275	$ 7,663
Restricted cash	5,000	—
Restricted cash, net of current portion	—	5,000
Total cash, cash equivalents, and restricted cash	$ 20,275	$ 12,663

All marketable securities are classified as available for sale and consist of commercial paper, U.S. government sponsored enterprise debt securities and corporate 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. The Company's investments are subject to a periodic impairment review for other-than-temporary declines in fair value. The Company's review includes the consideration of the cause of the impairment including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in the market value. When the Company determines that the decline in fair value of an investment is below its accounting basis and this decline is other than temporary, it reduces the carrying value of the security it holds and records a loss in the amount of such decline.

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 product sales revenue consists of sales of Zalviso in Europe by Grünenthal. The Company's contract and collaboration revenue consists of non-cash royalty revenue, royalty revenue, and other revenue under the Grünenthal Agreements. See Note 8, "Revenue from Contracts with Customers" 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.

Zalviso was sold in Europe by Grünenthal through May 2021.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets, generally three to five years. Leasehold improvements are amortized over the shorter of the estimated useful life of the improvements or the remaining lease term. Expenditures for repairs and maintenance, which do not extend the useful life of the property and equipment, are expensed as incurred. Upon retirement, the asset cost and related accumulated depreciation are relieved from the accompanying consolidated balance sheets. Gains and losses associated with dispositions are reflected as a component of interest income and other income, net in the accompanying consolidated statements of operations.

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. See Note 5, "Property and Equipment, Net" below.

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.

Leases

The Company follows the provisions of Accounting Standards Update, or ASU, 2016-02, *Leases (Topic 842)*. At the inception of an arrangement, the Company determines whether the arrangement is, or contains, a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received.

Lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on the consolidated balance sheets as operating lease right-of-use assets, operating lease liabilities current and operating lease liabilities non-current.

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. The Company sells 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.

Product Sales Revenue

The Company sells its product primarily through distributors. Revenues from product sales are recognized when distributors obtain control of the Company's product, which occurs at a point in time, upon delivery to such distributors. These distributors subsequently resell the product to certified medically supervised healthcare settings. In addition to distribution agreements with these customers, the Company enters into arrangements with group purchasing organizations, or GPOs, and other certified medically supervised healthcare settings that provide for privately negotiated discounts with respect to the purchase of its products. For revenue recognition under bill-and-hold arrangements, wherein the customer agrees to buy product from the Company but requests delivery at a later date, the Company deems that control passes to the customer when the product is ready for delivery. The Company recognizes revenue under these types of arrangements when a signed agreement is in place, the transaction is billable, the customer has significant risk and rewards for the product and the ability to direct the asset, the product has been set aside specifically for the customer, and the product cannot be redirected to another customer. Revenue from product sales is recorded at the transaction price, net of estimates for variable consideration consisting of chargebacks, government rebates, returns, distribution fees, GPO fees and product returns. Variable consideration is recorded at the time product sales are recognized resulting in a reduction in product revenue. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Variable consideration is estimated using the most-likely amount method, which is the single-most likely outcome under a contract and is typically at the stated contractual rate. Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted in accordance with the expected value method under ASC Topic 606 for relevant factors. These factors include current contractual and statutory requirements, specific known market events and trends, industry data, and/or forecasted customer buying and payment patterns. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary materially from the Company's estimates, the Company will adjust these estimates, which will affect revenue from product sales and earnings in the period such estimates are adjusted. These estimates include:

Chargebacks – The Company's customers subsequently resell its product to qualified healthcare providers. In addition to distribution agreements with customers, the Company enters into arrangements with qualified healthcare providers that provide discounts with respect to the purchase of its product. Chargebacks represent the estimated obligations resulting from contractual commitments to sell product to qualified healthcare providers at prices lower than the list prices charged to customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue-related accrued liabilities on the consolidated balance sheets. Chargeback amounts are determined at the time of resale to the qualified healthcare providers by customers, and the Company issues credits for such amounts generally within a few weeks of the customer's notification to the Company of the resale. Reserves for chargebacks consists of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period end that the Company expects will be sold to the qualified healthcare providers, and chargebacks for units that the Company's customers have sold to the qualified healthcare providers, but for which credits have not been issued.

Government Rebates – The Company is subject to discount obligations under state Medicaid programs. The Company estimates its Medicaid rebates, and reserves are recorded in the same period the related product revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability that is included in accrued liabilities on the consolidated balance sheets.

Returns – The Company allows its distributors to return product for credit 6 months prior to, and up to 12 months after, the product expiration date. As such, there may be a significant period of time between the time the product is shipped and the time the credit is issued on returned product.

Distribution Fees – Distribution fees include fees paid to certain customers for sales order management, data and distribution services. Distribution fees are recorded as a reduction of revenue in the period the related product revenue is recognized.

GPO Fees – The Company pays administrative fees to GPOs for services and access to data. These fees are based on contracted terms and are paid after the quarter in which the product was purchased by the GPOs' members.

Trade Discounts and Allowances - The Company provides its customers with discounts which include early payment incentives that are explicitly stated in its contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized.

The Company believes its estimated allowances for chargebacks, government rebates and product returns require a high degree of judgment and are subject to change based on its limited experience and certain quantitative and qualitative factors. The Company believes its estimated allowances for distribution fees, GPO fees and trade discounts and allowances do not require a high degree of judgment because the amounts are settled within a relatively short period of time. The Company will continue to assess its estimates of variable consideration as it accumulates additional historical data and will adjust these estimates accordingly. Changes in product revenue allowance estimates could materially affect the Company's results of operations and financial position.

Contract and Other Collaboration Revenue

The Company generates revenue from collaboration agreements. These agreements typically include payments for upfront signing or license fees, cost reimbursements for development and manufacturing services, milestone payments, product sales, and royalties on licensee's future product sales. Product sales related revenue under these collaboration agreements is classified as product sales revenue, while other revenue generated from collaboration agreements is classified as contract and other collaboration revenue.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in ASC Topic 606. The Company's performance obligations include delivering products to its distributors, commercialization license rights, development services, services associated with the regulatory approval process, joint steering committee services, demonstration devices, manufacturing services, material rights for discounts on manufacturing services, and product supply.

The Company has optional additional items in contracts, which are considered marketing offers and are accounted for as separate contracts when the customer elects such options. Arrangements that include a promise for future commercial product supply and optional research and development services at the customer's or the Company's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, such material rights are accounted for as separate performance obligations. If the Company is entitled to additional payments when the customer exercises these options, any additional payments are recorded in revenue when the customer obtains control of the goods or services.

