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 September 30, 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.)**

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

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

Title of Each Class:	**Trading symbol(s)**	**Name of Each Exchange on Which registered:**
Common Stock, $0.001 par value	**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 November 3, 2023, the number of outstanding shares of the registrant's common stock was 16,952,269.

ACELRX PHARMACEUTICALS, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2023

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Unless the context indicates otherwise, the terms "AcelRx," "AcelRx Pharmaceuticals," "we," "us" and "our" refer to AcelRx Pharmaceuticals, Inc., and its consolidated subsidiary. "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 conduct ourselves, or through a contract research organization, clinical trials in a timely and effective manner to advance the development of our product candidates, including our lead nafamostat developmental product candidate, Niyad™;
- 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 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 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 (unaudited)

AcelRx Pharmaceuticals, Inc.

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

	September 30, 2023	December 31, 2022[1]
Assets		
Current Assets:		
Cash and cash equivalents	$ 13,389	$ 15,275
Restricted cash	—	5,000
Short-term investments	—	495
Prepaid expenses and other current assets	1,017	1,865
Assets of discontinued operations	16	1,931
Total current assets	14,422	24,566
In-process research and development asset	8,819	8,819
Other assets	20	166
Assets of discontinued operations	—	13,936
Total Assets	$ 23,261	$ 47,487
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,026	$ 1,256
Accrued and other liabilities	1,792	2,531
Long-term debt, current portion	—	5,363
Liabilities of discontinued operations, current portion	756	4,620
Total current liabilities	3,574	13,770
Warrant liability	1,380	7,098
Other long-term liabilities	—	810
Liabilities of discontinued operations	—	3,995
Total Liabilities	4,954	25,673
Commitments and Contingencies		
Stockholders' Equity:		
Common stock, $0.001 par value—200,000,000 shares authorized as of September 30, 2023 and December 31, 2022; 16,952,269 and 8,243,680 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	17	8
Additional paid-in capital	457,999	447,635
Accumulated deficit	(439,709)	(425,829)
Total Stockholders' Equity	18,307	21,814
Total Liabilities and Stockholders' Equity	$ 23,261	$ 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, which were recast to reflect discontinued operations and filed with the Company's Current Report on Form 8-K on August 1, 2023.

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 September 30,		Nine Months Ended September 30,	
	2023	**2022(1)**	**2023**	**2022(1)**
Royalty revenue	$ 117	$ —	$ 370	$ —
Operating costs and expenses:				
Research and development	1,178	799	3,777	2,729
Selling, general and administrative	2,248	3,724	9,199	11,784
Impairment of property and equipment	—	—	—	4,901
Total operating costs and expenses	3,426	4,523	12,976	19,414
Loss from operations	(3,309)	(4,523)	(12,606)	(19,414)
Other income (expense):				
Interest expense	—	(245)	(134)	(928)
Interest income and other income, net	1,893	140	6,963	229
Non-cash interest income on liability related to the sale of future royalties	—	—	—	1,136
Gain on extinguishment of liability related to the sale of future royalties	—	—	—	84,052
Total other income (expense)	1,893	(105)	6,829	84,489
Net income (loss) before income taxes	(1,416)	(4,628)	(5,777)	65,075
Provision for income taxes	(2)	(11)	(5)	(14)
Net income (loss) from continuing operations	(1,418)	(4,639)	(5,782)	65,061
Net income (loss) from discontinued operations – See Note 3	61	(2,111)	(8,098)	(9,822)
Net income (loss)	(1,357)	(6,750)	(13,880)	55,239
Deemed dividends related to Series A Redeemable Convertible Preferred Stock	—	(186)	—	(186)
Income allocated to participating securities	—	—	—	(5,980)
Net income (loss) attributable to Common Shareholders, basic	$ (1,357)	$ (6,936)	$ (13,880)	$ 49,073
Net income (loss) attributable to Common Shareholders, diluted	$ (1,357)	$ (6,936)	$ (13,880)	$ 49,078
Net income (loss) per share attributable to stockholders:				
Basic earnings (loss) per share				
Income (loss) from continuing operations	$ (0.08)	$ (0.65)	$ (0.45)	$ 8.03
Income (loss) from discontinued operations	$ 0.00	$ (0.29)	$ (0.63)	$ (1.34)
Net income (loss) per share	$ (0.08)	$ (0.94)	$ (1.08)	$ 6.69
Diluted earnings (loss) per share				
Income (loss) from continuing operations	$ (0.08)	$ (0.65)	$ (0.45)	$ 8.02
Income (loss) from discontinued operations	$ 0.00	$ (0.29)	$ (0.63)	$ (1.34)
Net income (loss) per share	$ (0.08)	$ (0.94)	$ (1.08)	$ 6.68
Shares used in computing net income (loss) per share of common stock, basic – See Note 10	16,758,322	7,377,363	12,880,338	7,338,853
Shares used in computing net income (loss) per share of common stock, diluted – See Note 10	16,758,322	7,377,363	12,880,338	7,345,954

(1) The condensed consolidated statements of operations for the three and nine months ended September 30, 2022 have been derived from the unaudited condensed consolidated financial statements for those periods included in the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022, which were recast to reflect discontinued operations and filed with the Company's Current Report on Form 8-K on August 1, 2023.

See notes to condensed consolidated financial statements.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	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
Stock-based compensation	—	—	471	—	471
Issuance of hold back common stock in connection with asset acquisition	69,808	—	77	—	77
Net loss	—	—	—	(4,371)	(4,371)
Balance as of June 30, 2023	10,994,102	11	448,760	(438,352)	10,419
Stock-based compensation	—	—	378	—	378
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	5,500	—	—	—	—
Exercise of prefunded warrants	595,883	1	—	—	1
Issuance of common stock upon ESPP purchase	16,193	—	14	—	14
Issuance of common stock and warrants, net	5,340,591	5	8,847	—	8,852
Net loss	—	—	—	(1,357)	(1,357)
Balance as of September 30, 2023	16,952,269	$ 17	$ 457,999	$ (439,709)	$ 18,307

	Series A Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance as of December 31, 2021	—	$ —	6,840,967	$ 7	$ 437,684	$ (473,584)	$ (35,893)
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)
Stock-based compensation	—	—	—	—	753	—	753
Issuance of common stock upon vesting of restricted stock units	—	—	11,147	—	—	—	—
Net income	—	—	—	—	—	70,663	70,663
Balance as of June 30, 2022	—	—	7,366,580	7	444,731	(411,595)	33,143
Stock-based compensation	—	—	—	—	701	—	701
Issuance of Series A Redeemable Convertible Preferred Stock and Warrants	3,000	129	—	—	110	—	110
Deemed dividends related to Series A Redeemable Convertible Preferred Stock		186			(186)		(186)
Net proceeds from issuance of common stock in connection with equity financings	—	—	35,900	—	192	—	192
Issuance of common stock upon vesting of restricted stock units	—	—	216	—	—	—	—
Issuance of common stock upon ESPP purchase	—	—	3,270	—	16	—	16
Net loss	—	—	—	—	—	(6,750)	(6,750)
Balance as of September 30, 2022	3,000	$ 315	7,405,966	$ 7	$ 445,564	$ (418,345)	$ 27,226

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Inc.

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

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net (loss) income	$ (13,880)	$ 55,239
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Non-cash interest income on liability related to royalty monetization	—	(1,136)
Depreciation and amortization	311	1,305
Non-cash interest expense related to debt financing	53	333
Non-cash issuance of Lowell holdback shares	(723)	—
Stock-based compensation	1,418	2,237
Non-cash gain on termination of liability related to royalty termination	—	(84,152)
Impairment of property and equipment	—	4,901
Revaluation of warrant liability	(5,718)	—
Impairment of net assets held for sale	6,853	—
Impairment of fixed assets	1,065	—
Gain on termination of lease liabilities	(1,098)	—
Gain on extinguishment of debt liability	(400)	—
Other	(15)	(47)
Changes in operating assets and liabilities:		
Accounts receivable	(97)	(352)
Inventories	61	210
Prepaid expenses and other assets	1,294	375
Other assets	226	—
Accounts payable	(957)	25
Accrued liabilities	(1,761)	(1,456)
Operating lease liabilities	(146)	(357)
Deferred revenue	(29)	(43)
Net cash used in operating activities	(13,543)	(22,918)
Cash flows from investing activities:		
Purchase of property and equipment	(100)	(316)
Purchase of investments	—	(7,369)
Sale of the DSUVIA assets	2,723	—
Cash paid for asset acquisition, net of cash acquired	—	(1,687)
Proceeds from maturities of investments	500	43,162
Net cash provided by investing activities	3,123	33,790
Cash flows from financing activities:		
Payment of long-term debt	(5,416)	(6,250)
Net proceeds from issuance of Issuance of Series A Redeemable Convertible Preferred Stock and Warrants	—	239
Net proceeds from issuance of common stock in connection with equity financings	8,924	192
Net proceeds from issuance of common stock in connection with exercise of prefunded warrants	3	—
Net proceeds from issuance of common stock through equity plans	45	74
Payment of employee tax obligations related to vesting of restricted stock units	(22)	(58)
Net provided by (cash used in) financing activities	3,534	(5,803)
Net change in cash, cash equivalents and restricted cash	(6,886)	5,069
Cash, cash equivalents and restricted cash—Beginning of period	20,275	12,663
Cash, cash equivalents and restricted cash—End of period	$ 13,389	$ 17,732
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Purchases of property and equipment in accounts payable and accrued liabilities	—	$ 1,327
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
Establishment of right-of-use asset and lease liability	—	$ 85
Offering costs in accounts payable	$ 72	—
Fair value of warrants issued to placement agent	$ 263	—

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 San Mateo, 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 DSUVIA Agreement, with Vertical Pharmaceuticals, LLC, a wholly owned subsidiary of Alora Pharmaceuticals, LLC, or Alora, pursuant to which Alora agreed to acquire certain assets and assume certain liabilities of 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 DSUVIA Agreement occurred on April 3, 2023 (see Note 3, "Discontinued Operations").

On January 7, 2022, the Company acquired Lowell Therapeutics, Inc., or Lowell, a privately held company (see Note 4, "Asset Acquisition" to the consolidated financial statements in the Company's 2022 Annual Report on Form 10-K for additional information) 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, if they are approved in the U.S.

Liquidity and Going Concern

The unaudited condensed consolidated financial statements for the three and nine months ended September 30, 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. Although in July 2023 the Company closed the private placement of its common stock, pre-funded warrants and common warrants for aggregate gross proceeds to the Company of $10.0 million, before deducting the placement agent's fees and other offering expenses payable by the Company, with an additional potential $16.3 million upon the exercise of the common warrants, which include an acceleration feature should the Company achieve certain performance milestones (see Note 7, "Stockholders' Equity"), 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. These conditions raise substantial doubt about the Company's ability to continue as a going concern. 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 subsidiary. 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 and nine months ended September 30, 2023, are not necessarily indicative of the results that may be expected for the year ending December 31, 2023, or any future period. The unaudited 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, which were recast to reflect discontinued operations and filed with the Company's Current Report on Form 8-K on August 1, 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 unaudited condensed 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 and nine months ended September 30, 2023, from those previously disclosed in its 2022 Annual Report on Form 10-K, except as follows:

Royalty Revenue

The Company recognizes revenue in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606). The Company applies the following five steps in order to determine the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements:

- identify the contract with a customer;
- identify the performance obligations in the contract;
- determine the transaction price;
- allocate the transaction price to performance obligations in the contract; and
- recognize revenue as the performance obligation is satisfied.

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

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

Discontinued Operations

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

The Company's DSUVIA business met the definition of a discontinued operation as of March 31, 2023. Accordingly, the Company has classified the results of the DSUVIA business as discontinued operations in its 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. (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 September 30, 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 September 30, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, cash equivalents and restricted cash:				
Cash	$ 1,656	$ —	$ —	$ 1,656
Money market funds	3,264	—	—	3,264
U.S. government agency securities	7,572	—	—	7,572
Commercial paper	897	—	—	897
Total cash and cash equivalents	$ 13,389	$ —	$ —	$ 13,389

	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 and nine months ended September 30, 2023 or the twelve months ended December 31, 2022. As such, we did not record a credit allowance for the three and nine months ended September 30, 2023.

Fair Value Measurement

The Company's financial instruments consist of Level I and II assets. Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments is readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy. For Level II instruments, the Company estimates fair value by utilizing third-party pricing services in developing fair value measurements where fair value is based on valuation methodologies such as models using observable market inputs, including benchmark yields, reported trades, broker/dealer quotes, bids, offers and other reference data. Such Level II instruments typically include U.S. Treasury, U.S. government agency securities and commercial paper. As of September 30, 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 unaudited condensed 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 September 30, 2023			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 3,264	$ 3,264	$ —	$ —
U.S. government agency securities	7,572	—	7,572	—
Commercial paper	897	—	897	—
Total assets measured at fair value	$ 11,733	$ 3,264	$ 8,469	$ —
Liabilities				
Warrant liability	$ 1,380	$ —	$ —	$ 1,380
Total liabilities measured at fair value	$ 1,380	$ —	$ —	$ 1,380

	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 table sets forth a summary of the changes in the fair value of the Company's Level III warrant liability for the three and nine months ended September 30, 2023 (in thousands):

	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2023
Fair value—beginning of period	$ 3,086	$ 7,098
Change in fair value of 2022 Warrants liability	(1,706)	(5,718)
Fair value—end of period	$ 1,380	$ 1,380

There was no such warrant liability for the three and nine months ended September 30, 2022.

There were no transfers between Level I, Level II or Level III of the fair value hierarchy during the three and nine months ended September 30, 2023 and the year ended December 31, 2022.

3. Discontinued Operations

Asset Purchase Agreement

On April 3, 2023, the Company, closed the transactions contemplated by the DSUVIA Agreement entered into on March 12, 2023, with Alora, pursuant to which Alora agreed to acquire certain assets and assume certain liabilities of 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 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 DSUVIA Agreement.

The DSUVIA Agreement contains customary representations, warranties, and covenants by each party. Alora agreed not to practice, license or otherwise exploit any of the intellectual property rights acquired by it under the DSUVIA Agreement to manufacture, develop or commercialize any product (other than Product) that is or has been commercialized by AcelRx or its affiliate as of the date of the DSUVIA Agreement, or any product that is competitive with any such product. In addition, Alora will use commercially reasonable efforts to maintain regulatory approvals for and commercialize Product in the United States. The DSUVIA 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 DSUVIA Agreement for, among other things, the development, manufacture, commercialization and exploitation of certain products, including Zalviso, (b) a transition services agreement, pursuant to which, during the period specified therein, 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 DSUVIA 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 DSUVIA 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 DSUVIA Agreement, AcelRx assigned the Amended DZUVEO Agreement and the Amended and Restated Supply Agreement to Alora.

In addition, AcelRx and Aguettant amended 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 (see Note 4, "In-License Agreement" below).

The Company's DSUVIA business met the definition of a discontinued operation as of March 31, 2023. Accordingly, the assets and liabilities associated with these operations have been classified as assets and liabilities of discontinued operations in the accompanying condensed consolidated balance sheets at September 30, 2023 and December 31, 2022. The operations and cash flows of the DSUVIA business are presented as discontinued for all periods presented.

The following table presents the results of the discontinued operations for the three- and nine-month periods ended September 30, 2023 and 2022 (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Total revenues	$ —	$ 507	$ 501	$ 1,519
Cost of goods sold	—	338	711	1,290
Selling, general and administrative expense	21	1,771	719	8,613
Impairment of net assets held for sale	(82)	—	6,853	—
Impairment of fixed assets	—	—	1,065	—
Gain on termination of lease liabilities	—	—	(1,098)	—
Research and development expenses	—	509	349	1,438
Net income (loss) from discontinued operations	$ 61	$ (2,111)	$ (8,098)	$ (9,822)

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).

	September 30, 2023	December 31, 2022
Accounts receivable, net	$ 11	$ 309
Inventories	-	1,178
Prepaid expenses and other current assets	5	444
Total current assets of discontinued operations	16	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	$ 16	$ 15,867
Accounts payable	$ 10	$ 784
Accrued liabilities	746	1,720
Operating lease liabilities, current portion	-	1,601
Note payable, current portion	-	400
Deferred revenue, current portion	-	115
Total current liabilities of discontinued operations	756	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	756	8,615
Net assets (liabilities) of discontinued operations	$ (740)	$ 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):

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Depreciation and amortization	$ 215	$ 1,176
Stock-based compensation	19	226
Impairment of net assets held for sale	6,853	-
Impairment of fixed assets	1,065	-
Gain on termination of lease liabilities	(1,098)	-
Gain on extinguishment of debt	(400)	-

The following table represents the gain (loss) on sale of discontinued operations for the three and nine months ended September 30, 2023:

	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2023
Cash proceeds	$ —	$ 2,723
Less: net assets transferred	—	(8,723)
Less: disposal costs	82	(853)
Loss on sale of discontinued operations, before income taxes	82	(6,853)
Income tax expense	—	—
Gain (loss) on sale of discontinued operations	$ 82	$ (6,853)

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.

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

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

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

In connection with 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 from $24 million to $21 million.

As of September 30, 2023, there have been no payments by the Company to Aguettant under the PFS Agreement.

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 September 30, 2023 and December 31, 2022, the accrued balance due under the Loan Agreement with Oxford was $0 and $5.4 million, respectively. Interest expense related to the Loan Agreement was immaterial for the three months ended September 30, 2023, and $0.1 million, $0.1 million of which represented amortization of the debt discount, for the nine months ended September 30, 2023. Interest expense related to the Loan Agreement was $0.2 million, $0.1 million of which represented amortization of the debt discount, and $0.9 million, $0.3 million of which represented amortization of the debt discount, for the three and nine months ended September 30, 2022, respectively.

In connection with the closing of the divestment of DSUVIA to Alora, on April 3, 2023, the Company paid Oxford the remaining amount due of approximately $3.4 million including accrued interest and fees under the Loan, and the Loan Agreement was terminated with no further obligations by either party.

6. Commitments and Contingencies

Litigation

On June 8, 2021, a securities class action complaint was filed in the U.S. District Court for the Northern District of California against the Company and two of its officers. The plaintiff is a purported stockholder of the Company. The complaint alleged that defendants violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by making false and misleading statements and omissions of material fact about the Company's disclosure controls and procedures with respect to its marketing of DSUVIA. The complaint sought unspecified damages, interest, attorneys' fees, and other costs. On December 16, 2021, the Court appointed co-lead plaintiffs. Plaintiffs' amended complaint was filed on March 7, 2022. The amended complaint named the Company and three of its officers and continued to allege that defendants violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by making false and misleading statements and omissions of material fact about the Company's disclosure controls and procedures with respect to its marketing of DSUVIA. The amended complaint also asserted a violation of Section 20A of the Exchange Act against the individual defendants for alleged insider trading. The amended complaint sought unspecified damages, interest, attorneys' fees, and other costs. On September 1, 2022, the Court held oral hearings on the Company's motion to dismiss the amended complaint with prejudice that was filed on July 21, 2022. On September 28, 2022, the Court issued a formal written opinion, or the First Opinion, dismissing all of the plaintiff's claims against the Company and the named defendants with leave for plaintiffs to amend their complaint. On November 28, 2022 the plaintiffs filed their second amended complaint. On July 7, 2023, the Court issued a formal written opinion, or the Second Opinion, dismissing all of the plaintiff's claims against the Company and the named defendants with leave for plaintiffs to amend their complaint in part and without leave to amend in part. On September 5, 2023, the plaintiffs filed a third amended complaint.

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. It is reasonably possible that this estimate may change in the near term. An adverse outcome regarding these matters could materially adversely affect the Company's financial condition, results of operations, and cash flows.

Termination Agreement and Mutual Release Between 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.

7. Stockholders' Equity

Common Stock

July 2023 Private Placement

On July 17, 2023, the Company entered into a securities purchase agreement, or the Purchase Agreement, with several institutional investors, or the Purchasers, relating to the issuance and sale to the Purchasers in a private placement of 5,340,591 shares of common stock, par value $0.001 per share, pre-funded warrants to purchase up to an aggregate of 2,012,356 shares of common stock at an exercise price of $0.001 per share, or the 2023 Pre-Funded Warrants; Series A common stock warrants to purchase up to an aggregate of 7,352,947 shares of common stock at an exercise price of $1.11 per share; and Series B common stock warrants to purchase up to an aggregate of 7,352,947 shares of common stock at an exercise price of $1.11 per share. See Note 8, "Warrants" for additional information regarding the 2023 Pre-Funded Warrants, and Series A and Series B common stock warrants. The private placement closed on July 20, 2023.

The combined offering price was $1.36 per share of common stock and accompanying Series A common stock warrant and Series B common stock warrant, or in the case of 2023 Pre-Funded Warrants, $1.359 per pre-funded warrant and accompanying Series A common stock warrant and Series B common stock warrant (which is the purchase price per share of common stock and accompanying warrants less $0.001). The aggregate gross proceeds to AcelRx from the private placement were approximately $10.0 million, before deducting placement agent fees and other expenses payable by AcelRx of approximately $1.1 million, and excluding the proceeds, if any, from the exercise of the 2023 Pre-Funded Warrants and Series A and Series B common stock warrants issued in the private placement. The potential gross proceeds from the Series A common stock warrants and Series B common stock warrants, if fully exercised for cash, is approximately $16.3 million.

In May 2023, AcelRx engaged H.C. Wainwright & Co., LLC to act as placement agent in the private placement. As compensation, AcelRx paid the placement agent a cash fee equal to 5.25% of the aggregate gross proceeds generated from the private placement and reimbursed certain expenses of the placement agent in connection with the private placement totaling $0.1 million. The placement agent will be entitled to an additional one-time payment of $200,000 upon the exercise of the Series A and Series B common stock warrants resulting in cumulative aggregate gross proceeds to AcelRx of at least $9.5 million in cash. As of September 30, 2023, no Series A or Series B common stock warrants were exercised. In addition, the Company issued to the placement agent fully vested Series A common stock warrants, or placement agent Series A common stock warrants, to purchase 183,824 shares of common stock and fully vested Series B common stock warrants, or placement agent Series B common stock warrants, to purchase 183,823 shares of common stock. See Note 8, "Warrants" for additional information regarding the placement agent Series A and Series B common stock warrants.

ATM Agreement

The Company has entered into the ATM Agreement with Cantor, as agent, pursuant to which the Company may offer and sell, from time to time through Cantor, shares of the Company's common stock having an aggregate offering price of up to $80.0 million.

The Company issued and sold approximately 0.04 million shares of common stock pursuant to the ATM Agreement and received net proceeds of $0.2 million, after deducting fees and expenses, during the three and nine months ended September 30, 2022. As of September 30, 2023, the Company did not have an effective shelf registration statement, and will be unable to make any further sales under the ATM Agreement until such time as the Company files a new shelf registration statement and it is declared effective by the SEC. In addition, the Company's ability to sell such shares under any future shelf registration statement the Company may file with the SEC and the ATM Agreement will be limited until the Company is no longer subject to the SEC's "baby shelf" limitations.

Stock Plan

Amended 2020 Equity Incentive Plan

On October 10, 2023, at the 2023 Annual Meeting of Stockholders of the Company, upon the recommendation of the Company's Board of Directors, the Company's stockholders approved an amendment and restatement of the Company's 2020 Equity Incentive Plan, or the Amended 2020 Plan, to increase the number of authorized shares reserved for issuance thereunder by 1,500,000 shares, subject to adjustment for certain changes in the Company's capitalization. The aggregate number of shares of the Company's common stock that may be issued under the Amended 2020 Plan will not exceed the sum of: (i) 1,990,000 shares, and (ii) up to 744,608 shares subject to outstanding awards granted under the 2011 Equity Incentive Plan that may become available for issuance under the Amended 2020 Plan, as such shares become available from time to time.

8. Warrants

The activity related to warrants during the nine months ended September 30, 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
2023 Pre-Funded Warrants issued	2,012,356	$ 0.001
Series A Common Stock Warrants issued	7,352,947	$ 1.11
Series B Common Stock Warrants issued	7,352,947	$ 1.11
Series A Common Stock Warrants issued to placement agent	183,824	$ 1.70
Series B Common Stock Warrants issued to placement agent	183,823	$ 1.70
2022 Pre-Funded Warrants exercised	(2,632,898)	$ 0.0001
2023 Pre-Funded Warrants exercised	(595,883)	$ 0.001
Outstanding at September 30, 2023	21,682,049	$ 1.40
Exercisable at September 30, 2023	21,682,049	$ 1.40

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 2023 Pre-Funded Warrants were exercisable immediately following the closing date of the July 2023 Private Placement, or July 20, 2023, and have an unlimited term and an exercise price of $0.001 per share. In addition, 595,883 of the 2023 Pre-Funded Warrants were exercised in the three months ended September 30, 2023. The 2022 Pre-Funded Warrants and the 2023 Pre-Funded Warrants were determined to be common stock equivalents.

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 September 30, 2023, the 2022 Warrants were valued at approximately $1.4 million, using the Black-Scholes option pricing model as follows: exercise price of $2.07 per share, stock price of $0.58 per share, expected life of 5.25 years, volatility of 94.73%, a risk-free rate of 4.60% and 0% expected dividend yield. See Note 2, “Investments and Fair Value Measurement” above. 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.

The Series A and Series B common stock warrants were exercisable immediately following the closing date of the July 2023 Private Placement and have a five-year term, unless certain milestone events are met which accelerate the expiration date to 45 days following such announcement, and have an exercise price of $1.11 per share. The Series A and Series B common stock warrants also include certain rights upon “fundamental transactions” as described in such warrants, including the right of the holders thereof to receive from AcelRx or a successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of common stock in such fundamental transaction in the amount of the Black Scholes value (as described in such warrants) of the unexercised portion of the applicable warrants on the date of the consummation of such fundamental transaction.

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

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

In July 2023, the warrants issued to Lincoln Park Capital Fund, LLC, or the August 2022 LPC Warrant, to purchase up to an aggregate of 81,150 shares of common stock down round feature was triggered due to the price per share received from the issuance of common stock and warrants in connection with the July 2023 Private Placement. The Company calculated the value of the effect of the down round feature measured as the difference between the warrants’ fair value, using the Black-Scholes option-pricing model, before and after the down round feature was triggered using the then current exercise price, $2.07, and the new exercise price, $1.11. The difference in fair value of the effect of the Down Round Feature was immaterial and had no impact on net loss per share in the periods presented. This down round feature expired on August 3, 2023.

The Series A and Series B common stock warrants, the placement agent Series A and Series B common stock warrants, the 2022 Warrants and the financing warrants issued in November 2021 are participating securities which, by definition, entitle the holders thereof to participate in dividends and other distributions of assets by the Company to its holders of common shares as though the holder then held common shares.

