UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2023

or

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

For the transition period from to

Commission File Number: 001-35068

ACELRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

25821 Industrial Boulevard, Suite 400
Hayward, CA 94545
(650) 216-3500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	**Trading symbol(s)**	**Name of Each Exchange on Which registered:**
Common Stock, $0.001 par value	**ACRX**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of May 5, 2023, the number of outstanding shares of the registrant's common stock was 10,924,294.

ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED MARCH 31, 2023

TABLE OF CONTENTS

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

Forward-Looking Statements

This Quarterly Report on Form 10-Q, or Form 10-Q, contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by that section. The forward-looking statements in this Form 10-Q are contained principally under "Part I. Financial Information - Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Part II. Other Information - Item 1A. Risk Factors". In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Many important factors affect our ability to achieve our objectives, including:

- our ability to obtain additional required financing and to continue as a going concern;
- our ability to manage our operating costs and reduce our cash burn;
- the accuracy of our estimates regarding the sufficiency of our cash resources, future revenues, expenses, and capital requirements;
- our ability to maintain listing of our securities trading on the Nasdaq exchange;
- the historical performance and high volatility in the market price of our common stock;
- macroeconomic uncertainties, including inflationary pressures, domestic and global supply chain disruptions, labor shortages, significant volatility in global markets, recession risks and the worldwide COVID-19 pandemic;
- our ability to file for and secure a potential Emergency Use Authorization for our lead nafamostat developmental product candidate, Niyad™;
- our ability to conduct ourselves, or through a contract research organization, clinical trials in a timely and effective manner to advance the development of our product candidates;
- our ability to successfully file for and obtain regulatory approval for, and then successfully launch and commercialize our developmental product candidates;
- the success of our new corporate partner, Vertical Pharmaceuticals LLC, a wholly owned subsidiary of Alora Pharmaceuticals, LLC, or Alora, in integrating and commercializing the DSUVIA asset in the United States, including their effectiveness in marketing, sales, and distribution of the DSUVIA product, itself or with potential collaborators;
- the extent of future sales of DSUVIA by Alora to the Department of Defense, or DoD;
- the size and growth potential of the potential markets for our developmental product candidates in the United States and in other jurisdictions, and our ability to serve those markets;
- our estimates of the existence of and commercial potential for markets for our developmental product candidates, if approved;
- our ability to realize the expected benefits and potential value created by the acquisition of Lowell Therapeutics, Inc., or Lowell, for our stockholders, on a timely basis or at all;
- our ability to develop sales and marketing capabilities in a timely fashion, whether alone through recruiting qualified employees, by engaging a contract sales organization, or with potential future collaborators;
- successfully establishing and maintaining commercial manufacturing and supply chain relationships with domestic and global third-party service providers;
- our ability to manage effectively, and the impact of any costs associated with, potential governmental investigations, inquiries, regulatory actions or lawsuits that may be, or have been, brought against us;
- our ability to obtain adequate government or third-party payer reimbursement for our developmental product candidates, if approved;
- our ability to gain access to formularies and establish and then maintain effective relationships with pharmaceutical benefit managers and/or group purchasing organizations for our developmental product candidates, if approved;
- our ability to attract additional collaborators with development, regulatory and commercialization expertise;
- our ability to identify and secure potential strategic partners to develop, secure regulatory approval for and then commercialize our developmental product candidates;
- our ability to successfully retain our key commercial, scientific, engineering, medical or management personnel and hire new personnel as needed;
- existing and future legislation and other regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers, including any supply chain impacts or work limitations;
- the success of competing therapies that are or become available; and
- our ability to obtain and maintain intellectual property protection for our approved products and product candidates.

In addition, you should refer to "Part II. Other Information - Item 1A. Risk Factors" in this Form 10-Q for a discussion of these and other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Also, forward-looking statements represent our estimates and assumptions only as of the date of this Form 10-Q. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Balance Sheets
(In thousands, except share data)

	March 31, 2023 (unaudited)	December 31, 2022[1]
Assets		
Current Assets:		
Cash and cash equivalents	$ 13,353	$ 15,275
Restricted cash	—	5,000
Short-term investments	—	495
Prepaid expenses and other current assets	525	1,865
Assets of discontinued operations	3,476	1,931
Total current assets	17,354	24,566
Operating lease right-of-use assets	49	96
In-process research and development asset	8,819	8,819
Other assets	70	70
Assets of discontinued operations	—	13,936
Total assets	$ 26,292	$ 47,487
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,398	$ 1,256
Accrued and other liabilities	1,418	2,431
Long-term debt, current portion	3,318	5,363
Operating lease liabilities, current portion	51	100
Liabilities of discontinued operations	3,278	4,620
Total current liabilities	9,463	13,770
Warrant liability	1,787	7,098
Other long-term liabilities	800	810
Liabilities of discontinued operations	—	3,995
Total liabilities	12,050	25,673
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.001 par value—200,000,000 shares authorized as of March 31, 2023 and December 31, 2022; 10,924,294 and 8,243,680 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	11	8
Additional paid-in capital	448,212	447,635
Accumulated deficit	(433,981)	(425,829)
Total stockholders' equity	14,242	21,814
Total Liabilities and Stockholders' Equity	$ 26,292	$ 47,487

(1) The condensed consolidated balance sheet as of December 31, 2022 has been derived from the audited financial statements as of that date included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	**2022**
Operating costs and expenses:		
Research and development	$ 1,047	$ 836
Selling, general and administrative	4,281	4,100
Total operating costs and expenses	5,328	4,936
Loss from operations	(5,328)	(4,936)
Other income:		
Interest expense	(119)	(390)
Interest income and other income, net	5,511	38
Non-cash interest income on liability related to sale of future royalties	—	673
Total other income	5,392	321
Net income (loss) from continuing operations	64	(4,615)
Net loss from discontinued operations– See Note 3	(8,216)	(4,059)
Net loss	$ (8,152)	$ (8,674)
Net income (loss) per share attributable to stockholders:		
Basic and diluted, continuing operations	$ 0.00	$ (0.63)
Basic and diluted, discontinued operations	$ (0.75)	$ (0.56)
Basic and diluted loss per share	$ (0.75)	$ (1.19)
Shares used in computing net loss per share of common stock, basic and diluted – See Note 10	10,893,954	7,281,187

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of December 31, 2022	8,243,680	$ 8	$ 447,635	$ (425,829)	$ 21,814
Stock-based compensation	—	—	569	—	569
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	21,700	—	(22)	—	(22)
Exercise of prefunded warrants	2,632,898	2	—	—	2
Issuance of common stock upon ESPP purchase	26,016	1	30	—	31
Net loss	—	—	—	(8,152)	(8,152)
Balance as of March 31, 2023	10,924,294	$ 11	$ 448,212	$ (433,981)	$ 14,242

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount			
Balance as of December 31, 2021	6,840,967	$ 7	$ 437,684	$ (473,584)	$ (35,893)
Stock-based compensation	—	—	783	—	783
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	25,769	—	(58)	—	(58)
Issuance of common stock in connection with asset acquisition	481,026	—	5,511	—	5,511
Issuance of common stock upon ESPP purchase	7,671	—	58	—	58
Net loss	—	—	—	(8,674)	(8,674)
Balance as of March 31, 2022	7,355,433	$ 7	$ 443,978	$ (482,258)	$ (38,273)

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (8,152)	$ (8,674)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash interest income on liability related to royalty monetization	—	(673)
Depreciation and amortization	262	420
Non-cash interest expense related to debt financing	38	134
Stock-based compensation	569	783
Revaluation of warrant liability	(5,311)	—
Impairment of net assets held for sale	7,007	—
Impairment of fixed assets	1,065	—
Gain on termination of lease liabilities	(1,098)	—
Gain on extinguishment of debt liability	(400)	—
Other	(15)	2
Changes in operating assets and liabilities:		
Accounts receivable	33	(24)
Inventories	61	57
Prepaid expenses and other assets	1,550	360
Accounts payable	100	249
Accrued liabilities	(960)	(1,512)
Operating lease liabilities	30	(56)
Deferred revenue	(29)	—
Net cash used in operating activities	(5,250)	(8,934)
Cash flows from investing activities:		
Purchase of property and equipment	(100)	(89)
Purchase of investments	—	(6,175)
Cash paid for asset acquisition, net of cash acquired	—	(1,156)
Proceeds from maturities of investments	500	27,596
Net cash provided by investing activities	400	20,176
Cash flows from financing activities:		
Payment of long-term debt	(2,083)	(2,083)
Net proceeds from issuance of common stock in connection with exercise of prefunded warrants	2	—
Net proceeds from issuance of common stock through equity plans	31	58
Payment of employee tax obligations related to vesting of restricted stock units	(22)	(58)
Net cash used in financing activities	(2,072)	(2,083)
Net change in cash, cash equivalents and restricted cash	(6,922)	9,159
Cash, cash equivalents and restricted cash—Beginning of period	20,275	12,663
Cash, cash equivalents and restricted cash—End of period	$ 13,353	$ 21,822
NONCASH INVESTING ACTIVITIES:		
Purchases of property and equipment in accounts payable and accrued liabilities	—	$ 1,275
Asset acquisition costs in accounts payable and accrued liabilities	—	$ 531
Liability for hold back shares in connection with asset acquisition in other long-term liabilities	—	$ 800
Issuance of common stock in connection with asset acquisition	—	$ 5,511

See notes to condensed 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.

On March 12, 2023, the Company entered into an Asset Purchase Agreement, or the Purchase Agreement, with Vertical Pharmaceuticals, LLC, a wholly owned subsidiary of Alora Pharmaceuticals, LLC, or Alora, pursuant to which Alora agreed to acquire certain assets and assume certain liabilities of 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 closing of the Purchase Agreement occurred on April 3, 2023 (see Note 3, "Discontinued Operations" and Note 11, "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 for acute kidney injury patients in the hospital, that the Company plans to study under an investigational device exemption, or IDE, and which has received Breakthrough Device Designation status from the FDA. While not approved for commercial use in the United States, the active drug component of Niyad, nafamostat, has been approved in Japan and South Korea as a regional anticoagulant for the dialysis circuit, disseminated intravascular coagulation, and acute pancreatitis. Niyad is a lyophilized formulation of nafamostat, a broad-spectrum, synthetic serine protease inhibitor, with anticoagulant, anti-inflammatory, and potential anti-viral activities. The second intended indication for Niyad is as a regional anticoagulant for the dialysis circuit for chronic kidney disease patients undergoing intermittent hemodialysis in dialysis centers. In addition, the Company acquired LTX-608, a 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.