Transaction Price

The Company has both fixed and variable consideration. Variable consideration for product revenue is described as Net product sales in the consolidated statements of operations. For collaboration agreements, non-refundable upfront fees and product supply selling prices are considered fixed, while milestone payments are identified as variable consideration when determining the transaction price. Funding of research and development activities is considered variable until such costs are reimbursed at which point, they are considered fixed. The Company allocates the total transaction price to each performance obligation based on the relative estimated standalone selling prices of the promised goods or services for each performance obligation.

At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the value of the associated milestone (such as a regulatory submission by the Company) is included in the transaction price. Milestone payments that are not within the control of the Company, such as approvals from regulators, are not considered probable of being achieved until those approvals are received.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (a) when the related sales occur, or (b) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Allocation of Consideration

As part of the accounting for collaboration arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price of each performance obligation identified in the contract. Estimated selling prices for license rights and material rights for discounts on manufacturing services are calculated using an income approach model and can include the following key assumptions: the development timeline, sales forecasts, costs of product sales, commercialization expenses, discount rate, the time which the manufacturing services are expected to be performed, and probabilities of technical and regulatory success. For all other performance obligations, the Company uses a cost-plus margin approach.

Timing of Recognition

Significant management judgment is required to determine the level of effort required under collaboration arrangements and the period over which the Company expects to complete its performance obligations under the arrangement. The Company estimates the performance period or measure of progress at the inception of the arrangement and re-evaluates it each reporting period. This re-evaluation may shorten or lengthen the period over which revenue is recognized. Changes to these estimates are recorded on a cumulative catch-up basis. If the Company cannot reasonably estimate when its performance obligations either are completed or become inconsequential, then revenue recognition is deferred until the Company can reasonably make such estimates. Revenue is then recognized over the remaining estimated period of performance using the cumulative catch-up method. Revenue is recognized for products at a point in time when control of the product is transferred to the customer in an amount that reflects the consideration the Company expects to be entitled to in exchange for those product sales, which is typically once the product physically arrives at the customer, and for licenses of functional intellectual property at the point in time the customer can use and benefit from the license. For performance obligations that are services, revenue is recognized over time proportionate to the costs that the Company has incurred to perform the services using the cost-to-cost input method.

Cost of Goods Sold

Cost of goods sold for product revenue includes third-party manufacturing costs, shipping and handling costs, and indirect overhead costs associated with production and distribution which are allocated to the appropriate cost pool and recognized when revenue is recognized. Indirect overhead costs in excess of normal capacity are recorded as period costs in the period incurred.

Under the Grünenthal Agreements, the Company sold Zalviso to Grünenthal at predetermined, contractual transfer prices that were less than the direct costs of manufacturing and recognized indirect costs as period costs where they were in excess of normal capacity and not recoverable on a lower of cost or net realizable value basis. Cost of goods sold for Zalviso shipped to Grünenthal included the inventory costs of API, third-party contract manufacturing costs, packaging and distribution costs, shipping, handling and storage costs, depreciation and costs of the employees involved with production.

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 AcelRx'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 are anticipated in connection with this cost reduction plan.

Non-Cash Interest Income (Expense) 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. 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 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 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 ARPI LLC 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 Royalty Monetization.

When the expected payments under the Royalty Monetization were lower than the gross proceeds of $65.0 million received, the Company deferred recognition of any probable contingent gain until the Royalty Monetization liability expired. See Note 11, "Liability Related to Sale of Future Royalties".

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss) and is disclosed in the consolidated statements of operations. For the Company, other comprehensive income (loss) consists of changes in unrealized gains and losses on the Company's investments.

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, 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, 2022 Warrants and the Series A Redeemable Convertible Preferred Stock (see Note 12, "Warrants" and Note 14, "Stockholder's Equity (Deficit)" below).

For additional information regarding the net income (loss) per share, see Note 16, “Net Income (Loss) per Share of Common Stock”.

Recently Adopted Accounting Pronouncements

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity’s Own Equity (Subtopic 815-40): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force)*, or ASU-2021-14, which provides guidance on modifications or exchanges of a freestanding equity-classified written call option that is not within the scope of another topic. An entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as an exchange of the original instrument for a new instrument, and provides further guidance on measuring the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange. ASU 2021-04 also provides guidance on the recognition of the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange on the basis of the substance of the transaction, in the same manner as if cash had been paid as consideration. ASU 2021-04 is effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply ASU 2021-04 prospectively to modifications or exchanges occurring on or after the effective date of ASU 2021-04.

The Company adopted ASU 2021-04 effective January 1, 2022, on a prospective basis. In conjunction with the warrant amendments discussed in Note 12, “Warrants”, the Company recorded issuance costs of $0.7 million as an expense and $0.1 million as a reduction of proceeds in additional paid-in capital for the corresponding increase to the remeasured fair value of the equity-classified warrants as of the modification date.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses: Measurement of Credit Losses on Financial Instruments,* or ASU 2016-13. ASU 2016-13 replaces the incurred loss impairment model in current GAAP with a model that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to determine credit loss estimates. ASU 2016-13 is effective for the Company beginning January 1, 2023, with early adoption allowed beginning January 1, 2020. In May 2019, the FASB issued ASU 2019-05, *Financial Instruments – Credit Losses*, or ASU 2019-05, to allow entities to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost upon adoption of the new credit losses standard. The new effective dates and transition align with those of ASU 2016-13. Management does not anticipate adoption of these new standards to have a material impact on the Company’s financial position, results of operations or cash flows.

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). Marketable securities which have maturities beyond one year as of the end of the reporting period are classified as non-current.

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

	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

	As of December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, cash equivalents and restricted cash:				
Cash	$ 1,443	$ —	$ —	$ 1,443
Money market funds	2,822	—	—	2,822
Commercial paper	8,398	—	—	8,398
Total cash, cash equivalents and restricted cash	12,663	—	—	12,663
Short-term investments:				
Commercial paper	29,504	—	—	29,504
Corporate debt securities	9,463	—	—	9,463
Total short-term investments	38,967	—	—	38,967
Total cash, cash equivalents, restricted cash and short-term investments	$ 51,630	$ —	$ —	$ 51,630

None of the available-for-sale securities held by the Company had material unrealized losses and there were no realized losses for the years ended December 31, 2022 and 2021. There were no other-than-temporary impairments for these securities as of December 31, 2022 or 2021. No gross realized gains or losses were recognized on the available-for-sale securities and, accordingly, there were no amounts reclassified out of accumulated other comprehensive income (loss) to earnings during the years ended December 31, 2022 and 2021.

As of December 31, 2022 and 2021, the contractual maturity of all investments held was less than one year.