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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 210	$ 139	$ 383	$ 466
Selling, general and administrative	168	519	1,016	1,545
Discontinued operations	—	43	19	226
Total	$ 378	$ 701	$ 1,418	$ 2,237

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	(40,106)	19.31
Forfeited	(2,926)	13.91
Restricted stock units outstanding, September 30, 2023	83,837	$ 7.96

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)
Stock options outstanding, January 1, 2023	725,623	$ 52.98		
Granted	264,520	1.76		
Forfeited	(9,003)	12.09		
Expired	(105,808)	83.31		
Stock options outstanding, September 30, 2023	875,332	$ 34.26	6.5	$ —
Vested and exercisable options— September 30, 2023	478,246	$ 54.66	4.5	$ —
Vested and expected to vest— September 30, 2023	875,332	$ 34.26	6.5	$ —

The per-share weighted average grant date fair value of the options granted during the nine months ended September 30, 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:

	Nine months ended September 30, 2023
Expected term (in years)	6.3
Risk-free interest rate	3.9%
Expected volatility	94%
Expected dividend rate	0%

As of September 30, 2023, total stock-based compensation expense related to unvested options to be recognized in future periods was $1.1 million which is expected to be recognized over a weighted-average period of 2.2 years. As of September 30, 2023, there were 151,953 shares available for grant under the Company's equity incentive plans and 169,667 shares available for grant under the Amended ESPP.

10. Net Income (Loss) per Share of Common Stock

The Company applies the two-class method to compute basic net income (loss) per share by dividing the net income (loss) attributable to common shareholders by the weighted average number of shares of common stock outstanding for the period. The diluted net income (loss) per share of common stock is computed by giving effect to all potential common stock equivalents outstanding for the period determined using the more dilutive of the 1) treasury stock method, if-converted method, or contingently issuable share method, as applicable, or 2) the two-class method. For purposes of this calculation, options to purchase common stock, RSUs, and warrants to purchase common stock were considered to be common stock equivalents.

During the nine months ended September 30, 2022, the Company presents diluted EPS using the two-class method as it was more dilutive. The Company's participating securities do not have a contractual obligation to share in the Company's losses, therefore, net loss for the three and nine months ended September 30, 2023 was attributed entirely to common stockholders. In periods with a reported net loss, common stock equivalents are excluded from the calculation of diluted net loss per share of common stock if their effect is antidilutive. Potential common shares that are issuable for little or no cash consideration, such as the Company's pre-funded warrants issued in December 2022 and July 2023 with a de minimis exercise price of $0.0001 per share, are considered outstanding common shares which are included in the calculation of basic and diluted net income (loss) per share in all circumstances.

The following table sets forth the computation of the Company's basic and diluted net income (loss) per share of common stock during the three and nine months ended September 30, 2023 and 2022 (in thousands, except for share and per share amounts):

	Three Months Ended September 30,	
	2023	2022
	(in thousands, except share and per share amounts)	
Basic net loss per common share:		
Net loss from continuing operations	$ (1,418)	$ (4,639)
Less: deemed dividend related to Series A Redeemable Convertible Preferred Stock	—	(186)
Net loss from continuing operations attributable to common shareholders, basic	(1,418)	(4,825)
Net income from discontinued operations attributable to common shareholders, basic	61	(2,111)
Net loss attributable to common shareholders, basic	$ (1,357)	$ (6,936)
Weighted average shares outstanding — basic	16,758,322	7,377,363
Loss from continuing operations, basic	$ (0.08)	$ (0.65)
Income from discontinued operations, basic	$ 0.00	$ (0.29)
Loss per share, basic	$ (0.08)	$ (0.94)
Diluted net loss per common share:		
Net loss from continuing operations	$ (1,418)	$ (4,639)
Less: deemed dividend related to Series A Redeemable Convertible Preferred Stock	—	(186)
Net loss from continuing operations attributable to common shareholders, diluted	(1,418)	(4,825)
Net income from discontinued operations attributable to common shareholders, diluted	61	(2,111)
Net loss attributable to common shareholders, diluted	$ (1,357)	(6,936)
Weighted average shares outstanding — diluted	16,758,322	7,377,363
Loss from continuing operations, diluted	$ (0.08)	$ (0.65)
Income from discontinued operations, diluted	$ 0.00	$ (0.29)
Net loss per share, diluted	$ (0.08)	$ (0.94)

	Nine Months ended September 30,	
	2023	2022
	(in thousands, except share and per share amounts)	
Basic net income (loss) per common share:		
Net income (loss) from continuing operations	$ (5,782)	$ 65,061
Less: deemed dividends related to Series A Redeemable Convertible Preferred Stock	—	(186)
Less: income allocated to participating securities	—	(5,980)
Net income (loss) from continuing operations attributable to common shareholders, basic	(5,782)	58,895
Net loss from discontinued operations attributable to common shareholders, basic	(8,098)	(9,822)
Net income (loss) attributable to common shareholders, basic	$ (13,880)	$ 49,073
Weighted average shares outstanding — basic	12,880,338	7,338,853
Income (loss) from continuing operations, basic	$ (0.45)	$ 8.03
Loss from discontinued operations, basic	$ (0.63)	$ (1.34)
Net income (loss) per share, basic	$ (1.08)	$ 6.69
Diluted net income (loss) per common share:		
Net income (loss) from continuing operations	$ (5,782)	$ 65,061
Less: deemed dividends related to Series A Redeemable Convertible Preferred Stock	—	(186)
Less: income allocated to participating securities	—	(5,975)
Net income (loss) from continuing operations attributable to common shareholders, diluted	(5,782)	$ 58,900
Net loss from discontinued operations attributable to common shareholders, diluted	(8,098)	$ (9,822)
Net income (loss) attributable to common shareholders, diluted	$ (13,880)	$ 49,078
Weighted average shares outstanding — basic	12,880,338	7,338,853
Dilutive effect of warrants	—	5,756
Dilutive effect of RSUs	—	1,345
Weighted average shares outstanding — diluted	12,880,338	7,345,954
Income (loss) from continuing operations, diluted	$ (0.45)	$ 8.02
Loss from discontinued operations, diluted	$ (0.63)	$ (1.34)
Net income (loss) per share, diluted	$ (1.08)	$ 6.68

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
RSUs, stock options and ESPP to purchase common stock	959,169	821,875	959,169	817,086
Common stock warrants	20,265,576	964,983	20,265,576	910,928

11. Subsequent Events

The Company evaluates events or transactions that occur after the balance sheet date, but prior to the issuance of the financial statements, to identify matters that require recognition or disclosure. The Company concluded that no subsequent events have occurred, that would require recognition or disclosure in the condensed consolidated financial statements.

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 condensed consolidated 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 the Annual Report, which were recast to reflect discontinued operations and filed with the Company's Current Report on Form 8-K on August 1, 2023.

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 our sufentanil sublingual tablet product referred to as DSUVIA or DZUVEO, or any other single-dose pharmaceutical product for use in medically supervised settings containing a sublingual tablet that includes sufentanil as the sole active ingredient, as a 30 mcg tablet or other dosage form or strength as reasonably necessary for lifecycle management, or the Product. Refer to Note 3, "Discontinued Operations" 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	Received an investigational device exemption, or IDE, and Breakthrough Device Designation from the United States Food and Drug Administration, or FDA. Plan to initiate a registrational trial in 2023 and submit a Premarket Approval, or PMA, application to the FDA in the second half of 2024.
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.

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 pre-filled syringe 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 DSUVIA Agreement, we are entitled to receive quarterly payments in an amount equal to 15% of net Product sales to all customers excluding net sales to the 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” 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" 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 initiating a registrational study of Niyad later this year and anticipate submitting a PMA application for Niyad to the FDA in the second half of 2024.

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 Quarterly Report on Form 10-Q 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, the COVID-19 pandemic has impacted our global supply chain and we may face further disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products if the global COVID-19 pandemic persists. 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 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 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. On September 22, 2023, the FDA notified us that due to the volume of EUA requests the FDA has received, the FDA has determined that review of the Niyad EUA is not a priority and has therefore declined to issue an EUA for Niyad at this time pursuant to the FDA's current prioritization of EUA requests. In the notice letter, the FDA encouraged us to continue to assess clinical development of the Niyad device. We plan to initiate a registrational study of Niyad later this year and anticipate submitting a PMA application for Niyad to the FDA in the second half of 2024.

On July 20, 2023, we closed the private placement of common stock, pre-funded warrants and common warrants for aggregate gross proceeds to us of $10.0 million, before deducting the placement agent's fees and other offering expenses payable by us, with an additional potential $16.3 million upon the exercise of the common warrants, which include an acceleration feature should the Company achieve certain performance milestones. Refer to Note 7, "Stockholders' Equity" to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information.

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 and nine months ended September 30, 2023 was $1.4 million and $13.9 million, respectively, compared to net loss for the three months ended September 30, 2022 of $6.8 million and net income for the nine months ended September 30, 2022 of $55.2 million. As of September 30, 2023, we had an accumulated deficit of $439.7 million. As of September 30, 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 and nine months ended September 30, 2023, from those previously disclosed in our Annual Report, as follows:

We recognize revenue in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606). We apply the following five steps in order to determine the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements:

- identify the contract with a customer;
- identify the performance obligations in the contract;
- determine the transaction price;
- allocate the transaction price to performance obligations in the contract; and
- recognize revenue as the performance obligation is satisfied.

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

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

Discontinued Operations

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

Our DSUVIA business met the definition of a discontinued operation as of March 31, 2023. Accordingly, we have classified the results of the DSUVIA business as discontinued operations in our 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 and nine months ended September 30, 2023 and 2022. Certain financial results (revenues and expenses) relating to the divestment of our DSUVIA/DZUVEO business are reflected in discontinued operations. See Note 3, "Discontinued Operations" to the 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 and Nine Months Ended September 30, 2023 and 2022

Revenue

For the three and nine months ended September 30, 2023, we recognized $0.1 million and $0.4 million in revenue, respectively, related to the DSUVIA Agreement with Alora under the Marketing Agreement executed in April 2023, pursuant to which AcelRx has the exclusive right to market and offer DSUVIA for sale to DoD and for which Alora pays us 75% of net sales of DSUVIA sold to DoD.

Research and Development Expenses

There were no research and development expenses capitalized during the three or nine months ended September 30, 2023.

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 and nine months ended September 30, 2023 and 2022 (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
Drug Indication/Description	**2023**	**2022**	**$ Change 2023 vs. 2022**	**% Change 2023 vs. 2022**	**2023**	**2022**	**$ Change 2023 vs. 2022**	**% Change 2023 vs. 2022**
				(In thousands, except percentages)				
Niyad	$ 273	$ 47	$ 226	481%	$ 1,232	$ 305	$ 927	304%
PFS	—	189	(189)	(100)%	4	309	(305)	(99)%
Zalviso	1	11	(10)	(91)%	29	24	5	21%
Overhead	904	552	352	64%	2,512	2,091	421	20%
Total research and development expenses	$ 1,178	$ 799	$ 379	47%	$ 3,777	$ 2,729	$ 1,048	38%

Research and development expenses for the three and nine months ended September 30, 2023 increased as compared to the three and nine months ended September 30, 2022, primarily due to increased spending on Niyad.

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 and nine months ended September 30, 2023 and 2022, were as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2023	2022	$ Change 2023 vs. 2022	% Change 2023 vs. 2022	2023	2022	$ Change 2023 vs. 2022	% Change 2023 vs. 2022
	(In thousands, except percentages)							
Selling, general and administrative expenses	$ 2,248	$ 3,724	$ (1,476)	(40)%	$ 9,199	$ 11,784	$ (2,585)	(22)%

Selling, general and administrative expenses decreased for the three months ended September 30, 2023, as compared to the three months ended September 30, 2022, primarily due to a $0.7 million reduction in employee compensation and related expenses as a result of a reduction in headcount, a $0.6 million reduction in consulting and legal fees, and a net reduction in other selling, general and administrative expenses of $0.2 million in the third quarter of 2023. For the nine months ended September 30, 2023, as compared to the nine months ended September 30, 2022, selling, general and administrative expenses decreased primarily due to a $1.9 million reduction in employee compensation and related expenses as a result of a reduction in headcount, a $0.5 million reduction in consulting and legal fees, and a net reduction in other selling, general and administrative expenses of $0.2 million in the first nine months of 2023.

Other Income(Expense)

Total other income (expense) for the three and nine months ended September 30, 2023 and 2022, was as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2023	2022	$ Change 2023 vs. 2022	% Change 2023 vs. 2022	2023	2022	$ Change 2023 vs. 2022	% Change 2023 vs. 2022
	(In thousands, except percentages)							
Interest expense	$ —	$ (245)	$ 245	(100)%	$ (134)	$ (928)	$ 794	(86)%
Interest income and other income (expense), net	1,893	140	1,753	1,252%	6,963	229	6,734	2,941%
Non-cash interest income (expense) on liability related to sale of future royalties	—	—	—	—%	—	1,136	(1,136)	(100)%
Gain on extinguishment of liability related to sale of future royalties	—	—	—	—%	—	84,052	(84,052)	(100)%
Total other income (expense)	$ 1,893	$ (105)	$ 1,998	(1,903)%	$ 6,829	$ 84,489	$ (77,660)	(92)%

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 and nine months ended September 30, 2023, as compared to the three and nine months ended September 30, 2022, primarily as a result of a lower average outstanding loan balance. 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” to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information.

Interest income and other income (expense), net, for the three and nine months ended September 30, 2023 and 2022, primarily consisted of changes in the fair value of our warrant liability, the Lowell holdback shares and interest earned on our investments. The increase in interest income and other income, net for the three months ended September 30, 2023 as compared to 2022, was primarily due to a $1.7 million decrease in the fair value of our warrant liability, while the increase for the nine months ended September 30, 2023 as compared to 2022, was primarily due to the $5.7 million decrease in the fair value of our warrant liability and a $0.7 million gain on the satisfaction of the contingency related to the liability for the Lowell holdback shares issued in June 2023.

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

Discontinued Operations

For the three months ended September 30, 2023, we recognized net income from discontinued operations of $0.1 million, and for the nine months ended September 30, 2023, we recognized a net loss from discontinued operations $8.1 million. For the three and nine months ended September 30, 2022, we recognized net losses from discontinued operations of $2.1 million and $9.8 million, respectively. Refer to Note 3, "Discontinued Operations" to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information.

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. Although, we closed the private placement of our common stock, pre-funded warrants and common warrants in July 2023 for aggregate gross proceeds to us of $10.0 million, before deducting the placement agent's fees and other offering expenses payable by us, with an additional potential $16.3 million upon the exercise of the common warrants, which include an acceleration feature should we achieve certain performance milestones (see Note 7, "Stockholders' Equity"), 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. These conditions raise substantial doubt about our ability to continue as a going concern. We 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 our product candidates. On October 18, 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 maintain 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 September 30, 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 repayment of the Loan Agreement with Oxford, development activities for our newly acquired late-stage pipeline product candidates, and business development activities, including the divestment of DSUVIA, partially offset by net proceeds of $8.9 million received in connection with our July 2023 equity financing (as described in further detail below). 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 and nine months ended September 30, 2023, while we issued and sold approximately 0.04 million shares of common stock pursuant to the ATM Agreement and received net proceeds of $0.2 million, after deducting fees and expenses, during the three and nine months ended September 30, 2022. As of September 30, 2023, we did not have an effective shelf registration statement, and we will not be able to make any further sales under the ATM Agreement until such time as we file a new shelf registration statement and it is declared effective by the SEC. In addition, our ability to sell such shares under any future shelf registration statement we may file with the SEC 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. 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” to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information.

On July 17, 2023, we entered into a securities purchase agreement, or the Purchase Agreement, with several institutional investors, or the Purchasers, relating to the issuance and sale to the Purchasers in a private placement of 5,340,591 shares of common stock, par value $0.001 per share, pre-funded warrants to purchase up to an aggregate of 2,012,356 shares of common stock at an exercise price of $0.001 per share; Series A common stock warrants to purchase up to an aggregate of 7,352,947 shares of common stock at an exercise price of $1.11 per share; and Series B common stock warrants to purchase up to an aggregate of 7,352,947 shares of common stock at an exercise price of $1.11 per share. Refer to Note 7, “Stockholders’ Equity” 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.

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):

	Nine Months Ended September 30,	
	2023	**2022**
Net cash used in operating activities	$ (13,543)	$ (22,918)
Net cash provided by investing activities	3,123	33,790
Net cash provided by (used in) financing activities	3,534	(5,803)

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 $13.5 million during the nine months ended September 30, 2023, reflected a net loss of $13.9 million, partially offset by aggregate non-cash charges of approximately $1.7 million and included an approximate $1.4 million net change in our operating assets and liabilities. Non-cash adjustments included an impairment charge of $6.9 million on our net assets held for sale in connection with our divestment of DSUVIA, an impairment charge of $1.1 million on fixed assets, a gain of $1.1 million related to the termination of lease liabilities, a $5.7 million decrease in the fair value of our warrant liability, $1.4 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 $1.3 million decrease in prepaid expenses and other assets, a $1.8 million decrease in accrued liabilities, and a $1.0 million decrease in accounts payable.

Cash used in operating activities of $22.9 million during the nine months ended September 30, 2022, reflected net income of $55.2 million, offset by aggregate non-cash items of $76.6 million and an approximate $1.6 million net change in our operating assets and liabilities. Non-cash inflows included an $84.2 million gain on the termination of the Royalty Monetization, partially offset by a $4.9 million charge for the impairment of Zalviso-related property and equipment and $2.2 million in stock-based compensation 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 nine months ended September 30, 2023, cash provided by investing activities of $3.1 million was primarily the net result of $2.7 million in cash proceeds on the sale of DSUVIA to Alora, $0.5 million in proceeds from the maturities of investments partially offset by $0.1 million for purchases of property and equipment.

During the nine months ended September 30, 2022, cash provided by investing activities of $33.8 million was primarily the net result $43.2 million in proceeds from maturity of investments partially offset by $7.4 million for purchases of investments and $1.7 million in cash paid for the Lowell asset acquisition, net of cash acquired.

Cash Flows from Financing Activities

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

During the nine months ended September 30, 2023, cash provided by financing activities of $3.5 million was primarily due to $8.9 million in net proceeds from the July 2023 equity financing, partially offset by $5.4 million in long-term debt payments under the Loan Agreement with Oxford. During the nine months ended September 30, 2022, cash used in financing activities of $5.8 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” 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.

Remediation of 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 have implemented measures to remediate the identified material weakness. Those remediation measures 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, have enhanced the review and analysis process around the earnings per share calculation and increased communications among our personnel and third-party professionals with whom we consult regarding complex accounting applications.

These actions resulted in an improved internal control environment that was in place for a period of time to allow for our management to conclude, based on evidence obtained in validating the design and operating effectiveness of these controls, that we have fully remediated the material weakness in the review procedures related to the technical accounting review and analysis over earnings per share calculations as of June 30, 2023.

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. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during our most recent fiscal quarter that have materially affected, or are 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 6, 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:

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

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 September 30, 2023, we had an accumulated deficit of $439.7 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℠ 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 September 30, 2023 were prepared on the basis of a going concern, which contemplates that we will be able to realize our assets and discharge liabilities in the normal course of business. These financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

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

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

- further scale back or discontinue the development of our product candidates;

- seek corporate partners for our product candidates on terms that might be less favorable than might otherwise be available; or

- relinquish, or license on unfavorable terms, our rights to technologies, products or product candidates that we otherwise would seek to develop or commercialize ourselves.

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

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

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

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

Our ability to generate revenue from commercial sales and/or royalties and achieve profitability depends on our ability, alone and with collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize our products. 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" 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 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 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 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 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 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, and finished product of our nafamostat-based product candidates and any disruption in the chain of supply may cause a delay in developing our product candidates.

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

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

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

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

The facilities of any of our future manufacturers of Niyad must be approved by the FDA before commercial distribution from such manufacturers occurs. We do not fully control the manufacturing process and are completely dependent on these third-party manufacturing partners for compliance with the FDA or other foreign regulatory agency's requirements for manufacture. In addition, although our third-party manufacturers are well-established 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 items used in our production are getting longer and may impact our ability to manufacture our products in a timely manner.

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

We 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 $0.57 and $2.59 during the nine months ended September 30, 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 maintain compliance with Nasdaq's continued listing requirements, our common stock may be delisted from The Nasdaq Global Market.

In order to maintain our listing on Nasdaq, we are required to comply with the Nasdaq requirements, which includes maintaining a minimum bid price and a minimum public float. In particular, we are required to maintain a minimum bid price of $1.00 per share. On October 18, 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, we cannot assure you that we will be able to regain compliance with the Nasdaq continued listing requirements.

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

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

Because we will continue to need additional capital in the future to continue to expand our business and our research and development activities, among other things, we may conduct additional equity offerings. Sales of a substantial number of shares of our common stock in the public market or 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 exercise of a warrant we issued in a private placement transaction in August 2022. In August 2023, we filed a resale registration to permit certain investors to sell the shares of common stock, as well as shares of common stock issuable upon exercise of warrants, we issued and sold to such investors in a private placement in July 2023. We may in the future issue additional shares of our common stock as consideration in mergers, acquisitions and other business development transactions. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. All of our shares of common stock outstanding are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements of Rule 144 under the Securities Act. Sales of stock by our stockholders could have a material adverse effect on the trading price of our common stock.

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

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

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

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

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

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

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

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

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

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

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

Risks of a General Nature

Litigation may substantially increase our costs and harm our business.

We have been, are, and may in the future become, party to lawsuits including, without limitation, actions and proceedings in the ordinary course of business relating to our directors, officers, stockholders, intellectual property rights, employment matters and the safety or efficacy of our products, which will cause us to incur legal fees and other costs related thereto, including potential expenses for the reimbursement of legal fees of officers and directors under indemnification obligations. The expense of defending against such litigation may be significant and there can be no assurance that we will be successful in any defense. Further, the amount of time that may be required to resolve such lawsuits is unpredictable, and these actions may divert management's attention from the day-to-day operations of our business, which could adversely affect our business, results of operations, and cash flows. Our insurance carriers may deny coverage, may be inadequately capitalized to pay on valid claims, or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on our consolidated operations, cash flows and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. Litigation is subject to inherent uncertainties, and an adverse result in such matters that may arise from time to time could have a material adverse effect on our business, results of operations, and financial condition. Please see Note 6 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 First Opinion, dismissing all of the plaintiff's claims against the Company and the named defendants with leave for plaintiffs to amend their complaint. On November 28, 2022 the plaintiffs filed their second amended complaint. On July 7, 2023, the Court issued a formal written opinion, or the Second Opinion, dismissing all of the plaintiff's claims against the Company and the named defendants with leave for plaintiffs to amend their complaint in part and without leave to amend in part. On September 5, 2023, the plaintiffs filed a third amended complaint. 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 6 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.

We continue to monitor the impact of the COVID-19 pandemic and there may be additional costs or impacts to our business and operations. 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, Use of Proceeds, and Issuer Purchases of Equity Securities

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
2.1+	Asset Purchase Agreement, between the Registrant and Vertical Pharmaceuticals, LLC, dated March 12, 2023				
3.1	Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	02/18/2011
3.2	Certificate of Amendment 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).				

+ Certain information in this exhibit has been omitted because it is both (i) not material and (ii) is the type that the Registrant treats as private and confidential.

* 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: November 14, 2023

AcelRx Pharmaceuticals, Inc.
(Registrant)

/s/ Raffi Asadorian

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

Exhibit 2.1

[***] Certain information in this document has been omitted from this exhibit because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

ASSET PURCHASE AGREEMENT

Between

ACELRX PHARMACEUTICALS, INC.

and

VERTICAL PHARMACEUTICALS, LLC

Dated as of March 12, 2023

ASSET PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT, executed on March 12, 2023 (the "Effective Date"), is made and entered into between AcelRx Pharmaceuticals, Inc., a Delaware corporation ("Seller"), and Vertical Pharmaceuticals, LLC, a Delaware limited liability company ("Buyer").

RECITALS:

WHEREAS, subject to the terms and conditions set forth in this Agreement, Seller desires to sell to Buyer and Buyer desires to purchase and assume from Seller certain assets and liabilities related to the Program (as defined below);

NOW, THEREFORE, in consideration of the foregoing, the premises and the mutual representations, warranties, covenants and undertakings contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, agree as follows:

ARTICLE I
DEFINITIONS AND TERMS

Section 1.1 Certain Definitions. As used in this Agreement, the following terms have the meanings set forth below:

"Adjusted Annual Net Sales" has the meaning set forth in Section 2.11(a).

"Affiliate" means, with respect to any Person, any Person directly or indirectly controlling, controlled by, or under common control with such first Person as of the date on which, or at any time during the period for which, the determination of affiliation is being made. For purposes of this definition, the term "control" (including the correlative meanings of the terms "controlled by" and "under common control with"), as used with respect to any Person, means the possession, directly or indirectly, of the power to direct or cause the direction of the management policies of such Person, whether through the ownership of voting securities or by contract or otherwise.

"Agreement" means this Asset Purchase Agreement, as may be amended or supplemented from time to time in accordance with the terms hereof.

"Aguettant" has the meaning set forth in Section 2.10(g).

"Aguettant Agreements" has the meaning set forth in Section 2.10(g).

"Aguettant Amendments" has the meaning set forth in Section 2.10(g).

"Ancillary Agreements" means all the documents set forth in Section 2.9 and Section 2.10, the Marketing Agreement, assignment agreements, and other documents and instruments, pursuant to which Seller's right, title or interest in any of the Transferred Assets is transferred to Buyer, and any other documents executed in connection with the Transaction.

"Annual Net Sales" means, with respect to a Product, Net Sales of such Product in the Territory in a Calendar Year.

"Anticorruption Laws" has the meaning set forth in Section 3.18(a).

"Assigned Contracts" has the meaning set forth in Section 2.1(e).

"Assumed Liabilities" has the meaning set forth in Section 2.3.

"Authorizations" means Governmental Authorizations and Non-Governmental Authorizations.

"Business Day" means any day other than a Saturday, a Sunday or a day on which banks in Atlanta, Georgia, or in California are authorized or obligated by Law or executive order to close.

"Buyer" has the meaning set forth in the Preamble.

"Buyer Indemnified Persons" has the meaning set forth in Section 8.1(a).

"Calendar Year" means each respective period of twelve (12) consecutive months beginning on January 1.

"Cap" has the meaning set forth in Section 8.1(c).

"Change of Control Transaction" means, with respect to a party, a transaction or series of transactions pursuant to which one or more Third Parties (i) acquires (whether by merger, consolidation or transfer or issuance of capital stock or otherwise) beneficial ownership, directly or indirectly, of more than 50% of such party's then outstanding voting securities, or (ii) acquires all or substantially all of the assets of such party; but excluding any such transaction or series of transactions described in clause (i) in which (a) such transaction or series of transactions is principally for bona fide equity financing purposes, or (b) such transaction or series of transactions is a consolidation or merger effected exclusively to change the domicile of such party.

"Chargebacks" means, collectively, all credits, chargebacks, reimbursements, administrative and other fees, costs, charges, rebates, and other payments arising from and/or in association with the sale of the Product to any wholesaler, retail pharmacy, distributor, group purchasing organization, insurer and other institution.

"Claim Notice" has the meaning set forth in Section 8.3(b).

"Claims" has the meaning set forth in Section 8.3(b).

"Closing" means the closing of the Transaction.

"Closing Date" means the date on which the Closing occurs.

"Code" means the Internal Revenue Code of 1986, as amended.

