

REFINITIV

DELTA REPORT

10-Q

TLPH - ACELRX PHARMACEUTICALS IN

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	6270
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CHANGES	112
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DELETIONS	3628
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ADDITIONS	2530
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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 March 31, 2024

or

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

For the transition period from to

Commission File Number: 001-35068

ACELRX PHARMACEUTICALS, TALPHERA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

41-2193603
(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: Class	Trading symbol(s)	Name of Each Exchange on Which Registered: registered:
Common Stock, \$0.001 par value	ACRX TLPH	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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 May 7, 2024, the number of outstanding shares of the registrant's common stock was 16,952,269 16,992,977.

ACELRX PHARMACEUTICALS, TALPHERA, INC.

QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2023 MARCH 31, 2024

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Unless the context indicates otherwise, the terms “AcelRx,” “AcelRx Pharmaceuticals,” “Talphera,” “we,” “us” and “our” refer to AcelRx Pharmaceuticals, Talphera, Inc., and its consolidated subsidiary. “Niyad” and “Fedsyra” are trademarks, and “ACELRX” and “Zalviso” are registered trademarks, all owned by AcelRx Pharmaceuticals, Talphera, Inc. This report Quarterly 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, and recession risks and the worldwide COVID-19 pandemic; risks;
- 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 estimates of the expected benefits existence of and commercial potential value created by the acquisition of Lowell Therapeutics, Inc., or Lowell, for markets for our stockholders, on a timely basis or at all; developmental product candidates, if approved;
- 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; providers, including single sources of supply for Niyad active pharmaceutical ingredients and finished goods located outside the U.S.;
- 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, Talphera, Inc.

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

September 30, 2023	December 31, 2022 ⁽¹⁾	March 31, 2024	December 31, 2023 ⁽¹⁾
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Assets				
Current Assets:				
Cash and cash equivalents	\$ 13,389	\$ 15,275	\$ 12,122	\$ 5,721
Restricted cash	—	5,000		
Short-term investments	—	495	6,462	3,660
Prepaid expenses and other current assets	1,017	1,865	1,369	2,195
Assets of discontinued operations	16	1,931		
Total current assets	14,422	24,566	19,953	11,576
In-process research and development asset	8,819	8,819	8,819	8,819
Other assets	20	166		
Assets of discontinued operations	—	13,936		
Total Assets	\$ 23,261	\$ 47,487		
Liabilities and Stockholders' Equity				
Total assets			\$ 28,772	\$ 20,395
Liabilities and Stockholders' Equity				
Current Liabilities:				
Accounts payable	\$ 1,026	\$ 1,256	\$ 1,274	\$ 1,336
Accrued and other liabilities	1,792	2,531	1,340	2,445
Long-term debt, current portion	—	5,363		
Liabilities of discontinued operations, current portion	756	4,620	730	731
Total current liabilities	3,574	13,770	3,344	4,512
Warrant liability	1,380	7,098	2,780	1,778
Other long-term liabilities	—	810		
Liabilities of discontinued operations	—	3,995		
Total Liabilities	4,954	25,673		
Liability related to the sale of future payments			6,314	—
Total liabilities			12,438	6,290
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		
Common stock, \$0.001 par value—200,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 16,992,726 and 16,952,219 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively			17	17
Additional paid-in capital	457,999	447,635	464,497	458,314
Accumulated deficit	(439,709)	(425,829)	(448,180)	(444,226)
Total Stockholders' Equity	18,307	21,814		
Total stockholders' equity			16,334	14,105
Total Liabilities and Stockholders' Equity	\$ 23,261	\$ 47,487	\$ 28,772	\$ 20,395

- (1) The condensed consolidated balance sheet as of **December 31, 2022** **December 31, 2023** 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 **December 31, 2023**.

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Talphera, 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

	Three Months Ended	
	March 31,	
	2024	2023
Operating costs and expenses:		
Research and development	\$ 1,433	\$ 1,047
Selling, general and administrative	2,804	4,281
Total operating costs and expenses	4,237	5,328
Loss from operations	(4,237)	(5,328)
Other income (expense), net:		
Interest expense	—	(119)
Interest income and other income, net	220	200
Gain on sale of future payments	1,246	—
Change in fair value of warrant liability	(1,002)	5,311
Non-cash interest expense on liability related to sale of future payments	(181)	—
Total other income (expense), net	283	5,392
Net (loss) income from continuing operations	(3,954)	64
Net loss from discontinued operations— See Note 3	—	(8,216)
Net loss	\$ (3,954)	\$ (8,152)
Net (loss) income per share attributable to stockholders:		
Basic and diluted, continuing operations	\$ (0.16)	\$ 0.00
Basic and diluted, discontinued operations	\$ 0.00	\$ (0.75)
Basic and diluted loss per share	\$ (0.16)	\$ (0.75)
Shares used in computing net loss per share of common stock, basic and diluted – See Note 10	24,721,964	10,893,954

(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.

AcelRx Pharmaceuticals, Inc.

Talpher, Inc.

Condensed Consolidated Statements of Stockholders' Equity (Deficit)

(Unaudited)

(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				Shares	Amount			
Balance as of December 31, 2022	8,243,680	\$ 8	\$ 447,635	\$ (425,829)	\$ 21,814					
Balance as of January 1, 2024						16,952,519	\$ 17	\$ 458,314	\$ (444,226)	\$ 14,105
Stock-based compensation	—	—	569	—	569	—	—	302	—	302
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	21,700	—	(22)	—	(22)	23,952	—	(17)	—	(17)
Exercise of prefunded warrants	2,632,898	2	—	—	2					

Net proceeds from issuance of pre-funded warrants in connection with equity financing						—	—	5,884	—	5,884
Issuance of common stock upon ESPP purchase	26,016	1	30	—	31	16,255	—	14	—	14
Net loss	—	—	—	(8,152)	(8,152)	—	—	—	(3,954)	(3,954)
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
Balance as of March 31, 2024				16,992,726	\$ 17 \$ 464,497 \$ (448,180) \$ 16,334

	Series A Redeemable				Additional	Accumulated	Total
	Convertible Preferred Stock		Common Stock		Paid-in	Deficit	Stockholders'
	Shares	Amount	Shares	Amount	Capital		Equity (Deficit)
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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of January 1, 2023	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

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Talphera, Inc.

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

Nine Months Ended September 30,				
2023		2022		Three Months Ended March 31,
				2024 2023

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)	
Net loss			\$ (3,954)	\$ (8,152)
Adjustments to reconcile net loss to net cash used in operating activities:				
Non-cash interest expense on liability related to sale of future payments			181	—
Depreciation and amortization		311	1,305	— 262
Non-cash interest expense related to debt financing		53	333	— 38
Non-cash issuance of Lowell holdback shares		(723)	—	
Stock-based compensation		1,418	2,237	302 569
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)	—	1,002 (5,311)
Impairment of net assets held for sale		6,853	—	— 7,007
Impairment of fixed assets		1,065	—	— 1,065
Gain on termination of lease liabilities		(1,098)	—	— (1,098)
Gain on extinguishment of debt liability		(400)	—	— (400)
Other		(15)	(47)	(72) (15)
Changes in operating assets and liabilities:				
Accounts receivable		(97)	(352)	
Inventories		61	210	— 61
Prepaid expenses and other assets		1,294	375	826 1,583
Other assets		226	—	
Accounts payable		(957)	25	(62) 100
Accrued liabilities		(1,761)	(1,456)	(1,106) (960)
Operating lease liabilities		(146)	(357)	— 30
Deferred revenue		(29)	(43)	— (29)
Net cash used in operating activities		(13,543)	(22,918)	(2,883) (5,250)
Cash flows from investing activities:				
Purchase of property and equipment		(100)	(316)	— (100)
Purchase of investments		—	(7,369)	(4,230) —
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	1,500 500
Net cash provided by investing activities		3,123	33,790	
Net cash (used in) provided by investing activities				(2,730) 400
Cash flows from financing activities:				
Payment of long-term debt		(5,416)	(6,250)	— (2,083)
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	—	

Gross proceeds from sale of future payments			6,654	—
Issuance costs related to sale of future payments			(521)	—
Net proceeds from issuance of prefunded warrants			5,884	2
Net proceeds from issuance of common stock through equity plans	45	74	(3)	9
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 cash provided by (used in) financing activities			12,014	(2,072)
Net change in cash, cash equivalents and restricted cash	(6,886)	5,069	6,401	(6,922)
Cash, cash equivalents and restricted cash—Beginning of period	20,275	12,663	5,721	20,275
Cash, cash equivalents and restricted cash—End of period	\$ 13,389	\$ 17,732	\$ 12,122	\$ 13,353
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	—		
NONCASH FINANCING ACTIVITIES:				
Equity issuance costs from warrant modification			251	—

See notes to condensed consolidated financial statements.

AcelRx Pharmaceuticals, Talphera, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

(In thousands, except where otherwise noted)

1. Organization and Summary of Significant Accounting Policies

The Company

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

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

On March 12, 2023, January 12, 2024, the Company and XOMA (US) LLC, or XOMA, entered into a Payment Interest Purchase Agreement, or the Purchase Agreement, for the sale by the Company to XOMA, in exchange for \$8.0 million, of the Company's right, title and interest in and to certain amounts payable to the Company, or collectively the Purchased Receivables, pursuant to the DSUVIA Agreement (as defined below) in respect of net sales of the Product (as defined below), excluding sales of DZUVEO by Laboratoire Aguettant, or Aguettant. See Note 4, "Sale of Future Payments" below for additional information.

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 the Company relating to its sufentanil sublingual tablet product referred to as DSUVIA or DZUVEO, or any other single-dose pharmaceutical product for use in medically supervised settings containing a sublingual tablet that includes sufentanil as the sole active ingredient, as a 30 mcg tablet or other dosage form or strength as reasonably necessary for lifecycle management, or the Product. The closing of the DSUVIA Agreement occurred on April April 3, 2023 (see Note 3, 2023 (see Note 3, "Discontinued Operations") below).

On January 7, 2022, 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 20222023 Annual Report on Form 10-K 10-K for additional information) and, as a result acquired the Niyad™,developmental product, a regional anticoagulant for the dialysis circuit during continuous renal replacement therapy for acute kidney injury patients in the hospital, that the Company plans to study under an investigational device exemption, or IDE, and which has received Breakthrough Device Designation status from the FDA. While not approved for commercial use in the United States, the active drug component of Niyad, nafamostat, has been approved in Japan and South Korea as a regional anticoagulant for the dialysis circuit, disseminated intravascular coagulation, and acute pancreatitis. Niyad is a lyophilized formulation of nafamostat, a broad-spectrum, synthetic serine protease inhibitor, with anticoagulant, anti-inflammatory, and potential anti-viral activities. The second intended indication for Niyad is as a regional anticoagulant for the dialysis circuit for chronic kidney disease patients undergoing intermittent hemodialysis in dialysis centers. In addition, the Company acquired LTX-608,LTX-608, a proprietary nafamostat formulation for direct IV infusion, that it intends to develop for the treatment of one or more of the following indications: ARDS, DIC, acute respiratory distress syndrome, pancreatitis or ARDS, and disseminated intravascular coagulation, or DIC, as an anti-viral agent.

On July 14, 2021, 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. See Note 5, "In-License Agreement" to the consolidated financial statements in the Company's 2023 Annual Report on Form 10-K for additional information.

Liquidity and Going Concern

The unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2023 March 31, 2024 were prepared on the basis of a going concern, which contemplates that the Company will be able to realize assets and discharge liabilities in the normal course of business. The Company has incurred recurring operating losses and negative cash flows from operating activities since inception and expects to continue to incur operating losses and negative cash flows in the future. Although in July 2023 These conditions raise substantial doubt about the Company closed the private placement of its common stock, pre-funded warrants and common warrants for aggregate gross proceeds Company's ability 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 continue as a going concern. Considering the Company's current cash resources and its current and expected levels of operating expenses for the next twelve months, management expects to need additional capital to fund its planned operations prior to the 12 month 12-month anniversary of the date this Quarterly Report on Form 10-Q 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 OfferingSM 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 Basis of Presentation

On September 23, 2022, at a special meeting The preparation 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 financial statements in a range of 1-for-10 to 1-for-30. The Board of Directors subsequently approved a reverse stock split conformity 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 accounting principles generally accepted in the common stock recorded at par value has been reclassified United States, or GAAP, requires management to additional paid-in-capital on a retroactive basis. All references to shares of common stock, stock options, restricted stock units make estimates and warrants and per share data for all periods presented assumptions that affect the amounts reported in the accompanying unaudited condensed consolidated financial statements and notes thereto the accompanying notes. Actual results could differ from those estimates.