On July 14, 2021, the Company entered into a License and Commercialization Agreement, or the PFS Agreement, with Laboratoire Aguettant, or Aguettant, pursuant to which the Company obtained the exclusive right to develop and, subject to FDA approval, commercialize in the United States an ephedrine pre-filled syringe, or PFS, containing 10 ml of a solution of 3 mg/ml ephedrine hydrochloride for injection, and (ii) a phenylephrine PFS containing 10 ml of a solution of 50 mcg/ml phenylephrine for injection. Aguettant will supply the Company with the products for use in commercialization and, if they are approved in the U.S.

Liquidity and Going Concern

The unaudited condensed consolidated financial statements for the three months ended March 31, 2023 were prepared on the basis of a going concern, which contemplates that the Company will be able to realize assets and discharge liabilities in the normal course of business. The Company has incurred recurring operating losses and negative cash flows from operating activities and expects to continue to incur operating losses and negative cash flows in the future. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Considering the Company's current cash resources and its current and expected levels of operating expenses for the next twelve months, management expects to need additional capital to fund its planned operations prior to the 12 month anniversary of the date this Quarterly Report on Form 10-Q 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 unaudited condensed consolidated financial statements and notes thereto have been adjusted to reflect the Reverse Stock Split on a retroactive basis.

Principles of Consolidation

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

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and the rules and regulations of the United States. Securities and Exchange Commission, or SEC. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation have been included.

Operating results for the three months ended March 31, 2023, are not necessarily indicative of the results that may be expected for the year ending December 31, 2023, or any future period. The condensed consolidated balance sheet as of December 31, 2022, was derived from the Company's audited financial statements as of December 31, 2022, included in the Company's Annual Report on Form 10-K filed with the SEC on March 31, 2023. These financial statements should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2022, which includes a broader discussion of the Company's business and the risks inherent therein.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the Consolidated Financial Statements and accompanying notes. 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.

Recently Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board, or FASB, issued Topic 326, or the Credit Losses standard, which the Company adopted using a modified retrospective approach on January 1, 2023. Topic 326 requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value. The adoption of this standard did not have a material impact on the Company's financial statements or related disclosures.

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

Significant Accounting Policies

The Company's significant accounting policies are detailed in its Annual Report on Form 10-K for the year ended December 31, 2022. There have been no significant changes to the Company's significant accounting policies during the three months ended March 31, 2023, from those previously disclosed in its 2022 Annual Report on Form 10-K, except as follows:

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

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

2. Investments and Fair Value Measurement

Investments

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

As of March 31, 2023, and December 31, 2022, the contractual maturity of all investments held was less than one year.

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

	As of March 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, cash equivalents and restricted cash:				
Cash	$ 1,716	$ —	$ —	$ 1,716
Money market funds	146	—	—	146
U.S. government agency securities	5,677	—	—	5,677
Commercial paper	5,814	—	—	5,814
Total cash, cash equivalents, and restricted cash	$ 13,353	$ —	$ —	$ 13,353

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

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. Impairment is assessed at the individual security level. Factors considered in determining whether a loss resulted from a credit loss or other factors include the Company's intent and ability to hold the investment until the recovery of its amortized cost basis, the extent to which the fair value is less than the amortized cost basis, the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, any historical failure of the issuer to make scheduled interest or principal payments, any changes to the rating of the security by a rating agency, any adverse legal or regulatory events affecting the issuer or issuer's industry, any significant deterioration in economic conditions. There were no material realized or unrealized gains or losses on marketable securities for the three months ended March 31, 2023 or the twelve months ended December 31, 2022. As such, we did not record a credit allowance for the three months ended March 31, 2023.

Fair Value Measurement

The Company's financial instruments consist of Level I and II assets. Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments 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 March 31, 2023 and December 31, 2022, the Company held, in addition to Level II assets, a warrant liability related to the 2022 Warrants (see Note 12, "Warrants" in the Company's 2022 Annual Report on Form 10-K for further description). The fair value of the warrant liability was estimated using the Black Scholes Model which uses as inputs the following weighted average assumptions: dividend yield, expected term in years; equity volatility; and risk-free interest rate (see Note 8, "Warrants" below). The Company follows the guidance in ASC 820 for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period. The estimated fair value of the warrant liability represents a Level III measurement. Changes to the estimated fair value of these liabilities are recorded in interest income and other income, net in the consolidated statements of operations.

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

	As of March 31, 2023			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 146	$ 146	$ —	$ —
U.S. government agency securities	5,677	—	5,677	—
Commercial paper	5,814	—	5,814	—
Total assets measured at fair value	$ 11,637	$ 146	$ 11,491	$ —
Liabilities				
Warrant liability	1,787	—	—	1,787
Total liabilities measured at fair value	$ 1,787	$ —	$ —	$ 1,787

	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

The following tables set forth a summary of the changes in the fair value of the Company's Level III warrant liability for the three months ended March 31, 2023 (in thousands):

	Three Months Ended March 31, 2023
Fair value—beginning of period	$ 7,098
Change in fair value of 2022 Warrants liability	(5,311)
Fair value—end of period	$ 1,787

There were no transfers between Level I, Level II or Level III of the fair value hierarchy during the three months ended March 31, 2023 and the year ended December 31, 2022.

3. Discontinued Operations

On March 12, 2023, the Company entered into the Purchase Agreement with Alora for Alora's acquisition of all assets related to DSUVIA, including inventories, equipment and intellectual property in exchange for consideration at closing of $1.1 million, a 15% royalty on commercial sales of DSUVIA, 75% royalty on sales of DSUVIA to the Department of Defense and up to $116.5 million in sales-based milestones.

The Company's DSUVIA business met the definition of a discontinued operation as of March 31, 2023. Accordingly, the assets and liabilities associated with these operations have been classified as assets and liabilities of discontinued operations in the accompanying condensed consolidated balance sheets at March 31, 2023 and December 31, 2022. The carrying value of the disposal group was higher than its fair value, less costs to sell, and accordingly, an impairment loss was required at March 31, 2023. The operations and cash flows of the DSUVIA business are presented as discontinued for all periods presented. The transaction closed on April 3, 2023 (see Note 11, "Subsequent Events" below).

The following table presents the results of the discontinued operations for the three-month period ended March 31, 2023 and March 31, 2022 (in thousands):

	Three months ended March 31,	
	2023	2022
Total revenues	$ 501	$ 442
Cost of goods sold	711	414
Selling, general and administrative expense	683	3,608
Impairment of net assets held for sale	7,007	—
Impairment of fixed assets	1,065	—
Gain on termination of lease liabilities	(1,098)	—
Research and development expenses	349	479
Loss from operations	8,216	4,059
Loss from discontinued operations before loss on disposal	$ 8,216	$ 4,059

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).

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ —	$ —
Accounts receivable, net	276	309
Inventories	1,117	1,178
Prepaid expenses and other current assets	231	444
Property, plant and equipment, net	8,509	—
Operating lease right-of-use assets	178	—
Other assets	172	—
Less: expected loss on sale of discontinued operations	(7,007)	—
Total current assets of discontinued operations	3,476	1,931
Property, plant and equipment, net	—	10,261
Operating lease right-of-use assets	—	3,499
Other assets	—	176
Total non-current assets of discontinued operations	—	13,936
Total assets of discontinued operations	$ 3,476	$ 15,867
Accounts payable	618	784
Accrued liabilities	1,184	1,720
Operating lease liabilities, current portion	354	1,601
Note payable, current portion	—	400
Deferred revenue, current portion	1,122	115
Total current liabilities of discontinued operations	3,278	4,620
Operating lease liabilities, net of current portion	—	2,959
Deferred revenue, net of current portion	—	1,036
Total non-current liabilities of discontinued operations	—	3,995
Total liabilities of discontinued operations	3,278	8,615
Net assets of discontinued operations	$ 198	$ 7,252

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

	Three months ended March 31,	
	2023	2022
Cash flows from operating activities:		
Depreciation and amortization	$ 215	$ 379
Stock-based compensation	19	145
Impairment of net assets held for sale	7,007	—
Impairment of fixed assets	1,065	—
Gain on termination of lease liabilities	(1,098)	—
Gain on extinguishment of debt	(400)	—

The following table represents the expected loss on sale of discontinued operations for the three months ended March 31, 2023:

	March 31, 2023
Expected cash proceeds	$ 2,723
Less: net assets transferred	(8,840)
Less: expected disposal costs	(890)
Expected loss on sale of discontinued operations, before income taxes	(7,007)
Income tax expense	—
Expected loss on sale of discontinued operations	$ (7,007)

Per ASC 450, we booked a contingent loss against the net assets held for sale in the three months ended March 31, 2023.

4. 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 March 31, 2023, there have been no payments by the Company to Aguettant under the PFS Agreement.

See Note 11, “Subsequent Events” below.

5. Long-Term Debt

Loan Agreement with Oxford

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

As of March 31, 2023 and December 31, 2022, the accrued balance due under the Loan Agreement with Oxford was $3.3 million and $5.4 million, respectively. Interest expense related to the Loan Agreement was $0.1 million, $39,000 of which represented amortization of the debt discount, for the three months ended March 31, 2023, and was $0.4 million, $0.1 million of which represented amortization of the debt discount, for the three months ended March 31, 2022.

See Note 11, “Subsequent Events” below.

6. Leases

Office Lease

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, ending on June 30, 2023, with monthly rental payments of approximately $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. Lease expense was approximately $50,000 for the three months ended March 31, 2023 and the remaining lease commitment of approximately $50,000 will be incurred in the second quarter of 2023.