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 are 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, 2022, the Company held, in addition to Level II assets, a warrant liability related to the 2022 Warrants (see Note 12, "Warrants" for further description). The fair value of the warrant liability was estimated using the Black Scholes Model which uses as inputs the following weighted average assumptions: dividend yield, expected term in years; equity volatility; and risk-free interest rate. The Company follows the guidance in ASC 820 for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period. The estimated fair value of the warrant liability represents a Level III measurement. Changes to the estimated fair value of these liabilities are recorded in 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, 2022			
	Fair Value	**Level I**	**Level II**	**Level III**
Assets				
Money market funds	$ 321	$ 321	$ —	$ —
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

	As of December 31, 2021			
	Fair Value	**Level I**	**Level II**	**Level III**
Assets				
Money market funds	$ 2,822	$ 2,822	$ —	$ —
Commercial paper	37,902	—	37,902	—
Corporate debt securities	9,463	—	9,463	—
Total assets measured at fair value	$ 50,187	$ 2,822	$ 47,365	$ —

3. Discontinued Operations

On April 3, 2023, the Company completed the sale of its DSUVIA business to Alora. The disposal of the DSUVIA business represents a strategic shift that will have a major qualitative effect on its personnel resources and quantitative effect on its financial results. Accordingly, the Company concluded, pursuant to ASC 205-20, "*Presentation of Financial Statements–Discontinued Operations*", that the disposal should be presented as discontinued operations in the consolidated balance sheets as of December 31, 2022 and 2021 and in the consolidated statements of operations as discontinued operations, net of tax, for the years ended December 31, 2022 and 2021. As such, the consolidated financial statements herein have been presented in accordance with ASC 205-20. Net loss from discontinued operations for the years ended December 31, 2022 and 2021, is as follows:

	Year ended December 31,	
	2022	2021
Total revenues	$ 1,771	$ 2,440
Cost of goods sold	1,508	1,959
Selling, general and administrative expense	9,744	16,670
Research and development expenses	1,852	1,660
Loss from operations	11,333	17,849
Interest expense	37	98
Loss from discontinued operations before loss on disposal	$ 11,370	$ 17,947

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, 2022	December 31, 2021
Cash and cash equivalents	$ —	$ —
Accounts receivable, net	309	160
Inventories	1,178	1,111
Prepaid expenses and other current assets	444	577
Total current assets of discontinued operations	1,931	1,848
Property, plant and equipment, net	10,261	11,021
Operating lease right-of-use assets	3,499	4,031
Other assets	176	196
Total non-current assets of discontinued operations	13,936	15,248
Total assets of discontinued operations	$ 15,867	$ 17,096
Accounts payable	$ 784	$ 1,204
Accrued liabilities	1,720	3,008
Operating lease liabilities, current portion	1,601	886
Note payable, current portion	400	463
Deferred revenue, current portion	115	87
Total current liabilities of discontinued operations	4,620	5,648
Operating lease liabilities, net of current portion	2,959	3,649
Deferred revenue, net of current portion	1,036	1,151
Total non-current liabilities of discontinued operations	3,995	4,800
Total liabilities of discontinued operations	8,615	10,448
Net assets of discontinued operations	$ 7,252	$ 6,648

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

	Year Ended December 31,	
	2022	2021
Cash flows from operating activities:		
Depreciation and amortization	$ 1,465	$ 1,537
Stock-based compensation	250	779
Inventory impairment charge	40	723
Non-cash interest expense related to debt financing	(37)	(98)

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 AcelRx 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 AcelRx 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 AcelRx'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, 2022, none of the contingent events has 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.

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

The IPR&D asset will be initially accounted for as an indefinite-lived asset, and as a long-lived asset, it will be 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 year ended December 31, 2022.

5. Property and Equipment, Net

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

	Balance as of	
	December 31, 2022	December 31, 2021
Laboratory equipment	$ 2,787	$ 2,821
Construction in process	—	4,872
Tooling	792	792
	3,579	8,485
Less accumulated depreciation and amortization	(3,579)	(3,578)
Property and equipment, net	$ —	$ 4,907

The Company decided to realign its cost structure from a focus on commercialization to a focus on advancing its recently acquired late-stage development pipeline, namely the pre-filled syringes and Niyad product candidates. As a result, the Company decided to not focus any development resources on Zalviso in the United States, and does not expect to resubmit the Zalviso NDA in the foreseeable future. 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 does not expect any revenues from Zalviso in Europe in the foreseeable future. Accordingly, the Company determined that it is no longer probable that it will realize the future economic benefit associated with the costs of the Zalviso-related purchased equipment and manufacturing-related facility improvements the Company has 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 each of the years ended December 31, 2022 and 2021.

6. 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 containing 10 ml of a solution of 3 mg/ml ephedrine hydrochloride for injection, and (ii) a phenylephrine pre-filled syringe containing 10 ml of a solution of 50 mcg/ml phenylephrine hydrochloride 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.

Aguettant is entitled to receive up to $24.0 million in sales-based milestone payments. 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.

As of December 31, 2022, there have been no payments by the Company to Aguettant under the PFS Agreement.

See Note 20, “Subsequent Events” below.

7. Out-License Agreements

Zalviso

On May 18, 2020, the Company received a notice from Grünenthal that it had exercised its right to terminate the Grünenthal Agreements, effective November 13, 2020. The terms of the Grünenthal Agreements were extended to May 12, 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 Zalviso Territory reverted back to the Company on May 12, 2021. In July 2022, the European Marketing Authorization for Zalviso was withdrawn.

8. Revenue from Contracts with Customers

The following table summarizes revenue from contracts with customers for the years ended December 31, 2022 and 2021 into categories that depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors (in thousands):

	December 31,	
	2022	**2021**
Product sales:		
Zalviso	$ —	$ 270
Total product sales	—	270
Contract and collaboration revenue:		
Non-cash royalty revenue related to Royalty Monetization (Note 11)	—	83
Royalty revenue	—	28
Other revenue	—	(3)
Total revenues from contract and other collaboration	—	108
Total revenue	$ —	$ 378

For additional detail on the Company’s accounting policy regarding revenue recognition, refer to Note 1, “Organization and Summary of Significant Accounting Policies - Revenue from Contracts with Customers.”

Product Sales

Zalviso was sold in Europe by the Company’s collaboration partner, Grünenthal, through May 12, 2021, at which time, due to the termination of the Grünenthal Agreements, the rights to market and sell Zalviso in Europe reverted back to the Company.