Reclassifications

Certain prior year amounts in the condensed consolidated financial statements have been adjusted reclassified to reflect conform to the Reverse Stock Split on a retroactive basis. current year's presentation. In particular, other assets has been reclassified as prepaid expenses and other current assets in the condensed consolidated balance sheets, the portion of interest income and other income, net related to the revaluation of liability-classified warrants has been reclassified to change in fair value of warrants in the condensed consolidated statements of operations, and accounts receivable has been reclassified as prepaid expenses and other current assets and payment of employee tax obligations related to vesting of restricted stock units has been reclassified to net proceeds from issuance of common stock through equity plans in the condensed consolidated statement of cash flows.

Principles of Consolidation

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

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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 10-K for the year ended December 31, 2022. December 31, 2023. There have been no significant changes to the Company's significant accounting policies during the three and nine months ended September 30, 2023, March 31, 2024, from those previously disclosed in its 2022 2023 Annual Report on Form 10-K, 10-K, except as follows:

Royalty Revenue Sale of Future Payments

The On January 12, 2024, the Company recognizes revenue in accordance entered into the Purchase Agreement with Accounting Standards Codification Topic 606, Revenue from Contracts with Customers (ASC 606). The Company applies the following five steps in order XOMA to determine the appropriate amount of revenue to be recognized as it fulfills its obligations under each monetize a portion 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 future payments for commercial sales of DSUVIA and services performed by the Company to the Company's portion of net revenue earned on the support sales of DSUVIA to the Department of Defense, or DoD, by Alora under the Marketing Agreement, (as defined in and sales milestones under the DSUVIA Agreement. Refer to Note 3). The Company's performance obligation is to serve as 4, "Sale of Future Payments" for further details on the exclusive sales agent for selling DSUVIA to the DoD through the term of the Marketing Purchase 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 Company recorded approximately \$6.1 million, net of \$0.5 million in issuance costs, of the Marketing Agreement reflects \$8.0 million proceeds as a variable amount liability, as this portion of the proceeds represents a sale of future revenues under ASC 470 for which the Company estimates has continuing involvement in the amount generation 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. cash flows. The Company includes recorded approximately \$1.2 million, net of \$0.2 million in issuance costs, of the transaction price \$8.0 million proceeds as other income, as this portion of proceeds represents the amount sale of all of the Company's interest in future payments related to commercial sales of DSUVIA for which if the Company is probable that no longer entitled to receive such payments and has no further continuing involvement. The Company utilized internal estimates to develop a significant reversal of cumulative revenue recognized will not occur. Royalty revenues are recognized when cash flow model based on business assumptions to determine the DoD obtains control allocation of the product, at which time the Company has an unconditional right to receive payment for such royalty earned. proceeds.

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

Discontinued Operations Recently Issued Accounting Pronouncements

In accordance November 2023, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, or ASU 2023-07, which requires all public entities, including public entities with ASC 205-20a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. Additionally, the standard requires disclosures of significant segment expenses and other segment items as well as incremental qualitative disclosures. The guidance in this update is effective for fiscal years beginning after December 15, 2023, and interim periods after December 15, 2024. The Company is evaluating the disclosure impact of ASU 2023-07; however, the adoption of ASU 2023-07 will not have a material impact on the Company's consolidated financial statements.

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

The Company does not believe other recently issued but not yet effective accounting standards, if currently adopted, would have a 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 material 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).

statements.

2. Investments and Fair Value Measurement

Investments

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

As of September 30, 2023, March 31, 2024, and December 31, 2022, December 31, 2023, the contractual maturity of all investments held was less than one year.

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

	As of 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				As of March 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, cash equivalents and restricted cash:								
Cash	\$ 13,275	\$ —	\$ —	\$ 13,275	\$ 585	\$ —	\$ —	\$ 585
Money market funds	321	—	—	321	1,283	—	—	1,283
U.S. government agency securities	2,444	—	—	2,444	5,478	—	—	5,478
Commercial paper	4,235	—	—	4,235	4,776	—	—	4,776
Total cash, cash equivalents and restricted cash	20,275	—	—	20,275				
Total cash and cash equivalents					12,122	—	—	12,122

Short-term investments:											
U.S. government agency securities				4,779 — — 4,779							
Commercial paper				495	—	—	495	1,683	—	—	1,683
Total short-term investments				495	—	—	495	6,462	—	—	6,462
Total cash, cash equivalents, restricted cash and short-term investments				\$ 20,770	\$ —	\$ —	\$ 20,770				
Total cash, cash equivalents, and short-term investments				\$ 18,584				\$ —	\$ —	\$ 18,584	
				As of December 31, 2023							
				Gross		Gross					
				Unrealized		Unrealized					
				Gains		Losses		Fair			
				Amortized Cost				Value			
Cash and cash equivalents:											
Cash				\$ 1,342	\$ —	\$ —	\$ 1,342				
Money market funds				90	—	—	90				
U.S. government agency securities				1,896	—	—	1,896				
Commercial paper				2,393	—	—	2,393				
Total cash and cash equivalents				5,721	—	—	5,721				
Short-term investments:											
U.S. government agency securities				3,362	—	—	3,362				
Commercial paper				298	—	—	298				
Total short-term investments				3,660	—	—	3,660				
Total cash, cash equivalents, and short-term investments				\$ 9,381	\$ —	\$ —	\$ 9,381				

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. Impairment is assessed at the individual security level. Factors considered in determining whether a loss resulted from a credit loss or other factors include the Company's intent and ability to hold the investment until the recovery of its amortized cost basis, the extent to which the fair value is less than the amortized cost basis, the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, any historical failure of the issuer to make scheduled interest or principal payments, any changes to the rating of the security by a rating agency, any adverse legal or regulatory events affecting the issuer or issuer's industry, any significant deterioration in economic conditions. There were no material realized or unrealized gains or losses on marketable securities for the three and nine months ended September 30, 2023 March 31, 2024 or the twelve months ended December 31, 2022. December 31, 2023. As such, we the Company did not record a credit allowance for the three and nine months ended September 30, 2023. March 31, 2024.

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 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** **March 31, 2024** and **December 31, 2022**, **December 31, 2023**, the Company held, in addition to Level II assets, a warrant liability related to the **December 2022 Warrants** (see **Note 12, "Warrants" in the Company's 2022 Annual Report on Form 10-K for further description**). **Common Stock Warrants**. 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), **rate**. The Company follows the guidance in ASC 820 for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period. The estimated fair value of the warrant liability represents a Level III measurement. Changes to the estimated fair value of these liabilities are recorded in **interest income and other income, net change in fair value of warrant liability** 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				As of March 31, 2024			
	Fair Value	Level I	Level II	Level III	Fair Value	Level I	Level II	Level III
Assets								
Money market funds	\$ 3,264	\$ 3,264	\$ —	\$ —	\$ 1,283	\$ 1,283	\$ —	\$ —
U.S. government agency securities	7,572	—	7,572	—	10,257	—	10,257	—
Commercial paper	897	—	897	—	6,459	—	6,459	—
Total assets measured at fair value	<u>\$ 11,733</u>	<u>\$ 3,264</u>	<u>\$ 8,469</u>	<u>\$ —</u>	<u>\$ 17,999</u>	<u>\$ 1,283</u>	<u>\$ 16,716</u>	<u>\$ —</u>
Liabilities								
Warrant liability	\$ 1,380	\$ —	\$ —	\$ 1,380	\$ 2,780	\$ —	\$ —	\$ 2,780
Total liabilities measured at fair value	<u>\$ 1,380</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,380</u>	<u>\$ 2,780</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,780</u>

	As of December 31, 2022				As of December 31, 2023			
	Fair Value	Level I	Level II	Level III	Fair Value	Level I	Level II	Level III
Assets								
Money market funds	\$ 321	\$ 321	\$ —	\$ —	\$ 90	\$ 90	\$ —	\$ —
U.S. government agency securities	2,444	—	2,444	—	5,258	—	5,258	—
Commercial paper	4,730	—	4,730	—	2,691	—	2,691	—
Total assets measured at fair value	<u>\$ 7,495</u>	<u>\$ 321</u>	<u>\$ 7,174</u>	<u>\$ —</u>	<u>\$ 8,039</u>	<u>\$ 90</u>	<u>\$ 7,949</u>	<u>\$ —</u>
Liabilities								
Warrant liability	\$ 7,098	\$ —	\$ —	\$ 7,098	\$ 1,778	\$ —	\$ —	\$ 1,778
Total liabilities measured at fair value	<u>\$ 7,098</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 7,098</u>	<u>\$ 1,778</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,778</u>

The following **table sets** **tables set** 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 March 31, 2024** **(in thousands):**

	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2023

			Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Fair value—beginning of period	\$	3,086	\$	7,098
Change in fair value of 2022 Warrants liability		(1,706)		(5,718)
Change in fair value of December 2022 Common Stock Warrants liability			1,002	(5,311)
Fair value—end of period	\$	1,380	\$	1,380
			\$ 2,780	\$ 1,787

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There was no such warrant liability. The common warrants issued in December 2022 to purchase an aggregate of 4,227,052 shares of common stock, or the December 2022 Common Stock Warrants, were accounted for by the three Company as a liability. At March 31, 2024, the December 2022 Common Stock Warrants were valued at approximately \$2.8 million, using the Black-Scholes option pricing model as follows: exercise price of \$2.07 per share, stock price of \$1.03 per share, expected life of 4.75 years, volatility of 97.89%, a risk-free rate of 4.21% and nine months ended September 30, 2022, 0% expected dividend yield.

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, March 31, 2024 and the year ended December 31, 2022, December 31, 2023.

3. Discontinued Operations

Asset Purchase Agreement

On April 3, 2023, March 12, 2023, the Company closed the transactions contemplated by the DSUVIA Agreement entered into on March 12, 2023, the Asset Purchase Agreement with Alora pursuant to Alora's acquisition of all assets related to which Alora agreed to acquire certain assets DSUVIA, including inventories, equipment 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 intellectual property in exchange 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 consideration at closing of \$1.1 million, a 15% payment on commercial sales of DSUVIA, 75% payment on sales of DSUVIA to the transaction, AcelRx is entitled to receive (a) Department of Defense and up to \$116.5 million in sales-based milestones, (b) quarterly payments in an amount equal to 15% of net sales based milestones. The transaction closed on sales of Product to all customers, other than sales April 3, 2023 (see Note 3, "Discontinued Operations") 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 consolidated

financial statements in the United States. The DSUVIA Agreement also contains indemnification rights Company's 2023 Annual Report on Form 10-K 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) additional information).