7. 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 its new motion to dismiss the second amended complaint and on March 16, 2023, plaintiffs filed their opposition to the Company’s new motion to dismiss and on April 17, 2023, the Company filed its reply to the plaintiffs’ opposition. Oral hearings on the new motion to dismiss are scheduled for May 25, 2023.

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.

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.

8. Warrants

The activity related to warrants during the three months ended March 31, 2023, is summarized as follows:

	Common Stock from Warrants	Weighted-average Exercise Price (per share)
Outstanding at December 31, 2022	7,824,933	$ 1.72
Pre-funded warrants exercised	2,632,898	$ 0.0001
Outstanding at March 31, 2023	5,192,035	$ 2.59
Exercisable at March 31, 2023	964,983	$ 4.89

The pre-funded warrants issued in December 2022 to purchase 2,632,898 shares of common stock, or the 2022 Pre-Funded Warrants, were exercised in full in the three months ended March 31, 2023. The common warrants issued in December 2022 to purchase an aggregate of 4,227,052 shares of common stock, or the 2022 Warrants, were accounted for by the Company as a liability. At March 31, 2023, the 2022 Warrants were valued at approximately $1.8 million, using the Black-Scholes option pricing model as follows: exercise price of $2.07 per share, stock price of $0.658 per share, expected life of 6 years, volatility of 97.06%, a risk-free rate of 3.58% and 0% expected dividend yield. See Note 2, "Investments and Fair Value Measurement" and Note 11, "Subsequent Events".

9. Stock-Based Compensation

The Company recorded total stock-based compensation expense for stock options, restricted stock units, or RSUs, and the Amended and Restated 2011 Employee Stock Purchase Plan, or the Amended ESPP, as follows (in thousands):

	March 31, 2023	**March 31, 2022**
Research and development	$ 93	$ 174
Selling, general and administrative	457	464
Discontinued operations	19	145
Total	$ 569	$ 783

The following table summarizes restricted stock unit activity under the Company's equity incentive plans:

	Number of Restricted Stock Units	**Weighted Average Grant Date Fair Value**
Restricted stock units outstanding, January 1, 2023	82,778	$ 16.97
Granted	44,091	1.76
Vested	(34,606)	21.61
Forfeited	(643)	17.91
Restricted stock units outstanding, March 31, 2023	91,620	$ 7.89

Upon vesting, certain of the Company's RSUs may be settled on a net-exercise basis to cover any required withholding tax with the remaining amount converted into an equivalent number of shares of common stock. There were 12,906 shares of common stock underlying vested RSUs that were withheld during the quarter ended March 31, 2023, based on the value of the RSUs as determined by the Company's closing stock price on the applicable vesting date.

The following table summarizes stock option activity under the Company's equity incentive plans:

	Number of Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
January 1, 2023	725,623	$ 52.98		
Granted	264,520	1.76		
Forfeited	(1,950)	19.41		
Expired	(90,802)	83.75		
Exercised	—	—		
March 31, 2023	897,391	$ 34.84	6.9	$ —
Vested and exercisable options— March 31, 2023	459,397	$ 58.42	4.7	$ —
Vested and expected to vest— March 31, 2023	897,391	$ 34.84	6.9	$ —

The per-share weighted average grant date fair value of the options granted during the quarter ended March 31, 2023 was estimated at $1.39 per share on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Three months ended March 31, 2023
Expected term (in years)	6.3
Risk-free interest rate	3.9%
Expected volatility	94%
Expected dividend rate	0%

As of March 31, 2023, total stock-based compensation expense related to unvested options to be recognized in future periods was $1.7 million which is expected to be recognized over a weighted-average period of 2.2 years. As of March 31, 2023, there were 127,611 shares available for grant under the Company's equity incentive plans and 185,860 shares available for grant under the Amended ESPP.

10. Net Loss per Share of Common Stock

The Company's basic net loss per share of common stock is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. The diluted net loss per share of common stock is computed by giving effect to all potential common stock equivalents outstanding for the period determined using the treasury stock 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. 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.

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

	Three Months Ended March 31,	
	2023	2022
RSUs, stock options and ESPP to purchase common stock	989,011	893,223
Common stock warrants	5,192,035	883,833

In addition, the shares held back and contingently issuable in connection with the Lowell Merger, as described in Note 4, "Asset Acquisition" to the Company's 2022 Annual Report on Form 10-K, have also been excluded from the computation of diluted net loss per share of common stock for the periods presented because the contingencies for issuance of these shares have not been met.

11. Subsequent Events

Asset Purchase Agreement

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.

Repayment of Loan Agreement with Oxford

In connection with the closing of the divestment of DSUVIA to Alora, the Company and Oxford agreed that the Company would repay the loan in full without any prepayment penalties or the payment of future remaining interest that otherwise would have been payable under the Loan. On April 3, 2023, the Company paid Oxford the remaining amount due of approximately $3.4 million including accrued interest and fees under the Loan, and the Loan Agreement was terminated with no further obligations by either party.

Amended and Restated 2022 Warrants

On April 25, 2023, the 2022 Warrants were amended to remove the 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.

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

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q, or Form 10-Q, and with the audited Consolidated Financial Statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2022, or Annual Report.

About AcelRx Pharmaceuticals, Inc.

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

Our Portfolio

Our portfolio consists of nafamostat product candidates and pre-filled syringe product candidates, as further described below. On April 3, 2023, we closed the transactions contemplated by the Asset Purchase Agreement, or the DSUVIA Agreement, with Vertical Pharmaceuticals, LLC, a wholly owned subsidiary of Alora Pharmaceuticals, LLC, or Alora, entered into on March 12, 2023, pursuant to which Alora acquired certain assets and assumed 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. Refer to Note 3, "Discontinued Operations" and Note 11, "Subsequent Events" to the unaudited condensed consolidated financial statements to this Quarterly Report on Form 10-Q for additional information. We do not have plans to further develop any sufentanil sublingual product candidates.

Nafamostat Product Candidates

Product/Product Candidate	Description	Target Use	Status
Niyad™	Lyophilized vial containing nafamostat for injection	Regional anticoagulant for injection into the extracorporeal circuit	Submitted an investigational device exemption, or IDE, and received Breakthrough Device Designation from the United States Food and Drug Administration, or FDA. Submitted a request for Emergency Use Authorization to the FDA.
LTX-608	Lyophilized vial containing nafamostat for injection	IV infusion as an anti-viral treatment for COVID-19	IND to be submitted following toxicology evaluation to enable Phase 2 study
LTX-608	Lyophilized vial containing nafamostat for injection	IV infusion for disseminated intravascular coagulation, or DIC	IND to be submitted following toxicology evaluation to enable Phase 2 study
LTX-608	Lyophilized vial containing nafamostat for injection	IV infusion for acute respiratory distress syndrome, or ARDS	IND to be submitted following toxicology evaluation to enable Phase 2 study
LTX-608	Lyophilized vial containing nafamostat for injection	IV infusion for acute pancreatitis	IND to be submitted following toxicology evaluation to enable Phase 2 study

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

The second indication for our nafamostat product development candidate, LTX-608, on which we are focused is for the treatment of ARDS and DIC, an indication for which nafamostat is approved in Japan and South Korea. We have pending patent applications directed to the use of nafamostat in DIC, as an antiviral agent (e.g., COVID treatment), in ARDS and other indications.

Pre-filled Syringe Product Candidates

Product/Product Candidate	Description	Target Use	Status
Fedsyra™	Ephedrine pre-filled syringe, containing 10 ml of a solution of 3 mg/ml ephedrine for injection	Clinically important hypotension occurring in the setting of anesthesia	Product candidate licensed from Aguettant; preparing New Drug Application, or NDA, for submission to FDA. Approved in the European Union; owned and marketed by Aguettant.
Phenylephrine	Phenylephrine pre-filled syringe containing 10 ml of a solution of 50 mcg/ml phenylephrine for injection	Clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia	Product candidate licensed from Aguettant; preparing NDA for submission to FDA. Approved in the European Union; owned and marketed by Aguettant.

Hospitals currently purchase non-FDA approved ready-to-use, pre-filled syringe products from compounding facilities, or manually dilute the products in-house. Our product candidates have been developed in a ready-to-use strength and pre-filled into syringes that can be immediately administered to patients, potentially eliminating the need for calculations and additional dilution and filling steps. We therefore believe that, if approved, our products may offer significant benefits to hospitals and surgery centers over the current compounded products. In addition, our pre-filled syringe product candidates will also compete with existing generic versions of concentrated vial forms of product, ready-to-use diluted vial forms of product, and for Fedsyra, two recently FDA-approved pre-filled syringes with a different formulation and/or concentration than our product candidate.

Overview

On April 3, 2023, we closed the transactions contemplated by the DSUVIA Agreement with Alora pursuant to which Alora acquired certain assets and assume certain liabilities relating to 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. Under the Purchase Agreement, we are entitled to receive quarterly payments in an amount equal to 15% of net Product sales to all customers excluding net sales to the 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. We are also entitled to receive sales milestones up to $116.5 million based on the achievement of Alora attaining certain levels of annual sales. Refer to Note 3, “Discontinued Operations” and Note 11, “Subsequent Events” to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information.

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 our 2022 Annual Report on Form 10-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 was originally entitled to receive up to $24 million in sales-based milestone payments. In connection with our and Aguettant's agreement to enter into the Amended DZUVEO Agreement (as defined below) and the Amended and Restated Supply Agreement (as defined below), we entered into an amendment to the PFS Agreement with Aguettant pursuant to which, effective on April 3, 2023, (a) Aguettant paid us a complementary payment in the amount of €1.5 million, and (b) the maximum amount in sales-based milestone payments that Aguettant is entitled to receive will reduce 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), we and Aguettant entered into an amendment to the DZUVEO Agreement, or the Amended DZUVEO Agreement, and an amendment and restatement to the supply agreement with respect to the manufacture and supply of DZUVEO, or the Amended and Restated Supply Agreement. The rights and obligations under the Amended DZUVEO Agreement and the Amended and Restated Supply Agreement were assumed by Alora, as part of the DSUVIA asset divestment agreement. We received €2.5 million, or approximately $2.9 million, in 2021 under the DZUVEO Agreement. Refer to Note 4, "In-License Agreement", and Note 11, "Subsequent Events" to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q 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 to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information.