Contract and Other Collaboration

Contract and other collaboration revenue includes revenue under the Grünenthal Agreements related to research and development services, non-cash royalty revenue related to the Royalty Monetization and royalty revenue for sales of Zalviso in Europe. For the year ended December 31, 2022, the Company did not record any contract and other collaboration revenue.

9. Long-Term Debt

Loan Agreement with Oxford

On May 30, 2019, the Company entered into the Loan Agreement with 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. The Company used approximately $8.9 million of the proceeds from the Loan to repay its outstanding obligations under its prior debt agreement. After deducting all loan initiation costs and outstanding interest on the prior debt agreement, the Company received $15.9 million in net proceeds.

The interest rate is calculated at a rate equal to the sum of (a) the greater of (i) the 30-day U.S. LIBOR rate reported in *The Wall Street Journal* on the last business day of the month that immediately precedes the month in which the interest will accrue and (ii) 2.50%, plus (b) 6.75%. Payments on the Loan were interest-only until July 1, 2020 followed by equal principal payments and monthly accrued interest payments through the scheduled maturity date of June 1, 2023. The Company's obligations under the Loan Agreement are secured by a security interest in all the assets of the Company, other than the Company's intellectual property which is subject to a negative pledge.

The Company may prepay the Loan at any time. If the Loan is paid prior to the maturity date, the Company will pay the Lender a prepayment charge, based on a percentage of the then outstanding principal balance, equal to 1%. Upon voluntary or mandatory prepayment, in addition to the prepayment charge, the Company is required to pay the EOT Fee, Lender's expenses and all outstanding principal and accrued interest through the prepayment date.

The Loan Agreement includes customary representations and covenants that, subject to exceptions, will restrict the Company's ability to do the following things: declare dividends or redeem or repurchase equity interests; incur additional liens; make loans and investments; incur additional indebtedness; engage in mergers, acquisitions, and asset sales; transact with affiliates; undergo a change in control; add or change business locations; and engage in businesses that are not related to its existing business. 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 Lender, tested monthly as of the last day of the month.

The Loan Agreement also includes standard events of default, including payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of the Lender's security interest or in the value of the collateral, a material adverse change in business, operations or the prospect of repayment, events relating to bankruptcy or insolvency. The Loan also contains a cross default provision, under which if a third party (under any agreement) has the right to accelerate indebtedness greater than $250,000, the Loan would also be considered in default. In addition, the Loan defines events which negatively impact government approvals, judgments in excess of $500,000 and the delisting of the Company's shares of common stock on the Nasdaq Global Market, or Nasdaq, as events of default. Upon the occurrence of an event of default, a default interest rate of an additional 5% may be applied to the outstanding loan balances, and the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. Acceleration would result in the payment of any applicable prepayment charges and application of the default interest rate to the outstanding balance until payment is made in full. The Company bifurcated a compound derivative liability related to a contingent interest feature and acceleration upon default provision (contingent put option) provided to the Lender. The bifurcated embedded derivative must be valued and separately accounted for in the Company's consolidated financial statements. The contingent put option liability is classified as a component of other long-term liabilities. As of December 31, 2022, the estimated fair value of the contingent put option liability was $10,000 which was determined by using a risk-neutral valuation model, wherein the fair value of the underlying debt facility is estimated, both with and without the presence of the default provisions, holding all other assumptions constant.

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 (deficit) 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 12, "Warrants".

The outstanding balance due under the Loan Agreement was $5.4 million and $13.3 million at December 31, 2022 and 2021, respectively. 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, $0.7 million of which represented amortization of the debt discount, for the years ended December 31, 2022 and 2021, respectively, and the effective interest rate was approximately 13.6% and 13.2% for the years ended December 31, 2022 and 2021, respectively.

Future Payments on Long-Term Debt

The following table summarizes the outstanding future payments associated with the Company's long-term debt as of December 31, 2022 (in thousands):

2023	$ 5,551
Total payments	5,551
Less amount representing interest	(134)
Notes payable, gross	5,417
Less: Unamortized portion of EOT Fee	(26)
Less: Unamortized discount on notes payable	(28)
Long-term debt	5,363
Less current portion	(5,363)
Long-term debt, net of current portion	$ —

10. Leases

Office Lease

The Company leased office and laboratory space for its former corporate headquarters, located at 301 – 351 Galveston Drive, Redwood City, California, and entered into an agreement to sublease approximately 12,106 square feet of this office and laboratory space.

On March 26, 2021, the Company entered into a Lease Termination Agreement with its landlord and a Sublease Termination Agreement with its sublessee, to terminate the lease and sublease agreements at its former corporate headquarters. The termination of both the lease and sublease was effective on April 30, 2021. As of the date of the Lease Termination Agreement, the Company remeasured its lease liability and recorded a gain of $0.5 million upon derecognition of the lease liability and right of use asset for the master lease, which was included in operating expenses for the year ended December 31, 2021. In connection with the Sublease Termination, the remaining deferred costs of $0.3 million were fully amortized through April 30, 2021, the effective date of the Sublease Termination, and included in operating expenses for the year ended December 31, 2021.

On March 26, 2021, the Company entered into a Sublease Agreement to sublet space for its new corporate headquarters, located at 25821 Industrial Boulevard, Hayward, California. The Sublease Agreement commencement date was April 1, 2021. The Sublease Agreement is for a period of two years and three months with monthly rental payments of $17,000, including one month of abated rent. On the lease commencement date, the Company recognized an operating lease right-of-use asset in the amount of $0.4 million.

The components of lease expense are presented in the following table (in thousands):

	Year ended December 31, 2022	Year ended December 31, 2021
Operating lease costs	$ 200	$ 537
Gain on derecognition of operating lease	—	(522)
Sublease income	—	(199)
Loss on termination of sublease	—	331
Net lease costs	$ 200	$ 147

The weighted average remaining lease term and discount rate related to the operating leases are presented in the following table:

	December 31, 2022	December 31, 2021
Weighted-average remaining lease term – operating leases (in years)	0.5	1.5
Weighted-average remaining discount rate – operating leases	12.9%	12.9%

Maturities of lease liabilities as of December 31, 2022 are presented in the following table (in thousands):

Year:	
2023	$ 104
Total future minimum lease payments	104
Less imputed interest	(4)
Total	$ 100
Reported as:	
Operating lease liabilities	$ 100
Operating lease liabilities, current portion	(100)
Operating lease liabilities, net of current portion	$ —

11. Liability Related to Sale of Future Royalties

On September 18, 2015, the Company entered into the Royalty Monetization with PDL for which it received gross proceeds of $65.0 million. Under the 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 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 the Zalviso Territory 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 Royalty Monetization for which the Company paid cash consideration of $0.1 million, and neither PDL nor SWK retains any further interest in the Royalty Monetization. Accordingly, effective May 31, 2022, the 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 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 years ended December 31, 2022 and 2021 was approximately 3.2% and 3.5%, respectively.