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- three-month period ended March 31, 2024 and nine-month periods ended September 30, 2023 and 2022March 31, 2023 (in thousands):

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2023	2022	2023	2022
				Three months ended

					March 31,	
					2024	2023
Total revenues	\$	—	\$	507	\$	501
Cost of goods sold		—		338		711
Selling, general and administrative expense		21		1,771		683
Impairment of net assets held for sale		(82)		—		7,007
Impairment of fixed assets		—		—		1,065
Gain on termination of lease liabilities		—		(1,098)		(1,098)
Research and development expenses		—		509		349
Net income (loss) from discontinued operations	\$	61	\$	(2,111)	\$	(8,098)
Loss from operations					—	8,216
Net (income) loss from discontinued operations	\$	—	\$	—	\$	8,216

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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

March 31, 2024

December 31, 2023

Accounts payable	\$	10	\$	10
Accrued liabilities		720		721
Total current liabilities of discontinued operations		730		731
Net assets (liabilities) of discontinued operations	\$	(730)	\$	(731)

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
Stock-based compensation	19	
Impairment of net assets held for sale	6,853	
Impairment of fixed assets	1,065	
Gain on termination of lease liabilities	(1,098)	
Gain on extinguishment of debt	(400)	
	Three months ended	
	March 31,	
	2024	2023
Cash flows from operating activities:		
Depreciation and amortization	\$ —	\$ —
Stock-based compensation	—	
Impairment of net assets held for sale	—	7
Impairment of fixed assets	—	1
Gain on termination of lease liabilities	—	(1
Gain on extinguishment of debt	—	
Purchases of property and equipment	—	

4. Sale of Future Payments

The following table represents In January 2024, the gain (loss) on sale of discontinued operations Company and XOMA entered into the Purchase Agreement for the threesale by the Company to XOMA, in exchange for \$8.0 million, of the Company's right, title and nine months ended September 30, 2023: interest in and to certain amounts payable to the Company, or collectively, the Purchased Receivables, pursuant to the DSUVIA Agreement in respect of net sales of the Product, excluding sales of the Product by Aguettant.

	Three Months Ended	Nine Months En
	September 30, 2023	September 30, 2
Cash proceeds	\$ —	\$ 2
Less: net assets transferred	—	(8
Less: disposal costs	82	
Loss on sale of discontinued operations, before income taxes	82	(6

Income tax expense	—	—
Gain (loss) on sale of discontinued operations	\$ 82	\$ (6)

4. In-License Agreement The Purchased Receivables include:

On July 14, 2021, (i) 100% of certain payments based on net sales of the Company entered into a License Product and Commercialization Agreement, potential sales-based milestone payments of up to \$116.5 million in respect of net sales of the Product, in each case made on and after January 1, 2024 and excluding sales of the Product by Aguettant, and of certain associated license and acquisition payments relating to the Product, until XOMA has received \$20.0 million of payments in respect of the foregoing, or the PFS Agreement, with Aguettant pursuant XOMA Threshold, or the Stepdown Date; and

(ii) following the Stepdown Date, (A) 100% of payments based on net sales of the Product other than net sales to 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 Department of a solution Defense, or DoD and (B) 50% 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 each of the calendar year after the first launch of a product (or December 31 following: (a) payments based on net sales 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 Product 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 DoD, (b) potential sales-based milestone payments that, combined with the PFS Purchase Price, will range from 40% to 45% in respect of net sales in of the United States.

The Company Product, and Aguettant will agree on minimum sales obligations twelve (12) months prior (c) certain associated license and acquisition payments relating to the launch of each product, Product.

The Company has retained its right, title and interest in and to, following the right to grant sublicenses to its affiliates or, with Stepdown Date, 50% of each of the prior approval following: (a) payments based on net sales of Aguettant, third parties, subject to certain limitations.

In connection with AcclRx'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 Product to the PFS Agreement, or the Amended PFS Agreement, pursuant to which, effective April 3, 2023, (a) Aguettant paid AcclRx a complementary payment in the amount of EUR 1,500,000, and DoD, (b) AcclRx's obligation to make a certain specified sales-milestone payment terminated such that the maximum amount in potential sales-based milestone payments in respect of net sales of the Product, and (c) of certain associated license and acquisition payments relating to the Product.

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

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

The Company evaluated the terms of the Purchase Agreement and concluded that Aguettant the features of the Purchased Receivables are similar to those of a debt instrument. Accordingly, the Company recorded the allocated proceeds of approximately \$6.6 million reduced by approximately \$0.5 million of transaction costs, as a liability. The Company accounts for the value of the debt at amortized cost. The amounts received by the Company will be

accreted to the total estimated amount of the payments necessary to extinguish the Company's obligation under the Purchase Agreement, which will be recognized as interest expense. The carrying value of the debt will decrease for payments made to XOMA.

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

As the payments are remitted to XOMA, the liability will be effectively repaid over the life of the agreement. In order to determine the amortization of the liability related to the sale of future payments, the Company is required to estimate the total amount of future payments to XOMA over the life of the Purchase Agreement. At execution and as of the three months ended March 31, 2024, the estimated effective interest rate under the agreement was 13.3%.

The Company did not recognize any non-cash payment interest revenue and recognized non-cash interest expense of approximately \$0.2 million during the three months ended March 31, 2024. The interest and amortization of issuance costs are reflected as non-cash interest expense for the sale of future payments in the condensed consolidated statements of operations.

The following table shows the activity within the liability account during the three months ended March 31, 2024 (in thousands):

	Three months ended March 31, 2024
Liability related to sale of future payments — beginning balance	\$
Proceeds from sale of future payments, net of issuance costs	6
Payments to XOMA	
Non-cash interest expense recognized	
Liability related to sale of future payments as of March 31, 2024	\$ 6

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. Interest expense related to the Loan Agreement was \$0.1 million, \$39,000 of which represented amortization of the debt discount, for the three months ended March 31, 2023.

6. Commitments and Contingencies

Litigation

On June 8, 2021, 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) 10(b) and 20(a) 20(a) of the Exchange Act and SEC Rule 10b-5 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, December 16, 2021, the Court appointed co-lead plaintiffs. Plaintiffs' amended complaint was filed on March 7, 2022, March 7, 2022. The amended complaint named the Company and three of its officers and continued to allege that defendants violated Sections 10(b) 10(b) and 20(a) 20(a) of the Exchange Act and SEC Rule 10b-5 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, 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, July 21, 2022. On September 28, 2022, 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 November 28, 2022, the plaintiffs filed their second amended complaint. On July 7, 2023, 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, September 5, 2023, the plaintiffs filed a third amended complaint. On May 7, 2024, the Court granted defendants' motion to dismiss the third amended complaint, with prejudice, and entered judgment for defendants on plaintiffs' claims.

On July 6, 2021, 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, September 30, 2021, October 26, 2021, and November 17, 2021, 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, December 6, 2021, the Court entered an order consolidating all four actions and staying the consolidated action pending the outcome of any motion to dismiss the securities class action.

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

Please see "Part 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 January 2024 Private Placement

On July 17, 2023, January 17, 2024, the Company entered into a securities purchase agreement, or the Purchase Agreement, private placement with several certain institutional investors or for aggregate gross proceeds of \$6.0 million upfront, an additional \$10.0 million committed upon the announcement of positive clinical trial results for the Company's NEPHRO CRRT study of Niyad, and an additional \$2.0 million if Talphera stock trades above a specified price following the NEPHRO CRRT registration trial announcement, before deducting offering expenses payable by the Company.

The terms of the Private Placement include:

- (i) the first tranche of the Private Placement, which closed on January 22, 2024, resulted in the aggregate gross proceeds to the Company of approximately \$6.0 million for Pre-Funded Warrants to purchase up to 7,792,208 to purchase shares of the Company's common stock, par value \$0.001 per share, or the Common Stock, excluding the proceeds, if any, from the exercise of the Pre-Funded Warrants issued in such tranche (see Note 8, "Warrants" for additional information).
- (ii) the second tranche of the Private Placement, which is a conditional purchase by the Purchasers subject to either (a) the satisfaction or waiver of achieving, by September 30, 2024, the NEPHRO CRRT primary and one of the secondary clinical trial endpoints, resulting in the Company issuing pre-funded warrants to purchase up to 12,987,013 shares of Common Stock, and receiving additional aggregate gross proceeds of approximately \$10.0 million, and/or (b) the satisfaction or waiver of the volume-weighted average price of the Common Stock for each of the immediately subsequent five (5) trading days following the Company's announcement of its NEPHRO CRRT trial data being at least \$0.92 per share, resulting in the Company issuing pre-funded warrants to purchase up to 2,597,402 shares of Common Stock and receiving additional aggregate gross proceeds of approximately \$2.0 million.

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

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

8. Warrants

The activity related to warrants during the three months ended March 31, 2024, is summarized as follows:

	Common Stock from Warrants	Weighted-average Exercise Price (per share)
Outstanding at December 31, 2023	21,682,049	\$ 1.40
Granted	7,792,208	\$ 0.001
Outstanding at March 31, 2024	29,474,257	\$ 0.96
Exercisable at March 31, 2024	29,474,257	\$ 0.96

January 2024 Pre-Funded Warrants and Amendment of Prior Warrants

On January 17, 2024, the Company entered into Securities Purchase Agreements (see Note 7, "Stockholders' Equity" for additional information), relating to the issuance and sale of up to 7,792,208 pre-funded warrants to the Purchasers in a two-tranche private placement, of 5,340,591 or the Private Placement, to purchase shares of common stock, par value \$0.001 the Company's Common Stock, at a purchase price of \$0.769 per share pre-funded warrants to purchase up to an aggregate of 2,012,356 shares of common stock at and an exercise price of \$0.001 per share, or the 2023 January 2024 Pre-Funded

Warrants: Warrants. The January 2024 Pre-Funded Warrants are exercisable immediately, subject to certain ownership restrictions, following each closing date of the Private Placement and have an unlimited term.

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

In July 2023, in connection with a prior private placement, the Company issued to certain of the Purchasers (i) Series A common stock purchase warrants to purchase up to an aggregate of 7,352,947 3,676,473 shares of common stock at an exercise price of \$1.11 per share; Common Stock and (ii) Series B common stock purchase warrants to purchase up to an aggregate of 7,352,947 3,676,473 shares of common stock at an exercise price Common Stock (the "Prior Warrants"). In connection with the January 2024 Private Placement, the Company and the Purchasers agreed to amend and restate, 2,941,178 of \$1.11 per share. See Note 8, "Warrants" for additional information regarding each 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 purchase warrants if fully exercised for cash, is approximately \$16.3 million.

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In May 2023, AcelRx engaged H.C. Wainwright & Co., LLC outstanding, by reducing their exercise price from \$1.11 to act as placement agent in \$0.77 per share. Pursuant to ASU 2021-04, the private placement. As compensation, AcelRx paid Company remeasured the placement agent a cash fee equal to 5.25% fair value of the aggregate gross proceeds generated from the private placement amended and reimbursed certain expenses restated Prior Warrants as of the placement agent modification date based on the modified terms and recorded the increase in connection with the private placement totaling \$0.1 million. fair value of \$0.3 million as equity issuance costs, all of which was allocated to additional paid in capital. 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 fair value assumptions related to the placement agent fully vested Series A common stock warrants, or placement agent Series A common stock warrants, to purchase 183,824 shares modification of common stock these 5,882,356 amended and fully vested Series B common stock warrants, or placement agent Series B common stock warrants, to purchase 183,823 shares restated Prior Warrants as 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

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The pre-funded warrants issued in December 2022 to purchase 2,632,898 shares of common stock, or the 2022 Pre-Funded Warrants, January 17, 2024 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\$0.77 per share, stock price of \$0.58\$0.769 per share, expected life of 5.254.5 years, volatility of 94.73%96.91%, 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 AceIRx 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% 4.02% 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,		March	March
	2023	2022	2023	2022	31, 2024	31, 2023
Research and development	\$ 210	\$ 139	\$ 383	\$ 466	\$ 107	\$ 93
Selling, general and administrative	168	519	1,016	1,545	195	457
Discontinued operations	—	43	19	226	—	19
Total	\$ 378	\$ 701	\$ 1,418	\$ 2,237	\$ 302	\$ 569

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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	Weighted Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Restricted stock units outstanding, January 1, 2023	82,778	\$ 16.97		

Restricted stock units outstanding, January 1, 2024			86,232	\$	7.57
Granted	44,091	1.76	131,724		1.03
Vested	(40,106)	19.31	(39,293)		12.06
Forfeited	(2,926)	13.91	—		—
Restricted stock units outstanding, September 30, 2023	83,837	\$	7.96		
Restricted stock units outstanding, March 31, 2024			178,663	\$	1.76

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** **15,090** shares of common stock underlying vested RSUs that were withheld during the quarter ended **March 31, 2023**, **March 31, 2024**, 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	\$ —

	Number of Stock Options Outstanding	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
January 1, 2024	893,321	\$ 33.41		
Granted	790,348	1.03		
Forfeited	—	—		
Expired	(12,320)	206.80		
Exercised	—	—		
March 31, 2024	1,671,349	\$ 16.82	7.9	\$ —
Vested and exercisable options— March 31, 2024	563,257	\$ 42.63	4.9	\$ —
Vested and expected to vest— March 31, 2024	1,671,349	\$ 16.82	7.9	\$ —

The per-share weighted average grant date fair value of the options granted during the nine months quarter ended September 30, 2023 March 31, 2024 was estimated at \$1.39 \$0.84 per share on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Nine Three months ended September 30, 2023 March 31, 2024	
Expected term (in years)	6.3	6.5
Risk-free interest rate	3.9	4.26 %
Expected volatility	94	98 %
Expected dividend rate		0 %

As of September 30, 2023, March 31, 2024, total stock-based compensation expense related to unvested options to be recognized in future periods was \$1.1 million \$1.4 million which is expected to be recognized over a weighted-average period of 2.2 2.9 years. As of September 30, 2023, March 31, 2024, there were 151,953 721,567 shares available for grant under the Company's equity incentive plans and 169,667 99,157 shares available for grant under the Amended ESPP.