General Trends and Outlook

Global Supply Chain

We continue to engage with various elements of our supply chain and distribution channel, including our customers, contract manufacturers, and logistics and transportation providers, to supply our product candidates for development purposes and to remain informed of any challenges within our supply chain. We intend to adapt our plans as needed to continue to drive our product development programs. However, we may face disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products if the COVID-19 pandemic persists for an extended period of time and continues to impact our global supply chain. Such supply disruptions may adversely impact our ability to continue development of our product candidates and ultimately generate sales of and revenues from any approved products, and our business, financial condition, results of operations and growth prospects could be adversely affected.

Inflation

We do not believe that inflation has had a material impact on our business or operating results during the periods presented. However, inflation, led by supply chain constraints, federal stimulus funding, increases to household savings, and the sudden macroeconomic shift in activity levels arising from the loosening or removal of many government restrictions 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.

Recent Developments

On April 3, 2023, we closed our divestment of DSUVIA to Alora. In connection with the closing of the transaction, we received a total of approximately $2.7 million from Aguettant and Alora. In connection with the closing, we also decided to fully repay our senior loan with Oxford Finance, LLC, or Oxford, leaving us debt-free after the closing of the transaction.

On April 25, 2023, we executed a Memorandum of Understanding, or MoU, with a contract manufacturer, or the CMO, for the active pharmaceutical ingredient, or API for Niyad. The MoU provides us with a secured supply of nafamostat API on an exclusive basis outside of all Asian countries for our request for Emergency Use Authorization, or EUA, submitted to the FDA in April 2023, and for our planned registrational study for Niyad later this year. The MoU also provides us access to the CMOs drug master file, or DMF for the nafamostat API. AcelRx and the CMO are required to use good faith efforts to execute a Master Supply Agreement, or MSA, with exclusivity outside of Asian countries, which will ensure a long-term supply of nafamostat API. The MoU requires that we make payments to the CMO based on the achievement of four separate milestones: (a) execution of the MoU, (b) receipt of an EUA from the FDA, (c) an approved Pre-Market Application, or PMA, from the FDA, and (d) execution of the MSA. The MoU is considered legally binding on both parties.

On April 27, 2023, we submitted a request for EUA for Niyad and responded to previous questions outlined by the FDA in a prior submission made by Lowell. Our submission included information on the active pharmaceutical ingredient and finished drug product, including stability testing data and a process validation protocol for Niyad, amongst other items requested by the FDA.

Financial Overview

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

Our net loss for the three months ended March 31, 2023 and 2022 was $8.2 million and $8.7 million, respectively. As of March 31, 2023, we had an accumulated deficit of $434.0 million. As of March 31, 2023, we had cash, cash equivalents and short-term investments totaling $13.4 million compared to $20.8 million as of December 31, 2022.

Critical Accounting Estimates

The accompanying discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements and the related disclosures, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. To the extent that there are material differences between these estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected. Our critical accounting policies and estimates are detailed in our Annual Report.

There have been no significant changes to our critical accounting policies or significant judgements and estimates for the three months ended March 31, 2023, from those previously disclosed in our Annual Report, as follows:

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

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

Recently Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board, or FASB, issued Topic 326, or the Credit Losses standard, which we adopted using a modified retrospective approach on January 1, 2023. Topic 326 requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value. The adoption of this standard did not have a material impact on our financial statements or related disclosures.

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

Results of Operations

Our unaudited condensed consolidated results of operations are presented for the three months ended March 31, 2023 and 2022. Certain financial results (revenues and expenses) relating to the divestment of our DSUVIA/DZUVEO business are reflected in Note 3, “Discontinued Operations” to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q 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.

Three Months Ended March 31, 2023 and 2022

Revenue

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

Cost of Goods Sold

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

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 during the three months ended March 31, 2023 and 2022 (in thousands, except percentages):

	Three Months Ended March 31,		$ Change	% Change
	2023	2022	2023 vs. 2022	2023 vs. 2022
Niyad	$ 472	$ —	$ 472	—%
PFS	4	57	(53)	(93)%
Zalviso	26	8	18	225%
Overhead	545	771	(226)	(29)%
Total research and development expenses	$ 1,047	$ 836	$ 211	25%

Research and development expenses for the three months ended March 31, 2023 increased as compared to the three months ended March 31, 2022, primarily due to Niyad research and development 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 three months ended March 31, 2023 and 2022, were as follows (in thousands, except percentages):

	Three Months Ended March 31,		$ Change	% Change
	2023	2022	2023 vs. 2022	2023 vs. 2022
Selling, general and administrative expenses	$ 4,281	$ 4,100	$ 181	4%

Selling, general and administrative expenses remained flat during the three months ended March 31, 2023, as compared to the three months ended March 31, 2022, due to a reduced headcount in 2023 partially offset by increased legal expenses related to the divestment of DSUVIA.

Other Income

Total other income for the three months ended March 31, 2023 and 2022, was as follows (in thousands, except percentages):

	Three Months Ended March 31,		$ Change	% Change
	2023	2022	2023 vs. 2022	2023 vs. 2022
Interest expense	$ (119)	$ (390)	$ 271	(69)%
Interest income and other income, net	5,511	38	5,473	14,403%
Non-cash interest income on liability related to sale of future royalties	—	673	(673)	(100)%
Total other income	$ 5,392	$ 321	$ 5,071	1,580%

Interest expense consisted primarily of interest accrued or paid on our debt obligation agreements and amortization of debt discounts. Interest expense decreased for the three months ended March 31, 2023, as compared to the three months ended March 31, 2022, primarily as a result of a lower average outstanding loan balance. As of March 31, 2023, the outstanding balance due under the Loan Agreement with Oxford was $3.3 million. On April 3, 2023, in connection with the closing of the DSUVIA Agreement, we fully repaid the Loan Agreement with Oxford. Refer to Note 5, “Long-Term Debt” and Note 11, “Subsequent Events” to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information.

Interest income and other income, net, for the three months ended March 31, 2023 and 2022, primarily consisted of changes in the fair value of our warrant liability and contingent put option and interest earned on our investments. The increase in interest income and other income, net for the three months ended March 31, 2023 as compared to 2022, was primarily due to the $5.3 million decrease in the fair value of our warrant liability.

The non-cash interest income on the liability related to the sale of future royalties is attributable to the royalty monetization which was fully terminated on May 31, 2022. Please refer to Note 11, “Liability Related to Sale of Future Royalties” to the consolidated financial statements in our 2022 Annual Report on Form 10-K for additional information.

Discontinued Operations

As of March 31, 2023, the DSUVIA business met all the conditions to be classified as held for sales, and because we consider the divestiture of the DSUVIA business to be a strategic shift that will have a major effect on our operations and financial results, represented a discontinued operation. All assets and liabilities associated with DSUVIA/DZUVEO were therefore classified as assets and liabilities of discontinued operations in our unaudited condensed consolidated balance sheets for the periods presented. Further, all historical operating results for DSUVIA/DZUVEO are reflected within discontinued operations in the unaudited condensed consolidated statements of operations for all periods presented. For the three months ended March 31, 2023, we recognized an impairment on net assets held for sale of $7.0 million and a loss from discontinued operations of $1.2 million. For the three months ended March 31, 2022, we recognized a loss from discontinued operations of $4.1 million.

Liquidity and Capital Resources

Liquidity and Going Concern

We have incurred losses and generated negative cash flows from operations and we expect to incur significant losses in 2023 and may incur significant losses and negative cash flows from operations in the future. These conditions raise substantial doubt about our ability to continue as a going concern. Considering our current cash resources and current and expected levels of operating expenses for the next twelve months, we expect to need additional capital to fund our planned operations prior to the twelve-month anniversary of the filing date of this Quarterly Report on Form 10-Q. We may seek to raise such additional capital through public or private equity offerings, including under the Controlled Equity Offering^{SM} Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, debt securities, a new debt facility, monetizing or securitizing certain assets, entering into product development, license or distribution agreements with third parties, or divesting any of our product candidates. On April 26, 2023, we received a notice from Nasdaq stating that we were not in compliance with Nasdaq Listing Rule 5450(a)(1) (the “Minimum Bid Price Rule”) because our common stock failed to maintain a minimum closing bid price of $1.00 for 30 consecutive business days. This notice had no immediate effect on the Nasdaq listing or trading of our common stock; however, our depressed stock price will make it more difficult for us to raise additional capital through equity offerings. Please see “Part II., Item 1A. Risk Factors— Risks Related to Ownership of Our Common Stock — If we cannot regain compliance with Nasdaq’s continued listing requirements, our common stock may be delisted from The Nasdaq Global Market.” While we believe our plans to raise additional funds will alleviate the conditions that raise substantial doubt about our ability to continue as a going concern, these plans are not entirely within our control and cannot be assessed as being probable of occurring. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to further reduce our workforce, reduce the scope of, or cease, the development of our product candidates in advance of the date on which our cash resources are exhausted to ensure that we have sufficient capital to meet our obligations and continue on a path designed to preserve stockholder value. In addition, if we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish rights to our technologies, future revenue streams or product candidates, or to grant licenses on terms that may not be favorable to us.

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, with revenues from sales of DSUVIA which we recently divested to Alora, and payments under the Amended DZUVEO Agreement with Aguettant.

As of March 31, 2023, we had cash, cash equivalents and investments totaling $13.4 million, compared to $20.8 million as of December 31, 2022. The decrease was primarily due to cash required to fund our continuing operations, including debt service, development activities for our newly acquired late-stage pipeline product candidates, and business development activities, including the divestment of DSUVIA. 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.

Pursuant to the ATM Agreement with Cantor, as our agent, we may offer and sell, from time to time through Cantor, shares of our common stock. There were no sales under the ATM Agreement for the three months ended March 31, 2023 or 2022. As of March 31, 2023, approximately $35.6 million of our common stock remained available for sale and issuance under the ATM Agreement; however, our ability to sell such shares under the shelf registration statement and the ATM Agreement will be limited until we are no longer subject to the SEC's "baby shelf" limitations.