"Commercially Reasonable Efforts" has the meaning set forth in Section 2.16(a).

"Confidential Information" has the meaning set forth in Section 5.9(a).

"Confidentiality Agreement" means the Mutual Confidentiality Agreement, dated August 1, 2022, between Seller and Acella Pharmaceuticals, LLC.

"Contract Consents" has the meaning set forth in Section 3.8(a).

"Contracts" means all agreements, contracts, leases and subleases, purchase orders, commitments, licenses, indentures, guarantees, notes, letters of credit, loan or credit agreements, marketing, lobbying, sales agent, and other agreements or arrangements (other than this Agreement), whether written or oral.

"Control" or "Controlled" means with respect to any Intellectual Property, possession by a party of the ability (whether by ownership, license or otherwise) to assign or to grant access, a right to use, a license or a sublicense (as applicable) to such Intellectual Property as set forth herein without violating the terms of any agreement or other arrangement with any Third Party.

"Copyrights" means copyrights and copyrightable works, and registrations and applications therefor, content (including website content), mask work rights, database and design rights, including data collections, and all other rights, including "moral" rights, corresponding thereto in any works of authorship (including copyrights in computer software and code), whether published or unpublished.

"Cost of Goods Sold" means, for any period, the reasonable, documented, direct and recognized cost of manufacturing the Product for such period determined in accordance with GAAP, excluding any allocation of overhead expenses.

"Customers" means, collectively, each customer of Seller that, during Calendar Year 2021 or 2022, paid Seller for purchases of Product.

"Damages" means any loss, damage (including incidental, consequential and punitive damages, but only to the extent such incidental, consequential or punitive damages are related to or arise from a Third Party Claim, as such term is defined in Section 8.3(b)), injury, liability, Order, Encumbrance, claim, demand, settlement, judgment, award, fine, penalty, Tax, fee (including reasonable attorneys' fees and expenses), diminution of value, court costs, charge, cost (including reasonable costs of investigation and seeking recovery under this Agreement and the Ancillary Agreements) or expense of any nature.

"Data Room" means the online data room maintained by Seller titled "AcelRx Pharmaceuticals, Inc." located at: https://www.sharevault.net.

"Department of Defense" or "DoD" means the United States Department of Defense. For purposes of clarity, the Department of Defense does not include the United States Department of Veterans Affairs or any Veterans Affairs medical centers or hospitals.

"Development" (and, with correlative meaning, "Develop," "Developed" and "Developing") means pre-clinical and clinical drug development activities, including clinical trials, relating to the development of pharmaceutical compounds and submission of information to a Regulatory Authority for the purpose of obtaining Regulatory Approval of a Product, and activities to develop manufacturing capabilities for the Product. Development includes optimization and pre-clinical activities, pharmacology studies, toxicology studies, formulation, manufacturing process development and scale-up (including bulk compound production), quality assurance and quality control, technical support, pharmacokinetic studies, clinical trials and regulatory affairs activities.

"Direct Claim" has the meaning set forth in Section 8.3(a).

"Direct Claim Notice" has the meaning set forth in Section 8.3(a).

"Discussion Period" has the meaning set forth in Section 8.3(a).

"Effective Date" has the meaning set forth in the Preamble.

"Encumbrance" means any pledge, hypothecation, charge, mortgage, security interest, encumbrance, equity, trust, equitable interest, claim, preference, right of possession, lease, tenancy, license, encroachment, covenant, infringement, interference, Order, proxy, option, right of first refusal, right of first negotiation, preemptive right, community property interest, legend, defect, impediment, exception, reservation, limitation, impairment, imperfection of title, prior assignment, or other lien (whether arising by Contract or by operation of law).

"EU" means the European Union, as it is constituted on the Closing Date.

"Ex-Im Laws" shall mean all Laws relating to export, reexport, transfer, and import of goods, services, information, and other items, including but not limited to the Export Administration Regulations, the International Traffic in Arms Regulations, trade sanctions and embargoes, tariffs, trade agreements, corruption, product origin, or other international trade issues, the Arms Export Control Act, Export Administration Act, the International Emergency Economic Powers Act, the regulations administered by the U.S. Treasury Department's Office of Foreign Asset Controls, regulations administered by the Drug Enforcement Administration, regulations administered by the Bureau of Alcohol, Tobacco, and Fire Arms, regulations administered by the Food and Drug Administration, executive orders relating to international trade matters, and the customs and import Laws administered by U.S. Customs and Border Protection, as well as any and all other U.S. Laws, executive agency guidance, and other laws relating to importation and exportation, and trade sanctions.

"Excluded Assets" has the meaning set forth in Section 2.2.

"Excluded Liabilities" means all Liabilities of Seller or any of its Affiliates other than the Assumed Liabilities. For clarity, the Excluded Liabilities shall explicitly include, but shall not be limited to, any Liabilities for, relating to or arising from: (i) without duplication, [***] ending on or prior to the Closing Date; (ii) [***] before the Closing Date; (iii) [***] for periods prior to the Closing; (iv) [***] for periods prior to the Closing; (v) [***] prior to the Closing; (vi) [***] after the Closing pursuant to [***], other than any Liability arising out of [***] following the Closing Date; and (vii) any and all Liabilities of Seller or its Affiliates relating to the period prior to the Closing Date or arising prior to the Closing Date, including but not limited to any and all Liabilities arising out of [***] prior to the Closing Date, and any and all Liabilities arising out of or relating to the [***] prior to the Closing Date. Except as provided in Section 2.3, where Buyer expressly assumes the Assumed Liabilities, and notwithstanding anything to the contrary, Buyer shall not assume, in connection with the Transaction or the transactions contemplated by the Ancillary Agreements, any additional Liability of Seller whatsoever, whether known or unknown, disclosed or undisclosed, accrued or hereafter arising, absolute or contingent, and Seller shall retain responsibility for all Excluded Liabilities.

"FDA" means the United States Food and Drug Administration or any successor entity thereto having the administrative authority to regulate the marketing of human pharmaceutical products in the United States.

"FDA Fraud Policy" has the meaning set forth in Section 3.12(d).

"FDCA" means the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.) and its implementing regulations and guidance documents.

"Fraud" means actual fraud under common law of the State of Delaware in the making of the representations and warranties set forth in this Agreement.

"GAAP" means United States generally accepted accounting principles in effect from time to time.

"General Assignment and Assumption Agreement" has the meaning set forth in Section 2.9(a).

"Generic Equivalent" shall mean, with respect to a Product and country in the Territory, any present or future drug product that (a) has obtained Regulatory Approval from the applicable Regulatory Authority in such country as an AB-rated or fully substitutable version of the Product, based on an abbreviated new drug application or foreign equivalent, filed by any Person, in which the Product is the reference listed drug, (b) is not Developed, manufactured or commercialized by or on behalf of Buyer or Seller or any of their Affiliates or licensees, or any Person that received rights to such drug product from, or purchased such drug product in a chain of distribution that included, Buyer or Seller or any of their Affiliates or licensees, and (c) is labelled in full or in part for the same approved indications as the Product.

"Government Contract" means any contract, subcontract, task order, delivery order, purchase order, license agreement, cooperative agreement, grant, security agreement, joint venture agreement, teaming agreement, or other similar agreement of any kind entered into between the Seller and a Government Entity. The term "Government Contract" also includes any contract, subcontract, task order, delivery order, grant, subrecipient agreement under a grant, or arrangement of any kind that relates to business, between the Seller and (a) any prime contractor or higher-tier subcontractor of a Government Entity in its capacity as a prime contractor or subcontractor or (b) any lower-tier subcontractor in the Seller's capacity as a prime contractor or subcontractor to any Government Entity, on the other hand.

"Government Contracts Enforcement Matters" has the meaning set forth in Section 3.17(c).

"Government Entity" means any:

(a) nation, state, county, city, town, borough, village, district or other jurisdiction;

(b) federal, state, local, municipal, foreign or other government;

(c) political, governmental or quasi-governmental authority of any nature (including any agency, branch, department, board, commission, court, tribunal or other entity exercising governmental or quasi-governmental powers);

(d) multinational organization or body;

(e) entity, authority, agency, ministry or other similar body exercising any legislative, executive, judicial, regulatory or administrative authority or functions of or pertaining to government, including any commission, tribunal, contractor, or other quasi-governmental entity established to perform any such function;

(f) Regulatory Authority;

(g) body exercising, or entitled or purporting to exercise, any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power; or

(h) official of any of the foregoing.

"Governmental Authorizations" means all licenses, permits, certificates, registrations and other authorizations, consents, waivers and approvals issued by or obtained from a Government Entity, including a Regulatory Authority.

"Gross Profit" means, with respect to any calendar quarter, an amount equal to (a) the Net Sales of Products sold or otherwise disposed of to DoD in such calendar quarter, *minus* (b) the Cost of Goods Sold for such Products sold or otherwise disposed of to DoD in such calendar quarter.

"Healthcare Laws" means all federal, state and local Laws relating to the regulation, provision, performance, reporting, marketing, selling or administration of, or payment for, pharmaceutical products, including (i) FDCA, the federal Anti Kickback Statute (42 U.S.C. §1320a 7b(b)), Sections 1320a 7 and 1320a 7a of Title 42 of the United States Code, the Physician Self-Referral Law, commonly known as the "Stark Law" (42 U.S.C. §§1395nn and 1396b), the False Statements Relating to Health Care Matters law (18 U.S.C. § 1035), Health Care Fraud (18 U.S.C. § 1347), and the False Claims Act (31 U.S.C. § 3729 et seq.). For clarity, Healthcare Laws are a subset of "Laws" as defined below.

"IND" means an investigational new drug application (as defined at 21 C.F.R. § 312.3 and more fully described in 21 C.F.R. § 312.20 et seq.) or equivalent application, and all amendments thereto, filed with the FDA in the United States or the applicable Regulatory Authority in a country or group of countries outside the United States (including any supra-national agency such as in the EU), including all documents, data, submissions, filings and other information concerning an investigational pharmaceutical product (or an investigational use of an approved pharmaceutical product) which are necessary for interstate shipment and administration of the product in clinical investigations.

"Indemnified Person" has the meaning set forth in Section 8.3(a).

"Indemnifying Person" has the meaning set forth in Section 8.3(a).

"Intellectual Property" means all worldwide intellectual property rights, whether statutory or common law rights, including rights in and to the following: (i) Patents; (ii) Marks; (iii) Copyrights; (iv) Know-How; (v) data exclusivity, databases (including knowledge databases, customer lists and customer databases) and any other data collections, and all rights therein; and (vi) any similar, corresponding or equivalent rights to any of the foregoing.

"Inventory" means all existing inventory of the Products owned by Seller in the form of finished goods and unfinished goods, raw materials (including active pharmaceutical ingredients), bulk product, packaging and labeling, whether held at any location or facility of Seller and of its Affiliates or in transit to Seller or any of its Affiliates, in each case as of the Closing Date.

"IP Agreement" has the meaning set forth in Section 2.9(d).

"IP Assignment" has the meaning set forth in Section 2.9(b).

"IRS" means the United States Internal Revenue Service.

"Know-How" means any and all inventions (whether or not patentable, reduced to practice or made the subject of a pending patent application) and any improvements to same; invention disclosures; processes, methods, algorithms and formulae; know-how, trade secrets, technology, ideas, research and Development information, proprietary information (whether confidential or not), technical data, designs, plans, proposals, drawings, computer programs (including source code), results of experiments, test data, including pharmacological, toxicological and clinical data and clinical research files, analytical and quality control data, manufacturing data and descriptions, market data, assays, chemical formulations, notes of experiments, specifications, compositions of matter, chemical and biological materials and compounds, whether in intangible, tangible, written, electronic or other form.

"Knowledge" or any similar phrase, with respect to a party, means [***].

"Law" means any federal, state, local, foreign or other law, statute, ordinance, rule, regulation, code, order, judgment, injunction, writ, permit, regulatory or administrative guidance, Order, constitution, treaty, principle of common law, license or decree enacted, issued, promulgated, enforced or entered by a Government Entity.

"Liabilities" means any and all debts, liabilities, commitments and obligations of any kind, character or description, whether known or unknown, fixed, contingent or absolute, matured or unmatured, liquidated or unliquidated, secured or unsecured, accrued or not accrued, joint or several, due or to become due, vested or unvested, asserted or not asserted, disputed or undisputed, known or unknown, executory, determined, determinable or otherwise, whenever or however arising (including, whether arising out of any contract or tort based on negligence or strict liability) and whether or not the same would be required by GAAP to be reflected in financial statements or disclosed in the notes thereto.

"License and Acquisition Income" means the gross consideration (in any form), but excluding any royalty payments based on sales of Products, (i) [***] received by Buyer and its Affiliates in connection with a grant to any Third Party or Third Parties of a license or other right, privilege or immunity to make, have made, use, sell, offer for sale, research, Develop, commercialize, import, export or exploit a Product, beyond the mere right to purchase such Product from or to provide distribution or other services on behalf of Buyer and/or its Affiliates (each such Third Party, a "Licensee"), including any license signing fee, upfront fee, license maintenance fee, option fee or milestone payment, any equity, distribution or joint marketing fee, any funding for research and Development to be performed by Buyer or any of its Affiliates for a Licensee [***] and any consideration received for an equity interest or other investment in Buyer or any of its Affiliates [***] and/or (ii) [***] received by Buyer or its Affiliates or equityholders as consideration in a sale or transfer of any ownership interest in any or all of the Transferred Assets to a Third Party, whether received at the closing of such transaction or at any time thereafter, including any contingent payments, but excluding consideration received in connection with a Change of Control Transaction with respect to Buyer. For clarity, License and Acquisition Income shall only include consideration received by Buyer and its Affiliates and equityholders (a) from a Licensee that is allocable to a Product (and shall not include consideration received by Buyer from such Licensee solely for, or allocable to, products that are not Products) and/or (b) from a Third Party that is allocable to the Transferred Assets or any Product and not solely for, or allocable to, any other assets purchased by such Third Party that are not related to any Product. [***].

"License and Acquisition Income Payments" means the potential payments payable pursuant to Section 2.14(a).

"License and Acquisition Income Report" has the meaning set forth in Section 2.14(b).

"Licensed Intellectual Property" means the Transferred Intellectual Property that is licensed to Seller or any of its Affiliates from a Third Party.

"Licensee" has the meaning set forth in the definition of "License and Acquisition Income".

"Marketing Agreement" has the meaning set forth in Section 2.9(e).

"Marks" means all United States and foreign trademarks, service marks, trade names, service names, brand names, trade dress rights, logos, internet domain names (including all uniform resource locators and web site addresses) and other indicia of commercial source or origin, whether registered or not, used solely in, or intended to be used solely in connection with, the Product, together with the goodwill associated with any of the foregoing, and all applications, registrations and renewals thereof.

"Material Adverse Effect" means any event, occurrence, fact, condition, change, or effect that is individually or in the aggregate materially adverse to the Transferred Assets, taken as a whole, or would reasonably be expected to impair the ability of Seller to consummate the Transaction on a timely basis; provided, however, that none of the following (individually or in combination) shall be deemed to constitute, or shall be taken into account in determining whether there has been, a Material Adverse Effect: (i) any adverse effect resulting from general business or economic conditions; (ii) any adverse effect resulting from conditions generally affecting any industry or industry sector to which the Program relates; (iii) any adverse effect resulting from the announcement, execution or delivery of this Agreement or the pendency or consummation of the transactions contemplated hereunder; (iv) any adverse effect resulting from any change in accounting requirements or principles or any change in applicable Laws or the interpretation thereof by Government Entities, including Regulatory Authorities; (v) any adverse effect resulting from any breach by Buyer of any provision of this Agreement; or (vi) any adverse effect resulting from acts of war, sabotage or terrorism, cyber-attacks or man-made or natural disasters (including hurricanes, tornadoes, floods, earthquakes, weather-related events, natural disasters and other "acts of God"), epidemics, plagues, pandemics or other outbreak or illness (including COVID-19), or material worsening thereof, including necessary responses thereto; *provided further, however*, that any event, occurrence, fact, condition, or change referred to in clauses (i), (ii), (iii) and (vi) immediately above shall be taken into account in determining whether a Material Adverse Effect has occurred or reasonably be expected to occur to the extent that such event, occurrence, fact, condition, or change has a disproportionate effect on the Program or Transferred Assets compared to the other participants in the industry or industry sector to which the Program relates.

"Milestone Event" has the meaning set forth in Section 2.11(a).

"Milestone Payment" means any of the potential payments set forth in Section 2.11(a).

"NDA" means a new drug application (as defined at 21 C.F.R. § 314.3 and more fully described in 21 C.F.R. § 314.50 et seq.) or equivalent application, and all amendments and supplements thereto, filed with the FDA in the United States or the applicable Regulatory Authority in a country or group of countries outside the United States (including any supra-national agency such as in the EU), including all documents, data, submissions, filings and other information concerning a pharmaceutical product which are necessary for gaining Regulatory Approval to market and sell such pharmaceutical product.

"NDC" means National Drug Code.

"Net Sales" means, with respect to a Product, the gross amounts invoiced by the Buyer and any Person making sales or other disposition of a Product on behalf of, or pursuant to rights obtained directly or indirectly from, Buyer (each, a "Selling Party") for sales or other dispositions of such Product to Third Parties in the Territory, less the following items, as allocable to such Product (if actually incurred, paid or accrued by the Buyer or such other Person and not otherwise previously deducted from the amount invoiced or recovered by or reimbursed to the Buyer or such other Person):

(1) trade, quantity and cash discounts, credits or allowances;

(2) credits or allowances additionally granted upon returns, rejections, damaged goods or recalls or for retroactive price reductions and billing errors;

(3) rebates, discounts and chargeback payments in any form granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), national, state/provincial, local, and other governments, their agencies and purchasers and reimbursers, or to trade customers; and

(4) all Taxes, duties, or other governmental charges levied on the Products and included in the gross amounts invoiced, but only to the extent that such Taxes, duties or other charges are recorded as deductions in net sales in the Buyer's financial statements, consistent with past practice; otherwise, they will not be deducted.

Upon any sale or other disposition of any Product for any consideration other than exclusively monetary consideration on bona fide arm's-length terms, for purposes of calculating Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for money at the average sales price during the applicable reporting period generally achieved for such Product in the same country.

In no event will any particular amount, identified above, be deducted more than once in calculating Net Sales. In addition, to the extent any amounts deducted pursuant to the above are subsequently recovered by or reimbursed to the applicable Selling Party, such recovered amounts shall be deemed "Net Sales" for the subsequent calendar quarter; provided that, if no royalties are owed by Buyer for such subsequent calendar quarter pursuant to this Agreement, Buyer shall promptly refund such recovered amounts to Seller. For purposes of determining Net Sales, the Product shall be deemed to be sold when invoiced. Sales of a Product between the Buyer and other Selling Parties for resale shall be excluded from the computation of Net Sales, but the subsequent resale of such Product to a Third Party shall be included within the computation of Net Sales. Any free-of-charge disposal or use of a Product for Development, regulatory or marketing purposes, such as clinical trials, expanded access or indigent patient programs, shall not be deemed a sale or disposition for purposes of calculating Net Sales. Net Sales shall explicitly exclude sales of the Product by [***]

Net Sales will be calculated in accordance with this definition and the Buyer's accounting policies generally consistent with GAAP on an accrual basis, as consistently applied. To the extent any accrued amounts used in the calculation of Net Sales are estimates, such estimates shall be trued-up in accordance with the Buyer's accounting policies generally consistent with GAAP, as consistently applied, and Net Sales and related payments under this Agreement shall be reconciled as appropriate.

"Non-Governmental Authorizations" means all licenses, permits, certificates, registrations and other authorizations, consents, waivers, and approvals other than Governmental Authorizations.

"Nontransferred Assets" has the meaning set forth in Section 2.20(a).

"Orders" has the meaning set forth in Section 3.10.

"Organizational Documents" means (a) the certificate or articles of incorporation, formation or organization, (b) the bylaws, operating agreement or limited liability company agreement, (c) any documents comparable to those described in clauses (a) and (b) as may be applicable pursuant to any Law, (d) any amendment or modification to any of the foregoing and (e) any shareholder, voting or similar agreement.

"Other Seller Materials" means (i) all research and Development reports and disclosure memoranda owned by Seller relating to the Product, including study reports, clinical trial related documents including consent forms, case study forms, study contracts, site agreements, manuscripts and in process publications, (ii) all of the marketing and promotional documents owned by Seller, such as customer lists, marketing and promotional plans, documents and materials, pricing and sales data, field force training manuals and materials, and the like, to the extent relating to the Product, (iii) all worldwide safety reports of Seller with respect to the Product in existence as of the Closing, (iv) all of Seller's formulation, Development and manufacturing information used in connection with the Product and owned by Seller, including manufacturing processes, master batch records, manufacturing documentation, Product specifications, equipment specifications, analytical specifications and validation reports, quality assurance and control data, including test data, studies, results, reports, batch records, and stability studies, Chemistry, Manufacturing and Control paperwork, certificates of analysis, component and labeling purchasing specifications, packaging specifications and packaging and quality control SOPs, and (v) all other necessary documentation and materials owned by Seller and pertaining to the Program, in each case (i)-(v) that are necessary for, or were generated or used by or on behalf of Seller prior to the Effective Date in connection with, the Development, manufacture, commercialization or other exploitation of the Product. For clarity, Other Seller Materials exclude any of the information or materials described in clauses (i)-(v) that were generated in connection with the Development, manufacture, commercialization or other exploitation of, or relate solely to, any product that is not a Product (including but not limited to the pharmaceutical product referred to as Zalviso). For the avoidance of doubt, Other Seller Materials include the information or materials described in clauses (i)-(v) that were generated in connection with the Development, manufacture, commercialization or other exploitation of any Product even if the information or materials were also generated in connection with the Development, manufacture, commercialization or other exploitation of any product that is not a Product (including but not limited to the pharmaceutical product referred to as Zalviso).

"Patent Files" means, with regard to a Program Patent: (i) the complete file histories for such Program Patent; and (ii) all files relating to such Program Patent that are held or maintained on Seller's behalf by Seller's outside patent counsel, including all contents of such files, in each case in electronic form.

"Patents" means all United States and foreign patents and utility models, and applications (including provisionals) therefor, including continuations, divisionals, continuations-in-part, renewals, reexaminations, extensions, substitutions, restorations (including supplemental protection certificates), re-issues, and equivalents thereof.

"Payments" means, collectively, the Milestone Payments, the Payments for DoD Marketing (as such term is defined in the Marketing Agreement), the License and Acquisition Income Payments and the Quarterly Payments.

"Payments for DoD Marketing" has the meaning set forth in Section 2.13.

"Payments Report" has the meaning set forth in Section 2.12(c).

"Permits" means all permits, licenses, franchises, approvals, authorizations, registrations, certificates, variances and similar rights obtained, or required to be obtained, from Government Entities.

"Permitted Encumbrance" means: (a) liens for Taxes, assessments or other governmental charges which are not yet due and payable or Taxes being contested in good faith by appropriate proceedings; (b) materialmens', mechanics', workmen's, repairmen's and other statutory liens imposed by Law and arising in the ordinary course of business for amounts that are not yet due and payable or that are being contested in good faith by appropriate proceedings; and (c) Encumbrances that will be released prior to or as of the Closing Date, including all mortgages and security interests securing indebtedness of Seller.

"Person" means an individual, a corporation, a partnership, an association, a limited liability company, sole proprietorship, association, labor union, business trust, joint stock company, a Government Entity, joint venture, a trust or other entity or organization.

"Proceeding" means any proceeding, action, arbitration, audit, arbitration, mediation, hearing, investigation, inquiry, litigation or suit (whether civil, criminal, administrative, judicial or investigative, whether formal or informal, whether public or private) commenced, brought, conducted, heard or pending by or before, or otherwise involving, any Government Entity, arbitrator or mediator.

"Product" means (a) the pharmaceutical product referred to as: (i) DSUVIA (sufentanil sublingual tablet, 30 mcg, CII) or (ii) DZUVEO (sufentanil sublingual tablet, 30 mcg); or (b) any other single-dose pharmaceutical product for use in medically supervised settings that contains 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. For clarity, Product expressly excludes: (x) the pharmaceutical product referred to as Zalviso (sufentanil sublingual tablets, each 15 mcg); (y) any other multi-dose administration system containing sufentanil sublingual tablets (whether as the sole active ingredient or in combination with other active ingredients); and (z) any single-dose formulation of sufentanil for use outside of a medically supervised setting.

"Program" means all of Seller's activities (including activities performed by any Third Party on behalf of Seller) directed specifically to the Development and manufacture (including synthesis, formulation, finishing, labeling or packaging), use, holding, marketing, offer for sale, sale, distribution, export or import of any Product prior to the Closing.

"Program Know-How" means Know-How not included in the Program Patents that is: (i) owned by Seller immediately prior to the Closing; and (ii) necessary for, or is used by Seller as of the Effective Date in connection with, the Development, manufacture (including synthesis, formulation, finishing or packaging), use, holding, marketing, offer for sale, sale, distribution, export or import of any Product; but excluding, in any event, any Know-How that is an Excluded Asset.

"Program Patents" means: (i) all patents and patent applications listed on Schedule 3.7(a)(A); (ii) any and all renewals, divisionals, continuations and continuations-in-part of the patents and patent applications referenced in the preceding clause (i), and any patent applications claiming direct or indirect priority to any of the foregoing in the preceding clause (i) or this clause (ii); (iii) all foreign patent applications associated with the patent applications referenced in the preceding clauses (i) and (ii); (iv) all patents issued or issuing from the patent applications referenced in the preceding clauses (i) through (iii); and (v) all reissues, reexaminations, restorations (including supplemental protection certificates) and extensions of any patent or patent application referenced in the preceding clauses (i) through (iv).

"Purchase Price Allocation" has the meaning set forth in Section 5.4(e).

"Quarterly Payment Term" has the meaning set forth in Section 2.12(b).

"Quarterly Payments" has the meaning set forth in Section 2.12(a).

"Regulatory Approval" means any and all approvals (including individual and national price and reimbursement approvals, as applicable), licenses, permits, certificates, registrations, or authorizations of any country, federal, supra-national, state or local regulatory agency, department, bureau or other governmental entity that are necessary to market and sell a pharmaceutical or biological product in any country or jurisdiction in the Territory.

"Regulatory Authority" mean any national, federal, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity whose review and/or approval is necessary for the manufacture, packaging, labeling, use, storage, holding, import, export, distribution, promotion, marketing, offer for sale and sale of a pharmaceutical or biological product in any country or jurisdiction in the Territory, including the FDA and EMA.