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 termination of liability related to sale of future royalties	(84,052)	(84,052)
Liability related to sale of future royalties as of December 31, 2022	$ —	$ —

As mentioned above, the Royalty Monetization was terminated on May 31, 2022.

12. Warrants

December 2022 Financing Warrants

On December 27, 2022, the Company entered into a securities purchase agreement, or the Purchase Agreement, with an institutional investor, or the Purchaser, relating to the issuance and sale, or the Offering, of (i) 748,744 shares of its common stock (see Note 14, "Stockholders' Equity (Deficit)"), par value $0.001 per share, (ii) pre-funded warrants to purchase 2,632,898 shares of common stock, or the 2022 Pre-Funded Warrants, and (iii) common warrants to purchase an aggregate of 4,227,052 shares of common stock, or the 2022 Warrants, and collectively, the December 2022 Financing.

The 2022 Pre-Funded Warrants were exercisable immediately following the closing date of the Offering, or December 29, 2022, and have an unlimited term and an exercise price of $0.0001 per share. The 2022 Warrants will be exercisable following the six-month anniversary of the closing date of the Offering and have a six-year term and an exercise price of $2.07 per share. The combined offering price is $2.22625 per share of common stock and accompanying 2022 Warrant, or in the case of 2022 Pre-Funded Warrants, $2.22615 per 2022 Pre-Funded Warrant and accompanying 2022 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.

The 2022 Warrants include full ratchet anti-dilutive adjustment rights in the event the Company issues 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. See Note 20, "Subsequent Events" below.

In the event of certain fundamental transactions involving the Company, the holder of the 2022 Warrants may require the Company to make a payment based on a Black-Scholes valuation, using specified inputs. The 2022 Pre-Funded Warrants do not provide similar rights to the Purchaser. Therefore, the Company accounted for the 2022 Warrants as a liability, while the 2022 Pre-Funded Warrants met the permanent equity criteria classification. The 2022 Pre-Funded Warrants are classified as a component of permanent equity, or APIC, because they are 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 2022 Pre-Funded Warrants do not provide any guarantee of value or return. The December 2022 Warrants were valued 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 2022 Pre-Funded Warrants being allocated values of $95,000 and $335,000, respectively, and such amount being recorded to stockholders' equity (deficit). The change in fair value of the Warrant liability from the date of issuance to December 31, 2022 was immaterial. The 2022 Warrants meet the definition of participating securities; however, there is no contractual obligation on the part of the warrantholders to participate in the Company's losses.

As of December 31, 2022, the 2,632,898 pre-funded warrants and the 4,227,052 common warrants remained outstanding. See Note 20, "Subsequent Events" below.

August 2022 LPC Warrant

On August 3, 2022, the Company entered into a securities purchase agreement with Lincoln Park Capital Fund, LLC, or LPC, pursuant to which the Company, in a private placement transaction, sold (i) an aggregate of 3,000 shares of the Company's Series A Redeemable Convertible Preferred Stock, and (ii) warrants to purchase up to an aggregate of 81,150 shares of common stock, for an aggregate purchase price of $0.3 million (see Note 14, "Stockholders' Equity (Deficit)"). In November 2022, the Company filed a resale registration statement to permit LPC to sell the shares of common stock issuable upon conversion of the Series A Redeemable Convertible Preferred Stock and upon exercise of the warrant.

The August 2022 LPC Warrant had an 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. The August 2022 LPC Warrant provides for proportional adjustment of the number and kind of securities purchasable upon exercise of the August 2022 LPC Warrant and the per share exercise price upon the occurrence of certain events such as stock splits, combinations, reverse stock splits and similar events. In addition, until August 3, 2023, if the Company issues or sells (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. 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 original exercise price, $4.07, and the new exercise price, $2.07. The difference in fair value of the effect of the Down Round Feature was immaterial and had no impact on net loss per share in the periods presented. The exercise price will continue to be adjusted in the event the Company issues additional shares of common stock below the current exercise price, in accordance with the terms of the 2022 LPC Warrant.

The August 2022 LPC Warrant was 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 $129,000 and $110,000, respectively, and recorded to stockholders' equity (deficit).

As of December 31, 2022, 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 (see Note 14, "Stockholders' Equity (Deficit)"). The November 2021 Financing Warrants meet the definition of participating securities; however, there is no contractual obligation on the part of the warrantholders to participate in the Company's losses.

The November 2021 Financing Warrants have an exercise price of $20.00 per share and become exercisable, if the holder's post-exercise beneficial ownership is less than or equal to 9.99%, 6 months after their issuance date and have a five-year term through November 15, 2026. All common stock issuable under the issued warrants, were added to the Company's effective registration statement on November 15, 2021.

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 (deficit).

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 for 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 remain outstanding at December 31, 2022, are currently exercisable at a price of $20.00 per share and expire on November 15, 2026.

Loan Agreement Warrants

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

The Company estimated the fair value of these Loan Agreement Warrants as of the issuance date to be $0.4 million, which was used in estimating the fair value of the debt instrument and was recorded as equity. The fair value of the Loan Agreement Warrants was calculated using the Black-Scholes option-valuation model, and was based on the strike price of $56.60, the stock price at issuance of $53.20, the ten-year contractual term of the warrants, a risk-free interest rate of 2.22%, expected volatility of 80.22% and 0% expected dividend yield.

As of December 31, 2022, 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.

13. 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 dismissing all of plaintiffs' claims against the Company and the named defendants with leave to amend, and on November 28, 2022, plaintiffs filed a second amended complaint naming the Company and three of its officers and asserting violations under Sections 10(b) and 20(a) of the Exchange Act on the same grounds as in the amended complaint and seeking unspecified damages, interest, attorneys' fees, and other costs. On January 30, 2023, the Company filed a motion to dismiss the second amended complaint with prejudice and on March 16, 2023, plaintiffs filed their opposition to the motion to dismiss the second amended complaint, The Company has an April 17, 2023 deadline to file its reply in support of the motion to dismiss the second amended complaint.

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. Please see "Part II., 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.

14. Stockholders' Equity (Deficit)

Reverse Stock Split

On September 23, 2022, at a special meeting of stockholders, the Company's stockholders authorized the Company's Board of Directors to effect the Reverse Stock Split of all outstanding shares of common stock in a range of 1-for-10 to 1-for-30 shares. The Board of Directors subsequently approved the Reverse Stock Split at a ratio of 1-for-20. The Reverse Stock Split became effective at 5:01 p.m. Eastern Time on October 25, 2022. The Company's common stock began trading on the Nasdaq Global Market on a split-adjusted basis on October 26, 2022. The Reverse Stock Split was primarily intended to bring the Company into compliance with the minimum bid price requirements for maintaining its listing on the Nasdaq Global Market.