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 March 31, 2023, the outstanding balance due under the Loan Agreement with Oxford was $3.3 million. On April 3, 2023, in connection with the closing of the DSUVIA Agreement, we fully repaid the Loan Agreement with Oxford. Refer to Note 5, "Long-Term Debt" and Note 11, "Subsequent Events" to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information.

Our cash and investment balances are held in a variety of interest-bearing instruments, including obligations of commercial paper, U.S. government sponsored enterprise debt securities and money market funds. Cash in excess of immediate requirements is invested with a view toward capital preservation and liquidity. We do not expect COVID-19 to have a material impact on our high quality, short-dated investments.

Cash Flows

The following is a summary of our cash flows for the periods indicated and has been derived from our unaudited condensed consolidated financial statements which are included elsewhere in this Form 10-Q (in thousands):

	Three Months Ended March 31,	
	2023	**2022**
Net cash used in operating activities	$ (5,250)	$ (8,934)
Net cash provided by investing activities	400	20,176
Net cash used in financing activities	(2,072)	(2,083)

Cash Flows from Operating Activities

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

Cash used in operating activities of $5.3 million during the three months ended March 31, 2023, reflected a net loss of $8.2 million, partially offset by aggregate non-cash charges of $2.1 million and included an approximate $0.8 million net change in our operating assets and liabilities. Non-cash adjustments included an impairment charge of $7.0 million on our net assets held for sale in connection with our divestment of DSUVIA, an impairment charge of $1.1 million on fixed assets, a gain of $1.1 million related to the termination of lease liabilities, a $5.3 million decrease in the fair value of our warrant liability and $0.6 million in stock-based compensation expense, a $0.4 million gain on extinguishment of debt, and $0.3 million in depreciation and amortization expense. The net change in our operating assets and liabilities included a $1.6 million decrease in prepaid expenses and other assets and a $1.0 million decrease in accrued liabilities.

Cash used in operating activities of $8.9 million during the three months ended March 31, 2022, reflected a net loss of $8.7 million, partially offset by aggregate non-cash charges of $0.7 million and included an approximate $0.9 million net change in our operating assets and liabilities. Non-cash charges included $0.8 million in stock-based compensation expense, $0.7 million in interest income on the liability related to the Royalty Monetization, and $0.4 million in depreciation expense. The net change in our operating assets and liabilities included a $1.5 million decrease in accrued liabilities.

Cash Flows from Investing Activities

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

During the three months ended March 31, 2023, cash provided by investing activities of $0.4 million was primarily the net result $0.5 million in proceeds from maturity of investments partially offset by $0.1 million for purchases of property and equipment.

During the three months ended March 31, 2022, cash provided by investing activities of $20.2 million was primarily the net result $27.6 million in proceeds from maturity of investments partially offset by $6.2 million for purchases of investments and $1.2 million in cash paid for the Lowell asset acquisition, net of cash acquired.

Cash Flows from Financing Activities

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

During the three months ended March 31, 2023, cash used in financing activities of $2.1 million was primarily due to long-term debt payments under the Loan Agreement with Oxford. During the three months ended March 31, 2022, cash used in financing activities of $2.1 million was primarily due to long-term debt payments under the Loan Agreement with Oxford. On April 3, 2023, in connection with the closing of the DSUVIA Agreement, we fully repaid the Loan Agreement with Oxford. Refer to Note 5, “Long-Term Debt” and Note 11, “Subsequent Events” to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information.

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 our 2022 Annual Report on Form 10-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."

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

We maintain disclosure controls and procedures (as defined in Exchange Act Rule 13a–15(e) and 15d-15(e)) that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Previously Reported Material Weakness

As disclosed in the section titled "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q, we previously identified a material weakness in our internal control over financial reporting related to the review procedures related to the technical accounting review and analysis over earnings per share calculations that were insufficient to prevent or detect errors in the calculation. Specifically, the error was due to management's failure to identify warrants issued in November 2021 as participating securities and consequently attribute earnings to these securities as part of a two-class EPS calculation. This material weakness resulted in the restatement of our unaudited condensed consolidated financial statements for the quarterly periods ended June 30, 2022 and September 30, 2022.

We commenced measures to remediate the identified material weakness. Those remediation measures are ongoing and include enhanced processes to identify and appropriately apply applicable accounting requirements related to the earnings per share calculation to better evaluate and understand the nuances of the complex accounting standards that apply to our financial statements. We continue to provide access to accounting literature, research materials and documents, enhance the review and analysis process around the earnings per share calculation and increase communications among our personnel and third-party professionals with whom we consult regarding complex accounting applications.

We believe we are making progress toward achieving the effectiveness of our internal controls and disclosure controls. The actions that we are taking are subject to ongoing senior management review, as well as audit committee oversight.

Evaluation of disclosure controls and procedures. As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Because of the material weakness in our internal control over financial reporting previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2022, our disclosure controls and procedures were not effective. In light of this fact, our management, including our Chief Executive Officer and Chief Financial Officer, has performed an enhanced review and analysis of the process around the earnings per share calculation and increased communications among our personnel and third-party professionals with whom we consult and has concluded that, notwithstanding the material weakness in our internal control over financial reporting, the condensed consolidated financial statements for the periods covered by and included in this Quarterly Report on Form 10-Q fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

Changes in internal control over financial reporting. We are taking actions to remediate the material weakness relating to our internal control over financial reporting, as described above. Except as otherwise described herein, there was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in legal proceedings relating to intellectual property, commercial, employment and other matters arising in the ordinary course of business. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position or cash flows. Please see the matters under the caption “Part I. Financial Information —Item 1. Financial Statements—Note 7, Commitments and Contingencies—Litigation.”

Item 1A. Risk Factors

This Quarterly Report on Form 10-Q contains forward-looking information based on our current expectations. Because our actual results may differ materially from any forward-looking statements made by or on behalf of us, this section includes a discussion of important factors that could affect our actual future results, including, but not limited to, our revenues, expenses, net loss and loss per share. You should carefully consider these risk factors, together with all of the other information included in this Quarterly Report on Form 10-Q as well as our other publicly available filings with the U.S. Securities and Exchange Commission, or SEC.

Summary Risk Factors

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

- Our Emergency Use Authorization, or EUA, Application for Niyad™ is premised on the declared COVID-19 health emergency.
- We may fail to realize the benefits expected from our acquisition of Lowell Therapeutics, Inc., or Lowell, which could adversely affect our stock price.
- We are dependent on the ability of Vertical Pharmaceuticals, LLC, a wholly owned subsidiary of Alora Pharmaceuticals, LLC, or together Alora, to successfully commercialize DSUVIA in order to receive royalties from DSUVIA. If Alora is unable to successfully commercialize DSUVIA, our business, financial condition, and results of operations will be materially harmed.
- Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.
- Our drug discovery and development efforts might not generate successful product candidates.
- If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- If we experience delays or difficulties in enrolling patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- If serious adverse effects or unexpected characteristics of our product candidates are identified during development, we may need to abandon or limit our development of some or all of our product candidates.
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- The process for obtaining approval of a Premarket Approval, or PMA, or New Drug Application, or NDA, is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources.
- Our expectations for U.S. Food and Drug Administration, or FDA, approvability of our product candidates may be inaccurate.
- We may experience difficulties in retaining our existing employees and managing our operations.
- If we, or current and potential partners, are unable to compete effectively, our products may not reach their commercial potential.
- Coverage and adequate reimbursement may not be available for our product candidates, if approved, in the United States and in Europe, which could make it difficult for us, or our partners, to sell our products profitably.
- The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.
- If we or our partners are unable to establish and maintain relationships with group purchasing organizations any future revenues or future profitability could be jeopardized.
- Existing and future legislation may increase the difficulty and cost for us to commercialize our products and affect the prices we may obtain.
- We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.
- We require additional capital and may be unable to raise such capital, which would force us to delay, reduce or eliminate our commercialization efforts and product development programs and could cause us to be unable to continue to operate as a going concern and cease operations.
- To fund our operations, and capital requirements, we may sell additional equity securities, which may result in dilution to our stockholders, or debt securities, which may impose restrictions on our business.
- We have not yet generated significant product revenue and may never be profitable.

- Future sales of DSUVIA to the Department of Defense, or DoD, are not predictable, may occur on an irregular basis and may not meet our expectations due to various United States government-related factors that are beyond our control.
- We rely on third party manufacturers and suppliers for our product candidates in the United States and Europe.
- We rely on limited sources of supply for the active pharmaceutical ingredients for nafamostat-based product candidates and any disruptions in the chain of supply may cause a delay in developing our product candidates.
- Manufacturing issues may arise that could delay or increase costs related to product development and regulatory approval.
- We rely on third parties to conduct, supervise and monitor our clinical trials.
- Our relationships with clinical investigators, health care professionals, consultants, commercial partners, third-party payers, hospitals, and other customers are subject to applicable anti-kickback, fraud and abuse and other healthcare laws, which could expose us to significant penalties.
- Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.
- Business interruptions could delay our operations and sales efforts.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- We may acquire companies, product candidates or products or engage in strategic transactions.
- We face potential product liability claims and, if such claims are successful, we may incur substantial liability.
- Our employees, agents and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.
- If we cannot defend our issued patents from third party claims or if our pending patent applications fail to issue, our business could be adversely affected.
- Litigation involving patents, patent applications and other proprietary rights is expensive and time consuming.
- It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.
- We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.
- Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be payable to the United States Patent and Trademark Office and various foreign governmental patent agencies annually in several stages over the lifetime of the patents and/or applications.
- We may not be able to enforce our intellectual property rights throughout the world.
- We have not yet registered our trademarks in all our potential markets, and failure to secure those registrations could adversely affect our business.
- The market price of our common stock has historically been and may continue to be highly volatile.
- Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.
- We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.
- Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.
- If we cannot regain compliance with Nasdaq’s listing requirements, Nasdaq may delist our securities from trading on its exchange, which could limit investors’ ability to make transactions in our securities and subject us to additional trading restrictions.
- Litigation may substantially increase our costs and harm our business.
- Our involvement in securities-related class action and related derivative litigation could divert our resources and management's attention and harm our business.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.
- Our effective tax rate may fluctuate, we may be adversely affected by changes in tax laws and regulations, and we may incur obligations in tax jurisdictions in excess of accrued amounts.
- Macroeconomic uncertainties, including inflationary pressures, supply chain disruptions, labor shortages, significant volatility in global markets, recession risks, and the COVID-19 pandemic have in the past and may continue to adversely affect our business, future results of operations, and financial condition, the effects of which remain uncertain.
- We have identified a material weakness in our internal control over financial reporting. This material weakness could continue to adversely affect our results of operations and financial condition accurately. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations.