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

The Company applies the two-class method to compute Company's basic net income (loss) loss per share of common stock is calculated by dividing the net income (loss) attributable to common shareholders loss by the weighted average number of shares of common stock outstanding for the period. The diluted net income (loss) 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 January 2024 and July 2023 with a de minimis exercise price of \$0.001 per share, and 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	<u>\$ (1,357)</u>	<u>\$ (6,936)</u>
Weighted average shares outstanding — basic	16,758,322	7,377,363
Loss from continuing operations, basic	<u>\$ (0.08)</u>	<u>\$ (0.65)</u>
Income from discontinued operations, basic	<u>\$ 0.00</u>	<u>\$ (0.29)</u>
Loss per share, basic	<u>\$ (0.08)</u>	<u>\$ (0.94)</u>
<i>Diluted net loss per common share:</i>		
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	<u>\$ (1,357)</u>	<u>\$ (6,936)</u>
Weighted average shares outstanding — diluted	16,758,322	7,377,363
Loss from continuing operations, diluted	<u>\$ (0.08)</u>	<u>\$ (0.65)</u>
Income from discontinued operations, diluted	<u>\$ 0.00</u>	<u>\$ (0.29)</u>
Net loss per share, diluted	<u>\$ (0.08)</u>	<u>\$ (0.94)</u>

	Nine Months ended September 30,	
	2023	2022
	(in thousands, except share and per share amounts)	
<i>Basic net income (loss) per common share:</i>		
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	<u>\$ (13,880)</u>	<u>\$ 49,073</u>
Weighted average shares outstanding — basic	12,880,338	7,338,853
Income (loss) from continuing operations, basic	<u>\$ (0.45)</u>	<u>\$ 8.03</u>
Loss from discontinued operations, basic	<u>\$ (0.63)</u>	<u>\$ (1.34)</u>
Net income (loss) per share, basic	<u>\$ (1.08)</u>	<u>\$ 6.69</u>
<i>Diluted net income (loss) per common share:</i>		
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)	<u>\$ 58,900</u>

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) 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,		Three Months Ended March 31,	
	2023	2022	2023	2022	2024	2023
RSUs, stock options and ESPP to purchase common stock	959,169	821,875	959,169	817,086	1,850,012	989,011
Common stock warrants	20,265,576	964,983	20,265,576	910,928	20,265,576	5,192,035

In addition, the shares held back and contingently issuable in connection with the Lowell Merger, as described in Note 4, "Asset Acquisition" to the Company's 2023 Annual Report on Form 10-K, have also been excluded from the computation of diluted net loss per share of common stock for the periods presented because the contingencies for issuance of these shares have not been met.

11. Subsequent Events

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 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 December 31, 2023, 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. Report.

About AcetRx Pharmaceuticals, Talphera, 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 nifamostat 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	TargetUse	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	TargetUse	Status
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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, January 2022, we acquired Lowell Therapeutics, Inc., or Lowell, a privately held company, pursuant to the Agreement and Plan of Merger, dated as of November 14, 2021, or the Merger Agreement, in a transaction for consideration of approximately \$32.5 million plus net cash acquired and certain other adjustments, and which includes up to approximately \$26.0 million of contingent consideration payable in cash or stock at AcelRx's our option, upon the achievement of regulatory and sales-based milestones, or the Merger Agreement. In connection with the Merger Agreement, we acquired Niyad 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 the year ended December 31, 2023 for additional information.

Nafamostat Product Candidates

Product/Product

Candidate	Description	TargetUse	Status
Niyad	Lyophilized vial containing nafamostat for injection	Regional anticoagulant for injection into the extracorporeal circuit	Received an investigational device exemption, or IDE, and Breakthrough Device Designation from the United States Food and Drug Administration, or FDA. Plan to begin enrollment in a registrational trial in the second quarter of 2024.
LTX-608	Lyophilized vial containing nafamostat for injection	IV infusion for disseminated intravascular coagulation, or DIC, acute respiratory distress syndrome, or ARDS, acute pancreatitis, or as an anti-viral treatment	IND to be submitted following toxicology evaluation to enable Phase 2 study.

Niyad

We are developing Niyad to become the first and currently only FDA-approved regional anticoagulant for injection into the extracorporeal circuit, such as the dialysis circuit during continuous renal replacement therapy, or CRRT, for acute kidney injury, or AKI, patients in the hospital, and for chronic kidney

disease patients undergoing intermittent hemodialysis, or IHD, in dialysis centers. Niyad is expected to be used during renal replacement therapy for AKI patients in the hospital and for end-stage renal disease, or ESRD, patients receiving dialysis in outpatient clinics. Niyad is being studied under an Investigational Device Exemption, or IDE, and has received Breakthrough Device Designation from the FDA and an ICD-10 procedural code from the U.S. Centers for Medicare & Medicaid Services. While not approved for commercial use in the United States, the active drug component of Niyad, nafamostat, has been approved in Japan and South Korea as a regional anticoagulant for the dialysis circuit, disseminated intravascular coagulation and acute pancreatitis. Niyad has the potential for six years of data exclusivity upon FDA approval of the device. Niyad is a lyophilized formulation of nafamostat, a broad-spectrum, synthetic serine protease inhibitor, which has a half-life of 8 minutes, with anticoagulant, anti-inflammatory and potential anti-viral activities.

On July 14, 2021, we entered into The Niyad NEPHRO CRRT Study, which has received both IDE approval from the FDA and central Institutional Review Board, or IRB, approval, is designed as a License prospective, double-blinded trial to be conducted at up to 10 U.S. hospital intensive care units. NEPHRO CRRT stands for Nafamostat Efficacy in Phase 3 Registrational Continuous Renal Replacement Therapy Study. The NEPHRO study is set to begin enrolling patients in the second quarter of 2024. We plan to submit an application for Premarket Approval, or PMA, to the FDA upon completion of the trial. The study will enroll and Commercialization Agreement, evaluate 166 adult patients undergoing renal replacement therapy, who cannot tolerate heparin or are at risk for bleeding. The primary endpoint of the PFS Agreement, study is mean post-filter activated clotting time using Niyad versus placebo over the first 24 hours. Key secondary endpoints include filter lifespan, number of filter changes over 72 hours, number of transfusions over 72 hours and dialysis efficacy (based on urea concentration) over the first 24 hours. We believe that decades of nafamostat studies on anticoagulation of the extracorporeal circuit can help guide and support our Niyad development efforts.

LTX-608

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

Pre-filled Syringe (PFS) Product Candidates

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

Fedsyra and Phenylephrine

The PFS product candidates are ready-to-use formulations of active ingredients that are currently approved in the United States (i) an in concentrated formulations that must be diluted prior to administration to patients, and more recently in ready-to-use vial, and in the case of ephedrine, ready-to-use pre-filled syringe formulations. Hospitals currently purchase ready-to-use, pre-filled syringe presentations of these active ingredients mainly from compounding

facilities that have not obtained FDA approval for the products, or manually dilute the products in-house. There have been two recently FDA-approved pre-filled ephedrine syringe products made available on the market. Our product candidates have been developed in a ready-to-use strength and pre-filled into syringes that can be immediately administered to patients, eliminating the need for calculations and additional dilution and filling steps. Aguetant pre-filled syringes are focused on delivering commonly used medicines safely and efficiently. Perioperative medication errors continue, and pre-filled syringes are preferred for improving safety while containing costs. We believe that, if approved, our pre-filled syringe products may offer significant benefits to hospitals and surgery centers and avoid potential disadvantages of the currently available compounded products. We are currently evaluating the timing of submitting the NDA for our ephedrine pre-filled syringe 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. Aguetant will supply us with given the two other FDA-approved products for use in commercialization and, if they are approved in recently made available on the U.S., Aguetant was originally entitled to receive up to \$24 million in sales-based milestone payments. In connection with our and Aguetant'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 Aguetant pursuant to which, effective on April 3, 2023, (a) Aguetant paid us a complementary payment in the amount of €1.5 million, and (b) the maximum amount in sales-based milestone payments that Aguetant is entitled to receive will reduce to \$21 million. market.

On July 14, 2021, we also entered into a License and Commercialization Agreement, or the DZUVEO Agreement, with Aguetant pursuant to which Aguetant 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 Aguetant with primary packaged product and Aguetant then completes secondary packaging of the finished product. Pursuant to the DSUVIA Agreement (as defined below), we and Aguetant 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

Our strategy is focused on developing, obtaining approval, and commercializing our product candidates, Niyad first and the pre-filled syringes. foremost, Niyad. Accordingly, we divested DSUVIA to Vertical Pharmaceuticals, LLC, a wholly owned subsidiary of Alora Pharmaceuticals, LLC, or Alora, in April 2023, who will continue to commercialize the product and pay us sales-based milestone and other payments. payments, as defined in the DSUVIA Agreement (see Note 3, "Discontinued Operations" to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information). Further, we will continue marketing DSUVIA to the Department of Defense, or DoD. We believe this will maximize the value of DSUVIA as Alora has more available resources to invest on DSUVIA commercialization and as a result can execute a more robust commercial plan to support DSUVIA sales expansion, while we further reduce our operating costs. expansion. We have no plans on to further developing develop or commercializing commercialize any of our other sufentanil sublingual products that were previously our product candidates. We are focused on initiating a registrational study. As described below, in January 2024, we entered into an agreement with XOMA (US) LLC, or XOMA, whereby we have sold our rights to all payments for services performed to support sales of Niyad later this year and anticipate submitting a PMA application for Niyad DSUVIA to the FDA DoD by Alora under the Marketing Agreement, and sales milestones we are entitled to under the DSUVIA Agreement with Alora, until XOMA receives a certain specified return on its investment, after which we will share equally in the second half payments earned on sales to the Department of 2024. On October 25, 2022, we filed a certificate Defense, milestones and other payments from Alora (see Note 4, "Sale 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 Future Payments" to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information. information). This transaction was consummated to provide further funding for the development of our lead product candidate, Niyad. We expect to begin enrollment in the Niyad registrational trial in the second quarter of 2024 to execute on our goal of obtaining FDA approval for Niyad.

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 global events have impacted our global supply chain and we may face further disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products if the global COVID-19 pandemic persists. products. Such supply disruptions may adversely impact our ability to continue development of our product candidates and ultimately generate sales of and revenues from any approved products, and our business, financial condition, results of operations and growth prospects could be adversely affected.