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. Upon the closing of the December 29, 2022 registered direct offering, the Company agreed to amend the August 2022 LPC Warrant to reduce the exercise price to $2.07 per share (see Note 12, "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 (deficit).

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

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 2022 Pre-Funded Warrants to purchase 2,632,898 shares of common stock, and (iii) the 2022 Warrants, which will accompany the common stock and 2022 Pre-Funded Warrants, to purchase an aggregate of 4,227,052 shares of common stock (see Note 12, "Warrants"). The shares of common stock and accompanying 2022 Warrants were sold at a combined offering price of $2.22625 per share and accompanying common warrant, and the 2022 Pre-Funded Warrants and accompanying 2022 Warrants were sold at a combined offering price of $2.22615 per 2022 Pre-Funded Warrant and accompanying 2022 Warrant. 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 the Company, excluding the proceeds, if any, from the exercise of the 2022 Pre-Funded Warrants and the 2022 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 12, "Warrants").

2021 Underwritten Public Offering

On January 22, 2021, the Company completed an underwritten public offering in which the Company issued and sold 725,000 shares of its common stock to the underwriter at a price of $35.25 per share. On January 27, 2021, the underwriters exercised their option in full and purchased an additional 108,750 shares at a price of $35.25 per share. The total net proceeds from this offering of an aggregate 833,750 shares were approximately $28.9 million.

2021 Registered Direct Offering

On November 17, 2021, the Company completed a registered direct offering in which the Company issued and sold 875,000 shares of its common stock at a price of $16.00 per share and warrants exercisable for an aggregate of 875,000 shares of its common stock at a price of $20.00 per share (see Note 12, "Warrants"). The total net proceeds from this offering were approximately $13.9 million. The November 2021 issued shares were valued at approximately $13.1 million based on the closing stock price of $14.92 per share on November 15, 2021. 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.

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 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, during the year ended December 31, 2022. During the year ended December 31, 2021, the Company issued and sold approximately 0.2 million shares of common stock pursuant to the ATM Agreement, and received net proceeds of approximately $7.5 million, after deducting fees and expenses.

As of December 31, 2022, 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.

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 0.1 million 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 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 approximately 0.3 million 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 approximately 0.7 million shares. The term of any option granted under the 2020 EIP is determined on the date of grant but shall not be longer than 10 years. The Company issues new shares for settlement of vested restricted stock units and exercises of stock options. The Company does not have a policy of purchasing its shares relating to its stock-based programs.

On June 17, 2021, at the 2021 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 2020 Plan, or as amended and restated, the Amended 2020 Plan, to increase the number of authorized shares reserved for issuance thereunder by approximately 0.2 million 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) approximately 0.2 million shares approved in connection with the adoption of the Amended 2020 Plan, (ii) approximately 0.3 million shares approved in connection with the original adoption of the 2020 Plan, and (iii) certain shares subject to outstanding awards granted under the 2011 Equity Incentive Plan that may become available for issuance under the 2020 Plan and 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 approximately 0.2 million 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, 2022, there were 10,941 shares issued under the Amended ESPP. The weighted average fair value of shares issued under the Amended ESPP in 2022 and 2021 was $6.82 and $20.23 per share, respectively. As of December 31, 2022, there were 211,876 shares available for future grant under the Amended ESPP.

15. 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, 2022	December 31, 2021
Cost of goods sold	$ —	$ 85
Research and development	570	813
Selling, general and administrative	2,069	2,932
Discontinued operations	250	779
Total	$ 2,889	$ 4,609

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, 2021	69,890	$ 35.75
Granted	57,448	33.65
Vested	(29,338)	37.75
Forfeited	(9,289)	31.56
Restricted stock units outstanding, December 31, 2021	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

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, 2021	714,085	$ 59.79		
Granted	117,022	7.75		
Forfeited	(35,645)	26.46		
Expired	(69,839)	60.42		
Exercised	—	—		
December 31, 2022	725,623	$ 52.98	5.3	$ —
Vested and exercisable options—December 31, 2022	515,933	$ 65.76	3.9	$ —
Vested and expected to vest—December 31, 2022	725,623	$ 52.80	5.3	$ —

As of December 31, 2022, there were 342,827 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, 2022 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
$4.62 - $8.03	88,096	9.2	$ 7.54	—	$ —
$8.36 - $12.54	19,046	9.1	$ 8.43	—	$ —
$14.40 - $21.60	20,941	6.9	$ 16.93	13,643	$ 16.84
$22.40 - $33.60	11,700	8.1	$ 28.62	10,774	$ 28.58
$34.40 - $51.60	311,695	6.0	$ 41.16	217,425	$ 42.75
$52.00 - $78.00	168,275	3.5	$ 62.66	168,221	$ 62.66
$78.40 - $117.60	62,756	1.0	$ 97.95	62,756	$ 97.95
$132.00 - $198.00	20,520	1.6	$ 133.16	20,520	$ 133.16
$204.40 - $306.60	22,594	1.0	$ 206.96	22,594	$ 206.96
	725,623	5.3	$ 52.98	515,933	$ 65.76

The weighted average grant-date fair value of options granted during the years ended December 31, 2022 and 2021 was $5.80 and $24.74 per share, respectively. As of December 31, 2022, total stock-based compensation expense related to unvested options to be recognized in future periods was $1.8 million which is expected to be recognized over a weighted-average period of 1.8 years. The grant date fair value of shares vested during the years ended December 31, 2022 and 2021 was $1.7 million and $2.4 million, respectively. The total intrinsic value of options exercised during the years ended December 31, 2021 and 2020 was $0 and $5.7 thousand, respectively.

On March 3, 2021, the Company granted 1.27 million performance-based stock options to certain of its executive officers, which are included in the stock option tables and associated disclosures above. The awards were granted under the 2020 EIP with an exercise price of $1.88 per share, the closing sales price as reported on the Nasdaq on the date of grant. 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, 2022 and 2021.