Risks Related to COVID-19 Pandemic

Our Emergency Use Authorization Application for Niyad™ is premised on the declared COVID-19 health emergency.

Our Emergency Use Authorization, or EUA, submission that is currently under review by FDA for Niyad is based upon the U.S. government's declaration of a national health emergency due to the COVID-19 pandemic. On January 30, 2023, President Joe Biden informed Congress that he will end the twin national emergencies for addressing COVID-19 on May 11, 2023. Although the FDA will maintain the discretion to keep EUAs in effect after the public health emergency has ended, the anticipation of its end may negatively impact our prospects for obtaining authorization in the first place, and even if authorized, any sales for a COVID-related indication may be limited and distract us from the goal of obtaining Premarket Approval, or PMA, for Niyad.

Risks Related to Drug Development and Commercialization

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

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

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

Whether we receive royalties from DSUVIA is dependent on the ability of Alora to successfully commercialize DSUVIA. If Alora is unable to successfully commercialize DSUVIA, our business, financial condition, and results of operations will be materially harmed.

We have divested DSUVIA to Alora, who will continue to commercialize the product and we will receive royalties and milestone payments based on their sales. The commercial success of DSUVIA will depend heavily on numerous factors, including:

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

If Alora is unable to successfully commercialize DSUVIA, our business, financial condition, and results of operations will be materially harmed.

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

We have experienced and may in the future experience delays in clinical trials of our product candidates. Our FDA-required clinical trials for our product candidates, could be delayed for a variety of reasons, including:

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

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

Our drug discovery and development efforts might not generate successful product candidates.

We plan to invest a significant portion of our efforts and financial resources in the identification or asset acquisition of our product candidates, Niyad, LTX-608 and the pre-filled syringes. Our ability to generate product revenue from these product candidates, which may not occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of Niyad, LTX-608 and the pre-filled syringes. The success of these product candidates and any other product candidates we may develop will depend on many factors, including the following:

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

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

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

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials could occur at any stage of testing. The outcome of early clinical trials may not be predictive of the success of later clinical trials, and interim results of a particular clinical trial do not necessarily predict final results of that trial.

Moreover, clinical data is often susceptible to multiple interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical or regulatory results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- our contracts for collaborative arrangements are or may be terminable at will on written notice and may otherwise expire or terminate, and we may not have alternatives available to achieve the potential for our products in those territories or markets;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration, including in connection with any contractual breach notice including force majeure tied to the COVID-19 pandemic;

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

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

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

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

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

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

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

We need to retain and maintain our existing managerial, operational, regulatory, developmental, finance and other personnel and resources in order to develop our product candidates and manage our operations. Our current infrastructure may be inadequate to support our strategy and any future workforce reduction, such as the reduction that eliminated approximately 40% of our workforce in May 2022 and subsequent related workforce reductions, may be disruptive to our operations, may negatively affect our productivity, and may constrain our commercialization activities. For example, a further workforce reduction could yield unanticipated consequences, such as attrition beyond planned staff reductions, negatively impacting employee morale and our corporate culture, or increased difficulties in our day-to-day operations, and prevent us from developing our product candidates as rapidly as planned. If we encounter such unanticipated consequences, we may have difficulty retaining and attracting personnel. In addition, the implementation of any additional workforce or expense reduction programs may divert the efforts of our management team and other key employees, which could adversely affect our business. Furthermore, we may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our cost reduction plan, due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the cost reduction plan, our operating results and financial condition would be adversely affected.

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

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

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

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

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

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

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

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

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

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

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

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

Many end-users of pharmaceutical and medical device products have relationships with group purchasing organizations, or GPOs, whereby such GPOs provide such end-users access to a broad range of pharmaceutical and medical device products from multiple suppliers at competitive prices and, in certain cases, exercise considerable influence over the drug and device purchasing decisions of such end-users. Hospitals and other end-users contract with the GPO of their choice for their purchasing needs. We expect to derive revenue from end-user customers that are members of GPOs for our product candidates, if approved. Establishing and maintaining strong relationships with these GPOs will require us to be a reliable supplier, remain price competitive and comply with FDA regulations. The GPOs with whom we have relationships may have relationships with manufacturers that sell competing products, and such GPOs may earn higher margins from these products or combinations of competing products or may prefer products other than ours for other reasons. If we, or our partners, are unable to establish or maintain our GPO relationships, sales of our product candidates, if approved, and related revenues could be negatively impacted.

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

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

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

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

There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the Affordable Care Act . For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that there will be additional health reform measures It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is also unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act. We expect that the Affordable Care Act and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to successfully commercialize our products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our products may lose regulatory approval and we may not achieve or sustain profitability, which would adversely affect our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. Aggregate reductions of Medicare payments to providers of 2% per fiscal year went into effect on April 1, 2013 and due to subsequent legislative amendments to the statute will stay in effect until 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. The American Taxpayer Relief Act further reduced Medicare payments to several providers, including hospitals. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug’s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

In the United States, there has been increasing legislative and enforcement interest with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing and reform government program reimbursement methodologies for drugs. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. In addition, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. Furthermore, even after initial price and reimbursement approvals, reductions in prices and changes in reimbursement levels can be triggered by multiple factors, including reference pricing systems and publication of discounts by third party payers or authorities in other countries. In Europe, prices can be reduced further by parallel distribution and parallel trade (i.e., arbitrage between low-priced and high-priced countries). If any of these events occur, revenue from sales of our products in Europe would be negatively affected.

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

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

Risks Related to Our Financial Condition and Need for Additional Capital

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

We have incurred significant net losses since our inception in July 2005, and as of March 31, 2023, we had an accumulated deficit of $434.0 million. In addition, we have generated negative cash flows from operations and we expect to incur significant losses in 2023 and may incur significant losses and negative cash flows from operations in the future. These conditions raise substantial doubt about our ability to continue as a going concern.

We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. To date, we have financed our operations primarily through the issuance of equity securities, borrowings, payments from Grünenthal, the monetization of certain future royalties and commercial sales milestones from the European sales of Zalviso by Grünenthal, funding from the Department of Defense, or DoD, with revenues from sales of DSUVIA, and payments under the Amended DZUVEO Agreement with Aguettant. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenues. We expect to continue to incur substantial expenses as we support research and development activities for our product candidates. If our product candidates are not successfully developed or commercialized in the U.S., or if revenues are insufficient following marketing approval, we will not achieve profitability and our business may fail. Our success is also dependent on current and future collaborations to market our products outside of the United States, which may not materialize or prove to be successful.

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

Launch of a commercial pharmaceutical product and pharmaceutical development activities can be time consuming and costly. We expect to incur significant expenditures in connection with supporting our research and development activities for our product candidates.

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

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

The unaudited condensed consolidated financial statements for the quarterly period ended March 31, 2023 were prepared on the basis of a going concern, which contemplates that we will be able to realize our assets and discharge liabilities in the normal course of business. The financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

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

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

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

During the past several years, domestic and international financial markets have experienced, and they may continue to experience, extreme disruption from time to time, including, among other things, high volatility, significant declines in stock prices and severely diminished liquidity and credit availability for both borrowers and investors. Such adverse capital and credit market conditions could make it more difficult to obtain additional capital on favorable terms, or at all, which could have a material adverse effect on our business and growth prospects. For example, our ability to raise additional capital may be adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the U.S. and worldwide resulting from the evolving effects of the COVID-19 pandemic and the ongoing military conflict between Russian and Ukraine and related sanctions imposed against Russia.

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

We expect that significant additional capital will be needed in the future to continue our planned operations and capital requirements. In the long-term, our existing capital resources will not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to sustain our operations. In order to raise additional funds to support our operations, we may sell additional equity securities, including under the ATM Agreement with Cantor. We may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. Selling additional equity securities may result in dilution to our existing stockholders and new investors may be materially diluted by subsequent sales. Incurring additional indebtedness, including through the sale of debt securities or entering into a new debt facility, would result in increased fixed payment obligations and could also result in additional restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions, such as minimum cash balances, that could adversely impact our ability to conduct our business. Sales of equity or debt securities may also provide new investors with rights superior to our existing stockholders. If we are unable to expand our operations or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected, and we may not be able to meet our debt service obligations.

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

Our ability to generate revenue from commercial sales and/or royalties and achieve profitability depends on our ability, alone and with collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize our products. Although we received FDA approval of DSUVIA and began the commercial launch of DSUVIA in the United States, we may never generate enough revenues from sales of DSUVIA, or our product candidates, if approved, in the United States to become profitable. There can be no assurance that Alora pursuant to the DSUVIA Agreement will successfully commercialize DSUVIA. Although we had a collaboration agreement with Grünenthal for commercialization of Zalviso in Europe and Australia, Grünenthal was unable to achieve a level of commercial sales of Zalviso to trigger sales milestone payments that would have been payable to us. The Grünenthal Agreements have been terminated and Grünenthal's rights to market and sell Zalviso reverted back to us on May 12, 2021. The European Marketing Authorization for Zalviso was withdrawn in July 2022.

We do not anticipate generating significant near-term revenues under the DSUVIA Agreement or from our product candidates, if approved, in the United States. Our ability to generate future revenues from product sales depends heavily on the success in:

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

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

Even if we are able to generate revenues under the DSUVIA Agreement or from our product candidates, if approved, in the United States, we may not become profitable and may need to obtain additional funding to continue operations.