Inflation

We do not believe that inflation has had a material impact on our business or operating results during the periods presented. However, inflation, led by supply chain constraints, federal stimulus funding, increases to household savings, and the sudden macroeconomic shift in activity levels arising from the loosening or removal of many government restrictions, 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, In January 2024, we closed entered into the XOMA Agreement pursuant to which we sold to XOMA our divestment right to amounts payable to us by Alora under the DSUVIA Agreement in exchange for \$8.0 million in order to monetize certain future payments for services performed to support sales of DSUVIA to Alora. In connection the DoD by Alora under the Marketing Agreement, payments on commercial sales of DSUVIA by Alora, and sales milestones we are entitled to under the DSUVIA Agreement with Alora, retaining the closing right, after XOMA has received \$20.0 million of payments in respect of such payments, or the XOMA Threshold, to 50% of the transaction, we received a total payments in respect of approximately \$2.7 million from Aguetant 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 net sales 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 DSUVIA to the CMOs drug master file, or DMF, for the nafamostat API. AcclRx DoD, 50% of potential sales-based milestones in respect of net sales of DSUVIA and the CMO are required 50% of certain associated license and acquisition payments relating to use good faith efforts to execute a Master Supply Agreement, or MSA, with exclusivity outside DSUVIA (see Note 4, "Sale 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" Future Payments" to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information. 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 March 31, 2024 and 2023 was \$1.4 million \$4.0 million and \$13.9 million \$8.2 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, respectively. As of September 30, 2023 March 31, 2024, we had an accumulated deficit of \$439.7 million \$448.2 million. As of September 30, 2023 March 31, 2024, we had cash, cash equivalents and short-term investments totaling \$13.4 million \$18.6 million compared to \$20.8 million \$9.4 million as of December 31, 2022 December 31, 2023.

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 March 31, 2024, from those previously disclosed in our Annual Report, except as follows:

Sale of Future Payments

On January 12, 2024, we entered into the Purchase Agreement with XOMA to monetize a portion of our future payments for services performed to support sales of DSUVIA to the DoD by Alora under the Marketing Agreement, and sales milestones under the DSUVIA Agreement. Refer to Note 4, "Sale of Future Payments" for further details on the Purchase Agreement.

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

We will periodically assess the amount and timing of expected payments using a combination of internal projections and historical data. To the extent our future estimates of future payments are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, we will adjust the amortization of the Sale of Future Payment Liability and prospectively recognize the related non-cash interest expense.

Recently Issued Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board, or FASB, issued Accounting Standard Update, or ASU, 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, or ASU 2023-07, which requires all public entities, including public entities with a single reportable segment, to provide in interim and annual periods one or more measures of segment profit or loss used by the chief operating decision maker to allocate resources and assess performance. Additionally, the standard requires disclosures of significant segment expenses and other segment items as well as

incremental qualitative disclosures. The guidance in this update is effective for fiscal years beginning after December 15, 2023, and interim periods after December 15, 2024. We are evaluating the disclosure impact of ASU 2023-07; however, the adoption of ASU 2023-07 will not have a material impact on our consolidated financial statements.

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

We 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, statements.

Results of Operations

Our unaudited condensed consolidated results of operations are presented for the three and nine months ended September 30, 2023 March 31, 2024 and 2022, 2023. Certain financial results (revenues and expenses) relating to the divestment of our DSUVIA/DZUVEO business are reflected in discontinued operations. See Note 3, "Discontinued Operations" to the 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.

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

Three and Nine Months Ended September 30, 2023 March 31, 2024 and 2022 2023

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 AcetRx 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, candidates.

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

Below is a summary of our research and development expenses during the three and nine months ended September 30, 2023 March 31, 2024 and 2022 2023 (in thousands, except percentages):

Drug Indication/Description	Three Months Ended September 30,				Nine Months Ended September 30,				Three Months Ended			
			\$	%			\$	%			\$	%
	2023	2022	Change 2023 vs. 2022	Change 2023 vs. 2022	2023	2022	Change 2023 vs. 2022	Change 2023 vs. 2022				
(In thousands, except percentages)									March 31,			
									2024	2023	Change 2024 vs. 2023	Change 2024 vs. 2023
Niyad	\$ 273	\$ 47	\$ 226	481 %	\$ 1,232	\$ 305	\$ 927	304 %	\$ 424	\$ 472	\$ (48)	(10) %
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 %	1,009	575	434	75 %
Total research and development expenses	\$ 1,178	\$ 799	\$ 379	47 %	\$ 3,777	\$ 2,729	\$ 1,048	38 %	\$ 1,433	\$ 1,047	\$ 386	37 %

Research and development expenses increased for the three and nine months ended September 30, 2023 increased March 31, 2024, as compared to the three and nine months ended September 30, 2022 March 31, 2023, primarily due to increased spending on Niyad, an increase in personnel related costs associated with Niyad development.

Selling, General and Administrative Expenses

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

Total selling, general and administrative expenses for the three and nine months ended September 30, 2023 March 31, 2024 and 2022 2023, were as follows (in thousands, except percentages):

Three Months Ended September 30,				Nine Months Ended September 30,			
		\$ Change 2023 vs. 2022	% Change 2023 vs. 2022			\$ Change 2023 vs. 2022	% Change 2023 vs. 2022
2023	2022			2023	2022		

(In thousands, except percentages)								
Selling, general and administrative expenses	\$	2,248	\$	3,724	\$	(1,476)	(40)%	\$ 9,199 \$ 11,784 \$ (2,585) (22)%

	Three Months Ended			
	March 31,		\$ Change	% Change
	2024	2023	2024 vs. 2023	2024 vs. 2023
Selling, general and administrative expenses	\$ 2,804	\$ 4,281	\$ (1,477)	(35)%

Selling, general and administrative expenses decreased for the three months ended **September 30, 2023** **March 31, 2024**, as compared to the three months ended **September 30, 2022** **March 31, 2023**, primarily due to the divestment of DSUVIA. More specifically, the decrease was attributed to a **\$0.7 million** **\$0.4 million** reduction in employee compensation and related expenses as a result of due to a reduction in headcount, a **\$0.6 million** **\$0.5 million** reduction in consulting and legal fees, a **\$0.3 million** decrease in stock-based compensation expense, 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, **\$0.3 million**.

Other **Income(Expense)** **Income (Expense), Net**

Total other income (expense), net for the three and nine months ended **September 30, 2023** **March 31, 2024** and **2022** **2023**, was as follows (in thousands, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
			\$ Change	% Change			\$ Change	% Change
			2023 vs.	2023 vs.			2023 vs.	2023 vs.
	2023	2022	2022	2022	2023	2022	2022	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)%

	Three Months Ended			
	March 31,		\$ Change	% Change
	2024	2023	2024 vs. 2023	2024 vs. 2023
Interest expense	\$ —	\$ (119)	\$ 119	(100)%
Interest income and other income, net	220	200	20	10 %

Gain on sale of future payments	1,246	—	1,246	— %
Change in fair value of warrant liability	(1,002)	5,311	(6,313)	(119)%
Non-cash interest expense on liability related to sale of future payments	(181)	—	(181)	— %
Total other income (expense), net	\$ 283	\$ 5,392	\$ (5,109)	(95)%

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 April 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 March 31, 2024 and 2022, 2023, primarily consisted of changes interest earned on our investments.

Gain on sale of future payments for the three months ended March 31, 2024 consisted of \$1.2 million in other income related to the XOMA Purchase Agreement (see Note 4, "Sale of Future Payments").

Change in fair value of warrant liability for the three months ended March 31, 2024 included a \$1.0 million increase 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 \$5.3 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 first quarter 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 expense on the liability related to the sale of future royalties payments 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 XOMA Purchase Agreement. Please refer to Note 4, "Sale of PDL BioPharma, Inc., or PDL) Future Payments" 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 unaudited condensed consolidated financial statements or other records as a sale of assets to PDL or SWK and all security interests and other liens of every type held by the parties to the royalty monetization have been terminated and automatically released without further action by any party. The \$84.1 million gain in this Quarterly Report on extinguishment of the liability related to the sale of future royalties is recognized in the consolidated statements of operations as other income. Form 10-Q for additional information.

Discontinued Operations

For the three months ended September 30, 2023 March 31, 2023, we recognized an impairment on net income assets held for sale of \$7.0 million and a loss 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 \$1.2 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 As of March 31, 2024, we had cash, cash equivalents and investments totaling \$18.6 million, compared to \$9.4 million as of December 31, 2023. Our cash and investment balances are held in a variety of interest-bearing instruments, including obligations of commercial paper, U.S. government sponsored enterprise debt securities and money market funds. Cash in excess of immediate requirements is invested with a view toward capital preservation and liquidity.

To date, we have incurred losses and generated negative cash flows from operations and we expect to incur significant losses in 2023 2024 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 raised additional capital 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"), January 2024 as discussed below, considering our current cash resources and current and expected levels of operating expenses for the next twelve months, we expect to need additional capital to fund our planned operations prior to the twelve-month anniversary of the filing date of this 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 OfferingsSM Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, issuance of 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 parties. Our existing capital resources will not be sufficient to fund our product candidates. On October 18, 2023, operations until such time as 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." able to generate sufficient revenues to sustain our operations.

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

We have funded XOMA Purchase Agreement

In January 2024, we entered into the Purchase Agreement with XOMA in exchange for \$8.0 million for the sale of our operations primarily through issuance of equity securities, borrowings, right, title and interest in and to amounts payable to us pursuant to the DSUVIA Agreement with Alora until the XOMA Threshold is attained, after which time we may share in certain future payments from Grünenthal, monetization Alora (see Note 4, "Sale of certain future royalties and commercial sales milestones from Future Payments" to 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. unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information).

As January 2024 Private Placement

In January 2024, we entered into securities purchase agreements with institutional investors, relating to the issuance and sale of September 30, 2023, we had cash, cash equivalents pre-funded warrants to the purchasers in a two-tranche private placement to purchase shares of Common Stock at a purchase price of \$0.769 per share and investments totaling \$13.4 million, compared to \$20.8 million as an exercise price of December 31, 2022. \$0.001 per share. The decrease was primarily due to cash required to fund our continuing operations, including repayment pre-funded warrants are exercisable immediately and have an unlimited term. The terms of the Loan Agreement private placement included:

- the first tranche of the private placement, which closed in January 2024, resulted in the aggregate gross proceeds of approximately \$6.0 million excluding the proceeds, if any, from the exercise of the pre-funded warrants issued in such tranche. In the first tranche of the private placement, we issued pre-funded warrants to purchase up to 7,792,208 shares of Common Stock.

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

In connection with Oxford, development activities for our newly acquired late-stage pipeline product candidates, the private placement, we agreed to amend and business development activities, including restate a portion of the divestment of DSUVIA, partially offset by net proceeds of \$8.9 million received outstanding warrants issued in connection with our the July 2023 equity financing (as described private placement (Refer to Note 9, "Stockholders' Equity" and Note 10, "Warrants" to the consolidated financial statements in further detail below). Our existing capital resources will not be sufficient our Annual Report on Form 10-K for the year ended December 31, 2023 for additional information), representing (i) Series A common stock purchase warrants to fund our operations until such time as purchase up to 2,941,178 shares of Common Stock and (ii) Series B common stock purchase warrants to purchase up to 2,941,178 shares of Common Stock, to reduce the exercise price thereunder to \$0.77 per share.

Registration Statement on Form S-3

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

Pursuant to Cantor Controlled Equity OfferingsSM Sales Agreement

In June 2016, we entered into a Controlled Equity OfferingsSM Sales Agreement, as amended, the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, as our agent, pursuant to which 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 March 31, 2024 or 2023. As of March 31, 2024, while we issued and sold approximately 0.04 million shares \$35.6 million of our common stock pursuant to remained available for sale and issuance under 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. Agreement. As of September 30, 2023 March 31, 2024, we did not have an effective shelf registration statement, and we will not be able had the ability to make any further sales sell approximately \$35.6 million of our common stock under the ATM Agreement, until such time as we file subject to the filing of a new shelf prospectus supplement with the SEC to our registration statement and it is declared effective by the SEC. In addition, our on Form S-3. 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.

Cash Flows

	Three Months Ended March 31,	
	2024	202
Net cash used in operating activities	\$ (2,883)	\$
Net cash (used in) provided by investing activities	(2,730)	
Net cash provided by (used in) financing activities	12,014	

On May 30, 2019, we entered into The discussion of our cash flows that follows includes the Loan Agreement with Oxford. Under the Loan Agreement, we borrowed an aggregate principal amount impact 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 discontinued operations. For additional information, see Note 5, "Long-Term Debt" 3.

"Discontinued Operations" to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information. 10-Q.