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

	Year Ended December 31,	
	2022	2021
Derived service period (in years)	—	2.3 – 2.6
Risk-free interest rate	—	1.5%
Expected volatility	—	90%
Expected dividend rate	—	0%

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

	Year Ended December 31,	
	2022	2021
Expected term (in years)	6.3	6.0 - 6.2
Risk-free interest rate	1.6% - 3.0%	0.9% - 1.3%
Expected volatility	88%	90%
Expected dividend rate	0%	0%

16. 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) allocable 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. During 2022, the Company presents diluted EPS using the two-class method as it was more dilutive. The Company's participating securities do not have a contractual obligation to share in the Company's losses, therefore, net loss for the year ended December 31, 2021 was attributed entirely to common stockholders. In periods with a reported net loss, common stock equivalents are excluded from the calculation of diluted net loss per share of common stock if their effect is antidilutive. Potential common shares that are issuable for little or no cash consideration, such as the Company's pre-funded warrants issued in December 2022 with a de minimis exercise price of $0.0001 per share, 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, 2022 and 2021 (in thousands, except for share and per share amounts):

	Year ended December 31,	
	2022	2021
	(in thousands, except share and per share amounts)	
Basic net income (loss) per common share from continuing operations:		
Net income (loss)	$ 59,125	$ (17,152)
Less: deemed dividend related to Series A Redeemable Convertible Preferred Stock	(186)	—
Less: income allocated to participating securities	(5,240)	—
Net income (loss) attributable to common shareholders	$ 53,699	$ (17,152)
Weighted average shares outstanding — basic	7,385,348	5,993,013
Net income (loss) — basic	$ 7.27	$ (2.86)

	Year ended December 31,	
	2022	2021
	(in thousands, except share and per share amounts)	
Basic net income (loss) per common share from discontinued operations:		
Net loss	$ (11,370)	$ (17,947)
Weighted average shares outstanding — basic	7,385,348	5,993,013
Net income (loss) — basic	$ (1.54)	$ (3.00)

	Year ended December 31,	
	2022	2021
	(in thousands, except share and per share amounts)	
Diluted net income (loss) per common share from continuing operations:		
Net income (loss)	$ 59,125	$ (17,152)
Less: deemed dividend related to Series A Redeemable Convertible Preferred Stock	(186)	—
Less: income allocated to participating securities	(5,227)	—
Net income (loss) attributable to common shareholders	$ 53,712	$ (17,152)
Weighted average shares outstanding — basic	7,385,348	5,993,013
Dilutive effect of warrants	20,285	—
Dilutive effect of RSUs	1,353	—
Weighted average shares outstanding — diluted	7,406,986	5,993,013
Net income (loss) — diluted	$ 7.25	$ (2.86)

	Year ended December 31,	
	2022	2021
	(in thousands, except share and per share amounts)	
Diluted net income (loss) per common share from discontinued operations:		
Net loss	$ (11,370)	$ (17,947)
Weighted average shares outstanding — basic	7,385,348	5,993,013
Dilutive effect of warrants	20,285	—
Dilutive effect of RSUs	1,353	—
Weighted average shares outstanding — diluted	7,406,986	5,993,013
Net income (loss) — diluted	$ (1.53)	$ (3.00)

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,	
	2022	2021
ESPP, RSUs and stock options to purchase common stock	815,710	816,421
Common stock warrants	133,833	883,833

In addition, the shares held back and contingently issuable in connection with the Lowell Merger, as described in Note 4 above, have also been excluded from the computation of diluted net income (loss) per share of common stock for the periods presented because the contingencies for issuance of these shares have not been met.

17. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	December 31,	
	2022	2021
Accrued compensation and employee benefits	$ 1,732	$ 2,122
Accrued professional services	456	1,131
Other accrued liabilities	243	176
Total accrued liabilities	$ 2,431	$ 3,429

18. 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 $0.3 million and $0.4 million for the years ended December 31, 2022 and 2021, respectively.

19. Income Taxes

The Company recorded a provision for income taxes of $13 thousand and $5 thousand for the years ended December 31, 2022 and 2021, respectively. The income tax expense associated with discontinued operations for each of the years ended December 31, 2022 and 2021 is $0.

Net deferred tax assets as of December 31, 2022 and 2021 consist of the following (in thousands):

	December 31, 2022	December 31, 2021
Deferred tax assets:		
Accruals and other	$ 1,738	$ 3,989
Research credits	7,392	7,275
Net operating loss carryforward	84,325	75,452
Section 59(e) R&D expenditures	3,496	5,070
Section 174 R&D expenditures	981	—
Deferred revenue	—	19,666
Total deferred tax assets	97,932	111,452
Valuation allowance	(97,932)	(111,452)
Net deferred tax assets	$ —	$ —

Reconciliations of the statutory federal income tax to the Company's effective tax during the years ended December 31, 2022 and 2021 are as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Tax at statutory federal rate	$ 10,031	$ (7,370)
State tax—net of federal benefit	823	231
Acquired assets	1,728	—
Stock options	611	718
Other	340	(20)
Change in valuation allowance	(13,520)	6,446
Provision for income taxes	$ 13	$ 5

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 decreased by $13.5 million and increased by $6.4 million during the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, the Company had federal net operating loss carryforwards of $346.4 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 $231.5 million generated from 2018 to 2022 will carryforward indefinitely but are subject to the 80% taxable income limitation. As of December 31, 2022, the Company had state net operating loss carryforwards of $167.9 million, which begin to expire in 2028.

As of December 31, 2022, the Company had federal research credit carryovers of $6.6 million, which begin to expire in 2026. As of December 31, 2022, the Company had state research credit carryovers of $4.1 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, 2022 and 2021 is as follows (in thousands):

	Year Ended December 31,	
	2022	**2021**
Unrecognized benefit—beginning of period	$ 2,635	$ 2,635
Gross increases—prior period tax positions	—	—
Gross increases—current period tax positions	43	—
Unrecognized benefit—end of period	$ 2,678	$ 2,635

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, 2022 and 2021. The Company files income tax returns in the United States, California, and other states. The tax years 2005 through 2014, and 2016 through 2022, 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, 2021 or 2022. 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, 2022.

20. Subsequent Events

On April 3, 2023, the Company closed the transactions contemplated by the Purchase Agreement entered into on March 12, 2023, with Alora, pursuant to which Alora agreed to acquire certain assets and assume certain liabilities of AcelRx 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, AcelRx 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 Product to all customers, other than sales to the United States Department of Defense, or DoD, under the Marketing Agreement (as defined below), pursuant to which Alora will pay AcelRx 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 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 Product, or by Alora or its affiliates or equityholders in connection with a sale or transfer to any third party of an ownership interest in any assets acquired by Alora under the Purchase Agreement.