"Regulatory Materials" means all United States and foreign regulatory applications, submissions and approvals (including all INDs and NDAs, and foreign counterparts thereof, and all Regulatory Approvals) related to any Product, and all correspondence with the FDA and other Government Entity relating to any Product or any of the foregoing regulatory applications, submissions and approvals, that, in each case, (a) are owned by Seller at the Closing Date, whether generated, filed or held by or for Seller or its Affiliates, and (b) are necessary for, or were generated or used by or on behalf of Seller prior to the Effective Date in connection with, the Development, manufacture, commercialization or other exploitation of the Product, but excluding any of the foregoing that that were generated in connection with the Development, manufacture, commercialization or other exploitation of, or relate solely to, any product that is not a Product (including but not limited to the pharmaceutical product referred to as Zalviso). Regulatory Materials include but are not limited to: (i) all adverse event reports and associated data, information and materials relating to adverse experiences with respect to any Product received by Seller; (ii) all written notices, filings, communications or other correspondence between either of Seller, on the one hand, and any Government Entity, on the other hand, relating to any Product, including any safety reports or updates, complaint files and Product quality reviews, and clinical or pre-clinical data derived from clinical studies conducted or sponsored by Seller, which data relates to the Product; and (iii) all other information regarding regulatory activities pertaining to any Product's compliance with any applicable Laws or regulations of any jurisdiction, including audit reports, corrective and preventive action documentation and reports, and relevant data and correspondence, maintained by or otherwise in the possession of Seller as of the Closing Date; in each case (i)-(iii) to the extent necessary for, or generated or used prior to the Effective Date in connection with, the Development, manufacture, commercialization or other exploitation of the Product, but excluding any of the foregoing described in clauses (i)-(iii) that were generated in connection with the Development, manufacture, commercialization or other exploitation of, or relate solely to, any product that is not a Product (including but not limited to the pharmaceutical product referred to as Zalviso), but including any of the foregoing described in clauses (i)-(iii) that were generated in connection with the Development, manufacture, commercialization or other exploitation of any Product even if the information or materials were also generated in connection with the Development, manufacture, commercialization or other exploitation of any product that is not a Product (including but not limited to the pharmaceutical product referred to as Zalviso).

"Representative" means with respect to a particular Person, any director, officer, manager, employee, agent, consultant, advisor, accountant, financial advisor, legal counsel or other representative of that Person.

"Reversion" has the meaning set forth in Section 2.16(b).

"Reversion Assets" has the meaning set forth in Section 2.16(b).

"Reversion Assumed Liabilities" has the meaning set forth in Section 2.16(b).

"Reversion Seller" has the meaning set forth in Section 2.16(b).

"Seller" has the meaning set forth in the Preamble.

"Selling Party" has the meaning set forth in the definition of "Net Sales."

"Straddle Period" means any taxable period beginning on or prior to and ending after the Closing Date.

"Tax" means (i) any U.S. federal, state, or local or any foreign tax, charge, fee, impost, levy, or other assessment in the nature of a tax of any type, including but not limited to any of the following types: income, alternative or add-on minimum, gross receipts, capital, sales, use, ad valorem, value added, transfer, franchise, profits, excess profits or windfall profits, inventory, capital stock, license, occupancy, business organization, withholding, payroll, employment (including employee withholding or employer payroll tax, FICA, or FUTA), social security, unemployment, excise, severance, stamp, occupation, real, personal, or intangible property, premiums, business and occupation, customs duties, or other taxes (including estimated taxes), in each case whether or not disputed; (ii) all interest, penalties, fines, additions to tax, or additional amounts imposed by any Taxing Authority with respect to any items described in clause (i), in each case whether or not disputed; and (iii) any liability with respect to any items described in clauses (i) or (ii) payable by reason of Contracts, assumption, transferee liability, successor liability, operation of law, obligations to indemnify, or Treasury Regulations Section 1.1502-6 (or any predecessor or successor thereof or any analogous or similar provision of state, local, or foreign law).

"Tax Claim" has the meaning set forth in Section 5.4(b).

"Tax Return" means any return, report or statement required to be filed with respect to any Tax (including any elections, declarations, schedules or attachments thereto and any amendment thereof), including but not limited to any information return, claim for refund, amended return or declaration of estimated Tax.

"Taxing Authority" means any Government Entity with any authority regarding the imposition, collection, enforcement or administration of any Tax.

"Territory" means all countries worldwide.

"Third Party" means any Person other than Seller or Buyer or an Affiliate of Seller or Buyer.

"Third Party Claim" has the meaning set forth in Section 8.3(b).

"Threshold Amount" has the meaning set forth in Section 8.1(b).

"Transaction" means all of the transactions contemplated by this Agreement.

"Transfer Taxes" has the meaning set forth in Section 5.4(a).

"Transferred Assets" has the meaning set forth in Section 2.1.

"Transferred Intellectual Property" means (i) the Program Patents and the Program Know-How and (ii) other than any Excluded Assets, any and all (a) Intellectual Property (other than Patents or Know-How) that is owned and Controlled by Seller or any of its Affiliates on the Closing Date and (b) Intellectual Property that is licensed by Seller or any of its Affiliates from a Third Party on the Closing Date pursuant to an Assigned Contract, that in each case (a) and (b) is necessary for, or is used by Seller as of the Effective Date in connection with, the Development, manufacture (including synthesis, formulation, finishing or packaging), use, holding, marketing, offer for sale, sale, distribution, export or import of any Product.

"Transition Services Agreement" has the meaning set forth in Section 2.9(c).

"Treasury Regulations" means the regulations promulgated under the Code.

"TSA Term" has the meaning set forth in Section 5.11.

"TSA Termination Date" has the meaning set forth in Section 5.11.

"United States" means the United States of America and its territories and possessions.

"Withholding Tax Action" has the meaning set forth in Section 2.15.

Section 1.2 Other Terms. Other terms may be defined elsewhere in the text of this Agreement and, unless otherwise indicated, shall have such meaning throughout this Agreement.

Section 1.3 Other Definitional Provisions. Unless the express context otherwise requires:

(a) the words "hereof," "herein" and "hereunder" and words of similar import, when used in this Agreement, shall refer to this Agreement as a whole and not to any particular provision of this Agreement;

(b) terms defined in the singular have a comparable meaning when used in the plural, and vice versa;

(c) the terms "Dollars" and "$" mean United States Dollars;

(d) references herein to a specific Section, Subsection or Schedule shall refer, respectively, to Sections, Subsections or Schedules of this Agreement;

(e) wherever the word "include," "includes," or "including" is used in this Agreement, it shall be deemed to be followed by the words "without limitation;" and

(f) references herein to any gender include each other gender.

ARTICLE II
PURCHASE AND SALE; LICENSE TO SELLER

Section 2.1 Purchase and Sale of Assets. On the terms and subject to the conditions set forth herein, at the Closing, Seller shall sell, convey, transfer, assign and deliver to Buyer, and Buyer shall purchase and acquire from Seller, all of Seller's right, title and interest worldwide, as of the Closing, in and to all assets owned by Seller and necessary for Buyer to Develop, manufacture (including synthesis, formulation, finishing or packaging), use, hold, import, export, market, distribute, sell, offer for sale or otherwise exploit the Products (except for Excluded Assets), whether tangible or intangible, real, personal or mixed, of every kind and description, wherever located (collectively, the "Transferred Assets"), including the following:

(a) Seller's rights in and to the Products;

(b) Seller's rights in and to all Transferred Intellectual Property, wherever held or registered, and Seller's right to sue and collect damages related thereto for past, present and future infringement of the Transferred Intellectual Property;

(c) all Patent Files with respect to the Program Patents;

(d) all Regulatory Materials;

(e) the Contracts listed on Schedule 2.1(e) (the "Assigned Contracts");

(f) the equipment set forth on Schedule 2.1(f);

(g) all Inventory, as set forth on Schedule 2.1(g);

(h) all claims, causes of action, rights of recovery and rights of set-off of any kind and accruing to the benefit of Seller to the extent arising out of the Product or the Transferred Assets; and

(i) all Other Seller Materials.

Section 2.2 Excluded Assets. Notwithstanding anything in this Agreement to the contrary, from and after the Closing, Seller and its Affiliates shall retain all of their existing right, title and interest in and to, anywhere in the world, and there shall be excluded from the sale, conveyance, assignment or transfer to Buyer and its Affiliates hereunder, and the Transferred Assets shall not include, the following (collectively, the "Excluded Assets"):

(a) any asset or class of assets not explicitly included in the definition of Transferred Assets set forth in Section 2.1;

(b) any Tax records or Tax documents of Seller (including all Tax returns);

(c) all rights of Seller to any refunds, or rights or claims to refunds, of Taxes, Tax deposits, Tax credits or other Tax assets related to Taxes that are Excluded Liabilities;

(d) all causes of action, lawsuits, judgments, claims and demands of any nature, whether arising by way of counterclaim or otherwise, whether choate or inchoate, known or unknown, contingent or noncontingent, relating to or arising out of any Excluded Liabilities;

(e) all Contracts other than the Assigned Contracts (the "Excluded Contracts"); and

(f) all rights of Seller under the Confidentiality Agreement and this Agreement.

Section 2.3 Assumption of Liabilities. On the terms and subject to the conditions set forth herein, at the Closing, Buyer shall assume and agrees to discharge or perform when due the following Liabilities, but only to the extent relating to the period after the Closing and arising after the Closing (the "Assumed Liabilities"):

(a) all Liabilities of Seller under or primarily relating to the Transferred Assets, including all obligations under the Assigned Contracts to the extent such obligations are required to be performed after the Closing and to the extent such obligations relate to the operation of the Transferred Assets arising after the Closing; provided, however, that Buyer is not assuming any Liabilities of Seller in respect of a breach of or default under any such Assigned Contracts to the extent such breach or default relates to an act, event or condition that existed or occurred prior to Closing;

(b) any Liabilities for (i) Taxes with respect to the Program and/or the Transferred Assets for any taxable period (or portion thereof) beginning after the Closing Date, (ii) Transfer Taxes for which Buyer is responsible pursuant to Section 5.4(a), and (iii) Taxes for any Straddle Period for which Buyer is responsible pursuant to Section 5.4(c);

(c) all Liabilities arising out of or relating to the acquisition or maintenance of the Transferred Intellectual Property arising after the Closing;

(d) all research, Development, manufacturing, registration, commercialization, use, handling, holding, marketing, storage, sale, offer for sale, distribution, import, export or other disposition or exploitation of the Products after the Closing, and all Liabilities arising therefrom; and

(e) all Liabilities arising from the ownership, operation, maintenance, possession, control, sale, lease, disposition, exploitation or use of the Transferred Assets occurring after the Closing,

in each case of (a) through (e), (i) to the extent with respect to circumstances, actions, events or conditions occurring or existing after the Closing and not arising before or with respect to circumstances, actions, events or conditions occurring or existing before the Closing or resulting from any breach of any Assigned Contract by Seller or any of its Affiliates before the Closing and/or (ii) except as included as an Excluded Liability pursuant to prongs (i)–(vi) of the second sentence of the definition of Excluded Liability. Except as provided in this Section 2.3 and notwithstanding anything to the contrary, Buyer shall not assume, in connection with the Transaction or the transactions contemplated by the Ancillary Agreements, any Liability of Seller whatsoever, whether known or unknown, disclosed or undisclosed, accrued or hereafter arising, absolute or contingent, and Seller shall retain responsibility for all such Liabilities.

For clarity, Buyer's assumption of Liabilities under this Section 2.3 shall be considered part of the consideration paid for the Transferred Assets.

Section 2.4 Excluded Liabilities. Buyer shall not, by virtue of its purchase of the Transferred Assets or entering into this Agreement, assume any Excluded Liabilities in connection with this Agreement, and Seller shall continue to be responsible for the Excluded Liabilities. For clarity, Buyer shall not assume any Liabilities for any action taken or not taken by Seller, by anyone on behalf of Seller or by anyone who has received rights related to the Product, in each case before the Closing, including but not limited to any offers for sale, sales or deliveries of the Product, and such Liabilities will not be Assumed Liabilities, but will be considered Excluded Liabilities, in each case.

Section 2.5 Payments to Seller. On the terms and subject to the conditions set forth herein, in consideration of the sale of the Transferred Assets, (i) at the Closing, in addition to the assumption of the Assumed Liabilities, Buyer shall pay to Seller an amount in cash equal to the total cost of the Inventory set forth in Schedule 2.1(g), as such exhibit is updated by Seller at the Closing, and (ii) Buyer shall make, as and when due, the Payments.

Section 2.6 Closing. The Closing shall take place through the exchange of executed documents electronically on the second Business Day following the date on which the conditions set forth in Sections 6.1 and 6.2 have been satisfied or waived in writing (other than those conditions that by their nature are to be satisfied at the Closing but subject to the fulfillment or waiver of those conditions), or at such other time and place as the parties hereto may mutually agree in writing. The Closing shall be effective as of 12:01 a.m. on the Closing Date. All actions to be taken and all documents to be executed or delivered at Closing will be deemed to have been taken, executed and delivered simultaneously, and no action will be deemed taken and no document will be deemed executed or delivered until all have been taken, delivered and executed, except in each case to the extent otherwise stated in this Agreement or any such other document.

Section 2.7 Intentionally Omitted.

Section 2.8 Intentionally Omitted.

Section 2.9 Deliveries by Buyer. At the Closing, Buyer shall deliver to Seller the following:

(a) a Bill of Sale and General Assignment and Assumption Agreement, to transfer the Transferred Assets to Buyer and to effect Buyer's assumption of the Assumed Liabilities and the effective assignment of any Assigned Contract, substantially in the form of Exhibit A (the "General Assignment and Assumption Agreement"), duly executed by Buyer;

(b) an intellectual property assignment agreement to transfer ownership of the Transferred Intellectual Property that is owned by Seller or any of its Affiliates to Buyer substantially in the form of Exhibit B (the "IP Assignment"), duly executed by Buyer;

(c) a Transition Services Agreement, in a form agreed by Buyer and Seller as of the Closing Date (the "Transition Services Agreement"), duly executed by Buyer;

(d) an intellectual property agreement to license back certain rights in the Transferred Intellectual Property to Seller and to govern the prosecution and enforcement of Program Patents, in a form agreed by Buyer and Seller as of the Closing Date (the "IP Agreement"), duly executed by Buyer;

(e) a marketing agreement, in a form agreed by Buyer and Seller as of the Closing Date (the "Marketing Agreement"), duly executed by Buyer;

(f) the certificate to be delivered pursuant to Section 6.2(c);

(g) copies of the letters to be delivered pursuant to Section 5.10(a)(ii); and

(h) such other documents as Seller may reasonably request for the purpose of facilitating the consummation or performance of the Transaction.

Section 2.10 Deliveries by Seller. At the Closing, Seller shall deliver, or cause to be delivered, to Buyer the following:

(a) the General Assignment and Assumption Agreement, duly executed by Seller;

(b) the IP Assignment, duly executed by Seller;

(c) the Transition Services Agreement, duly executed by Seller;

(d) the IP Agreement, duly executed by Seller;

(e) the Marketing Agreement, duly executed by Seller;

(f) a Bill of Sale for the Inventory, duly executed by Seller;

(g) amendments, in a form reasonably acceptable to Buyer, to the License and Commercialization Agreement between Seller and Laboratoire Aguettant ("Aguettant"), effective as of July 14, 2021, and to the Supply Agreement between Seller and Aguettant, effective as of December 6, 2021 (such agreements, the "Aguettant Agreements" and such amendments, the "Aguettant Amendments");

(h) copies of all Contract Consents set forth on Schedule 2.10(h);

(i) evidence, in form and substance reasonably satisfactory to Buyer, that all outstanding Encumbrances (other than Permitted Encumbrances) against any of the Transferred Assets have been released;

(j) a certificate of the Secretary of the Seller certifying and attaching all requisite resolutions or actions of the Seller's governing body approving the execution and delivery of this Agreement, the Ancillary Agreements and the consummation of the Transaction and the transactions contemplated hereby and by the Ancillary Agreements, and certifying to the incumbency and signatures of the officers of the Seller executing this Agreement and any other document relating to the Transaction;

(k) copies of the letters to be delivered pursuant to Section 5.10(a)(ii);

(l) an IRS Form W-9 duly executed by Seller;

(m) the certificate to be delivered pursuant to Section 6.1(c);

(n) an updated Schedule 2.1(g) reflecting the Inventory as of the Closing;

(o) a thumb drive, compact disc or other format acceptable to Buyer in its sole discretion containing all files uploaded to the Data Room, without password protection, without watermark, and in an easily-accessible format (e.g., .docx, .pdf, .xlsx); and

(p) such other documents as Buyer may reasonably request for the purpose of facilitating the consummation or performance of the Transaction.

Section 2.11 Milestone Payments for Milestone Event.

(a) Following the first occurrence of each of the events set forth in the table below (each, a "Milestone Event"), Buyer shall pay to Seller the non-refundable, non-creditable milestone payment corresponding to such Milestone Event no later than thirty (30) calendar days after the end of the calendar quarter in which such Milestone Event is first achieved. In determining whether a Milestone Event has been reached, Seller shall only receive credit for [***] of the Annual Net Sales made by or on behalf of Buyer or any other Selling Party to DoD but will receive full credit for all other Annual Net Sales made by or on behalf of Buyer or any other Selling Party (such [***] of Annual Net Sales to DoD plus all other Annual Net Sales, the "Adjusted Annual Net Sales"). By way of example, if the Annual Net Sales made by Buyer are $[***], and $[***] of those Annual Net Sales are attributable to DoD, then, for purposes of calculating Adjusted Annual Net Sales for the determination of achieving a Milestone Event, the Adjusted Annual Net Sales shall be $[***] total with $[***] ($[***]%) attributable to DoD sales and $[***] for sales to others. Notwithstanding the foregoing, for any Net Sales based on sales to DoD that are not subject to Payments for DoD Marketing under the Marketing Agreement, 100% of such Net Sales will be included in Annual Net Sales for purposes of determining whether a Milestone Event has been reached. For clarity, the Milestone Events are additive, such that if more than one Milestone Event is achieved in the same time period, then the Milestone Payments for all such Milestone Events shall be payable. For clarity, the total aggregate Milestone Payments payable hereunder if all Milestone Events are achieved is One Hundred Sixteen Million Five Hundred Thousand Dollars ($116,500,000). For purposes of clarity, sales made by Seller in accordance with the Transition Services Agreement will be booked by Buyer and included in the calculation of Adjusted Annual Net Sales.

Milestone Event	Milestone Payment
1. The aggregate amount of Adjusted Annual Net Sales of all Products in the Territory first exceeds [***]	$[***]
2. The aggregate amount of Adjusted Annual Net Sales of all Products in the Territory first exceeds [***]	$[***]
3. The aggregate amount of Adjusted Annual Net Sales of all Products in the Territory first exceeds [***]	$[***]
4. The aggregate amount of Adjusted Annual Net Sales of all Products in the Territory first exceeds [***]	$[***]
5. The aggregate amount of Adjusted Annual Net Sales of all Products in the Territory first exceeds [***]	$[***]
6. The aggregate amount of Adjusted Annual Net Sales of all Products in the Territory first exceeds [***]	$[***]
7. The aggregate amount of Adjusted Annual Net Sales of all Products in the Territory first exceeds [***]	$[***]
8. The aggregate amount of Adjusted Annual Net Sales of all Products in the Territory first exceeds [***]	$[***]
9. The aggregate amount of Adjusted Annual Net Sales of all Products in the Territory first exceeds [***]	$[***]

(b) Termination of Milestone Payments. All Milestone Payments will terminate at payment of aggregate Milestone Payments of One Hundred Sixteen Million Five Hundred Thousand Dollars ($116,500,000) by Buyer to Seller under this Section 2.11. Net Sales for a given Product in a given country for which the Quarterly Payment Term has expired will not be included in the Annual Net Sales for purposes of the Milestone Events or Milestone Payments.

Section 2.12 Quarterly Payments.

(a) Quarterly Payments. Buyer will make payments every quarter in an amount equal to 15% of Net Sales by or on behalf of Buyer or any other Selling Party for sales or other disposition of any Product to any Person other than DoD ("Quarterly Payments"); provided that, subject to Section 2.12(b), for any Net Sales based on sales to DoD that are not subject to Payments for DoD Marketing under the Marketing Agreement, such Net Sales will be subject to Quarterly Payments.

(b) Continuation and Termination of Quarterly Payments. Quarterly Payments shall be paid on a country-by-country and Product-by-Product basis beginning on the Closing Date and, with respect to a country and a Product, continuing until occurrence of all of the following: (1) a Generic Equivalent of such Product is first sold in such country; and (2) the unit sales of all Generic Equivalents of such Product in such country exceed [***] of the sum of unit sales of such Product plus unit sales of all Generic Equivalents of such Product in such country, as such unit sales are determined by IQVIA or alternative agreed by Buyer and Seller in writing (the "Quarterly Payment Term").

(c) Reports and Timing of Payment. Within thirty (30) calendar days following the end of each calendar quarter during the period in which Quarterly Payments accrue, Buyer shall provide Seller with a report of Net Sales of Product sold (i.e., invoiced) to an entity (but excluding sales to DoD unless sales to DoD are subject to Quarterly Payments pursuant to Section 2.12(a)), each in sufficient detail to permit confirmation of the accuracy of the Quarterly Payments made, including, on a Product-by-Product and country-by-country basis: the number of Products sold; the gross sales and Net Sales of each Product (including a calculation of all deductions made); the Quarterly Payments payable; and the method used (including exchange rate) to calculate the Quarterly Payments (the "Payments Report"). Any Quarterly Payment due to Seller will be paid on the date of delivery of such Payments Report, but in any event no later than the thirtieth (30th) calendar day following the end of each applicable calendar quarter. In the event that either party determines that the calculation of Net Sales for a calendar quarter deviates from the amounts previously reported to Seller for any reason (such as, on account of additional amounts collected or Product returns), Buyer and Seller shall reasonably cooperate to promptly reconcile any such deviations to the extent necessary under applicable legal or financial reporting requirements.

Section 2.13 Marketing Agreement. Notwithstanding anything to the contrary herein, from and after the Closing, Seller shall have the exclusive right to market and offer the Products for sale to DoD pursuant to the Marketing Agreement. Pursuant to the Marketing Agreement, Buyer will pay to Seller non-refundable, non-creditable payments in an amount equal to 75% of Net Sales of Products sold or otherwise disposed of by or on behalf of Buyer or any Selling Party to DoD ("Payments for DoD Marketing"). If for any calendar quarter, the Payments for DoD Marketing exceed the Gross Profit for such calendar quarter, then [***]. The determination of whether Payments for DoD Marketing exceed Gross Profits will be made without taking into account [***]. Consider the following example:

- [***]

Section 2.14 License and Acquisition Income Payments.

(a) License and Acquisition Income Payment Amount. Buyer will pay to Seller an amount equal to [***] of any License and Acquisition Income. For clarity, in the event of a sale or transfer of ownership with respect to the Transferred Assets comprising a series of related transactions, Buyer's payment obligation under this Section 2.14(a) shall pertain to the totality of such related transactions. For clarity, this __ shall not apply to a Change of Control Transaction (and any consideration received thereunder) involving Buyer or its Affiliates.

(b) License and Acquisition Income Reports and Payment. Within seven (7) calendar days (i) following the effective date of an applicable license grant to a Third Party if any License and Acquisition Income is anticipated to be earned as a result thereof, or (ii) following the closing date of an applicable sale or transfer of any ownership interest transaction with respect to the Transferred Assets if any License and Acquisition Income is anticipated to be earned as a result thereof, Buyer will provide to Seller a true and complete copy of the applicable Contract (including any subsequent amendments thereto) (provided that Buyer may redact from such copies any confidential or proprietary information that is not reasonably necessary for Seller to ascertain its entitlement to payments hereunder). Within thirty (30) calendar days following the end of any calendar quarter in which there is License and Acquisition Income, Buyer shall provide Seller with a report containing the following information for such calendar quarter (the "License and Acquisition Income Report"): the amount of any License and Acquisition Income, a calculation of the payment due on such License and Acquisition Income and, if not previously provided, a true and complete copy of each applicable Contract (including any subsequent amendments thereto) pursuant to which any License and Acquisition Income has been earned (provided that Buyer may redact from such copies any confidential or proprietary information that is not reasonably necessary for Seller to ascertain Buyer's compliance with its payment obligations hereunder). Any License and Acquisition Income Payments due to Seller will be paid on the date of delivery of such report, but in any event no later than the 30th calendar day following the end of each applicable calendar quarter.

Section 2.15 Withholding. Buyer shall be entitled to deduct and withhold from any amounts payable or otherwise deliverable pursuant to this Agreement only such Taxes as Buyer is required to deduct or withhold therefrom under any applicable Law and shall pay the amounts deducted or withheld to the appropriate Taxing Authority. At least three (3) Business Days prior to any such deduction or withholding, Buyer shall provide written notice to Seller, together with reasonably sufficient details regarding the nature of the relevant Tax to be deducted or withheld. If any valid reduction of or exemption from such Tax is available under applicable Law, Buyer shall cooperate with Seller to the extent commercially reasonable to obtain any such reduction or exemption. The parties hereto agree to provide each other with commercially reasonably requested assistance to enable the Transaction to qualify for such reduction or exemption, which assistance shall include, but is not limited to, provision of any Tax forms and other information that may be reasonably necessary in order for Buyer to validly not deduct or withhold Tax or to deduct or withhold Tax at a reduced rate under an applicable bilateral income Tax treaty and the redaction of sensitive information. To the extent Taxes are required to be deducted or withheld from amounts payable or otherwise deliverable pursuant to this Agreement under applicable Law, Buyer will: (a) deduct or withhold those Taxes from such amounts, (b) properly remit those Taxes to the appropriate Taxing Authority, and (c) send evidence of the obligation, together with proof of Tax payment, to Seller on a reasonable and timely basis following such payment. To the extent any such Taxes are so deducted or withheld and properly remitted to the appropriate Taxing Authority, such Taxes shall be treated for all purposes under this Agreement as having been paid to the Person in respect of which such deduction or withholding was made. Notwithstanding anything to the contrary contained herein, if Buyer (or any of its Affiliates or assignees) is required by applicable Law to deduct or withhold any Taxes from any amounts payable or otherwise deliverable pursuant to this Agreement, and if such obligation arises or is increased solely as a result of any action by Buyer (or any of its Affiliates or assignees) after the Closing Date, including, without limitation, any assignment of this Agreement by Buyer, any change in the tax residency of Buyer, any change in the entity paying or otherwise delivering any amounts pursuant to this Agreement, and any failure of Buyer to comply with applicable Law (each, a "Withholding Tax Action"), such amounts shall be increased as necessary so that, after all required deduction or withholding (including any deduction or withholding applicable to additional amounts payable under this Section 2.15), the Person in respect of which such deduction or withholding was made receives an amount equal to the sum it would have received had no such Withholding Tax Action occurred.

Section 2.16 Diligence; Reversion Right.

(a) Buyer shall, and shall cause each Selling Party to, use Commercially Reasonable Efforts to maintain Regulatory Approvals for and commercialize a Product in the United States. "Commercially Reasonable Efforts" means, with respect to the efforts expended by a Person with respect to a particular objective, that level of efforts and resources consistent with commercially reasonable practices of a company in the pharmaceutical industry with respect to the research, Development or commercialization of a pharmaceutical product at a similar stage of research, Development or commercialization.