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)	\$
Net cash provided by investing activities	3,123	
Net cash provided by (used in) financing activities	3,534	

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 payments and interest expense related to our debt financings.

Cash used in operating activities of \$13.5 million \$2.9 million during the nine three months ended September 30, 2023 March 31, 2024, reflected a net loss of \$13.9 million \$4.0 million, partially offset by aggregate non-cash charges of approximately \$1.7 million \$1.4 million. Significant non-cash adjustments included a \$1.0 million increase in the fair value of our warrant liability, \$0.3 million in stock-based compensation expense, and \$0.2 million in interest expense related to the sale of future payments. The net change in our operating assets and liabilities was primarily due to a \$0.8 million decrease in prepaid expenses and other assets and a \$1.1 million decrease in accrued liabilities.

Cash used in operating activities of \$5.3 million during the three months ended March 31, 2023, reflected a net loss of \$8.2 million, partially offset by aggregate non-cash charges of \$2.1 million and included an approximate \$1.4 million \$0.8 million net change in our operating assets and liabilities. Non-cash adjustments included an impairment charge of \$6.9 million \$7.0 million on our net assets held for sale in connection with our divestment of DSUVIA, an impairment charge of \$1.1 million on fixed assets, a gain of \$1.1 million related to the termination of lease liabilities, a \$5.7 million \$5.3 million decrease in the fair value of our warrant liability \$1.4 million and \$0.6 million in stock-based compensation expense, a \$0.4 million gain on extinguishment of debt, and \$0.3 million in depreciation and amortization expense. The net change in our operating assets and liabilities included a \$1.3 million \$1.6 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** **three** months ended **September 30, 2023** **March 31, 2024**, cash used in investing activities of \$2.7 million was primarily the net result of \$4.2 million in purchases of investments and \$1.5 million in proceeds from maturity of investments.

During the **three** months ended **March 31, 2023**, cash provided by investing activities of **\$3.1 million** **\$0.4 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** **maturity** 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**, **financings**, including the sale of future payments.

During the **nine** **three** months ended **September 30, 2023** **March 31, 2024**, cash provided by financing activities of **\$3.5 million** **\$12.0 million** was primarily due to **\$8.9 million** net proceeds from the XOMA Purchase Agreement of \$6.1 million, and \$5.9 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. **January 2024** private placement.

During the **nine** **three** months ended **September 30, 2022** **March 31, 2023**, cash used in financing activities of **\$5.8 million** **\$2.1 million** was primarily due to long-term debt payments under the Loan Agreement with Oxford. On April 3, 2023, in connection with the closing of the DSUVIA Agreement, we fully repaid the Loan Agreement with Oxford. Refer to Note 5, "Long-Term Debt" 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**. **candidates**. These assumptions may change as a result of many factors. We will continue to evaluate the work necessary to gain approval of our product candidates in the United States and intend to update our cash forecasts accordingly. Considering our current cash resources and current and expected levels of operating expenses for the next twelve months, we expect to need additional capital to fund our planned operations for at least the next twelve months.

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

- the ability to **retain** **successfully initiate and complete our clinical trial for the** **listing of our common stock on the Nasdaq exchange;** **Niyad** **product candidate.**
- expenditures related to the** **potential commercialization** **outcome, timing and cost of the development** of our **other nafamostat** product **candidates, if approved;** **candidates;**

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

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

Please see “Part 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, chief executive officer and Chief Financial Officer, 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, disclosure controls and Procedures, 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, internal control over Financial Reporting, financial reporting.

There have been no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter, the period covered by this Quarterly Report on Form 10-Q that have, has materially affected, or are, is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in legal proceedings relating to intellectual property, commercial, employment and other matters arising in the ordinary course of business. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position or cash flows. Please see the matters under the caption "Part I. Financial Information—Item 1. Financial Statements—Note 6, Commitments and Contingencies—**Litigation.**" **Litigation** in this Quarterly Report on Form 10-Q.

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.
- We may fail to initiate, properly conduct and/or successfully complete our clinical trial for our lead product candidate, Niyad™.
- If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- If we experience delays or difficulties in enrolling patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- If serious adverse effects or unexpected characteristics of our product candidates are identified during development, we may need to abandon or limit our the development of some or all of our product candidates.
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

- The process for obtaining approval of a Premarket Approval, or PMA, application or New Drug Application, or NDA, is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources.
- Our expectations for U.S. Food and Drug Administration, or FDA, approvability of our product candidates may be inaccurate.
- We may experience difficulties in retaining our existing employees and managing our operations.
- If we, or current and potential partners, are unable to compete effectively, our products may not reach their commercial potential.
- Sales of our divested product, DSUVIA, may fail to attain the threshold revenue levels required for us to share in future revenues from those sales.
- Coverage and adequate reimbursement may not be available for our product candidates, if approved, in the United States and in Europe, which could make it difficult for us, or our partners, to sell our products profitably.
- The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.
- If we or our partners are unable to establish and maintain relationships with group purchasing organizations any future revenues or future profitability could be jeopardized.
- Existing and future legislation may increase the difficulty and cost for us to commercialize our products and affect the prices we may obtain.
- We have incurred significant losses since our inception and anticipate that we will continue to incur losses in the future.
- To fund our operations, and capital requirements, we may sell additional equity securities, which may result in dilution to our stockholders, or debt securities, which may impose restrictions on our business.
- We have not yet generated significant product revenue and may never be profitable.
- We rely on third party manufacturers and suppliers for our product candidates in Asia and the United States and Europe. States.
- We rely on limited single sources of supply for the active pharmaceutical ingredients and finished product for our nafamostat-based product candidates and any disruptions in the chain of supply may cause a delay in developing our product candidates.
- Manufacturing issues may arise that could delay or increase costs related to product development and regulatory approval.
- We rely on third parties to conduct, supervise and monitor our clinical trials.
- Our relationships with clinical investigators, health care professionals, consultants, commercial partners, third-party payers, hospitals, and other customers are subject to applicable anti-kickback, fraud and abuse and other healthcare laws, which could expose us to significant penalties.
- Significant disruptions of our information technology systems or data security incidents could result in significant financial, legal, regulatory, business and reputational harm to us.
- Business interruptions could delay our operations and sales efforts.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- We may acquire companies, product candidates or products or engage in strategic transactions.
- We face potential product liability claims and, if such claims are successful, we may incur substantial liability.
- Our employees, agents and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.
- If we cannot defend our issued patents from third party claims or if our pending patent applications fail to issue, our business could be adversely affected.
- Litigation involving patents, patent applications and other proprietary rights is expensive and time consuming.
- It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.
- We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

- Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications will be due to be payable to the United States Patent and Trademark Office and various foreign governmental patent agencies annually in several stages over the lifetime of the patents and/or applications.
- We may not be able to enforce our intellectual property rights throughout the world.
- We have not yet registered our trademarks in all our potential markets, and failure to secure those registrations could adversely affect our business.
- The market price of our common stock has historically been and may continue to be highly volatile.
- Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.
- We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.
- Provisions in our amended and restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.
- If we cannot maintain compliance with Nasdaq's listing requirements, Nasdaq may delist our securities common stock from trading, on its exchange, which could limit investors' ability to make transactions in our securities common stock and subject us to additional trading restrictions.
- Litigation may substantially increase our costs and harm our business.
- Our involvement in securities-related class action and related derivative litigation could divert our resources and management's attention and harm our business.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.
- Our effective tax rate may fluctuate, we may be adversely affected by changes in tax laws and regulations, and we may incur obligations in tax jurisdictions in excess of accrued amounts.
- Macroeconomic uncertainties, including inflationary pressures, supply chain disruptions, labor shortages, significant volatility in global markets and recession risks 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. 2005. In addition, we have generated negative cash flows from operations and we expect to incur significant losses in 2023 2024 and may incur significant losses and negative cash flows from operations in the future. These conditions raise substantial doubt about our ability to continue as a going concern.

We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. To date, we have financed our operations primarily through the issuance of equity securities, borrowings, payments from Grünenthal GmbH, or Grünenthal, the monetization of certain future royalties and commercial sales milestones from the European sales of Zalviso by Grünenthal, funding from the Department of Defense, or DoD, with revenues from sales of DSUVIA, the monetization of certain future payments and commercial sales milestones from the sales of DSUVIA under the DSUVIA Agreement, and payments under the Amended DZUVEO Agreement with Aguetant. On January 12, 2024, we entered into the XOMA Agreement to monetize a portion of our future payments for services performed to support sales of DSUVIA to the DoD by Alora under the

Marketing Agreement, and sales milestones we are entitled to under the DSUVIA Agreement with Alora, retaining the right, after XOMA has received \$20.0 million of payments in respect of such payments and potential sales-based milestone payments, or the XOMA Threshold, to 50% of the payments in respect of net sales of DSUVIA to the DoD, 50% of potential sales-based milestones in respect of net sales of DSUVIA and 50% of certain associated license and acquisition payments relating to DSUVIA. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenues. We expect to continue to incur substantial expenses as we support research and development activities for our product candidates. If our product candidates are not successfully developed or commercialized in the U.S., or if revenues are insufficient following marketing approval, we will not achieve profitability and our business may fail. Our success is also dependent on current and future collaborations to market our products outside of the United States, which may not materialize or prove to be successful.

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

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

Clinical trials, regulatory reviews, and the launch of a commercial product are expensive activities. In addition, commercialization costs for our product candidates, if approved, in the United States may be significantly higher than estimated as a result of technical difficulties or otherwise. Revenues may be lower than expected and costs to produce such revenues may exceed those revenues. We will need to seek additional capital to continue operations. Such capital demands could be substantial. In the future, we may seek to raise such additional capital through public or private equity offerings, including under the Controlled Equity OfferingsSM 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 March 31, 2024 were prepared on the basis of a going concern, which contemplates that we will be able to realize our assets and discharge liabilities in the normal course of business. These financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

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

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

- further scale back or discontinue the development of our product candidates;
- seek corporate partners for our product candidates on terms that might be less favorable than might otherwise be available; or

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

During the past several years, domestic and international financial markets have experienced, and they may continue to experience, extreme disruption from time to time, including, among other things, high volatility, significant declines in stock prices and severely diminished liquidity and credit availability for both borrowers and investors. Such adverse capital and credit market conditions could make it more difficult to obtain additional capital on favorable terms, or at all, which could have a material adverse effect on our business and growth prospects. For example, our ability to raise additional capital may be adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the U.S. and worldwide resulting from the 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 or medical device product, pharmaceutical necessary product development activities and the regulatory environment, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are delayed in

receiving regulatory approval for our product candidates in the United States, or if we are required by the FDA to complete activities in addition to those we currently anticipate or have already completed.

Even if we are able There can be no assurance that Alora will successfully commercialize DSUVIA pursuant to generate revenues under the DSUVIA Agreement or Agreement. The XOMA Threshold may never be attained, and we may never realize sufficient payments from our retained future interest in DSUVIA from Alora to become profitable. Although we had a collaboration agreement with Grünenthal for commercialization of Zalviso in Europe and Australia, Grünenthal was unable to achieve a level of commercial sales of Zalviso to trigger sales milestone payments that would have been payable to us.

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

Future sales of DSUVIA to the DoD are not predictable, may occur on an irregular basis and may not meet our expectations due to various U.S. government-related factors that are beyond our control and into which we have little to no visibility, including the timing and extent of future U.S. military deployments. 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 is responsible for commercializing DSUVIA except that we will retain the responsibility for driving the demand within the DoD, and, if the XOMA Threshold is achieved, we will be entitled to receive quarterly payments in an amount equal to one-half of the 75% of net Product DSUVIA 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 the XOMA Threshold is achieved such that we receive payments, we may never generate revenue that is significant or predictable, which could impair our value and our ability to raise capital, expand our business or continue our operations. 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 to integrate the business, operations and products of Lowell successfully and efficiently with our business. The challenges involved in this integration include, but are not limited to, (i) difficulties entering new markets and integrating new product candidates with which we have no or limited direct prior experience; and (ii) successfully managing relationships with our combined supplier base.