The Purchase 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 Purchase Agreement to manufacture, develop or commercialize any product (other than Product) that is or has been commercialized by AcelRx or its affiliate as of the date of the Purchase 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 Product in the United States. If Alora (together with other relevant parties, taken as a whole) fails to commercialize, sell and distribute Product within the six-month period beginning on July 1, 2023, then all rights granted to Alora pursuant to the Purchase Agreement will, upon AcelRx’s written notice, revert back to AcelRx. The Purchase Agreement also contains indemnification rights for each of AcelRx 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 AcelRx and Aguettant, as well as certain ancillary agreements between AcelRx and Alora. Such ancillary agreements include (a) an intellectual property agreement, pursuant to which Alora granted fully-paid, royalty-free and perpetual licenses to AcelRx under certain specified intellectual property rights acquired by Alora under the Purchase 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, AcelRx 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 Product transferred to Alora under the Purchase Agreement, and (c) a marketing agreement, or the Marketing Agreement, pursuant to which AcelRx will have the exclusive right to market and offer Product for sale to DoD and Alora will pay to AcelRx 75% of net sales of Product sold to DoD, subject to adjustment in certain circumstances.

Amendments to Certain Agreements Between AcelRx and Aguettant

AcelRx 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 AcelRx to Aguettant, or the Supply Agreement. Pursuant to the Purchase Agreement, AcelRx 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) AcelRx 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 Product, and (c) after Aguettant has established such semi-automated packaging line, AcelRx 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 Purchase Agreement, AcelRx assigned the Amended DZUVEO Agreement and the Amended and Restated Supply Agreement to Alora.

In addition, AcelRx and Aguettant are parties to the License and Commercialization Agreement, dated July 14, 2021, pursuant to which AcelRx 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. In connection with AcelRx'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 AcelRx a complementary payment in the amount of EUR 1,500,000, and (b) AcelRx'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 to $21 million.

Termination Agreement and Mutual Release Between AcelRx and Catalent

On March 12, 2023, AcelRx 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 AcelRx 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.

2022 Pre-Funded Warrants

The 2022 Pre-Funded Warrants to purchase 2,632,898 shares of common stock were fully exercised in the first quarter of 2023.

21. Restatement (Unaudited)

Restatement of Previously Issued Unaudited Interim Condensed Consolidated Financial Statements

In connection with the Company's year-end financial statement close and preparation of its Annual Report on Form 10-K for the year ended December 31, 2022, an error in the earnings per share calculations was identified in the interim financial statements (the "Prior Period Financial Statements") for the three and six months ended June 30, 2022 and nine months ended September 30, 2022 (the "Interim Periods"). The error in the earnings per share calculation was due to the Company not properly applying the two-class method of calculating earnings per share with respect to, or disclose that, the warrants issued in November 2021 are participating securities. The financial statements for the year ended December 31, 2021 and the three months ended March 31, 2022, did not require the application of the two-class method of calculating earnings per share, and therefore were not impacted by the issuance of the warrants in November 2021.

The error has no impact on the Company's cash balance, liquidity, revenues, operating expenses, or total net income. Further, there is no impact to the Company's balance sheet accounts or cash flows.

On March 30, 2023, the Company's management and the Audit Committee of the Company determined that the Company's Prior Period Financial Statements for the Interim Periods, should no longer be relied upon because of the error in the earnings per share calculations. The Company's management and the Audit Committee concluded that it is appropriate to restate the Prior Period Financial Statements for the Interim Periods noted above.

The following tables present the impact of the error on basic and diluted EPS for the three and six months ended June 30, 2022, and the nine months ended September 30, 2022 (amounts in thousands, except per share data, 1-for-20 reverse stock split adjusted).

	Three Months Ended June 30, 2022		
	As Previously Reported	Adjustment	As Restated
Basic net income per common share:			
Net income	$ 70,663	$ —	$ 70,663
Income allocated to participating securities	—	(7,511)	(7,511)
Net income attributable to Common Shareholders, basic	$ 70,663	$ (7,511)	$ 63,152
Net income attributable to Common Shareholders per share, basic	$ 9.60	$ (1.02)	$ 8.58
Shares used in computing net income attributable to Common Shareholders per share, basic	7,356,952	—	7,356,952
Diluted net income (loss) per common share:			
Net income	$ 70,663	$ —	$ 70,663
Income allocated to participating securities	—	(7,508)	(7,508)
Net income attributable to Common Shareholders, diluted	$ 70,663	$ (7,508)	$ 63,155
Net income attributable to Common Shareholders per share, diluted	$ 9.60	$ (1.02)	$ 8.58
Shares used in computing net income attributable to Common Shareholders per share, diluted	7,360,453	—	7,360,453

	Six Months Ended June 30, 2022		
	As Previously Reported	Adjustment	As Restated
Basic net income per common share:			
Net income	$ 61,989	$ —	$ 61,989
Income allocated to participating securities	—	(6,619)	(6,619)
Net income attributable to Common Shareholders, basic	$ 61,989	$ (6,619)	$ 55,370
Net income attributable to Common Shareholders per share, basic	$ 8.47	$ (0.91)	$ 7.56
Shares used in computing net income attributable to Common Shareholders per share, basic	7,319,279	—	7,319,279
Diluted net income per common share:			
Net income	$ 61,989	$ —	$ 61,989
Income allocated to participating securities	—	(6,618)	(6,618)
Net income attributable to Common Shareholders, diluted	$ 61,989	$ (6,618)	$ 55,371
Net income attributable to Common Shareholders per share, diluted	$ 8.47	$ (0.91)	$ 7.56
Shares used in computing net income attributable to Common Shareholders per share, diluted	7,321,022	—	7,321,022

	Nine Months Ended September 30, 2022		
	As Previously Reported	Adjustment	As Restated
Basic net income per common share:			
Net income	$ 55,239	$ —	$ 55,239
Deemed dividend related to Series A Redeemable Convertible Preferred Stock	(186)	—	(186)
Income allocated to participating securities	(129)	(5,851)	(5,980)
Net income attributable to Common Shareholders, basic	$ 54,924	$ (5,851)	$ 49,073
Net income attributable to Common Shareholders per share, basic	$ 7.48	$ (0.79)	$ 6.69
Shares used in computing net income attributable to Common Shareholders per share, basic	7,338,853	—	7,338,853
Diluted net income per common share:			
Net income	$ 55,239	$ —	$ 55,239
Deemed dividend related to Series A Redeemable Convertible Preferred Stock	(186)	—	(186)
Income allocated to participating securities	(129)	(5,846)	(5,975)
Net income attributable to Common Shareholders, diluted	$ 54,924	$ (5,846)	$ 49,078
Net income attributable to Common Shareholders per share, diluted	$ 7.46	$ (0.78)	$ 6.68
Shares used in computing net income attributable to Common Shareholders per share, diluted	7,367,293	(21,339)	7,345,954