(b) If the Buyer (together with other Selling Parties, taken as a whole) fails to commercialize, sell and distribute any Product within [***], then all rights granted to Buyer pursuant to this Agreement shall, upon Seller's written notice to Buyer of such failure, revert back to Seller ("Reversion"). If the Reversion occurs, then (i) Buyer shall, and shall cause its applicable Affiliates and designees and all other Persons that own or otherwise hold any rights, interests or assets to be conveyed in the Reversion (each, a "Reversion Seller") to, as promptly as practicable sell, convey, transfer, assign and deliver, without consideration other than Seller's or its designated Affiliates' assumption of the Reversion Assumed Liabilities (as defined in this Section), to Seller or its designated Affiliates, free and clear of all Encumbrances (other than Permitted Encumbrances), all of the Reversion Sellers' right, title and interest in and to all of the following (collectively, the "Reversion Assets"): (A) all Transferred Assets other than the Inventory, (B) all remaining inventories of the Products, and (C) all rights and assets to the extent assignable (including Intellectual Property, Regulatory Materials, Contracts and other necessary documentation and materials pertaining to the Products) developed or acquired by a Reversion Seller after the Closing Date that are used primarily for the Development and manufacture (including synthesis, formulation, finishing, labeling or packaging), use, holding, marketing, offer for sale, sale, distribution, export or import of one or more Products. In connection with the Reversion: (i) Reversion Sellers shall be responsible, at their own cost and expense, for obtaining all Authorizations necessary to consummate the Reversion; (ii) Seller or its designated Affiliates will assume all liabilities arising out of the Reversion Assets from and after the effective date of the Reversion (but excluding any such liabilities arising out of any noncompliance with Law or any breach or violation of or failure to perform under any Reversion Asset by any Reversion Seller) (collectively, the "Reversion Assumed Liabilities"); and (iii) each Reversion Seller and Seller or its designated Affiliates shall cooperate with one another and use its commercially reasonable efforts to take or cause to be taken in an expeditious manner all actions and to do or cause to be done all things commercially reasonable to consummate the Reversion as promptly as practicable. Seller's rights under this Section 2.16(b) shall not limit, diminish or otherwise impair in any respect any other rights or remedies to which Seller is entitled under this Agreement with respect to any breach by Buyer of any of its obligations hereunder. As the result of a Reversion, Seller shall have no right to market or promote the Product using Buyer's name or NDC number.

Section 2.17 Exchange Rate; Manner and Place of Payment. All payments hereunder shall be payable in United States dollars. With respect to each quarter, for countries other than the United States, whenever conversion of payments from any foreign currency shall be required, such conversion shall be at an exchange rate equal to the weighted average of the rates of exchange for the currency of the country in which Net Sales were made as published by the *Wall Street Journal*, Eastern Edition (or such other source agreed in writing by the parties), during the calendar quarter for which a payment is due. All payments owed under this Agreement to Seller shall be made by wire transfer to a bank and account designated in writing by Seller at least two (2) Business Days prior to applicable payment date, unless otherwise specified in writing by Seller.

Section 2.18 Audit. For a period of [***] following the end of the calendar quarter to which they pertain, Buyer shall, and shall require each Selling Party to, keep complete and accurate records pertaining to the sale or other disposition of Products and License and Acquisition Income in sufficient detail to permit Seller to confirm the accuracy of the Payments due hereunder and under the Marketing Agreement, including Buyer's Cost of Goods Sold for the Product. Seller, at its sole cost and expense, shall have the right to cause a Third Party independent, certified public accountant to audit such records to confirm Net Sales, Cost of Goods Sold and/or Payments for a period covering not more than the preceding [***]. Such audits may be conducted during normal business hours upon reasonable prior written notice to Buyer, but no more than frequently than [***]. No accounting period of Buyer shall be subject to audit more than one time by Seller, unless after an accounting period has been audited by Seller, Buyer restates its financial results for such accounting period, in which event Seller may conduct a second audit of such accounting period in accordance with this Section 2.18. Prompt adjustments (including remittances of underpayments with interest from the date originally due as provided in Section 2.19 or overpayments disclosed by such audit) shall be made by the parties to reflect the results of such audit. Seller shall bear the full cost of such audit unless such audit discloses an underpayment by Buyer of [***] or more of the amount of Payments due for the period audited under this Agreement or the Marketing Agreement, or an overstatement of Cost of Goods Sold, in which case Buyer shall bear the reasonable cost of such audit. Seller acknowledges and agrees that Buyer shall, at its sole discretion, be permitted to withhold commercially sensitive information or data subject to privilege from the records used to conduct audit(s) pursuant to this Section 2.18 to the extent such information or data is not necessary to confirm the accuracy of the Payments due hereunder or Cost of Goods Sold reported by Buyer.

Section 2.19 Late Payments. In the event that any payment due under this Agreement is not made when due, the payment shall accrue interest from the date due at the lesser of: (i) [***]; or (ii) the maximum legal annual interest rate. The payment of such interest shall not limit Seller from exercising any other rights it may have as a consequence of the lateness of any payment.

Section 2.20 Post-Closing Transfers; Product Returns; Chargebacks.

(a) Following the Closing, the parties shall cooperate with each other to identify any assets that were not transferred as part of the Transferred Assets at the Closing but that, pursuant to the provisions of this Agreement, were required to be transferred (the "Nontransferred Assets"). To the extent any Nontransferred Assets are identified, Seller shall promptly take all actions to transfer such Nontransferred Assets to Buyer. In the event Seller is required to obtain the consent of any Person prior to the transfer of any Nontransferred Asset, then Seller shall use its commercially reasonable efforts to promptly obtain such consent, and upon obtaining such approval or consent, shall promptly transfer such Nontransferred Asset to Buyer. In the event Seller is unable to obtain such consent, then Seller and Buyer shall discuss in good faith an appropriate resolution for the transfer of the economic benefit of such Nontransferred Asset to Buyer.

(b) This Agreement shall not be construed as an agreement to assign any Assigned Contract that by its terms is not capable of being assigned without the consent of the counterparty thereto, unless and until such consent is obtained. Seller shall use commercially reasonable efforts, and Buyer shall cooperate reasonably with Seller, for a period of [***] after the Closing Date to obtain such consents. In the event any such consents have not been obtained prior to the Closing Date, Seller will cooperate with Buyer in any lawful and economically feasible arrangement, at Buyer's sole cost and expense, to provide that Buyer shall receive the interest of Seller in the benefits under any such Assigned Contract, if feasible and at Buyer's sole cost and expense, as agent; provided that Buyer shall undertake to pay or satisfy the corresponding Liabilities for the enjoyment of such benefit to the extent Buyer would have been responsible therefor hereunder if such consents had been obtained.

(c) All returned Products that were sold by Seller prior to the Closing Date shall be the responsibility of Buyer, and/or its successors and assigns; provided that to the extent Buyer incurs payments to wholesalers in connection with such returns in an amount exceeding $[***], Seller will reimburse the amounts paid by Buyer to such wholesalers in connection with such returns. All returned Products that were sold by Buyer after the Closing Date shall be the responsibility of Buyer and shall be sent to Buyer. Returns will be processed by Seller in accordance with the current returned goods policy provided to Buyer prior to the Closing. Returns will be processed by Buyer in accordance with the returned goods policy provided to Seller prior to the Closing.

(d) Buyer shall be responsible for processing all Chargebacks related to the Product sold by Seller prior to Closing and shall bear 100% of the cost of any such Chargebacks; provided that to the extent Buyer incurs payments in connection with such Chargebacks in an amount exceeding $[***], Seller will reimburse the amounts paid by Buyer in connection with such Chargebacks. Buyer shall be responsible for processing all Chargebacks related to the Product sold on or after Closing and shall bear 100% of the cost of any such Chargebacks.

ARTICLE III
REPRESENTATIONS AND WARRANTIES OF SELLER

Seller represents and warrants to Buyer as of the Effective Date and as of the Closing Date as follows, except as otherwise explicitly set forth on Schedule 3 delivered by Seller to Buyer in connection with the execution of this Agreement:

Section 3.1 Organization and Qualification. Seller is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Seller is duly qualified to do business and is in good standing in each jurisdiction where the ownership or operation of the Transferred Assets or the conduct of the Program requires the Seller to be so qualified or in good standing, as the case may be.

Section 3.2 Corporate Authorization. Seller has full corporate power and authority to execute and deliver this Agreement and the Ancillary Agreements and to perform its obligations hereunder and thereunder, and to consummate the Transaction. The execution, delivery and performance by Seller of this Agreement and the Ancillary Agreements, the performance by Seller of its obligations hereunder and thereunder, and the consummation of the Transaction and the transactions contemplated by the Ancillary Agreements have been duly and validly authorized by all requisite corporate and shareholder action on the part of Seller and no additional corporate or shareholder authorization or consent is required in connection with the execution, delivery and performance by Seller of this Agreement and the Ancillary Agreements, the performance by Seller of its obligations hereunder and thereunder, or the consummation of the Transaction and the transactions contemplated by the Ancillary Agreements. The execution, delivery and performance by Seller of this Agreement and the Ancillary Agreements, and the consummation of Transaction and the transactions contemplated by the Ancillary Agreements, do not and will not violate any provision of the Organizational Documents of Seller. The Organizational Documents of Seller that have previously been furnished to the Buyer reflect all amendments thereto and are correct and complete. This Agreement and the Ancillary Agreements, when executed and delivered by Buyer, will constitute valid and legally binding obligations of Seller enforceable against it in accordance with the terms hereof and thereof. This Agreement has been, and each of the other Ancillary Agreements will be at or prior to the Closing, duly and validly executed and delivered by Seller and (assuming due authorization, execution, and delivery by Buyer) this Agreement constitutes, and each of the other Ancillary Agreements to which Seller is a party when so executed and delivered will constitute, legal, valid, and binding obligations of Seller, enforceable against Seller in accordance with its terms. The Person(s) signing this Agreement and the other Ancillary Agreements on behalf of Seller has been duly authorized to execute and deliver this Agreement and the other Ancillary Agreements.

Section 3.3 Title to and Sufficiency of Transferred Assets. Seller has good and marketable title to, or a valid leasehold interest in, the Transferred Assets, free and clear of any Encumbrances (other than Permitted Encumbrances). Other than the Excluded Assets, the Transferred Assets include all tangible and intangible property and assets owned or, in the case of Licensed Intellectual Property, in-licensed by Seller that are (a) necessary and sufficient for the continued conduct of Seller's business as it relates to the Product and the Program after Closing in the same manner as conducted prior to Closing or (b) necessary for Buyer to Develop, manufacture (including synthesis, formulation, finishing or packaging), use, hold, import, export, market, distribute, sell, offer for sale or otherwise exploit the Products as such Products exist and as such activities are being conducted by Seller as of the Effective Date. The transfer of the Transferred Assets hereunder conveys to the Buyer good, valid and indefeasible title to the Transferred Assets (other than the Licensed Intellectual Property), free and clear of any Encumbrances (other than Permitted Encumbrances). Except as set forth on Schedule 3.3, there are no assets of Seller or any other Person used in the Program or necessary for the Product as in existence as of the Effective Date other than the Transferred Assets (and the Excluded Assets), and except for the Licensed Intellectual Property, no Transferred Assets are owned or held by any Person other than Seller.

Section 3.4 Inventory. All Inventory and packaging to be included in the Transferred Assets consists of quality and quantity usable or salable in the ordinary course of business and none of the finished goods in the Inventory to be delivered to Buyer was manufactured more than twelve (12) months prior to delivery to Buyer. All items of finished goods inventory included in the Inventory have a minimum shelf life as set forth on Schedule 3.4, and all items of unfinished goods included in the Inventory that have an expiration date have a minimum shelf life or retest of twelve (12) months from the Closing Date. Seller is not in possession of any Product inventory not owned by Seller. None of the Inventory is obsolete, damaged, or defective, and all Inventory conforms in all respects to all applicable specifications and has been manufactured, labeled, tested, quality released, handled and stored in accordance with all United States manufacturing practices. No item of Inventory has been misbranded or adulterated within the meaning of the FDCA.

Section 3.5 No Conflict. The execution and delivery of this Agreement and the Ancillary Agreements by Seller do not, and the consummation of the Transaction and the transactions contemplated by the Ancillary Agreements will not, directly or indirectly, with or without notice or lapse of time: (a) conflict with or violate any provision of the Organizational Documents of Seller; (b) conflict with or violate any Law applicable to Seller or by which any of the Transferred Assets or Seller is bound or affected; (c) contravene, conflict with or result in any breach of or result in a default (or an event which with the giving of notice or lapse of time or both would reasonably be expected to become a default) under, or give to others any right of termination, amendment, acceleration or cancellation or modification of or the exercise of any remedy under, any Contract to which Seller is a party or by which Seller is bound or to which any Transferred Asset is subject or under which Seller has any rights or the performance of which is guaranteed by Seller, or result in the creation of an Encumbrance on any of the Transferred Assets or Assigned Contracts (other than Permitted Encumbrances); or (d) contravene, conflict with or result in a violation of any of the terms or requirements of, or give any Government Entity the right to revoke, withdraw, suspend, cancel, terminate or modify, any filing, permit, authorization, consent, approval, right or Order that is to be included in the Transferred Assets or is held by Seller and relates to the Transferred Assets.

Section 3.6 Required Filings and Consents. The execution and delivery of this Agreement and the Ancillary Agreements by Seller do not, and the consummation of the Transaction and the transactions contemplated by the Ancillary Agreements will not, require any consent, approval, authorization or permit of, or filing by Seller with or notification by Seller to, any Government Entity, except for the letters to the applicable Regulatory Authorities and filings under applicable securities laws or rules of the applicable stock exchange set forth in Section 5.10(a).

Section 3.7 Intellectual Property.

(a) Disclosure and Ownership of Program Patents. Schedule 3.7(a), part A lists all of the Program Patents, setting forth in each case the jurisdictions in which the Program Patents have been filed. Except as set forth on Schedule 3.7(a), Seller has a valid, legally enforceable, and exclusive right to use and license all Program Patents. Schedule 3.7(a), part B lists all Marks, setting forth in each case the jurisdictions in which such trademarks and trademark applications have been filed. Except as set forth on Schedule 3.7(a), Seller has a valid, legally enforceable, and exclusive right to use and license all of such trademarks. Neither Seller nor any of its Affiliates has received any written notice of and has no Knowledge of any basis for any inventorship challenge, interference, invalidity or unenforceability with respect to Program Patents.

(b) Ownership of and Right to Use Program Know-How; No Encumbrances. Seller has good and valid title to, free and clear of all Encumbrances (other than the Assumed Liabilities and those arising under the Assigned Contracts and Permitted Encumbrances), or a valid, legally enforceable right to use and license, the Program Know-How.

(c) Warranty with Respect to Intellectual Property. Seller warrants that the Transferred Intellectual Property are all the intellectual property rights owned by or licensed to Seller that are used in or necessary for the Development, manufacture (including synthesis, formulation, finishing or packaging), use, holding, marketing, offer for sale, sale, distribution, export or import of the Product as such Product exists and as such activities are being conducted by Seller as of the Effective Date.

(d) No Conflicting Third Party Rights in Transferred Intellectual Property.

(i) No Employee Ownership. No current or former officer, director, or employee of Seller or any of its Affiliates or, to Seller's Knowledge, any consultant of Seller or any of its Affiliates, has any right, title or interest in, to or under any Transferred Intellectual Property developed by such person in the course of providing services to Seller or any of its Affiliates that has not been irrevocably assigned, transferred or licensed to Seller or any of its Affiliates.

(ii) No Challenges. Neither Seller nor its Affiliates has received any written communication from any Person challenging or threatening to challenge, nor is Seller or its Affiliate a party to any pending and served proceeding or, to Seller's Knowledge, pending but not served proceeding in which any Person is challenging Seller's or its Affiliate's ownership of, or right to use and license, any Transferred Intellectual Property.

(iii) No Restrictions. Seller and its Affiliates are not subject to any outstanding Order or stipulation restricting in any manner the use, transfer or licensing of the Transferred Intellectual Property by Seller or any of its Affiliates.

(e) No Notice of Infringement of Third Party IP Rights. Seller has not received any written notice of any, and to Seller's Knowledge, there are no, claims, judgments, or settlements against, or amounts with respect thereto, owed by Seller or any of its Affiliates relating to the Transferred Intellectual Property. To Seller's Knowledge, no claim or litigation has been brought or threatened against Seller by any Person alleging that the Program or any Product has infringed, misappropriated or otherwise violated any Intellectual Property right of another Person.

(f) Third Party Infringement. To Seller's Knowledge, none of the Transferred Intellectual Property owned by or licensed to Seller is being infringed by any Third Party. Seller has not given any notice to any Person asserting infringement or misappropriation by any such Person of any of the Transferred Intellectual Property in a manner that relates specifically to any Product.

(g) Confidentiality. Each of Seller and its Affiliates has taken all commercially reasonable and customary measures and precautions necessary to protect and maintain the confidentiality of the Program Know-How.

(h) Employee, Consultant and Contractor Agreements. All current and former employees, consultants and contractors of Seller or its Affiliates who are or were involved in, or who have contributed to, the creation or Development of any Transferred Intellectual Property owned by Seller or its Affiliates have executed and delivered to Seller or its Affiliates a written agreement regarding the protection of proprietary information and assignment to the Seller of any intellectual property rights in such Transferred Intellectual Property arising from services performed by such Persons. To the Seller's Knowledge, no current or former employee, consultant or contractor is in violation of any term of any such agreement.

Section 3.8 Contracts and Licenses.

(a) Schedule 3.8(a) contains a true and accurate list of all material Contracts, including the Assigned Contracts, pursuant to which Seller enjoys any right or benefit or undertakes any obligation exclusively related to the Transferred Assets or the Program, other than (i) non-disclosure agreements; (ii) licenses granted to the Seller for off-the-shelf software; (iii) invention assignment agreements with employees, consultants and contractors that assign or grant to Seller or its Affiliate ownership of inventions and intellectual property developed in the course of providing services to Seller or its Affiliate by such employees, consultants and contractors; and (iv) the Excluded Contracts. Each of the Assigned Contracts is valid and binding on Seller or its Affiliate in accordance with its terms and is in full force and effect and enforceable by Seller or its Affiliate in accordance with its terms. Except as set forth on Schedule 3.8(a), no consents are necessary for the effective assignment to and assumption by the Buyer of any of the Assigned Contracts or the consummation of the Transaction (the "Contract Consents"). Except as set forth on Schedule 3.8(a), no Assigned Contract fails to comply in any material respect with any Healthcare Laws.

(b) The consummation of the Transaction will not, in and of itself, result in a breach by Seller of any Assigned Contract.

(c) Except as set forth in Schedule 3.8(c), there exists no default or event of default or event, occurrence, condition or act, with respect to Seller, or to Seller's Knowledge, with respect to the other contracting party, which, with the giving of notice, the lapse of the time or the happening of any other event or conditions, may contravene, conflict with, or result in a violation in any material respect or breach of, or give Seller or other Person the right to declare a default or exercise any remedy under, or to accelerate the maturity or performance of, or to cancel, terminate, or modify, any Assigned Contract, and Seller has neither given nor received from any other Person any written notice regarding any actual, alleged, possible, or potential violation or breach of, or default under, any Assigned Contract identified in Schedule 3.8(a). Except as set forth in Schedule 3.8(c), Seller has not received written notice of, and has no Knowledge of any intent to effect, the acceleration, cancellation, modification or termination of any Assigned Contract. True, correct and complete copies of all Assigned Contracts, including all amendments thereto, have been made available to Buyer in the Data Room.

Section 3.9 Taxes.

(a) All Tax Returns required to be filed by Seller with respect to the Program or the Transferred Assets have been timely filed and such Tax Returns are true and correct in all material respects. All Taxes due and owing by Seller with respect to the Program or the Transferred Assets have been fully and timely paid. Seller has withheld all applicable Taxes required to be withheld in respect of payments arising in connection with the Program or the Transferred Assets to any employee, independent contractor, shareholder, creditor or any other Third Party and has fully and timely remitted all such withheld Taxes to the appropriate Taxing Authority.

(b) There are no Encumbrances for unpaid Taxes on the Transferred Assets (other than Encumbrances for Taxes not yet due and payable or being contested in good faith).

(c) Seller has not received any written notice from any Taxing Authority of any Tax deficiency, Tax audit or examination, or other Tax proceeding that relates to Taxes with respect to the Program or the Transferred Assets, which deficiency, audit, examination or proceeding has not been resolved or settled in full with no remaining unpaid Tax assessment or deficiency, nor is any such audit, examination or proceeding currently pending.

(d) None of the Transferred Assets are "section 197(f)(9) intangibles" (as defined in Treasury Regulations Section 1.197-2(h)(1)(i)).

Section 3.10 Compliance with Laws. Seller is not in conflict with or in default or violation of any order, judgment, preliminary or permanent injunction, temporary restraining order, award, citation, decree, consent decree or writ of any Government Entity (collectively, "Orders") affecting or relating to the Transferred Assets, the Program, the Assumed Liabilities or the Product, or the Laws of any Government Entity affecting or relating to the Transferred Assets. Seller has not received from any Government Entity any notification in writing with respect to possible conflicts, defaults or violations of Laws affecting or relating to the Transferred Assets or the Product. Seller is and has been in compliance in all material respects with all Laws and Orders that are imposed or issued by any Government Entity applicable to the Transferred Assets, the Program and/or the Product. No event has occurred or circumstances exist that (with the giving of notice or lapse of time or both) would result in a violation by Seller in any material respect with any such Laws or Orders.

Section 3.11 Claims and Proceedings. There is no outstanding Order of any Government Entity against or involving the Transferred Assets, the Program, the Product or the Assumed Liabilities or for product liability, breach of warranty, defective product or service, back charge, additional work, or other claims by any third party (whether or not based on contract or tort and whether or not relating to personal injury, including death, property damage or economic loss) arising from the Program or related to the Products or Transferred Assets. There is no action, suit, litigation, Order, claim or counterclaim or legal, administrative or arbitral Proceeding or investigation, pending or, to the Seller's Knowledge, (i) threatened against or involving the Transferred Assets, the Program, the Product, Seller's business or the Assumed Liabilities and/or (ii) that challenges or seeks to prevent, enjoin or otherwise delay the transactions contemplated by this Agreement, and to Seller's Knowledge, there are no existing facts or circumstances that would reasonably be expected to result in such an action, suit, litigation, Order, claim or counterclaim or legal, administrative or arbitral Proceeding or investigation in connection with the Program, the Product, the Assumed Liabilities or the Transferred Assets.

Section 3.12 Regulatory Compliance; Permits.

(a) Except as set forth on Schedule 3.12(a), neither Seller nor, to Seller's Knowledge, any contract manufacturer of Seller has received any written notice, regulatory communication, request for information, demand letter, or other written communication, including warning letters, untitled letters, It Has Come To Our Attention letters or FDA Form 483 Notices of Inspectional Observations from any Government Entity (i) contesting the Regulatory Approval of, the uses of or the manufacture (including synthesis, formulation, finishing, labeling or packaging), holding, marketing, offer for sale, sale, distribution, export, import and promotion of any Product; or (ii) otherwise alleging any violation of any Laws by the Seller or any contract manufacturer of Seller with respect to any Product.

(b) All Development, manufacturing and commercialization activities conducted or sponsored by the Seller regarding the Program were and continue to be conducted in compliance in all material respects with all Governmental Authorizations and applicable Laws, including those related to good clinical practice (including 21 CFR Parts 54 and 312), good laboratory practice (including 21 CFR Part 58), good manufacturing practice (including 21 CFR Parts 210 and 211), the protection of human study subjects (including 21 CFR Parts 50, 56 and 312) and safety reporting (including 21 CFR §§ 312.32 and 314.80). There has not been, nor is there currently under consideration by Seller or any of its Affiliates, any recall or warning in respect of any Product. To Seller's Knowledge, there has not been, nor is there currently under consideration by any Government Entity, any recall or warning in respect of any Product. Neither Seller nor any of its Affiliates has received any notice that any Government Entity has (i) commenced or threatened to initiate any action to withdraw its approval or request the recall of any Product, or (ii) commenced or threatened to initiate, any action to enjoin the manufacture, sale, or use of any Product.

(c) No Product is under consideration by the Seller or, to Seller's Knowledge, its contract manufacturers, its customers or by the FDA or similar foreign Government Entity for a recall, withdrawal, suspension, seizure or discontinuation, or has been recalled, withdrawn, suspended, seized or discontinued by the Seller, its contract manufacturers or its customers in any part of the world (whether voluntarily or otherwise).

(d) All data, information and representations made by Seller and contained in any submission to, or communications with, the FDA or other similar foreign Government Entity regarding the Program were accurate, complete, truthful and non-misleading in all material respects when submitted or communicated to FDA or other similar foreign Government Entity (or were corrected in or supplemented by a subsequent filing) and, to the Knowledge of the Seller, remain so currently. The Seller is not the subject of any pending or, to the Knowledge of the Seller, threatened investigation regarding any Product by the FDA pursuant to its "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities" Final Policy set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto ("FDA Fraud Policy"), or similar policy enforced by any other similar Government Entity. With regard to the Program, the Seller has not, nor has, to the Knowledge of the Seller, any officer, employee or agent of the Seller made an untrue statement of material fact to the FDA or any other similar Government Entity, failed to disclose a material fact required to be disclosed to the FDA or any other similar Government Entity, or committed an act, made a statement or failed to make a statement that, at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA or any other similar Government Entity to invoke the FDA Fraud Policy or any similar policy.

(e) Seller has obtained and has in force all material Permits necessary to conduct the Program and own and operate the Transferred Assets in the places and in the manner in which the Program is now operating. Schedule 3.12(e) contains a complete and accurate list of all such Permits. Seller is, and has been, in compliance in all material respects with all such Permits. Seller has not received any notice that it is in default (or with the giving of notice or lapse of time or both, would be in default) under any such Permit. Prior to the Effective Date, Seller made available to Buyer in the Data Room true and complete copies of all such Permits.

Section 3.13 Product Financial Information. Seller has provided in the Data Room under Additional DD requests > Acella Requests > Schedules the following financial materials for the year ended December 31, 2021, and for the nine (9) month period ended September 30, 2022: (A) sales in units and sales value of the Product, (B) returns and allowances recorded within net sales of the Product, (C) actual returns of the Product received in units and value, (D) direct cost of sales of the Product recorded within cost of goods sold, and (E) disputed customer accounts receivable recorded on Seller's balance sheet at December 31, 2021 and September 30, 2022. The net sales and cost of goods sold information are derived from and reconcile to the specific financial line items in Seller's publicly filed financial statements.