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

Whether we receive royalties from payments for services performed to support sales of DSUVIA to the DoD after the XOMA Threshold is reached 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 may in the future share in certain payments including sales milestone payments based on their sales from Alora pursuant to the XOMA Agreement. In particular, we divested to XOMA our rights to payments from Alora, subject to our retained interest in certain future payments in the event the XOMA Threshold is met. The commercial success of DSUVIA will depend heavily on numerous factors, including:

- Alora's ability to market, sell, and distribute DSUVIA;
- Alora's ability to establish and maintain commercial manufacturing relationships with 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, candidates. Our ability to generate product revenue from these our 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. these product candidates. The success of these product candidates and any other product candidates we may develop, in-license or acquire will depend on many factors, including the following:

- successful enrollment in, and completion of, clinical trials;
- demonstrating safety and efficacy;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;

- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates;
- developing a sales and marketing organization or outsourcing these functions to third parties;
- launching commercial sales of the product candidates, if and when approved, whether alone or selectively in collaboration with others;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors; payers;
- effectively competing with other products;
- a continued acceptable safety profile of the products following approval;
- enforcing and defending intellectual property rights and claims; and
- other legal, regulatory, compliance, privacy, and fraud and abuse matters.

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

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

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

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

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

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate; enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

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

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

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

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the 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 the development of some or all of our product candidates.

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

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

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

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

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

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

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

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

On July 14, 2021, we entered into the PFS Agreement with Aguettant pursuant to which we obtained the exclusive right to develop and, subject to FDA approval, commercialize in the United States (i) an ephedrine pre-filled syringe for injection, and (ii) a phenylephrine pre-filled syringe for injection. Aguettant will supply us with the products for use in commercialization, if they are approved in the U.S. Our current expectation based on our

communication with the FDA is that FedSYRA, the PFS ephedrine product candidate, will be approvable by the FDA without additional manufacturing changes or clinical development. We have not yet received all the available data to support the planned NDA submission for the PFS phenylephrine product. If we or the FDA determine that additional development work will be needed for U.S. approval of either of the PFS product candidates, we would incur additional expense and be delayed in obtaining any revenue from that product.

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

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

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical or regulatory results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- our contracts for collaborative arrangements are or may be terminable at will on written notice and may otherwise expire or terminate, and we may not have alternatives available to achieve the potential for our products in those territories or markets;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration, including in connection with any contractual breach **notice including force majeure tied to the COVID-19 pandemic; notice;**
- we have limited control over the decisions of our partners, and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delays to the partnered program;
- our ability to generate future payments and royalties from our partners depends upon the abilities of our partners to establish the safety and efficacy of our drugs and devices, maintain regulatory approvals and our ability to successfully manufacture and achieve market acceptance of our products;
- we or our partners may fail to properly initiate, maintain or defend our intellectual property rights, where applicable, or a party may use our proprietary information in such a way as to invite litigation that could jeopardize or potentially invalidate our proprietary information or expose us to potential liability;
- our partners may not devote sufficient capital or resources towards our products; and
- our partners may not comply with applicable government regulatory requirements necessary to successfully market and sell our products.

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

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

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

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

The U.S. biotechnology and pharmaceutical industries are characterized by intense competition and cost pressure. Our Niyad product candidate, if approved in the U.S., may compete with currently available anticoagulants such as heparin and citrate. The **LTX-608 nafamostat product candidates, if approved in the U.S., may compete with existing or emerging third party products**. The PFS product candidates, if approved in the U.S., may compete with other ready-to-use formulations of ephedrine and phenylephrine. **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. **Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.**

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

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

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

If we cannot successfully manage the promotion of our product candidates, if approved, in the United States, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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

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

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

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

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

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

There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the Affordable Care Act. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that there will be additional health reform **measures 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, 2032, 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 which began on January 1, 2024.

In the United States, there has been increasing legislative and enforcement interest with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing and reform government program reimbursement methodologies for drugs. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although they may be the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In addition, response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration released announced an additional executive order on October 14, 2022 initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, directing HHS the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to report on how exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries, framework. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. Furthermore, even after initial price and reimbursement approvals, reductions in prices and changes in reimbursement levels can be triggered by multiple factors, including reference pricing systems and publication of discounts by third party payers or authorities in other countries. In Europe, prices can be reduced further by parallel distribution and parallel trade (i.e., arbitrage between low-priced and high-priced countries). If any of these events occur, revenue from sales of our products in Europe would be negatively affected.

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

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

Risks Related to Our Reliance on Third Parties

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

We currently use third party manufacturers to 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 essential product components or finished goods, such that if we are unable to secure a sufficient supply of these product components or finished goods, we will be unable to manufacture, supply and sell our products in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified secondary or backup suppliers for those essential components or finished goods that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, economic sanctions, or government orders related to the COVID-19 pandemic; pandemics;
- carrier disruptions due to international conflicts and/or increased costs that are beyond our control; and
- the failure to deliver our products under specified storage conditions and in a timely manner.

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

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

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

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

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

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

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

The facilities of any of our future manufacturers of Niyad must be approved by the FDA before commercial distribution from such manufacturers occurs. We do not fully control the manufacturing process and are completely dependent on these third-party manufacturing partners for compliance with the FDA or other foreign regulatory agency's requirements for manufacture. In addition, although our third-party manufacturers are well-established **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 will utilize 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 plans to rely upon CROs to monitor and manage data for our post-approval clinical programs for or any FDA-required clinical programs for our product candidates, as well as the execution of nonclinical and clinical trials. We control only certain aspects of our CROs' activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

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

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

Risks Related to Our Business Operations and Industry

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

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

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

- the federal civil and criminal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, among other things, imposes criminal liability for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly or willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, which impose certain obligations, including mandatory contractual terms, on covered healthcare providers, health plans and clearinghouses, and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- foreign laws, regulations, standards and regulatory guidance which govern the collection, use, disclosure, retention, security and transfer of personal data, including the European Union General Data Privacy Regulation, or GDPR, which introduces strict requirements for processing personal data of individuals within the European Union;
- the federal [transparency law](#), [Physician Payment Sunshine Act](#), enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies to report annually to the [Centers for Medicare & Medicare Services](#), or CMS information related to payments and other transfers of value provided to physicians, (defined to include, doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous state laws that may apply to our business practices, including but not limited to, state laws that require pharmaceutical companies to implement compliance programs and/or comply with the pharmaceutical industry's voluntary compliance guidelines; state laws that impose restrictions on pharmaceutical companies' marketing practices and require manufacturers to track and file reports relating to pricing and marketing information, which requires tracking and reporting gifts, compensation and other remuneration and items of value provided to healthcare professionals and entities, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, with differing effects; and
- the federal Foreign Corrupt Practices Act of 1977, United Kingdom Bribery Act 2010 and other similar anti-bribery laws in other jurisdictions which generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage.

Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more frequent and aggressive investigations and enforcement proceedings by both the Department of Justice and the SEC. A determination that our operations or activities are not, or were not, in compliance with United States or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of

supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. Other internal or government investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

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

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

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

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

There is no way of knowing with certainty whether we have experienced any data security incidents that have not been discovered. While we have no reason to believe this to be the case, attackers have become very sophisticated in the way they conceal access to systems, and many companies that have been attacked are not aware that they have been attacked. Any event that leads to unauthorized access, use or disclosure of personal information, including but not limited to personal information regarding our patients or employees, could disrupt our business, harm our reputation, compel us to comply

with applicable federal and state breach notification laws and foreign law equivalents, subject us to time consuming, distracting and expensive litigation, regulatory investigation and oversight, mandatory corrective action, require us to verify the correctness of database contents, or otherwise subject us to liability under laws, regulations and contractual obligations, including those that protect the privacy and security of personal information. This could result in increased costs to us, and result in significant legal and financial exposure and/or reputational harm. In addition, any failure or perceived failure by us or our vendors or business partners to comply with our privacy, confidentiality or data security-related legal or other obligations to third parties, or any further security incidents or other inappropriate access events that result in the unauthorized access, release or transfer of sensitive information, which could include personally identifiable information, may result in governmental investigations, enforcement actions, regulatory fines, litigation, or public statements against us by advocacy groups or others, and could cause third parties, including clinical sites, regulators or current and potential partners, to lose trust in us or we could be subject to claims by third parties that we have breached our privacy- or confidentiality-related obligations, which could materially and adversely affect our business and prospects. Moreover, data security incidents and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. While we have implemented security measures and obtained and maintain cybersecurity insurance intended to protect our information technology systems and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or security incidents, incidents, or adequately protect us against any such occurrences.

Business interruptions could delay our operations and sales efforts.

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

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

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

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

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

We may acquire or invest in companies, product candidates or products that we believe could complement or expand our business or otherwise offer growth opportunities. The pursuit of potential acquisitions or investments may divert the attention of management and has caused, and in the future may cause, us to incur various costs and expenses in identifying, investigating, and pursuing them, whether or not they are consummated. We may not be able to identify desirable acquisitions or investments or be successful in completing or realizing anticipated benefits from such transactions. In addition, the

acquisition of product candidates and products is a highly competitive area, and many other companies are pursuing the same or similar product candidates to those that we may consider attractive. Larger companies with more well-established and diverse revenue streams may have a competitive advantage over us due to their size, financial resources and more extensive clinical development and commercialization capabilities.

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

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

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

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

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

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

We are exposed to the risk that our employees, independent contractors, investigators, consultants, commercial partners and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates (1) regulations implemented by the FDA and similar foreign regulatory bodies; (2) laws requiring the reporting of true, complete and accurate information to such regulatory bodies; (3) healthcare fraud and abuse laws of the United States and similar foreign fraudulent misconduct laws; and (4) laws requiring the

reporting of financial information or data accurately. The promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry are subject to extensive laws designed to prevent misconduct, including fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of pricing, discounting, marketing, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. It is not always possible to identify and deter employee and other third-party misconduct. The precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws. If any such actions are instituted against us, and we are not successful in defending ourselves, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar agreements to resolve allegations of non-compliance with these laws, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Our Intellectual Property

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

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

As we continue to develop our product candidates, **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 needs** only prove infringement by a preponderance of the evidence, which is a lower burden of proof.

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

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

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

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

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

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

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

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

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

If we do not adequately protect our intellectual property rights, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could materially harm our business, negatively affect our position in the marketplace, limit our ability to commercialize any of our **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 the use of third-party vendors, to manage payment of periodic maintenance fees, renewal fees, annuity fees and various other patent and application fees. The United States Patent and Trademark Office, or the USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. There are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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