Future sales of DSUVIA to the DoD are not predictable, may occur on an irregular basis and may not meet our expectations due to various U.S. government-related factors that are beyond our control and into which we have little to no visibility, including the timing and extent of future U.S. military deployments. If DoD spending on DSUVIA does not meet our expectations, it could adversely affect our expected results of operations, financial condition and liquidity.

In April 2020, DSUVIA achieved Milestone C approval by the DoD, a decision that clears the path for the DoD to begin placing orders for DSUVIA to fulfill its updating requirements for all Army Sets, Kits, and Outfits, or SKOs, for deployed/deploying troops. Completion of this SKO fulfillment process 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. Under the DSUVIA Agreement, Alora will be responsible for commercializing DSUVIA except that we will retain the responsibility for driving the demand within the DoD, and we will receive quarterly payments in an amount equal to 75% of net Product sales to the DoD. Refer to Note 3, "Discontinued Operations" and Note 11, "Subsequent Events" to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information. Future sales of DSUVIA by Alora to the DoD are not predictable, may occur on an irregular basis, and may not meet expectations due to various U.S. government-related factors that are beyond our control and into which we have little to no visibility, including the timing and extent of future U.S. military deployments. Even if Alora does generate revenue from such sales and we receive payments, we may never generate revenue that is significant or predictable, which could impair our value and our ability to raise capital, expand our business or continue our operations. The placement of new orders by the DoD is, among other things, contingent upon overall U.S. government policies, budget and appropriation decisions and processes which are driven by numerous factors, including geo-political events, deployment of military units, macroeconomic conditions, and the ability of the U.S. government to enact relevant legislation, such as appropriations bills and accords on the debt ceiling. The timing and size of initial stocking orders for the SKOs and other orders by the DoD are based on troop deployment schedules. If DoD spending on DSUVIA does not meet our expectations, it could have a material adverse effect on our expected results of operations, financial condition and liquidity.

Risks Related to Our Reliance on Third Parties

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

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

- the inability to meet our product specifications and quality requirements consistently;
- the inability to procure raw materials in a timely fashion due to ongoing challenges in the global supply chain;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to maintain in good order our production and manufacturing equipment for our products;
- a failure to comply with cGMP and similar foreign standards;
- the inability to negotiate manufacturing or supply agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing or supply agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for product components, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell our products in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified backup suppliers for those components that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, or government orders related to the COVID-19 pandemic;
- carrier disruptions or increased costs that are beyond our control; and
- the failure to deliver our products under specified storage conditions and in a timely manner.

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

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

We currently have a single source of supply of API for our nafamostat-based product candidates. If supply from that vendor is interrupted or discontinued, there could be a significant impact on our development activities for those product candidates.

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

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

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

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

We may not be able to establish additional sources of supply for Niyad. Such suppliers are subject to FDA and other foreign regulatory agency's regulations requiring that materials be produced under cGMPs or Quality System Regulations, or QSR. Failure by any of our suppliers to comply with applicable regulations may result in delays. In addition, due to the recent strains on the global supply chain, the lead times for many components used in our production are getting longer and may impact our ability to manufacture our products in a timely manner.

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

We utilized contract research organizations, or CROs, for the conduct of the Phase 2 and 3 clinical trials of DSUVIA, as well as our Phase 3 clinical program for Zalviso. We will also utilize CROs for development of our product candidates. We will continue to rely on such CROs, as well as clinical trial sites, to ensure the proper and timely conduct of our clinical trials and document preparation. While we have agreements or will enter into such agreements governing their activities, we have limited influence over their actual performance. We have relied and plan to continue to rely upon CROs to monitor and manage data for our post-approval clinical programs for any FDA-required clinical programs for our product candidates, as well as the execution of nonclinical and clinical trials. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

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

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

Risks Related to Our Business Operations and Industry

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

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

- the federal healthcare Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;

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

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

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

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

- the federal transparency law, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies to report annually to the CMS information related to payments and other transfers of value provided to physicians, (defined to include, doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

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

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

Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the SEC. A determination that our operations or activities are not, or were not, in compliance with United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

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

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

We are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of sensitive information, including intellectual property, proprietary business information, personal information and other confidential information. It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such sensitive information. We have also outsourced elements of our operations (including elements of our information technology infrastructure) to third parties, and as a result, we manage a number of third-party vendors who may or could have access to our computer networks or our confidential information. In addition, many of those third parties in turn subcontract or outsource some of their responsibilities to third parties. While all information technology operations are inherently vulnerable to inadvertent or intentional security breaches, incidents, attacks and exposures, the accessibility and distributed nature of our information technology systems, and the sensitive information stored on those systems, make such systems potentially vulnerable to unintentional or malicious internal and external attacks on our technology environment. Potential vulnerabilities can be exploited from inadvertent or intentional actions of our employees, third-party vendors, business partners, or by malicious third parties. Attacks of this nature are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. In addition to the extraction of sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. In addition, the prevalent use of mobile devices increases the risk of data security incidents.

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

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

Business interruptions could delay our operations and sales efforts.

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

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

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

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

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

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

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

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

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

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

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. In addition, our current product liability insurance contains an exclusion related to any claims related to our products from a governmental body, or payer, or those claims arising from a multi-plaintiff action for bodily injury or property damage. Multi-plaintiff claims caused by product defects are covered. This exclusion does not apply to any bodily injury claim related to our products made by an individual. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim, or series of claims, brought against us could cause our stock price to decline and, if judgments are excluded from our insurance coverage or exceed our insurance coverage, could adversely affect our results of operations and business. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. There can be no assurance that such coverage will be adequate to protect us against any future losses due to liability.

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

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

Risks Related to Our Intellectual Property

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

To protect our proprietary technology, we rely on patents as well as other intellectual property protections including trade secrets, nondisclosure agreements, and confidentiality provisions. We are pursuing a number of U.S. patent applications and foreign national applications directed to Niyad, and LTX-608. The patent applications that we have filed and have not yet been granted may fail to result in issued patents in the United States or in foreign countries. Even if the patents do successfully issue, third parties may challenge the patents. We have entered into the DSUVIA Agreement with Alora pursuant to which Alora acquired all patents and trademarks related to DSUVIA and DZUVEO. In addition, we and Alora entered into an intellectual property agreement pursuant to which Alora granted fully-paid, royalty-free and perpetual licenses to us under certain specified intellectual property rights acquired by Alora under the DSUVIA Agreement for, among other things, the development, manufacture, commercialization and exploitation of certain products, including Zalviso.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

If we do not adequately protect our intellectual property rights, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize any of our Fedsyra, phenylephrine, Niyad or LTX-608 product opportunities, if approved, and delay or render impossible our achievement of profitability.

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

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our business partners, employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information without misappropriating our rights. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position.

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

We have systems in place, including use of third-party vendors, to manage payment of periodic maintenance fees, renewal fees, annuity fees and various other patent and application fees. The United States Patent and Trademark Office, or the USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. There are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

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

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. Additionally, claims may be brought regarding the validity of our patents by third parties in the United States and foreign countries. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property rights.

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

We have registered our ACELRX mark in the United States, Canada, the EU and India, and we have applied for registration of our Niyad and Fedsyra marks. Although we are not currently aware of any oppositions to or cancellations of our registered trademarks or pending applications, it is possible that one or more of the applications and/or registrations could be subject to rejection, opposition or cancellation. In addition, we will need to seek FDA approval to use Niyad and Fedsyra as part of future potential applications for marketing approval of the relevant developmental products. The registrations will be subject to use and maintenance requirements. It is also possible that we have not yet registered all of our trademarks in all of our potential markets, and that there are names or symbols other than “ACELRX” that may be protectable marks for which we have not sought registration, and failure to secure those registrations could adversely affect our business. Opposition or cancellation proceedings may be filed against our trademarks and our trademarks may not survive such proceedings.

Risks Related to Ownership of Our Common Stock

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

The trading price of our common stock has experienced significant volatility and is likely to be volatile in the future. For example, the closing price of our common stock ranged between $0.58 and $2.59 during the three months ended March 31, 2023, and $1.78 and $12.10 during the year ended December 31, 2022. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- failure to receive payments for the sale by Alora of DSUVIA in the United States, or to successfully develop and commercialize our product candidates in the United States;

- inability to obtain additional funding needed to conduct our planned business operations;
- the integration and performance of any assets or businesses we acquire;
- our inability to develop and commercialize products and product candidates that we in-license;
- uncertainties regarding the magnitude and duration of impacts we are experiencing due to COVID-19;
- the perception of limited market sizes or pricing for our products;
- safety issues;
- adverse results or delays in future clinical trials;
- changes in laws or regulations applicable to our products;
- inability to obtain adequate product supply for our products, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- changes in the structure of the healthcare payment systems;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- decisions by our collaboration partners regarding market access, pricing, and commercialization efforts in countries where they have the right to commercialize our products;
- failure to maintain our existing collaborations or enter into new collaborations;
- the perception of the pharmaceutical industry generally, and of opioid manufacturers more specifically, by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or other significant transactions, including disposition transactions, or capital commitments by us or our competitors;
- disputes or other developments relating to employment matters, business development efforts, proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key management or scientific personnel;
- costs associated with potential governmental investigations, inquiries, regulatory actions or lawsuits that may be brought against us as a result of us being an opioid manufacturer;
- other types of significant lawsuits, including patent, stockholder, securities class action and derivative litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future;
- our ability to maintain compliance with Nasdaq listing requirements;
- liquidity of our common stock; and
- trading volume of our common stock.

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

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

In order to maintain our listing on Nasdaq, we are required to comply with the Nasdaq requirements, which includes maintaining a minimum bid price and a minimum public float. In particular, we are required to maintain a minimum bid price of $1.00 per share. On April 26, 2023, we received a notice from Nasdaq stating that we were not in compliance with Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Price Rule") because our common stock failed to maintain a minimum closing bid price of $1.00 for 30 consecutive business days. This notice had no immediate effect on the Nasdaq listing or trading of our common stock.