Section 3.14 Absence of Certain Changes, Events and Conditions. Except as set forth in Schedule 3.14, since September 30, 2022, Seller has conducted the Program in the ordinary course of business consistent in all material respects with past practices, and there has not been any:

(a) event, occurrence or development that has had, individually or in the aggregate, a Material Adverse Effect;

(b) incurrence, assumption or guarantee of any indebtedness for borrowed money in connection with the Program except unsecured current obligations and Liabilities incurred in the ordinary course of business consistent with past practice;

(c) transfer, assignment, sale or other disposition of any of the Transferred Assets, except for the sale of inventory in the ordinary course of business;

(d) cancellation of any debts or claims related to the Transferred Assets or amendment, termination or waiver of any rights constituting Transferred Assets;

(e) material damage, destruction or loss, or any material interruption in use, of any Transferred Asset, whether or not covered by insurance;

(f) imposition of any Encumbrance (other than Permitted Encumbrances) upon any of the Transferred Assets;

(g) purchase, lease or other acquisition of the right to own, use or lease any property or assets in connection with the Program for an amount in excess of $[***], individually (in the case of a lease, per annum) or $[***] in the aggregate (in the case of a lease, for the entire term of the lease, not including any option term), except for purchases of inventory or supplies in the ordinary course of business consistent with past practice;

(h) Contract or agreement related to the Program entered into outside the ordinary course of business;

(i) cancellation or notification of the intent to cancel any Contract related to the Program as a result of the Transaction;

(j) sold, assigned, transferred, exclusively licensed or conveyed, any Transferred Intellectual Property; or

(k) any Contract to do any of the foregoing, or any action or omission that would result in any of the foregoing.

Section 3.15 Customers and Suppliers. Schedule 3.15 sets forth a complete and accurate list of: (a) all Customers representing net revenue of at least $[***]; and (b) all contract manufacturers used to produce the Product to which Seller incurred at least $[***], in each case (a) and (b) during the fiscal year ended December 31, 2022. Except as set forth on Schedule 3.15, no such Customer (or former Customer representing net revenue of at least $[***]) and no such contract manufacturer (or former contract manufacturer to which Seller incurred at least $[***]) during the twelve (12) months preceding the Effective Date has canceled, terminated or, to the Knowledge of Seller, made any threat to cancel or otherwise terminate any of its contracts with Seller or its Affiliates.

Section 3.16 Insurance. Seller has in force the product liability insurance policy set forth on Schedule 3.16. Within the past three (3) years, Seller has had a product liability insurance policy in place. There are no claims which relate to the Transferred Assets, the Assumed Liabilities, the Product or the Program currently pending under any of Seller's insurance policies and, to the Knowledge of Seller, there is no basis for any such claims.

Section 3.17 Government Contracts.

(a) Government Contract No. W81XWH20C0133 by and between Seller and the DoD (the "DSUVIA DoD Supply Agreement"), a true and complete copy of which was made available to Buyer in Seller's electronic data room, is the only pending Government Contract of Seller in connection with the Program, the Transferred Assets and the Products. All representations made by Seller under the DSUVIA DoD Supply Agreement were accurate, complete, truthful and non-misleading in all material respects when submitted and entered into under that agreement and, to Seller's Knowledge, remain so currently. Seller is in full compliance with all terms and conditions of the DSUVIA DoD Supply Agreement, and Seller is in full compliance with all Laws governing such agreement.

(b) No Government Entity has ever suspended or debarred Seller or proposed the Seller for suspension or debarment or given Seller a notice to show cause why it should not be suspended or debarred, nor has Seller received any other similar notice and there is no cause or basis for such suspension or debarment.

(c) Neither Seller nor its personnel has been investigated, charged civilly or criminally, convicted of any crime or civil offense, subpoenaed, assessed any penalties, called as a witness, participated in or been the subject of any mandatory or voluntary self-disclosure relating to, or otherwise been involved in any enforcement matter pertaining to Government Contracts or the matters set forth in Federal Acquisition Regulation Clause 52.209-5, nor conducted any internal review to confirm whether any self-disclosure may be appropriate (collectively "Government Contracts Enforcement Matters") during the six (6) years prior to Closing, and there is no reason to think Seller will become involved in such Government Contracts Enforcement Matters before or after Closing.

(d) The DSUVIA DoD Supply Agreement was awarded to Seller partially or entirely on the basis of small business, social disadvantage, or other standing under government socio-economic programs, and, to Seller's Knowledge, no approvals, consents, or notifications are required to be made relating to the Transactions for the continued performance of such agreement before or after Closing. Seller has truthfully represented itself to be eligible for such agreement and has maintained compliance with any requirements relating to such agreement, whether applicable to Seller under the terms of any agreement or applicable Law, including but not limited to any limitations on subcontracting. The DSUVIA DoD Supply Agreement does not include a provision requiring notice or termination of such contracts upon the loss of small business or other socio-economic status.

(e) The DSUVIA DoD Supply Agreement is a firm fixed price contract, and Seller has not submitted to the DoD any cost or pricing data, and Seller has complied with all applicable Laws relating to the manner in which the DSUVIA DoD Supply Agreement was established, performed, and billed.

(f) Seller has not licensed any of its Intellectual Property relating to the Product, or ceded ownership of the same to a Government Entity or any other party under the DSUVIA DoD Supply Agreement.

(g) No funding from any Government Entity was used in the creation or development of the Transferred Intellectual Property.

Section 3.18 International Trade.

(a) Seller has not at any time during the five (5) years preceding Closing violated any applicable Ex-Im Laws or Laws relating to anti-bribery or anticorruption (including but not limited to the U.S. Foreign Corrupt Practices Act of 1977, as amended and the U.K. Bribery Act 2010, in each case, as in effect at the time of such action (all such Laws, "Anticorruption Laws")) relating to the Product.

(b) No director, member, manager, officer, agent, employee, representative, consultant or other Person acting for or on behalf of Seller has, with respect to the Product, violated any Anticorruption Law or Ex-Im Law, and Seller has not received any written notice alleging any such violation of any Anticorruption Law or Ex-Im Law.

Section 3.19 No Affiliate Product Sales or Marketing. Except as set forth in Schedule 3.19, Seller is the only Person that has sold and marketed the Product in the Territory, and no Affiliate of Seller has sold or marketed the Product. Other than the Product, neither Seller nor any Affiliate of Seller has any line extension containing sufentanil as the sole active ingredient which is for individual use.

Section 3.20 Other Seller Materials and Regulatory Materials. The Other Seller Materials and Regulatory Materials that have been made available by Seller to Buyer for examination are complete and correct in all material respects and constitute all Other Seller Materials and Regulatory Materials owned or controlled by Seller and its Affiliates. Other than Seller, no party owns any Other Seller Materials or Regulatory Materials, and other than Seller and Aguettant, no party controls any Other Seller Materials or Regulatory Materials.

Section 3.21 Brokers. No broker, finder, investment banker, or other Person is entitled to any brokerage, finder's, or other fee or commission from Seller in connection with the Transaction.

Section 3.22 Product Liability. Schedule 3.22 sets forth all pending claims and, to Seller's Knowledge, all claims threatened in writing against Seller, for product liability, breach of warranty, defective product or service, back charge, additional work, or other claims by any third party (whether or not based on contract or tort and whether or not relating to personal injury, including death, property damage or economic loss) arising from Products sold or services rendered by Seller relating to the Transferred Assets or the Program. All Products Developed, manufactured (including synthesis, formulation, finishing or packaging), used, held, marketed, offered for sale, sold, distributed, exported or imported by Seller relating to the Transferred Assets or the Program are and have been in conformity in all material respects with all contractual commitments and all express and implied warranties, and the Seller has no product Liability in connection therewith.

ARTICLE IV
REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer represents and warrants to Seller as of the Effective Date and as of the Closing Date as follows:

Section 4.1 Organization and Qualification. Buyer is a limited liability company duly organized, validly existing and in good standing under the laws of Delaware. Buyer has all requisite corporate power and authority to own and operate its respective properties and assets and to carry on its business as currently conducted. Buyer is duly qualified to do business and is in good standing in each jurisdiction where the ownership or operation of its respective properties and assets or the conduct of its respective business requires such qualification, except for failures to be so qualified or in good standing, as the case may be, that would not, individually or in the aggregate, impair or delay Buyer's ability to perform its obligations hereunder.

Section 4.2 Corporate Authorization. Buyer has full corporate power and authority to execute and deliver this Agreement and the Ancillary Agreements and to perform its obligations hereunder and thereunder, and to consummate the Transaction. The execution, delivery and performance by Buyer of this Agreement and the Ancillary Agreements, the performance by Buyer of its obligations hereunder and thereunder, and the consummation of the Transaction and the transactions contemplated by the Ancillary Agreements have been duly and validly authorized and except as set forth on Schedule 4.2, no additional corporate or shareholder authorization or consent is required in connection with the execution, delivery and performance by Buyer of this Agreement and the Ancillary Agreements and the consummation of the Transaction. The execution, delivery and performance by Buyer of this Agreement and the Ancillary Agreements, and the consummation of the Transaction and the transactions contemplated by the Ancillary Agreements, do not and will not violate any provision of the Organizational Documents of Buyer. This Agreement has been, and each of the Ancillary Agreements will be at or prior to the Closing duly and validly executed and delivered by Buyer and (assuming due authorization, execution, and delivery by Seller) this Agreement constitutes, and each of the other Ancillary Agreements to which Buyer is a party when so executed and delivered by Seller, will constitute valid and legally binding obligations of Buyer enforceable against it in accordance with the terms hereof and thereof. The Person(s) signing this Agreement and the other Ancillary Agreements on behalf of Buyer has been duly authorized to execute and deliver this Agreement and the other Ancillary Agreements.

Section 4.3 No Conflict. The execution and delivery of this Agreement and the Ancillary Agreements by Buyer, Buyer's compliance with the terms and conditions hereof and thereof, and the consummation by Buyer of the Transaction and the transactions contemplated by the Ancillary Agreements, do not and will not: (a) conflict with or violate any provision of Organizational Documents of Buyer; (b) conflict with or violate any Law or Order applicable to Buyer; (c) conflict with, result in a breach of, constitute a default under (whether with or without notice or the lapse of time or both), accelerate or permit the acceleration of the performance required by, or require any consent, authorization, or approval under, any material Contract to which Buyer is a party or by which it is bound or to which any of its assets or property is subject; or (d) result in the creation of any Encumbrance upon the assets or property of Buyer.

Section 4.4 Required Filings and Consents. The execution and delivery of this Agreement by Buyer do not, and the performance by Buyer of its obligations hereunder and the consummation of the Transaction will not, require any consent, approval, authorization or permit of, or filing by Buyer with or notification by Buyer to, any Government Entity, except for the letters to the applicable Regulatory Authorities set forth in Section 5.10(a).

Section 4.5 No Brokers. No broker, finder or investment banker is entitled to any brokerage commission, finder's fee or similar payment in connection with the Transactions based upon arrangements made by or on behalf of Buyer.

Section 4.6 Legal Proceedings. There is no action, suit, claim or counterclaim or legal, administrative or arbitral proceeding or investigation, pending or threatened against Buyer that would prevent or delay the ability of Buyer to enter into and perform its obligations under this Agreement, the Ancillary Agreements, the Transaction or the transactions contemplated by the Ancillary Agreements. There is no Order to which Buyer is subject or that is pending or threatened that would prevent or delay the ability of Buyer to enter into and perform its obligations under this Agreement, the Ancillary Agreements, the Transaction or the transactions contemplated by the Ancillary Agreements.

Section 4.7 Availability of Funds; Solvency. Buyer will have available, sufficient cash to enable it to pay for the Inventory pursuant to Section 2.5. Buyer is solvent and currently: (i) is able to pay its debts as they become due; (ii) owns property that has a fair saleable value greater than the amounts required to pay its debts (including a reasonable estimate of the amount of all contingent liabilities); and (iii) has adequate capital to carry on its business. No transfer of property is being made and no obligation is being incurred in connection with the Transaction and/or the transactions contemplated by the Ancillary Agreements with the intent to hinder, delay or defraud either present or future creditors of Buyer.

Section 4.8 Approval. Except for the approval of Buyer's board of directors, no vote or other action of the members or manager of Buyer is required by applicable Law, the Organizational Documents of Buyer or otherwise in order for Buyer to consummate the Transaction and the transactions contemplated by the Ancillary Agreements.

Section 4.9 Buyer Acknowledgement. Buyer acknowledges that: (a) it has completed to its satisfaction its own due diligence review with respect to Seller, the Product, the Program and the Transferred Assets and it is entering into the Transaction and the transactions contemplated by the Ancillary Agreements based on such investigation and, except for the specific representations and warranties made by Seller in Article III of this Agreement, it is not relying upon any representation or warranty made by or on behalf of any Person, nor upon the accuracy of any record, projection or statement made available or given to Buyer in the performance of such investigation, (b) it has had access to its full satisfaction to Seller and its books and records, contracts, agreements and documents, and Representatives, and (c) it has had such opportunity to seek accounting, legal or other advice or information in connection with its entry into this Agreement and the Ancillary Agreements as it has seen fit. Buyer has no Knowledge that the representations and warranties of Seller in this Agreement are not true and correct. In connection with the due diligence investigation of Seller by Buyer and its Affiliates, stockholders and Representatives, Buyer and such Persons may have received and may continue to receive after the date of this Agreement from Seller and its Affiliates, stockholders and Representatives certain estimates, projections, forecasts and other forward-looking information, as well as certain business plan information, regarding Seller and its business and operations, including the Transferred Assets, the Product and the Program (the "Seller Projections"). Buyer hereby acknowledges that there are uncertainties inherent in attempting to make such Seller Projections, and that Buyer, except in the case of Fraud, will have no claim against Seller, or any of its Affiliates, stockholders or Representatives or any other Person, with respect to any Seller Projections.

Section 4.10 No Implied Representations. Buyer agrees that neither Seller nor any other Person acting on behalf of Seller has made or is making any representations or warranties, express or implied, except those representations set forth in Article III of this Agreement. Buyer acknowledges and agrees that, in determining to enter into this Agreement and consummate the transactions contemplated hereby, other than the representations explicitly set forth in Article III, it has not relied and is not relying upon any representation or warranty of any kind, express or implied, made or purportedly made by or on behalf of any Person. WITHOUT LIMITING THE GENERALITY OR EFFECT OF THE FOREGOING, BUYER ACKNOWLEDGES THAT EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, BUYER IS ACQUIRING THE TRANSFERRED ASSETS "AS-IS" AND "WHERE-IS" AS OF THE CLOSING DATE, WITHOUT ANY EXPRESS OR IMPLIED REPRESENTATIONS OR WARRANTIES AS TO THE FITNESS, MERCHANTABILITY, NON-INFRINGEMENT OR CONDITION OF THE ASSETS OR AS TO ANY OTHER MATTER. Notwithstanding the foregoing, no event shall this Section 4.10 limit in any way Buyer from pursuing a claim of Fraud against any Person.

ARTICLE V
COVENANTS

Section 5.1 Access and Information. From the Effective Date until the earlier of the termination of this Agreement or the Closing, subject to reasonable rules and policies of Seller and any applicable Laws, Seller shall, upon reasonable advance notice: (i) afford Buyer and its Representatives reasonable access, during regular business hours, to the Transferred Assets and employees or consultants of Seller with knowledge of the Transferred Assets; (ii) furnish Buyer with copies of such Contracts, other relevant agreements and Governmental Authorizations held by Seller or any of its Affiliates that are included in or specifically related to the Transferred Assets as Buyer may reasonably request; and (iii) furnish, or cause to be furnished, to Buyer any financial and operating data and other information that is readily available and specifically related to the Transferred Assets as Buyer from time to time reasonably requests. No investigation pursuant to this Section 5.1 shall alter any representation or warranty given hereunder by Seller. All information received pursuant to this Section 5.1 shall be governed by the terms of the Confidentiality Agreement.

Section 5.2 Conduct of Business. During the period from the Effective Date to the Closing, except as otherwise contemplated by this Agreement or as Buyer otherwise agrees in writing in advance, Seller shall: (a) use its commercially reasonable efforts to preserve intact the Transferred Assets as in existence on the Effective Date and shall continue to operate the Transferred Assets in the ordinary course of business consistent with its past practices and in accordance with all Laws and restrictions; (b) not take or omit to take, or agree to take or omit to take, any action that would cause any of the representations or warranties of the Seller to be untrue or incorrect in any material respect, or that could cause a violation in any material respect of any covenant, term or condition to be complied with, fulfilled or performed by Seller under this Agreement; and (c) not, without the prior written consent of Buyer, which consent shall not be unreasonably withheld, delayed or conditioned, engage in any practice, take any action, or enter into any transaction of the sort described in Section 3.14.

Section 5.3 Commercially Reasonable Efforts. Seller and Buyer shall cooperate and use their respective commercially reasonable efforts to fulfill as promptly as practicable the conditions precedent to the other party's obligations hereunder, including securing as promptly as practicable all Authorizations required in connection with the transactions contemplated hereby.

Section 5.4 Taxes.

(a) Transfer Taxes. All excise, sales, use, value added, transfer (including real property transfer or gains), stamp, documentary, filing, recordation and other similar Taxes imposed or assessed as a result of the Transaction and/or the transactions contemplated by the Ancillary Agreements ("Transfer Taxes") shall be borne by Buyer. Any Tax Returns and other required documentation that must be filed in connection with Transfer Taxes shall be prepared and filed by Buyer, at its sole expense, as and when due. To the extent required by applicable Law, Seller shall cooperate with Buyer by executing the applicable Tax Returns or other required documentation relating to such Transfer Taxes.

(b) Tax Claims. Seller shall control the defense of any Tax Proceeding with respect to the Program and/or the Transferred Assets for any taxable period (or portion thereof) ending on or prior to the Closing Date or that could reasonably be expected to give rise to a claim for indemnification pursuant to this Agreement (each, a "Tax Claim"); provided that (i) Seller shall keep Buyer reasonably informed with respect to the commencement and status of such Tax Claim and (ii) Buyer shall be entitled to, at its sole cost and expense, participate in the defense of such Tax Claim. The parties hereto shall, as soon as reasonably practicable after obtaining knowledge of any Tax Claim, notify each other in writing and in reasonable detail of such Tax Claim. This Section 5.4(b), not Section 8.3(b), shall apply to Tax Claims.

(c) Tax Apportionment. For purposes of this Agreement, in the case of any real property, personal property, and similar Taxes (other than Transfer Taxes) with respect to the Program and/or the Transferred Assets for any Straddle Period, the portion of such Taxes that relates to the portion of such taxable period ending on the Closing Date and for which Seller shall be responsible shall be deemed to be the amount of such Taxes for the entirety of such taxable period, multiplied by a fraction the numerator of which is the number of days in the portion of such taxable period ending on the Closing Date and the denominator of which is the number of days in the entirety of such taxable period; and the portion of such Taxes that relates to the portion of such taxable period beginning after the Closing Date and for which Buyer shall be responsible shall be deemed to be the amount of such Taxes for the entirety of such taxable period, multiplied by a fraction the numerator of which is the number of days in the portion of such taxable period beginning after the Closing Date and the denominator of which is the number of days in the entirety of such taxable period.

(d) Cooperation. The parties hereto shall fully cooperate, as and to the extent reasonably requested by each other, in connection with the preparation and filing of any Tax Return with respect to the Program and/or the Transferred Assets and the defense of any Tax Claim. Such cooperation shall include the retention and (upon request) the provision of records, documents, and other information reasonably relevant to such Tax Return or Tax Claim. Such cooperation shall also include making employees available on a mutually convenient basis to provide additional information and explanation of any material provided pursuant to this Section 5.4(d).

(e) Purchase Price Allocation. The payments for Inventory, Assumed Liabilities, Milestone Payments, Payments for DoD Marketing, Quarterly Payments and any other amounts properly treated as consideration paid for the Transferred Assets shall be allocated among the Transferred Assets (the "Purchase Price Allocation") in accordance with Section 1060 of the Code and the Treasury Regulations promogulated thereunder and consistent with Schedule 5.4(e). The Purchase Price Allocation shall be conclusive and binding on the parties hereto for applicable Tax purposes. The parties hereto shall prepare all Tax Returns (including IRS Form 8594) consistent with, and shall not take (or cause to be taken) any action or filing position inconsistent with, the Purchase Price Allocation, unless otherwise required pursuant to a "determination" within the meaning of Section 1313(a) of the Code (or any analogous or similar provision of state, local, or foreign Law).

(f) Intended Tax Treatment. For applicable Tax purposes, (i) the Transaction shall be treated as a taxable asset purchase and sale, (ii) the rights of Seller to the Milestone Payments, the Payments for DoD Marketing, and the Quarterly Payments shall be treated as deferred contingent purchase price eligible for installment treatment under Section 453 of the Code, and (iii) interest may be imputed on such payments if required by Sections 483 or 1274 of the Code.

Section 5.5 Notification. Between the Effective Date and the Closing, Seller shall promptly notify Buyer in writing if it becomes aware of: (i) any fact, circumstance, event or action the existence, occurrence or taking of which (A) is a Material Adverse Effect, (B) has resulted in, or would reasonably be expected to cause, any representation or warranty made by Seller hereunder to be untrue or inaccurate, or (C) has resulted in, or would reasonably be expected to result in, the failure of any of the conditions set forth in Section 6.1 to be satisfied; (ii) any notice or other communication from any Person alleging that the consent of such Person is or may be required in connection with the Transaction and/or the transactions contemplated by the Ancillary Agreements; (iii) any notice or other communication from any Government Entity in connection with the Transaction and/or the transactions contemplated by the Ancillary Agreements; and (iv) any Proceeding commenced or, to Seller's Knowledge, threatened in writing against Seller and directly involving the Transferred Assets, the Program or the Assumed Liabilities. Notwithstanding the foregoing, except as otherwise explicitly set forth herein, Seller shall not have the right to update any Schedule delivered to Buyer on the Effective Date. Between the Effective Date and the Closing, Buyer shall promptly notify Seller in writing if it becomes aware of (i) any fact, circumstance, event or action the existence, occurrence or taking of which (A) has resulted in, or would reasonably be expected to cause, any representation or warranty made by Buyer hereunder to be untrue or inaccurate, (B) has caused, or would reasonably be expected to cause, any covenant or agreement of Buyer hereunder not to be complied with, or (C) has resulted in, or would reasonably be expected to result in, the failure of any of the conditions set forth in Section 6.2 to be satisfied; (ii) any notice or other communication from any Person alleging that the consent of such Person is or may be required in connection with the Transaction and/or the transactions contemplated by the Ancillary Agreements; (iii) any notice or other communication from any Government Entity in connection with the Transaction and/or the transactions contemplated by the Ancillary Agreements; and (iv) any Proceeding commenced against or directly involving Buyer that would reasonably be expected to affect Buyer's ability to effect the Closing.

Section 5.6 Further Assurances. At any time and from time to time after the Closing, as and when requested by any party hereto and at such requesting party's expense, the other party hereto shall, and shall cause its Affiliates, promptly to execute, acknowledge and deliver any other assurances or documents or instruments of transfer reasonably requested by the requesting party hereto and necessary for the requesting party to satisfy its obligations hereunder or to obtain the benefits of the Transaction.

Section 5.7 Exclusivity. During the period from the Effective Date until the Closing Date or the earlier termination of this Agreement, Seller shall not and shall cause its Affiliates and each of their respective officers, directors, employees, representatives and agents not to, on behalf of the Seller or its Affiliate, directly or indirectly, encourage, solicit, initiate, engage or participate in discussions or negotiations with any Person (other than the Buyer) or enter into any agreements or other instruments (whether or not binding) concerning the disposition of all or any portion of the Transferred Assets to any Third Party. Notwithstanding the foregoing, nothing in this Agreement shall be construed to prohibit or otherwise prevent the Seller or any of its Affiliates or any of their respective officers, directors, employees, representatives or agents from encouraging, soliciting, initiating, engaging or participating in discussions or negotiations with any Person or entering into any agreements or other instruments concerning (i) any Change of Control Transactions with respect to Seller (or any of its controlling Affiliates), (ii) any transaction for equity financing purposes, (iii) any transaction effected exclusively to change the form or domicile of Seller, or (iv) any transactions that do not involve the disposition of all or any portion of the Transferred Assets to any Third Party. Seller agrees that the rights and remedies for noncompliance with this Section 5.7 shall include having such provision specifically enforced by any court having equity jurisdiction, it being acknowledged and agreed that any such breach or threatened breach shall cause irreparable injury to Buyer and that money damages would not provide an adequate remedy to Buyer.

Section 5.8 Transferred Intellectual Property. After the Closing Date, Seller shall not practice, license or otherwise exploit any of the Transferred Intellectual Property that is licensed back to Seller pursuant to the IP Agreement outside of the scope of the license granted to Seller in the IP Agreement, and shall not, in any event, practice, license or otherwise exploit any of the Transferred Intellectual Property to manufacture, Develop or commercialize any Product. Buyer shall not practice, license or otherwise exploit any of the Transferred Intellectual Property to manufacture, Develop or commercialize any product that is, or that is competitive with, any product (other than a Product) that is or has been commercialized by Seller or its Affiliate as of the Effective Date.

Section 5.9 Confidentiality.

(a) Except as otherwise provided herein, Seller shall treat as confidential and shall safeguard any and all nonpublic, confidential or proprietary information included in the Transferred Assets ("Confidential Information"), in each case by using the same degree of care as it uses to protect proprietary or confidential information of its own, but no less than a reasonable standard of care, to prevent the unauthorized use, dissemination or disclosure of such Confidential Information.

(b) Buyer and Seller acknowledge that the confidentiality obligations set forth herein shall not extend to (i) any information which was in, or comes into, the public domain through no breach of this Agreement by Seller, (ii) any information that is independently developed or discovered without reference to nonpublic, confidential or proprietary information included in the Transferred Assets, (iii) any information that is communicated to Seller by a Third Party, free and clear of any obligation of confidence, or (iv) any information that is or was communicated by Buyer to a Third Party free of any obligation of confidence. In addition, Seller shall not be prohibited from disclosing any portion of the Confidential Information (A) that Seller is required to disclose by judicial or administrative process or, in the opinion of legal counsel, by other requirements of Law, including applicable securities laws and rules of the applicable stock exchange; (B) in connection with the enforcement of any right or remedy relating to this Agreement or the Ancillary Agreements or the transactions contemplated hereby or thereby; or (C) that is necessary or useful for the performance of or the exercise of Seller's rights under this Agreement. In the case of disclosure compelled by judicial or administrative process, Seller shall notify Buyer promptly of the request or requirement so that Buyer may seek an appropriate protective Order or waive compliance with the provisions of this Section 5.9. If, in the absence of a protective order or the receipt of a waiver hereunder, Seller is, on the written advice of counsel, compelled to disclose any Confidential Information by judicial or administrative process, Seller may so disclose the Confidential Information; *provided, however*, that, at the written request of Buyer, Seller shall use commercially reasonable efforts to obtain, at the expense of Buyer, an Order or other assurance that confidential treatment will be accorded to such portion of the Confidential Information required to be disclosed.

Section 5.10 Transfer of Transferred Assets. In furtherance of Seller's obligations to deliver the Transferred Assets and, in each case, at Buyer's expense:

(a) On the Closing Date, at Buyer's expense, Buyer and Seller shall each (i) send letters (in form and substance reasonably satisfactory to Buyer) to the FDA and any other Government Entity, as required to effect the transfer of the Transferred Assets, indicating that the Regulatory Materials are transferred to Buyer and that Buyer is the new owner of and has all rights to the Regulatory Materials as of the Closing Date, and (ii) provide to the other party a copy of any such letters.

(b) On or within ten (10) calendar days after the Closing Date, Seller will forward to Buyer a complete copy of the Regulatory Materials and Other Seller Materials.