We have a compliance period for the Minimum Bid Price Rule of 180 calendar days, or until October 23, 2023, in which to regain compliance, pursuant to Nasdaq Marketplace Rule 5810(c)(3)(A). If, at any time before that date the bid price of our common stock closes at $1.00 per share or more for a minimum of 10 consecutive business days, Nasdaq will notify us that we have achieved compliance with the Rule.

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

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

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

Because we will continue to need additional capital in the future to continue to expand our business and our research and development activities, among other things, we may conduct additional equity offerings. For example, under the universal shelf registration statement filed by us in June 2020 and declared effective by the SEC in July 2020, we may offer and sell any combination of common stock, preferred stock, debt securities and warrants in one or more offerings, up to a cumulative value of $150 million. To date, we have approximately $68.6 million (including shares that may be sold under the ATM Agreement with Cantor) remaining under such universal shelf registration statement; however, our ability to sell securities under the shelf registration statement will be limited until we are no longer subject to the SEC's "baby shelf" limitations. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants under our equity incentive plans. Grants under our equity incentive plans may also cause our stockholders to experience additional dilution, which could cause our stock price to fall. In May 2022 we filed a resale registration statement to permit the former stockholders of Lowell to sell the shares of common stock we issued such stockholders in exchange for their shares of Lowell capital stock. In addition, in November 2022 we filed a resale registration statement to permit Lincoln Park Capital Fund, LLC to sell the shares of common stock that are issuable upon conversion of the Series A Redeemable Convertible Preferred Stock and that are issuable upon exercise of the warrant, which were issued in a private placement transaction in August 2022. We may in the future issue additional shares of our common stock as consideration in mergers, acquisitions and other business development transactions. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. All of our shares of common stock outstanding are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements of Rule 144 under the Securities Act. Sales of stock by our stockholders could have a material adverse effect on the trading price of our common stock.

We have identified a material weakness in our internal control over financial reporting. This material weakness could continue to adversely affect our results of operations and financial condition. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations.

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

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

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

Management has implemented enhanced internal controls to remediate the material weakness. Specifically, we enhanced our processes to identify and appropriately apply applicable accounting requirements related to the earnings per share calculation to better evaluate and understand the nuances of the complex accounting standards that apply to our financial statements. We plan to continue to provide access to accounting literature, research materials and documents, enhance the review and analysis process around the earnings per share calculation and increase communications among our personnel and third-party professionals with whom we consult regarding complex accounting applications. The elements of our remediation plan can only be accomplished over time, and we can offer no assurance that these initiatives will ultimately have the intended effects.

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

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

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

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

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

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

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

Risks of a General Nature

Litigation may substantially increase our costs and harm our business.

We have been, are, and may in the future become, party to lawsuits including, without limitation, actions and proceedings in the ordinary course of business relating to our directors, officers, stockholders, intellectual property rights, employment matters and the safety or efficacy of our products, which will cause us to incur legal fees and other costs related thereto, including potential expenses for the reimbursement of legal fees of officers and directors under indemnification obligations. The expense of defending against such litigation may be significant and there can be no assurance that we will be successful in any defense. Further, the amount of time that may be required to resolve such lawsuits is unpredictable, and these actions may divert management's attention from the day-to-day operations of our business, which could adversely affect our business, results of operations, and cash flows. Our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our consolidated operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. Litigation is subject to inherent uncertainties, and an adverse result in such matters that may arise from time to time could have a material adverse effect on our business, results of operations, and financial condition. Please see Note 7 to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information about pending legal proceedings.

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

The stock markets have from time-to-time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations may cause the market price of our common stock to decline. In addition, the market price of our common stock may vary significantly based on AcelRx-specific events, such as receipt of Complete Response Letters, Warnings Letters, such as the Warning Letter we received from the FDA on February 11, 2021, negative clinical results, a negative vote or decision by an FDA advisory committee, or other negative feedback from the FDA, EMA, or other regulatory agencies. In the past, securities-related class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their investigational drug candidate development programs and the FDA's review of their NDAs. Following receipt of the FDA's Warning Letter, a securities class action complaint was filed against us and two of our officers on June 8, 2021 in the United States District Court for the Northern District of California. The amended securities class action complaint, which was filed on March 7, 2022, named a third officer as a defendant. On September 28, 2022, the Court issued a formal written opinion, or the Opinion, dismissing all of the plaintiff's claims against the Company and the named defendants. On November 28, 2022 the plaintiffs filed their second amended complaint. On January 30, 2023 the Company filed its new motion to dismiss the second amended complaint and on March 16, 2023, plaintiffs filed their opposition to the Company's new motion to dismiss and on April 17, 2023, the Company filed its reply to the plaintiffs' opposition. Oral hearings on the new motion to dismiss are scheduled for May 25, 2023. On July 6, 2021, September 30, 2021, October 26, 2021 and November 17, 2021, four purported shareholder derivative complaints were filed in the United States District Court for the Northern District of California asserting state and federal claims based on the same alleged misstatements as the securities class action complaint. On December 6, 2021, the Court entered an order consolidating all four actions and staying the consolidated action pending the outcome of any motion to dismiss the securities class action. Please refer to Note 7 to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information about these pending legal proceedings. Securities-related class action litigation often is expensive and diverts management's attention and our financial resources, which could harm our business. Additional lawsuits related to the pending litigation may follow. Moreover, if AcelRx experiences a decline in its stock price, we could face additional securities class action lawsuits.

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

As of December 31, 2022, we 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. $231.5 million of such federal net operating losses were generated after December 31, 2017. As of December 31, 2022, we had state net operating loss carryforwards of $167.9 million, which begin to expire in 2028. Under current law, federal net operating losses generated in tax years beginning prior to January 1, 2018 generally will expire 20 years after they were generated if not used prior thereto; federal net operating losses generated in tax years beginning after December 31, 2017 will carryforward indefinitely, but the deductibility of such federal net operating losses generally is limited to 80% of current year taxable income. Many states have similar laws. Our ability to use our federal and state net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the net operating losses, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses. Accordingly, our federal and state net operating losses could expire unused and be unavailable to offset future income tax liabilities. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. The completion of the July 2013 public equity offering, together with our public equity offering in December 2012, our initial public offering, private placements and other transactions that have occurred, have triggered such an ownership change. We may experience additional ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. Furthermore, our ability to utilize net operating losses of companies that we have acquired or may acquire in the future may be subject to limitations. In the future, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards or other tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us and could adversely affect our business, results of operations, and cash flows.

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

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

Macroeconomic uncertainties, including inflationary pressures, supply chain disruptions, labor shortages, significant volatility in global markets, recession risks, and the COVID-19 pandemic have in the past and may continue to adversely affect our business, future results of operations, and financial condition, the effects of which remain uncertain.

Global economic and business activities continue to face widespread macroeconomic uncertainties, including inflation, supply chain disruptions, labor shortages, as well as recession risks, which may continue for an extended period. In addition, the mitigation measures we have taken in responses to the COVID-19 pandemic have represented a significant disruption in how we operate our business, including a loss of productivity. The operations of our partners, suppliers, and other third parties with whom we have a business relationship have likewise been disrupted. While our offices are now reopened, many of our employees who were hired remotely during the pandemic continue to work remotely and others are working on a hybrid basis. We do not currently have visibility on whether we may return to normal operations of having everyone work in office on a full-time basis. Our efforts to keep our offices open safely may not be successful and could expose our employees to health risks. If there are further waves or variants of the virus, we may need to further modify our business practices in a manner that may impact our business. If our employees are not able to perform their job duties due to illness or are unable to perform them as efficiently at home for an extended period of time, we may not be able to deliver on our business priorities, and we may experience an overall lower productivity of our workforce.

The COVID-19 pandemic has already had an adverse effect on the global economy and our business. Actual and potential impacts include:

- the ability of our employees to travel has been limited and we have altered, postponed, or canceled planned industry events or shifted them to a virtual only format, and we may continue to do so;
- overall lower productivity of our workforce;
- extreme volatility in financial and other capital markets as a result of concerns over the economic impact of the COVID-19 pandemic, which have in the past and may in the future adversely affect our stock price and our ability to access capital markets.

We continue to monitor the impact of the COVID-19 pandemic and there may be additional costs or impacts to our business and operations, including in connection with returning to our offices, if we return to normal operations of having everyone work in office on a full-time basis. In addition, there is no guarantee that a future outbreak of this or any other widespread epidemics will not occur, or that the global economy will recover, either of which could seriously harm our business. The potential long-term impact of the COVID-19 pandemic or a similar health epidemic on our business, operations, or the global economy as a whole remains uncertain. Accordingly, it remains difficult for us to predict the duration and extent to which this will affect our business, future results of operations, and financial condition at this time.

To the extent that macroeconomic uncertainties and the COVID-19 pandemic continue to harm our business, many of the other risks described in these risk factors may be exacerbated.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	02/18/2011
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	06/25/2019
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	10/25/2022
3.4	Amended and Restated Bylaws of the Registrant.	8-K	001-35068	3.1	08/12/2022
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.				
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.				
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*				
101.INS	Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Schema Document.				
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.				
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document.				
101.LAB	Inline XBRL Taxonomy Label Linkbase Document.				
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document.				
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.INS, 101.SCH, 101.CAL, 101.DEF, 101.LAB, and 101.PRE).				

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

SIGNATURES

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

Date: May 10, 2023

AcelRx Pharmaceuticals, Inc.
(Registrant)

/s/ Raffi Asadorian

Raffi Asadorian
Chief Financial Officer
(Duly Authorized and Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION

I, Vincent J. Angotti, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AcelRx Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2023

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

Exhibit 31.2

CERTIFICATION

I, Raffi Asadorian, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AcelRx Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2023

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

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Vincent J. Angotti, Chief Executive Officer of AcelRx Pharmaceuticals, Inc. (the "Company"), and Raffi Asadorian, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended March 31, 2023, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

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

In Witness Whereof, the undersigned has set his hands hereto as of the 10th day of May 2023.

/s/ Vincent J. Angotti
Vincent J. Angotti
Chief Executive Officer

/s/ Raffi Asadorian
Raffi Asadorian
Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of AcelRx Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.