(c) Between the Effective Date and the Closing, Seller shall be responsible for maintaining the Regulatory Materials and Other Seller Materials in accordance with its past practice and Seller will promptly provide Buyer with copies of all communications to or from the FDA relating to the Products and/or the manufacture thereof. After such transfer, Buyer will assume all responsibility for the Regulatory Materials, at Buyer's sole cost and expense.

(d) On or within ten (10) calendar days after the Closing Date, Seller will transfer to Buyer any and all documented Program Know-How that is part of the Transferred Intellectual Property and in its possession and control, and Seller will, to the extent any such Program Know-How exists in a form suitable for electronic transfer, make any transfer electronically. To the extent any such Program Know-How is held by any Third Party vendors as of the Closing Date, Seller shall provide Buyer with an introduction to such Third Party vendor and deliver to such vendor written authorization to transfer or provide access to such Program Know-How to Buyer.

(e) If requested in writing by Buyer, on or promptly after the Closing, Seller shall ship the Inventory to Buyer at such address as Buyer specifies in writing to Seller at Closing at Buyer's expense. On or promptly after Closing, Seller shall also deliver to Buyer, at such address as Buyer specifies in writing to Seller at Closing, any electronic files and original documents (or, if no originals exist and Seller or its Affiliates only have copies thereof, such copies) that, in each case, are within the Transferred Assets at Buyer's expense (provided that Seller shall have the right to retain copies thereof in order to monitor its ongoing legal obligations).

Section 5.11 Transition Services Agreement. At the Closing Date, Buyer and Seller will enter into the Transition Services Agreement, pursuant to which, until the termination of the Transition Services Agreement in accordance with its terms (the "TSA Termination Date") (the term of the Transition Services Agreement, the "TSA Term"), among other things, Seller will provide certain services, including manufacturing technology transfer, supply chain, regulatory and medical affairs services, to Buyer, and Seller will distribute, on behalf of Buyer (which will book all sales), the Inventory (or some portion thereof) through Seller's existing distribution contracts using Seller's name and Seller's NDC number.

Section 5.12 Adverse Event Reports and Customer Complaints. After the Closing, Seller shall comply with applicable Law with respect to all adverse event information or material customer complaints brought to the attention of Seller in respect of the Product or the safety or efficacy of the Product and for a period of one (1) year after the latest expiration date, submit to Buyer all adverse event information or material customer complaints brought to the attention of Seller in respect of the Product or the safety or efficacy of the Product, to enable Buyer to perform all required regulatory actions with respect thereto.

Section 5.13 Initial Supply to Aguettant. After the Closing, Seller will be responsible for the payment of all contract manufacturers for, and will have the right to receive all payments from Aguettant in connection with, the supply of the first [***] units of Bulk Product (as defined in the Aguettant Agreements, as amended as of the Closing) to be delivered to Aguettant in 2023, as specified in Section 6.1 of the Amended and Restated Supply Agreement between Seller and Aguettant, effective on the Closing Date. Specifically, Buyer, with Seller's assistance, will procure from and manage the respective contract manufacturers required to produce such [***] units of Bulk Product, and Seller shall reimburse Buyer for the amounts paid to the contract manufacturers for supply of the specific materials purchased. Buyer will remit to Seller the payment received from Aguettant for such [***] units of Bulk Product as specified in Section 6.1 of such Amended and Restated Supply Agreement within five Business Days after receipt thereof. After such [***] units of Bulk Product are manufactured, Seller has no further responsibility, financial or otherwise, for Bulk Product or any other product to be delivered to Aguettant under such Amended and Restated Supply Agreement.

Section 5.14 Wrong Pockets. If Seller or its Affiliates receive any payment after the Closing relating to the sale of the Product or rendering of services by Buyer after the Closing, Seller will promptly notify Buyer of such receipt and will promptly remit, but in no event more than fifteen (15) days after the receipt thereof, or will cause such Affiliate to promptly remit, but in no event more than fifteen (15) days after the receipt thereof, such payment to Buyer without depositing such payment in an account of Seller or such Affiliate, unless in error, and Seller, or such Affiliate, shall not be entitled to offset such payment against any payments due Seller, unless otherwise agreed to in writing by Buyer. If Seller or Affiliate receives an invoice or request for payment relating to the sale of the Product after the Closing, or with respect to any Assumed Liability after the Closing, Seller will promptly notify Buyer of such request or invoice and forward the invoice and all other appropriate information to Buyer for payment. In the event Buyer or its Affiliates receive any payment after the Closing relating to an Excluded Asset, Buyer will promptly notify Seller of such receipt and will promptly remit, but in no event more than fifteen (15) days after the receipt thereof, or will cause such Affiliate to promptly remit, but in no event more than fifteen (15) days after the receipt thereof, such payment to Seller without depositing such payment in an account of Buyer, or such Affiliate, unless in error, and Buyer, or such Affiliate, shall not be entitled to offset such payment against any payments due Buyer from Seller and its Affiliates, unless otherwise agreed to in writing by Seller.

Section 5.15 Retention of Records. Each party agrees to cooperate with and to grant to each other party and their respective officers, employees, attorneys, accountants, representatives and agents, during normal business hours and upon reasonable request and upon reasonable advance notice, reasonable access to the other party's management personnel and such other information and records exclusively relating to the Product or the Transferred Assets in their possession or control after the Closing and to permit copying or, where reasonably necessary, to furnish original documents exclusively relating to the Product or the Transferred Assets for the purposes of: (i) any investigation, inspection or audit being conducted by the FDA, or any Government Entity in coordination therewith, involving the Product or the Transferred Assets; or (ii) to comply with any applicable Law in regards to the Product; provided, however, that Seller shall not be required to provide in duplication any Other Seller Materials or Regulatory Materials acquired by Buyer at Closing; provided that each party shall (A) treat as confidential and shall safeguard any and all nonpublic, confidential or proprietary information received from the other party under this Section 5.15, in each case by using the same degree of care as it uses to protect proprietary or confidential information of its own, but no less than a reasonable standard of care, to prevent the unauthorized use, dissemination or disclosure of such nonpublic, confidential or proprietary information, and (B) comply with the last two sentences of Section 5.9(b), *mutatis mutandis*, in the event of disclosure of such nonpublic, confidential or proprietary information by such party compelled by judicial or administrative process. Each party shall use its commercially reasonable best efforts to ensure that its access to and requests for records and documents pursuant to this Section 5.15 are conducted so as not to interfere with the normal and ordinary operation of the other party's business. Each party shall retain all information and records of the nature described above for such period of time as is required by applicable Law.

Section 5.16 Restrictive Covenants.

(a) Seller agrees and acknowledges that Seller is familiar with the trade secrets and other information of a confidential or proprietary nature regarding the Program and that will be included in the Transferred Assets that are sold and transferred to Buyer at the Closing. Seller also agrees and acknowledges that Buyer would be irreparably damaged if Seller or any of its Affiliates were to provide services to, or otherwise participate in the operations or business of, any Person competing with Buyer following the Closing in connection with the Development and/or commercialization of a single-dose pharmaceutical product that includes a fentanyl derivative as the sole active ingredient for management of acute pain in a medically supervised setting ("Competing Product"), if such services or participation are directed to such Competing Product, and that any such competition may result in a significant loss of goodwill in respect of Buyer and the Transferred Assets. Seller further agrees and acknowledges that the covenants and agreements set forth in this Section 5.16 were a material inducement to Buyer to enter into this Agreement and to perform its obligations hereunder, and that Buyer and its Affiliates would not obtain the benefit of the bargain set forth in this Agreement as specifically negotiated by the parties hereto if Seller or its Affiliates breached any of the provisions of this Section 5.16. Therefore, in further consideration of the amounts to be paid under this Agreement and the other covenants and promises contained therein for the Transferred Assets and without limiting any other obligation pursuant to this Agreement, Seller shall not, directly or indirectly, either for Seller or its controlled Affiliates or for or through any other Person (other than on behalf of Buyer as contemplated by this Agreement or any Ancillary Agreement, as applicable), during the period beginning on the Closing Date and ending on [***] (the "Restricted Period"):

(i) Non-Competition. As an advisor, agent, consultant, director, equityholder, manager, co-partner or in any other individual or representative capacity, own, operate, manage, control, engage in, invest in, or participate in any manner in, act as a consultant or advisor to, render services for (alone or in association with any Person), any venture or enterprise that [***]. Nothing contained herein shall be construed to prevent Seller from owning an equity interest in Buyer or its Affiliates, or purchasing or otherwise acquiring up to (but not more than) [***] of any class of the securities of any Person if such securities are listed on any national or regional securities exchange or have been registered under Section 12(g) of the Securities Exchange Act of 1934, as amended, and Seller does not participate in the management of such Person.

(ii) Non-Disparagement. Make any material public (including, for the avoidance of doubt, to any employees, advisors, independent contractors, customers, clients, vendors, suppliers, licensors, licensees, lessors or other business relations of Buyer) defamatory or maliciously false statements or communications about the Program or the Products.

(iii) For the avoidance of doubt, following the Closing, the performance of any duties under this Agreement or any Ancillary Agreement, in itself, shall not be considered a breach of this Section 5.16.

(b) Additional Acknowledgments. Seller acknowledges that the provisions of this Section 5.16 are in consideration of the direct and indirect benefits to be derived by Seller under this Agreement. Seller agrees and acknowledges that the potential harm to Buyer of the non-enforcement of any provision of this Section 5.16 outweighs any potential harm to the Seller or its controlled Affiliates of its enforcement by injunction or otherwise. Seller acknowledges that Seller has carefully read this Section 5.16 and consulted with legal counsel of Seller's choosing regarding its contents, has given careful consideration to the restraints imposed upon Seller by this Section 5.16 and is in full accord as to their necessity for the reasonable and proper protection of confidential and proprietary information to be acquired by Buyer as a result of the consummation of the transactions contemplated by this Agreement and the Ancillary Agreements. Seller acknowledges that it is represented by Cooley LLP in negotiating the terms of this Agreement, which includes terms designating the venue in which a controversy arising hereunder may be adjudicated and the choice of law to be applied hereto, and that Cooley LLP has reviewed this Agreement. Seller expressly acknowledges and agrees that each and every restraint imposed by this Section 5.16 is reasonable with respect to subject matter, time period and geographical area. Because the protection of the Confidential Information and the other legitimate business interests acquired by Buyer pursuant to the Agreement, Buyer and its respective Affiliates require that Seller and its Affiliates comply with the covenants in this Section 5.16 for the full Restricted Period, Seller agrees that the Restricted Period will be extended for a period of time equal to the time period that Seller or its Affiliates breached any of the covenants in this Section 5.16, such that Seller and its controlled Affiliates are ultimately foreclosed from engaging in the activities set forth in this Section 5.16, for a time period equal to the Restricted Period.

(c) Enforcement. If, at the time of enforcement of this Section 5.16, a court of competent jurisdiction holds that the restrictions stated herein are unreasonable under circumstances then existing, the parties hereto agree that the maximum duration, scope or geographical area reasonable under such circumstances shall be substituted for the stated period, scope or area and that such court shall be allowed to revise the restrictions contained herein to cover the maximum duration, scope and area permitted by law, and such determination will not affect the validity or enforceability of the balance hereof, and such balance will remain in full force and effect. Seller acknowledges that a breach or threatened breach of any of the terms set forth in this Agreement by it or its Affiliates may result in an irreparable and continuing harm to Buyer and its Affiliates for which there may be no adequate remedy at law. Buyer or its Affiliates will be entitled to seek injunctive and other equitable relief in order to prevent a breach of this Agreement or to enforce its provisions, in addition to any other remedies available to Buyer or its Affiliates. Seller agrees that neither it nor its Affiliates will assert in any such action that an adequate remedy exists at law. Nothing contained herein will be construed as prohibiting Buyer or its Affiliates from pursuing any other remedies available to it for such breach or threatened breach, including the recovery of any damages which it is able to prove and each of Buyer and its Affiliates will be entitled to its costs of enforcement of the provisions of this Agreement.

Section 5.17 Insurance. Until August 31, 2025, Seller shell maintain products liability insurance covering subject matter and in amounts consistent with Seller's current policies.

Section 5.18 Equipment Reimbursement. Buyer will reimburse Seller for all costs reasonably incurred by Seller for disassembling and crating the automated packaging line [***], up to but not to exceed [***]. Seller will invoice Buyer for such costs, and Buyer will pay such invoice within thirty (30) days after receipt thereof. Seller will arrange for, and be responsible for, transportation of the crated automated packaging line equipment from the Catalent Pharma Solutions, LLC location to a location desired by Buyer.

ARTICLE VI
CONDITIONS TO CLOSING

Section 6.1 Conditions to the Obligations of Buyer. The obligation of Buyer to effect the Closing is subject to the satisfaction (or waiver by Buyer) prior to the Closing of the following conditions:

(a) Representations and Warranties. No event or events shall have occurred since the effective date of this Agreement which, individually or in the aggregate, has had a Material Adverse Effect. The representations and warranties of Seller set forth in Article III shall be true and correct on and as of the Effective Date and as of the Closing, as though made on and as of the Closing (except to the extent expressly made as of an earlier date, in which case as of the earlier date).

(b) Covenants. Seller shall have performed and complied with all of its covenants contained in Article V at or before the Closing (to the extent that such covenants require performance by Seller at or before the Closing).

(c) Certificate. Buyer shall have received a certificate, signed by a duly authorized officer of Seller and dated the Closing Date, to the effect that the conditions set forth in Sections 6.1(a) and 6.1(b) have been satisfied.

(d) Deliverables. Seller shall have furnished to Buyer all deliverables set forth in Section 2.10.

(e) Marketing Agreement. The Marketing Agreement shall be in full force and effect at the Closing.

(f) Transition Services Agreement. The Transition Services Agreement shall be in full force and effect at the Closing.

(g) IP Agreement. The IP Agreement shall be in full force and effect at the Closing.

(h) Aguettant Amendments. The Aguettant Amendments shall be in full force and effect at the Closing, and Buyer shall have obtained consent to assign the Aguettant Agreements, including the Aguettant Amendments.

(i) No Prohibition. No temporary restraining Order, preliminary or permanent injunction or other Order preventing the consummation of the Transaction and/or the transactions contemplated by the Ancillary Agreements shall have been issued by any court of competent jurisdiction and remain in effect.

Section 6.2 Conditions to the Obligations of Seller. The obligation of Seller to effect the Closing is subject to the satisfaction (or waiver by Seller) prior to the Closing of the following conditions:

(a) Representations and Warranties. The representations and warranties of Buyer shall be true and correct on and as of the Effective Date and as of the Closing, as though made on and as of the Closing (except to the extent expressly made as of an earlier date, in which case as of the earlier date).

(b) Covenants. Buyer shall have performed and complied with all of its covenants contained in Article V at or before the Closing (to the extent that such covenants require performance by Buyer at or before the Closing).

(c) Certificate. Seller shall have received a certificate, signed by a duly authorized officer of Buyer and dated the Closing Date, to the effect that the conditions set forth in Sections 6.2(a) and 6.2(b) have been satisfied.

(d) Deliverables. Buyer shall have furnished to Seller all deliverables set forth in Section 2.9.

(e) No Prohibition. No temporary restraining Order, preliminary or permanent injunction or other Order preventing the consummation of the Transaction and/or the transactions contemplated by the Ancillary Agreements shall have been issued by any court of competent jurisdiction and remain in effect.

ARTICLE VII
SURVIVAL

Section 7.1 Survival.

(a) All representations and warranties contained in this Agreement and all claims with respect thereto shall terminate eighteen (18) months after the Closing. Notwithstanding the foregoing, the representations and warranties contained in Section 3.1 (Organization and Qualification), Section 3.2 (Corporate Authorization), Section 3.3 (Title to Transferred Assets), Section 3.7 (Intellectual Property), Section 3.9 (Taxes), and Section 3.21 (Brokers), Section 4.1 (Organization and Qualification), Section 4.2 (Corporate Authorization), and Section 4.5 (No Brokers) (the "Fundamental Representations") shall survive until the later of (i) the fourth anniversary of the Closing, and (ii) 30 days following the expiration of the applicable statute of limitations. Notwithstanding the foregoing, any Claims asserted in writing by notice from the Indemnified Person (as defined in Section 8.3(a)) seeking indemnification under this Agreement to an Indemnifying Person (as defined in Section 8.3(a)) prior to the expiration date of the applicable survival period shall not thereafter be barred by the expiration of the relevant representation or warranty and such claims shall survive until finally resolved.

(b) The respective agreements and covenants of the parties contained in this Agreement to the extent to be performed prior to Closing will survive the execution and delivery hereof and the Closing Date for a period of one year. The respective agreements and covenants of the parties contained in this Agreement to the extent to be performed at or after Closing will survive the execution and delivery hereof and the Closing Date, in accordance with their terms or if no end date is provided, forever.

(c) For purposes of clarity, the survival periods set forth in this Section 7.1 shall not apply to Fraud.

ARTICLE VIII
INDEMNIFICATION

Section 8.1 Indemnification by Seller.

(a) Subject to the terms and conditions of this Article VIII, from and after the Closing, Seller shall indemnify and hold harmless Buyer, its Affiliates and their respective officers, directors, managers, shareholders, members, employees, agents, Affiliates, successors and permitted assigns ("Buyer Indemnified Persons"), against and from, and will reimburse any Buyer Indemnified Persons for, any and all Damages which are suffered, paid, sustained or incurred, directly or indirectly, by any of the foregoing Buyer Indemnified Persons (regardless of whether or not such Damages relate to any Third Party Claim) and which arise from or as a result of: (i) any inaccuracy in or breach of any representation or warranty of Seller set forth in this Agreement or any Ancillary Agreement; (ii) any breach of any covenant, agreement or obligation to be performed under this Agreement by Seller; (iii) the Excluded Liabilities, including any failure to satisfy, perform, or discharge an Excluded Liability; (iv) any Excluded Asset, and any Liabilities related thereto; (v) any claim by a Third Party based upon, arising out of, with respect to or resulting from the Transferred Assets, the Product, operations, properties, assets or obligations of the Seller or its Affiliates conducted, existing or arising on or prior to the Closing Date; and (vi) each of the matters set forth in Schedule 8.1(a)(vi).

(b) No amount shall be payable and there shall be no liability for Seller for indemnification under Section 8.1(a)(i), unless the amount of Damages incurred by a Buyer Indemnified Person exceeds One Hundred Thousand Dollars ($100,000) in the aggregate (the "Threshold Amount"), after which point the Threshold Amount shall be recoverable along with all other amounts for Damages by a Buyer Indemnified Person.

(c) Seller's maximum liability under this Agreement for Damages incurred by Buyer Indemnified Persons shall not exceed two hundred fifty thousand ($250,000) ***plus*** the total amounts received by Seller from Buyer under Section 2.5, Section 2.11, Section 2.12 and Section 2.13, and under the Marketing Agreement (the "Cap").

(d) Notwithstanding anything contained herein to the contrary, for purposes of determining whether there has been a breach and the amount of Damages that are the subject matter of a claim for indemnification or reimbursement hereunder, each representation and warranty in this Agreement and the Schedules and exhibits hereto shall be read without regard and without giving effect to the terms "material" or "Material Adverse Effect" or similar phrases contained in such representation or warranty (as if such words were deleted from such representation or warranty).

(e) Notwithstanding anything to the contrary contained herein, the limitations set forth in this Section 8.1 shall not apply to Damages arising out of or resulting from (I) Fraud, (II) the items set forth in Section 8.1(a)(ii), 8.1(a)(iii), 8.1(a)(iv), 8.1(a)(v), and 8.1(a)(vi), or (III) a breach of the Fundamental Representations.

Section 8.2 Indemnification by Buyer.

(a) Subject to the terms and conditions of this Article VIII, from and after the Closing, Buyer shall indemnify and hold harmless Seller, its Affiliates and their respective officers, directors, managers, employees, agents, successors and permitted assigns ("Seller Indemnified Persons"), against and from any and all Damages which are suffered, sustained or incurred by any of the foregoing Seller Indemnified Persons (regardless of whether or not such Damages relate to any Third Party Claim) and which arise from or as a result of: (i) any inaccuracy in or breach of any representation or warranty of Buyer set forth in this Agreement or any Ancillary Agreement; (ii) any breach of any covenant, agreement or obligation to be performed under this Agreement by Buyer; (iii) any failure to satisfy, perform or discharge any Assumed Liabilities; or (iv) except for Excluded Liabilities, any Liability arising out of the ownership or operation of the Transferred Assets or the Product after the Closing Date, including any Liability arising out of the Development, manufacture, commercialization or other exploitation of any Product.

(b) No amount shall be payable and there shall be no liability for Buyer for indemnification under Section 8.2(a)(i), unless the amount of Damages incurred by a Seller Indemnified Person exceeds the Threshold Amount, after which point the Threshold Amount shall be recoverable along with all other amounts for Damages by a Seller Indemnified Person.

(c) Buyer's maximum liability under this Agreement for Damages incurred by Seller Indemnified Persons shall not exceed the Cap.

(d) Notwithstanding anything to the contrary contained herein, the limitations set forth in this Section 8.2 shall not apply to Damages arising out of or resulting from (I) Fraud, (II) the items set forth in Section 8.2(a)(ii), 8.2(a)(iii), and 8.2(a)(iv), (III) a breach of the Fundamental Representations, or (IV) any failure of Buyer to pay the amount payable for the Inventory or the Payments to Seller.

Section 8.3 Indemnification Procedure.

(a) If a claim for indemnification under this Article VIII does not involve a Third Party Claim (as defined in Section 8.3(b)) (a "Direct Claim"), the Person entitled to indemnification or reimbursement pursuant to this Article VIII (an "Indemnified Person") shall notify the party obligated to indemnify such Indemnified Person (such notified party, the "Indemnifying Person") in writing, describing in reasonable detail the facts constituting the basis for such Direct Claim, the specific basis for the claim for indemnification under this Article VIII, and the amount, to the extent known, of the Direct Claim asserted (such notice, a "Direct Claim Notice"). The Indemnifying Person will have a period of thirty (30) days within which to respond in writing to such Direct Claim. If the Indemnifying Person does not so respond within such thirty (30) day period, the Indemnifying Person will be deemed to have accepted such claim, in which event the Indemnified Person shall be free to pursue such remedies as may be available to the Indemnified Person on the terms and subject to the provisions of this Agreement. If an objection is timely interposed by the Indemnifying Person, then the Indemnified Person and the Indemnifying Person may discuss such objection for a period of thirty (30) days from the date the Indemnified Person receives such objection (such period, or such longer period as agreed in writing by the parties, is hereinafter referred to as the "Discussion Period"). If the Direct Claim that is the subject of the Direct Claim Notice has not been resolved prior to the expiration of the Discussion Period, the Indemnifying Person and the Indemnified Person may submit the dispute for resolution to a court of competent jurisdiction in accordance with Section 10.9 hereof and each will be free to pursue such remedies as may be available to them on the terms and subject to the provisions of this Agreement. Notwithstanding the foregoing, no delay on the part of the Indemnified Person in notifying the Indemnifying Person shall relieve the Indemnifying Person from any obligation hereunder.

(b) If an Indemnified Person is entitled to indemnification under this Article VIII because a claim is filed or instituted by any Third Party, including any Government Entity ("Third Party Claim" and together with a Direct Claim, "Claims"), as soon as reasonably practicable after obtaining knowledge thereof, such Indemnified Person shall notify the Indemnifying Person in writing, and in reasonable detail, of such Third Party Claim (the "Claim Notice"). Any failure on the part of an Indemnified Person to so notify the Indemnifying Person shall not limit any of the obligations of the Indemnifying Person under Article VIII except to the extent such failure actually and materially prejudices the defense of such Third Party Claim. In the event of the initiation of any Third Party Claim against the Indemnified Person, the Indemnifying Person shall have the sole and absolute right after the receipt of notice, at the Indemnifying Person's option and at the Indemnifying Person's own expense, to be represented by counsel reasonably satisfactory to the Indemnified Person and, subject to the last sentence of this Section 8.2(b), to control, defend against, negotiate, settle or otherwise deal with any Proceeding, claim, or demand which relates to any Damages indemnified against hereunder, so long as (i) within ten (10) days after receipt of the Claim Notice, the Indemnifying Person notifies the Indemnified Person in writing that the Indemnifying Person will, subject to the applicable limitations of this Article VIII, indemnify the Indemnified Person from and against any Damages the Indemnified Person may incur relating to or arising out of the Third Party Claim, (ii) the Indemnifying Person provides the Indemnified Person with evidence reasonably acceptable to the Indemnified Person that the Indemnifying Person will have the financial resources to defend against the Third Party Claim and fulfill its indemnification obligations hereunder, (iii) the Third Party Claim involves only money damages and does not seek an injunction or other equitable relief, (iv) the Indemnified Person does not have additional defenses to the Third Party Claim not available to the Indemnifying Person, (v) the Indemnifying Person conducts the defense of the Third Party Claim actively and diligently, and (vi) the Indemnifying Person keeps the Indemnified Person apprised of all developments, including settlement offers, with respect to the Third Party Claim and permits the Indemnified Person to participate in the defense of the Third Party Claim. If any condition in this Section 8.3(b) is or becomes unsatisfied, (A) the Indemnified Person may defend against, and consent to the entry of any judgment or enter into any settlement with respect to, the Third Party Claim in any manner it may deem appropriate (and the Indemnified Person need not consult with, or obtain any consent from, the Indemnifying Person in connection therewith), (B) the Indemnifying Person will reimburse the Indemnified Person promptly and periodically (but no less often than monthly) for the reasonable costs of defending against the Third Party Claim, including reasonable attorneys' fees and reasonable expenses, and (C) the Indemnifying Person will remain responsible for any Damages the Indemnified Person may incur relating to or arising out of the Third Party Claim to the fullest extent provided in this Article VIII. The parties hereto agree to cooperate fully with each other in connection with the defense, negotiation or settlement of any such Proceeding, claim or demand. To the extent that the Indemnifying Person elects not to defend such Proceeding, claim or demand, and the Indemnified Person defends against or otherwise deals with any such Proceeding, claim or demand, the Indemnified Person may retain counsel and control the defense of such Proceeding, subject to the last sentence of this Section 8.3(b). Neither the Indemnifying Person, on the one hand, nor the Indemnified Person, on the other hand, may settle any such Proceeding, which settlement obligates the other party to pay money, to perform obligations or to admit liability without the consent of the other party, such consent not to be unreasonably withheld, conditioned or delayed. Section 5.4(b), not this Section 8.3(b), shall apply to Tax Claims.

Section 8.4 Right of Setoff. Buyer may, but is not obligated to, set off any amount to which (a) Buyer and Seller agree in writing that Buyer is entitled under this Article VIII, (b) Buyer has been awarded under this Article VIII by a court of competent jurisdiction or through arbitration or mediation, or (c) Buyer is entitled resulting from a definitive Third Party Claim if Seller has controlled the defense of such Third Party Claim or consented to the settlement thereof, against any amount otherwise payable by Buyer or its Affiliates to Seller; provided, however, except in the case of a mediation or arbitration, if Seller is ultimately determined to not be entitled to such Damages by a court of competent jurisdiction, then Buyer must pay Seller back the amount set off under this Section. The exercise of such set-off right in good faith will not constitute a breach or event of default under any Contract relating to any amount against which the set-off is applied. Neither the exercise of nor the failure to exercise such right of set-off will constitute an election of remedies or limit the Buyer in any manner in the enforcement of any other remedies that may be available to it.

Section 8.5 Mitigation. Buyer and Seller shall use their commercially reasonable efforts to mitigate, reduce or eliminate any Damages to which it may be entitled; provided, that such mitigation obligations shall not require a Buyer Indemnified Person, Seller Indemnified Person or any of their respective Affiliates to make claims against customers or suppliers if, in Buyer's reasonable view, such claim would harm the Program, the Product, the Transferred Assets, or the Assumed Liabilities. Failure to comply with this Section 8.5 will not relieve a party of its indemnification obligations hereunder to the extent that the Indemnifying Person is not materially harmed.

Section 8.6 Survival Periods. The parties acknowledge that the time periods set forth in Article VII for the survival and assertion of Claims under this Agreement are the result of arms'-length negotiation between the parties and that they intend for the time periods to be enforced as agreed by the parties.

Section 8.7 Exclusive Remedy. The remedies provided by this Article VIII shall be the sole and exclusive monetary remedies of the Buyer Indemnified Persons and Seller Indemnified Persons for the recovery of Damages resulting from, relating to or arising out of this Agreement or the transactions contemplated hereby. Notwithstanding the foregoing or anything else in this Agreement to the contrary, nothing herein shall limit any Buyer Indemnified Person's right or ability to make, pursue, enforce or prosecute a claim for (i) equitable relief pursuant to Section 10.15, (ii) Fraud, (iii) breach or violation of Section 5.16, or (iv) breach or violation of the Ancillary Agreements (including but not limited to the Transition Services Agreement).

Section 8.8 Tax Treatment of Indemnification Payments. For all purposes hereunder, any indemnification payments made pursuant to this Article VIII will be treated as an adjustment to the payment for Inventory under Section 2.5, except as otherwise required pursuant to a "determination" within the meaning of Section 1313(a) of the Code (or any analogous or similar provision of state, local, or foreign Law).

ARTICLE IX
TERMINATION

Section 9.1 Termination. This Agreement may be terminated at any time prior to the Closing:

(a) by Buyer by written notice to Seller if Buyer is not then in material breach of any provision of this Agreement and there has been a material breach, inaccuracy in or failure to perform any representation, warranty, covenant or agreement made by Seller pursuant to this Agreement that would give rise to the failure of any of the conditions specified in Section 6.1(a) or Section 6.1(b) and such breach, inaccuracy or failure has not been cured by Seller within thirty (30) calendar days of Seller's receipt of written notice of such breach from Buyer;

(b) by Seller by written notice to Buyer if Seller is not then in material breach of any provision of this Agreement and there has been a material breach, inaccuracy in or failure to perform any representation, warranty, covenant or agreement made by Buyer pursuant to this Agreement that would give rise to the failure of any of the conditions specified in Section 6.2(a) or Section 6.2(b) and such breach, inaccuracy or failure has not been cured by Buyer within 30 calendar days of Buyer's receipt of written notice of such breach from Seller;

(c) by Buyer or Seller if the Transaction has not been consummated by April 30, 2023; provided, however, that a party shall not be permitted to terminate this Agreement pursuant to this Section 9.1(c) if the failure to consummate the Transaction within such period is attributable to a material breach by such party of any of its representations, warranties, covenants or agreements contained in this Agreement;

(d) by Buyer or Seller in the event that a court of competent jurisdiction shall have issued a final and nonappealable Order having the effect of permanently restraining, enjoining or otherwise prohibiting the Transaction; provided, however, that a party shall not be permitted to terminate this Agreement pursuant to this Section 9.1(d) if such party did not use reasonable best efforts to have such Order vacated prior to its becoming final and nonappealable; or

(e) by mutual written consent of Buyer and Seller.

Section 9.2 Effect of Termination. In the event of the termination of this Agreement in accordance with Section 9.1, this Agreement shall thereafter become void and have no effect, and no party hereto shall have any liability to the other party hereto or their respective Affiliates, or their respective directors, officers or employees, except for the obligations of the parties hereto contained in this Article IX and in Article X (and any related definitional provisions set forth in Article I), and except that nothing in this Article IX shall relieve any party from liability for any willful and material breach of this Agreement that arose prior to such termination.

ARTICLE X
MISCELLANEOUS

Section 10.1 Notices. All notices, requests, consents, claims, demands, waivers and other communications hereunder shall be in writing and shall be deemed to have been given (a) when delivered by hand (with proof of delivery), (b) when received by the addressee if sent by a nationally recognized overnight courier (receipt requested), (c) if sent by email, on the date sent by e-mail if sent during normal business hours of the recipient, and on the next Business Day if sent after normal business hours of the recipient, or (d) when received by the addressee if sent by certified or registered mail, return receipt requested, postage prepaid. Such communications must be sent to the respective parties at the following addresses (or at such other address for a party as shall be specified in a notice given in accordance with this Section 10.1):

To Buyer:

c/o Acella Holdings, LLC
1880 McFarland Parkway, Suite 110
Alpharetta, Georgia 30005
[***]

With a copy to, provided that such copy shall not constitute legal notice to Buyer:

Nelson Mullins Riley & Scarborough LLP
Atlantic Station
201 17th Street NW, Suite 1700
Atlanta, Georgia 30363
Attention: William J. Ching
Email: billy.ching@nelsonmullins.com

To Seller:

AcelRx Pharmaceuticals, Inc.
25821 Industrial Blvd., Suite 400
Hayward, California 94545
[***]

With a copy to, provided that such copy shall not constitute legal notice to Seller:

AcelRx Pharmaceuticals, Inc.
25821 Industrial Blvd., Suite 400
Hayward, California 94545
[***]

Section 10.2 Amendment; Waiver; Remedies Cumulative. Any provision of this Agreement may be amended or waived if, and only if such amendment or waiver is in writing and signed, in the case of an amendment, by Buyer and Seller, or in the case of a waiver, by the party against whom the waiver is to be effective. No notice or demand on one party will be deemed to be a waiver of any obligation of that party or the right of the party giving a notice or demand to take further action without notice or demand as provided in this Agreement. No waiver that may be given by a party will be applicable except for the specific instance for which it is given. No failure or delay by any party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege.

Section 10.3 No Benefit to Third Parties. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors, legal representatives and permitted assigns. Nothing in this Agreement, express or implied, is intended to confer upon any Person, other than Buyer, Seller, the Buyer Indemnified Persons, the Seller Indemnified Persons and their respective successors, legal Representatives and permitted assigns, any legal or equitable right, remedy or claim under or by reason of this Agreement.

Section 10.4 Entire Agreement. This Agreement (including all Schedules hereto) contains the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral or written, with respect to such matters, except for the Confidentiality Agreement, which shall remain in full force and effect.

Section 10.5 Intentionally Omitted.

Section 10.6 Public Disclosure. Following the Effective Date, neither party shall issue any press release or make (or cause to be made) any other public disclosures concerning the existence or contents of this Agreement or any Ancillary Agreement without the prior written consent of the other party. Notwithstanding the foregoing, each party may without such written consent (a) make disclosures it reasonably believes are required by Law (including any regulation of any applicable stock or securities exchange or otherwise), in which case such disclosing party shall allow the other party reasonable prior notice and time to comment on such release or announcement in advance of such issuance or (b) make disclosures so long as such statements are consistent with previous press releases, public disclosures or public statements made jointly by the parties (or individually, if approved by the other party). The parties will consult with each other on the provisions of this Agreement to be redacted in any public filings made by a party as required by applicable Law; provided that each party shall have the right to make any such filing or recording of license grant as it reasonably determines necessary under applicable Law.

Section 10.7 Expenses. Except as otherwise expressly provided in this Agreement, whether or not the transactions contemplated by this Agreement are consummated, all costs and expenses incurred in connection with the preparation, negotiation, execution and performance of this Agreement and the Transaction (including legal fees and expenses) shall be borne by the party incurring such costs and expenses.

Section 10.8 Bulk Sales. Seller and Buyer agree to waive compliance with Article 6 of the Uniform Commercial Code as adopted in each of the jurisdictions in which any of the Transferred Assets are located to the extent that such Article is applicable to the transactions contemplated hereby.

Section 10.9 Governing Law. THE AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF DELAWARE WITHOUT REGARD TO PRINCIPLES OF CONFLICTS OF LAW THAT WOULD REQUIRE THE APPLICATION OF ANY OTHER LAW.

Section 10.10 Intentionally Omitted.

Section 10.11 Assignment. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be transferred, conveyed or assigned, in whole or in part, by operation of Law or otherwise, by either party without the prior written consent of the other party, except that: (i) Buyer may assign, in its sole discretion, any or all of its rights, interests and obligations under this Agreement (a) to any of its Affiliates, but no such assignment shall relieve Buyer of any of its obligations hereunder, or (b) in connection with the transfer or sale of all or substantially all of Buyer's business related to the Transferred Assets to a Third Party, whether by merger, sale of stock, sale of assets or otherwise; provided that such Third Party expressly undertakes, for the benefit of Seller, to assume and perform all assigned obligations in accordance with their terms; and (ii) Seller may, in its sole discretion, (a) assign any or all of its rights, interests and obligations under this Agreement to any of its Affiliates, but no such assignment shall relieve Seller of any of its obligations hereunder, or (b) assign, convey, transfer or dispose of, in any form or manner, its rights to receive the Payments and all related rights under Section 2.11 through Section 2.20 or pursuant to the Marketing Agreement. Any assignment not in accordance with the foregoing shall be void. Subject to the preceding sentences, this Agreement will be binding upon, inure to the benefit of and be enforceable by, the parties and their respective permitted successors and assigns. Notwithstanding the foregoing, either party may also grant a security interest in and collaterally assign its rights under this Agreement to one or more of such party's debt financing sources without the prior consent of the other party hereto; provided, that no such assignment shall relieve the assigning party of any of its obligations hereunder; and provided further, that no such grant or assignment shall be effective until immediately after the Closing. Nothing in this Section shall prohibit Buyer from licensing any of the Transferred Assets, and any license by Buyer of any of the Transferred Assets to Seller or a Third Party shall not be considered a violation of this Section; provided that Buyer shall remain liable for all of its obligations hereunder that are related to or conducted by a licensee (including payments related to Product sales by a licensee).

Section 10.12 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which shall constitute one and the same Agreement. The exchange of copies of this Agreement and of signature pages by facsimile transmission or other electronic means shall constitute effective execution and delivery of this Agreement as to the parties and may be used in lieu of the original Agreement for all purposes. Signatures of the parties transmitted by facsimile or email shall be deemed to be their original signatures for all purposes. No party may raise (a) the use of a facsimile or email transmission to deliver a signature or (b) the fact that any signature, agreement or instrument was signed and subsequently transmitted or communicated through the use of a facsimile or email transmission as a defense to the formation or enforceability of a contract, and each party forever waives any such defense.

Section 10.13 Headings. The heading references herein and the table of contents hereof are for convenience purposes only, and shall not be deemed to limit or affect any of the provisions hereof.

Section 10.14 Severability. The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof. If any provision of this Agreement, or the application thereof to any Person or any circumstance, is invalid or unenforceable, (a) a suitable and equitable provision shall be substituted therefore in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid or unenforceable provision and (b) the remainder of this Agreement and the application of such provision to other Persons or circumstances shall not be affected by such invalidity or unenforceability, nor shall such invalidity or unenforceability affect the validity or enforceability of such provision, or the application thereof, in any other jurisdiction.

Section 10.15 Remedies; Specific Performance. The parties agree that irreparable damage may occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached or threatened to be breached and that an award of money damages may be inadequate in such event. Accordingly, except as otherwise expressly provided in Article VIII, each of the parties hereto agrees that, in addition to any other remedy to which such party may be entitled at law or in equity, they each shall be entitled to an injunction or injunctions or other equitable relief to prevent breaches of the provisions of this Agreement and to enforce specifically this Agreement, the terms and provisions hereof, without the necessity of posting a bond or other security or proving actual damages and without regard to the adequacy of any remedy at law. A party's right to specific performance shall be in addition to all other legal or equitable remedies available to such party. The prevailing party in any Proceeding to enforce any provision of this Agreement shall be entitled to recover from the losing party (or parties) all reasonable attorneys' fees and expenses.

Section 10.16 Attorneys' Fees. If any action at law or in equity (including, arbitration) is necessary to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to reasonable attorneys' fees, costs and necessary disbursements in addition to any other relief to which such party may be entitled.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties have executed or caused this Agreement to be executed as of the date first written above.

SELLER:

AcelRx Pharmaceuticals, Inc.

By: /s/ Vincent J. Angotti
Name: Vincent J. Angotti
Title: Chief Executive Officer

BUYER:

Vertical Pharmaceuticals, LLC

By: /s/ Harold J. Deas
Name: Harold J. Deas, Jr.
Title: Chief Executive Officer

LIST OF EXHIBITS

Exhibit A Form of General Assignment and Assumption Agreement
Exhibit B Form of IP Assignment

LIST OF SCHEDULES

Schedule 2.1(e)	Assigned Contracts
Schedule 2.1(f)	Purchased Equipment
Schedule 2.1(g)	Inventory
Schedule 2.10(h)	Contract Consents
Schedule 3	Disclosure Schedule
Schedule 4.2	Buyer Authorization
Schedule 5.4(e)	Purchase Price Allocation
Schedule 8.1(a)(vi)	Specific Indemnity Items

Exhibit A

BILL OF SALE
and
ASSIGNMENT AND ASSUMPTION AGREEMENT

This Bill of Sale and Assignment and Assumption Agreement (this "**Bill of Sale**") is made as of _____ _, 2023 by and between AcelRx Pharmaceuticals, Inc., a Delaware corporation ("**Seller**"), and Vertical Pharmaceuticals, LLC, a Delaware limited liability company ("**Buyer**" and, together with Seller, collectively the "**Parties**" and each, a "**Party**"). Unless otherwise defined, all capitalized terms in this Bill of Sale have the meanings ascribed to them in the Agreement (as defined below).

RECITAL

Seller and Buyer are parties to an Asset Purchase Agreement dated March 12, 2023 (the "**Agreeme**nt"), pursuant to which Seller agreed to sell, and Buyer agreed to purchase and assume from Seller, certain assets and liabilities related to the Program.

The Parties desire to carry out the intent and purpose of the Agreement by the execution and delivery of this instrument evidencing the vesting in Buyer of all right, title and interest in, to and under the Transferred Assets and Buyer's assumption of the Assumed Liabilities.

AGREEMENTS

For good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

Section 1. Transfer and Assignment of the Transferred Assets. Seller hereby sells, conveys, transfers, assigns and delivers to Buyer, and Buyer hereby purchases, acquires and accepts from Seller, all of the right, title and interest of Seller worldwide in, to and under the Transferred Assets, free and clear of all Encumbrances other than Permitted Encumbrances. Notwithstanding anything contained herein or in the Agreement to the contrary, Seller does not hereby sell, convey, transfer, assign or deliver to Buyer any Excluded Asset or any other asset, property or right of Seller or any other person or entity (other than the Transferred Assets) by this Bill of Sale.

Section 2. Assumed Liabilities. Buyer hereby assumes and agrees to discharge or perform when due the Assumed Liabilities (other than the Assumed Liabilities, no other obligations and liabilities of Seller shall be required to be assumed, paid, performed or discharged by Buyer pursuant to the Agreement or this Bill of Sale). Notwithstanding the foregoing, nothing herein shall be construed as Seller transferring, conveying, assigning or delivering to Buyer, or Buyer acquiring or assuming from Seller, any Excluded Liability.

Section 3. Further Assurances. Each Party covenants that at any time, and from time to time, after the Closing Date, but subject to the express provisions of the Agreement and without expanding any Party's express obligations thereunder, it will execute such additional instruments and take such actions as may be reasonably requested by the other Party to more fully effectuate (i) Seller's sale and assignment of the Transferred Assets to Buyer and the vesting of title to the Transferred Assets in Buyer and (ii) Buyer's assumption of the Assumed Liabilities and otherwise to carry out the intent and purposes of this Bill of Sale.

Section 4. Relation to Agreement. The conveyance of the Transferred Assets and the assumption of the Assumed Liabilities made hereunder is made in accordance with and subject to the Agreement (including, without limitation, the representations, warranties, covenants, indemnities and agreements contained therein), which is incorporated herein by reference. In the event of a conflict between the terms and conditions of this Bill of Sale and the terms and conditions of the Agreement, the terms and conditions of the Agreement shall govern, supersede, and prevail. Notwithstanding anything to the contrary in this Bill of Sale, nothing in this Bill of Sale shall (and is not intended to) be deemed to defeat, limit, reduce, alter, impair, enhance, enlarge, or supersede any right, obligation, liability, claim, or remedy created by the Agreement or any Ancillary Agreement. The provisions of this Bill of Sale shall not merge in or be superseded by and shall survive (to the extent provided for in the Agreement) the completion of the transactions provided for in the Agreement or any Ancillary Agreement.

Section 5. Counterparts; Facsimile; Electronic Mail. This Bill of Sale may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Bill of Sale and all of which, when taken together, will be deemed to constitute one and the same Bill of Sale. The exchange of copies of this Bill of Sale and of signature pages by facsimile, pdf format, docusign or electronic mail transmission shall constitute effective execution and delivery of this Bill of Sale as to the Parties and may be used in lieu of the original Bill of Sale for all purposes. Signatures of the Parties transmitted by facsimile or electronic mail shall be deemed to be their original signatures for all purposes.

Section 6. Governing Law. Section 10.9 (Governing Law) of the Agreement shall also apply with respect to this Bill of Sale, *mutatis mutandis*.

Section 7. Amendments; Waivers. This Bill of Sale may only be amended by a writing signed by the Parties. Any waiver of rights hereunder must be set forth in writing. A waiver of any breach or failure to enforce any of the terms or conditions of this Bill of Sale shall not in any way affect, limit or waive any Party's rights at any time to enforce strict compliance thereafter with every term or condition of this Bill of Sale.

Section 8. Third Party Beneficiaries and Obligations. This Bill of Sale is for the sole benefit of the Parties and their respective successors and permitted assigns and nothing herein, express or implied, is intended to or shall confer upon any other person or entity any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Bill of Sale.

Section 9. Notices. Any notice, request, or other document to be given hereunder to any Party shall be given in the manner specified in Section 10.1 (Notices) of the Agreement.

Section 10. Severability. If any term or provision of this Bill of Sale is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Bill of Sale or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon such determination that any term or other provision is invalid, illegal or unenforceable, the Parties shall negotiate in good faith to modify this Bill of Sale so as to effect the original intent of the Parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

Section 11. Entire Agreement. This Bill of Sale, together with the Agreement, Ancillary Agreements, and the other exhibits and documents referred to in the Agreement and the Ancillary Agreements, contain the entire understanding between the Parties with respect to the transactions contemplated hereby and thereby, supersede all prior agreements, understandings, representations and statements, oral or written, between the Parties on the subject matter hereof, which such prior agreements, understandings, representations and statements, oral or written, shall be of no further force or effect.

[Remainder of page intentionally left blank]

Seller and Buyer have executed and delivered this Bill of Sale and Assignment and Assumption Agreement as of the date set forth above.

SELLER:

AcelRx Pharmaceuticals, Inc.

By: _____
Name:
Title:

BUYER:

Vertical Pharmaceuticals, LLC

By: _____
Name:
Title:

[Signature Page to Bill of Sale and Assignment and Assumption Agreement]

Exhibit B

INTELLECTUAL PROPERTY ASSIGNMENT AGREEMENT

This Intellectual Property Assignment Agreement (this "**IP Assignment Agreement**") is made as of _____ _, 2023 by and between AcelRx Pharmaceuticals, Inc., a Delaware corporation ("Seller"), and Vertical Pharmaceuticals, LLC, a Delaware limited liability company ("Buyer" and, together with Seller, collectively the "**Parties**" and each, a "**Party**"). Unless otherwise defined, all capitalized terms in this IP Assignment Agreement have the meanings ascribed to them in the Agreement (as defined below).

RECITAL

Seller and Buyer are parties to an Asset Purchase Agreement dated March 12, 2023 (the "**Agreement**"), pursuant to which Seller agreed to sell, and Buyer agreed to purchase and assume from Seller, certain assets and liabilities related to the Program, including the Transferred Intellectual Property and the Regulatory Materials.

The Parties desire to carry out the intent and purpose of the Agreement by the execution and delivery of this instrument evidencing the vesting in Buyer of all right, title and interest in, to and under the Transferred Intellectual Property.

AGREEMENTS

For good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

Section 1. Transfer and Assignment of the Transferred Intellectual Property. Seller hereby sells, conveys, transfers, assigns and delivers to Buyer, and Buyer hereby purchases, acquires and accepts from Seller, all of the right, title and interest of Seller in, to and under the Transferred Intellectual Property, free and clear of all Encumbrances other than Permitted Encumbrances, including the following: (a) all patents and patent applications listed on Exhibit A, any and all inventions described by, embodied in, and/or claimed by such patents and patent applications, and any substitute applications which may be filed upon any such inventions; (b) any and all renewals, divisionals, continuations and continuations-in-part of the patents and patent applications listed on Exhibit A; (c) any patent applications claiming direct or indirect priority to any of the foregoing; (d) all foreign patent applications associated with and/or claiming priority to the patent applications referenced in the preceding clauses (a)-(c); (e) all patents issued or issuing from the patent applications referenced in the preceding clauses (a)-(d); (f) all reissues, reexaminations, restorations (including supplemental protection certificates) and extensions of any patent or patent application referenced in the preceding clauses (a)-(e); (g) the right to file for any patent applications in the United States or in foreign countries for the inventions references in preceding clause (a); (h) all trademark registrations and applications listed on Exhibit B; (i) all common law or other rights in any trademarks, trade dress, or other identifying indicia associated with the Product that are necessary for, or are used by Seller as of the Effective Date in connection with, the Development, manufacture (including synthesis, formulation, finishing or packaging), use, holding, marketing, offer for sale, sale, distribution, export or import of any Product; (j) Seller's right to sue and collect damages for past, present and future infringement, dilution, misappropriation, unauthorized use and/or any other violation of the Transferred Intellectual Property; and (k) all income, royalties, damages or payments due on or after the Closing Date relating to, or resulting from the licensing or enforcement of, the Transferred Intellectual Property (except with respect to Seller's rights under the Transferred Intellectual Property granted by Buyer pursuant to the Intellectual Property Agreement between the Parties entered into in connection with the Agreement). Seller hereby authorizes and requests the issuing authority of any patent, trademark, or other intellectual property protection to issue any and all patents, trademark, or other intellectual property certificates with respect to the Transferred Intellectual Property to Buyer as assignee of the entire interest therein.

Section 2. Trademark Rights. With respect to the transfer of any trademarks that are Transferred Intellectual Property, Seller hereby sells, conveys, transfers, assigns and delivers to Buyer all goodwill associated with and symbolized by such trademarks.

Section 3. Further Assurances. Each Party covenants that at any time, and from time to time, after the Closing Date, but subject to the express provisions of the Agreement and without expanding any Party's express obligations thereunder, it will execute, at the executing Party's own cost, such additional instruments and take such actions as may be reasonably requested by the other Party to effectuate Seller's sale and assignment of the Transferred Intellectual Property to Buyer, vest title to the Transferred Intellectual Property in Buyer, and otherwise carry out the intent and purposes of this IP Assignment Agreement, including, but not limited to, Seller executing the necessary documents to transfer rights in any Madrid Protocol trademarks to Buyer.

Section 4. Relation to Agreement. This IP Assignment Agreement is executed and delivered pursuant to and subject to the Agreement (including, without limitation, the representations, warranties, covenants, indemnities and agreements contained therein), which is incorporated herein by reference. In the event of a conflict between the terms and conditions of this IP Assignment Agreement and the terms and conditions of the Agreement, the terms and conditions of the Agreement shall govern, supersede, and prevail. Notwithstanding anything to the contrary in this IP Assignment Agreement, nothing in this IP Assignment Agreement shall (and is not intended to) be deemed to defeat, limit, reduce, alter, impair, enhance, enlarge, or supersede any right, obligation, liability, claim, or remedy created by the Agreement or any Ancillary Agreement. The provisions of this IP Assignment Agreement shall not merge in or be superseded by and shall survive (to the extent provided for in the Agreement) the completion of the transactions provided for in the Agreement or any Ancillary Agreement.

Section 5. Counterparts; Facsimile; Electronic Mail. This IP Assignment Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this IP Assignment Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement. The exchange of copies of this IP Assignment Agreement and of signature pages by facsimile, pdf format, docusign or electronic mail transmission shall constitute effective execution and delivery of this IP Assignment Agreement as to the Parties and may be used in lieu of the original IP Assignment Agreement for all purposes. Signatures of the Parties transmitted by facsimile or electronic mail shall be deemed to be their original signatures for all purposes.

Section 6. Governing Law. Section 10.9 (Governing Law) of the Agreement shall also apply with respect to this IP Assignment Agreement, *mutatis mutandis*.

Section 7. Amendments; Waivers. This IP Assignment Agreement may only be amended by a writing signed by the Parties. Any waiver of rights hereunder must be set forth in writing. A waiver of any breach or failure to enforce any of the terms or conditions of this IP Assignment Agreement shall not in any way affect, limit or waive any Party's rights at any time to enforce strict compliance thereafter with every term or condition of this IP Assignment Agreement.

Section 8. Third Party Beneficiaries and Obligations. This IP Assignment Agreement is for the sole benefit of the Parties and their respective successors and permitted assigns and nothing herein, express or implied, is intended to or shall confer upon any other person or entity any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this IP Assignment Agreement.

Section 9. Notices. Any notice, request, or other document to be given hereunder to any Party shall be given in the manner specified in Section 10.1 (Notices) of the Agreement.

Section 10. Severability. If any term or provision of this IP Assignment Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this IP Assignment Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon such determination that any term or other provision is invalid, illegal or unenforceable, the Parties shall negotiate in good faith to modify this IP Assignment Agreement so as to effect the original intent of the Parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

Section 11. Entire Agreement. This IP Assignment Agreement, together with the Agreement, Ancillary Agreements, and the other exhibits and documents referred to in the Agreement and the Ancillary Agreements, contain the entire understanding between the Parties with respect to the transactions contemplated hereby and thereby, supersede all prior agreements, understandings, representations and statements, oral or written, between the Parties on the subject matter hereof, which such prior agreements, understandings, representations and statements, oral or written, shall be of no further force or effect.

[Remainder of page intentionally left blank]

Seller and Buyer have executed and delivered this IP Assignment Agreement as of the date set forth above.

SELLER:

AcelRx Pharmaceuticals, Inc.

By: _____
Name:
Title:

BUYER:

Vertical Pharmaceuticals, LLC

By: _____
Name:
Title:

[Signature Page to Intellectual Property Assignment Agreement]

EXHIBIT A

Program Patents

[***]

EXHIBIT B

Marks

[***]

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 subsidiary, 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: November 14, 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 subsidiary, 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: November 14, 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 September 30, 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 14th day of November 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.