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

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

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

We have registered our ACELRX mark filed a trademark application for TALPHERA in the United States Canada, the EU and India, and will file related trademark applications in other major foreign pharmaceutical jurisdictions of interest. In addition, we have applied for registration obtained approval of our Niyad and Fedsyra marks. marks in the United States and are awaiting our first use of those marks in commerce in order to secure our federal registrations. Although we are not currently aware of any oppositions to or cancellations of our registered trademarks or pending applications, it is possible that one or more of the applications and/or registrations could be subject to rejection, opposition or cancellation. In addition, we will need to seek FDA approval to use Niyad and Fedsyra other potential product trademarks as part of future potential applications for marketing approval of the relevant developmental products. The registrations will be subject to use and maintenance requirements. It is also possible that we have not yet registered all of our trademarks in all of our potential markets, and that there are names or symbols 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 our issuance of common stock warrants, or the perception that these sales or issuances might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants under our equity incentive plans. Grants under our equity incentive plans may also cause our stockholders to experience additional dilution, which could cause our stock price to fall. 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 "Part I. Financial Information—Item 1. Financial Statements—Note 6, to the unaudited condensed consolidated financial statements Commitments and Contingencies—Litigation" 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 Talphera-specific events, such as receipt of Complete Response Letters, Warnings Letters, such as the Warning Letter we received from the FDA on February 11, 2021, negative clinical results, a negative vote or decision by an FDA advisory committee, or other negative feedback from the FDA, EMA, or other regulatory agencies. In the past, securities-related class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies often experience significant stock price volatility in connection with their investigational drug or medical device product candidate development programs and the FDA's review of their NDAs. Following receipt of the FDA's Warning Letter, a securities class action complaint was filed against us and two of our officers on June 8, 2021 in the United States District Court for the Northern District of California. The amended securities class action complaint, which was filed on March 7, 2022, named a third officer as a defendant. On September 28, 2022, the Court issued a formal written opinion, or the First Opinion, dismissing all of the plaintiff's claims against the Company and the named defendants with leave for plaintiffs to amend their complaint. On November 28, 2022, the plaintiffs filed their second amended complaint. On July 7, 2023, the Court issued a formal written opinion, or the Second Opinion, dismissing all of the plaintiff's claims against the Company and the named defendants with leave for plaintiffs to amend their complaint in part and without leave to amend in part. On September 5, 2023, the plaintiffs filed a third amended complaint. On May 7, 2024, the Court granted defendants' motion to dismiss the third amended complaint, with prejudice, and entered judgment for defendants on plaintiffs' claims. On July 6, 2021, September 30, 2021, October 26, 2021 and November 17, 2021, four purported shareholder derivative complaints were filed in the United States District Court for the Northern District of California asserting state and federal claims based on the same alleged misstatements as the securities class action complaint. On December 6, 2021, the Court entered an order consolidating all four actions and staying the consolidated action pending the outcome of any motion to dismiss the securities class action. On February 16, 2024, another purported shareholder derivative complaint was filed in the Court of Chancery of the State of Delaware, asserting the same claims as those in the previously filed derivative actions. The case has been stayed pending the

outcome of any motion to dismiss the securities class action. Please refer to “Part I. Financial Information—Item 1. Financial Statements—Note 6, to the unaudited condensed consolidated financial statements Commitments and Contingencies—Litigation” in this Quarterly Report on Form 10-Q for additional information about these pending legal proceedings. Securities-related class action litigation is 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 AcetRx Talphera experiences a decline in its stock price, we could face additional securities class action lawsuits.

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

As of December 31, 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 and 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. 2024 Annual Meeting of Stockholders

Our Board of Directors has established June 24, 2024 as the date of our 2024 Annual Meeting of Stockholders, or the 2024 Annual Meeting, as previously announced on the Current Report on Form 8-K filed with the SEC on April 19, 2024. The time and location of the 2024 Annual Meeting are as set forth in our definitive proxy statement for the 2024 Annual Meeting filed with the SEC on April 29, 2024.

Stockholders who intended to present proposals for inclusion in the proxy materials for the 2024 Annual Meeting pursuant to Rule 14a-8 promulgated under the Exchange Act, must ensure that such proposals were received by us, in writing, at 1850 Gateway Drive, Suite 175, San Mateo, California 94404, and were directed to the attention of the Corporate Secretary, no later than April 23, 2024, which we determined to be a reasonable time before we expect to begin to deliver and make available our proxy materials, and must have furthermore complied with all applicable requirements of Rule 14a-8.

Pursuant to our Amended and Restated Bylaws, to be considered timely, stockholders who intended to present proposals for director nominations or any other proposal at the 2024 Annual Meeting must have provided notice in writing to us at 1850 Gateway Drive, Suite 175, San Mateo, California 94404, and

have directed such notice to the attention of the Corporate Secretary, no later than the close of business on April 29, 2024, the tenth calendar day following the date of Current Report on Form 8-K filed with the SEC on April 19, 2024, publicly announcing the date of the 2024 Annual Meeting.

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).

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3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	06/25/2019
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	10/25/2022
3.5	Amended and Restated Bylaws of the Registrant.	8-K	001-35068	3.2	01/09/2024
10.1\$#	Payment Interest Purchase Agreement between the Registrant and XOMA (US) LLC, dated as of January 12, 2024.				
10.2	Form of Securities Purchase Agreement, dated January 17, 2024, by and among the Registrant and entities affiliated with Nantahala Capital Management, LLC.	8-K	001-35068	10.1	01/22/2024
10.3	Form of Securities Purchase Agreement, dated January 17, 2024 by and between the Registrant and Investor Company ITF Rosalind Master Fund L.P.	8-K	001-35068	10.2	01/22/2024
10.4	Form of Registration Rights Agreement, dated January 17, 2024.	8-K	001-35068	10.3	01/22/2024
10.5	Form of Pre-Funded Warrant (January 2024).	8-K	001-35068	10.4	01/22/2024
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.				
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+ 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.

- § Schedules omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of any omitted schedule upon request by the SEC.
- # Material in the exhibit marked with an "[*]" has been omitted because it is confidential, not material, and would be competitively harmful if publicly disclosed.
- * The certifications attached as Exhibit 32.1 accompany this 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 May 14, 2024

AcelRx Pharmaceuticals, Talphera, Inc.
(Registrant)

/s/ Raffi Asadorian

Raffi Asadorian

Chief Financial Officer

**(Duly Authorized and Principal Financial
and
Accounting Officer)**

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Exhibit 2.1 10.1

*** 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.

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED (INDICATED BY: ***) FROM THE EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) THE TYPE OF INFORMATION THAT THE REGISTRANT CUSTOMARILY AND ACTUALLY TREATS AS PRIVATE OR CONFIDENTIAL.

ASSET

PAYMENT INTEREST PURCHASE AGREEMENT

Between BY AND BETWEEN

ACELRX PHARMACEUTICALS, TALPHERA, INC.

and AND

VERTICAL PHARMACEUTICALS, XOMA (US) LLC

DATED AS OF JANUARY 12, 2024

Dated as

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List of Exhibits

- A Form of Bill of Sale
- B Disclosure Schedules
- C Vertical Notice and Waiver
- D Form of Vertical Instruction Letter
- E Form of Legal Opinion
- F Sale Agreement and Marketing Agreement

ASSET PAYMENT INTEREST PURCHASE AGREEMENT

THIS ASSET PURCHASE AGREEMENT, executed on March 12, 2023 (the This Payment Interest Purchase Agreement is dated as of January 12, 2024 (this “Effective Date Agreement”), is made by and entered into between AcelRx Pharmaceuticals, Inc.TALPHERA, INC., a Delaware corporation (“Seller”), and XOMA (US) LLC, a Delaware limited liability company, as Buyer (“Buyer”).

RECITALS

WHEREAS, Seller is a party to that certain Asset Purchase Agreement, dated as of March 12, 2023 (as may be amended, amended and restated or otherwise modified from time to time, the "Sale Agreement"), between Seller and Vertical Pharmaceuticals, LLC, a Delaware limited liability company ("Buyer Vertical").

RECITALS: , pursuant to which, among other things, (i) Seller sold to Vertical certain assets, and Vertical assumed from Seller certain liabilities, in each case related to the Program, and (ii) Seller is entitled to receive from Vertical, among other things, the Purchased Receivables, as more fully set forth in the Sale Agreement; and

WHEREAS, subject to the terms and conditions set forth in this Agreement, Seller desires to sell, transfer, assign and convey to Buyer, and Buyer desires to purchase, acquire and assume accept from Seller, certain assets all of Seller's right, title and liabilities related interest in and to the Program (as defined below); Purchased Receivables, for the consideration and on the terms and subject to the conditions set forth in this Agreement.

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

ARTICLE I

DEFINITIONS AND TERMS

DEFINITIONS; INTERPRETATION

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

"Adjusted Annual Net Sales Affected Receivables" has the meaning set forth is defined in Section 2.11(a). 7.8.

"Affiliate" means, with respect to any Person, any other Person that directly, or indirectly controlling, controlled through one or more intermediaries, Controls, or is Controlled by, or is under common control Control with, such first Person as of the date on which, or at any time during the period for which, the determination of affiliation Person.

"Agreed Amount" 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 defined in Section 8.3.

"Applicable Amount" is defined in Section 7.6(c)(iii).

"Applicable Law" means, with respect to any Person, means the possession, directly or indirectly, all laws, rules, regulations, codes and orders of the power Governmental Authorities applicable 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). its properties or assets.

"Assigned Contracts Applicable Withholding Certificate" has means a valid and properly executed IRS Form W-9 (or any applicable successor form) certifying that the meaning set forth applicable party hereto (or its regarded owner, as applicable) is a "United States person" as defined in Section 2.1(e), 7701(a)(30) of the Code and is exempt from U.S. federal withholding tax and backup withholding tax with respect to all payments under this Agreement to such party.

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

"Authorizations Bill of Sale" means Governmental Authorizations that certain bill of sale, substantially in the form of Exhibit A attached hereto, entered into by Seller and Non-Governmental Authorizations. Buyer as of the Closing.

"Business Day" means any day other than (a) a Saturday or Sunday or (b) a day on which banks banking institutions located in Atlanta, Georgia, or in San Francisco, California, are authorized permitted or obligated required by Applicable Law or executive order to close, remain closed.

"Buyer" has the meaning set forth is defined in the Preamble, preamble.

"Buyer Fundamental Representations" means Section 5.1 (Organization), Section 5.2 (Authorization), Section 5.3 (Enforceability), Section 5.4 (Absence of Conflicts), and Section 5.7 (Brokers' Fees).

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

"Calendar Year Buyer Material Adverse Effect" means each respective period any one or more of: (a) a material adverse effect on the ability of twelve (12) consecutive months beginning Buyer to consummate the transactions contemplated by the Transaction Documents and perform its obligations under the Transaction Documents and (b) a material adverse effect on January 1, the validity or enforceability of the Transaction Documents against Buyer or the rights of Seller thereunder.

"Cap Buyer Participated Audit" has the meaning set forth is defined in Section 8.1(c), 7.4(b)(ii).

"Buyer Transaction Expenses" is defined in Section 10.4.

"Cash Tax Savings" is defined in Section 6.2(c).

"Change of Control Transaction" means, with respect to a Seller, the consummation of any bona fide third party a tender offer, merger, acquisition, consolidation or other similar transaction, in one transaction or a series of related transactions, pursuant to the result of which one is that any "person" (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, other than Seller or its subsidiaries, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of (a) 50% or more Third Parties (i) acquires (whether by merger, consolidation of the total voting power of the voting stock of Seller (or the surviving entity) 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 (b) all or substantially all of the assets of such party; Seller's and its Affiliates' assets; but excluding any such transaction or series of transactions described in clause (i) in which (a) such transaction or series of transactions is principally effected exclusively for bona fide equity financing purposes or (b) such any consolidation or merger transaction or series of transactions is a consolidation or merger effected exclusively to change the domicile of such party, Seller's domicile.

"Chargebacks Change of Control Adjustment" means, collectively, all credits, chargebacks, reimbursements, administrative and other fees, costs, charges, rebates, and other payments arising from and/or is defined in association with the sale of the Product to any wholesaler, retail pharmacy, distributor, group purchasing organization, insurer and other institution, Section 7.8.

"Claim Amount" is defined in Section 8.3.

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

"Claims Claim Notice Response" has the meaning set forth is defined in Section 8.3(b), 8.3.

"Closing" means the closing of the Transaction, is defined in Section 3.1.

- "Closing Date" means the date on which the Closing occurs, is defined in Section 3.1.

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

- "Commercially Reasonable Efforts" has means the meaning set forth efforts Seller would reasonably be expected to expend if Seller had the sole right, title and interest in Section 2.16(a), and to the Purchased Receivables to which such efforts relate.

- "Confidential Information" is defined in Section 6.1(b).

"Confidentiality Agreement" is defined in Section 6.1(d).

"Consent" means any consent, approval, license, permit, order, authorization, registration, filing or notice.

"Contract" means any contract, license, indenture, instrument, arrangement, understanding or agreement.

"Control" and its derivatives mean the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities or other voting interests, by contract or otherwise.

"Disclosing Party" is defined in Section 6.1(b).

"Disclosure Schedules" means the disclosure schedules attached hereto as Exhibit B.

"DoD" has the meaning set forth in the Marketing Agreement.

"DoD Net Sales" means Net Sales which generate amounts payable by Vertical pursuant to Section 5.9(a), 2.13 of the Sale Agreement and Section 5 of the Marketing Agreement.

"Escrow Account" means the escrow account created pursuant to the Escrow Agreement.

"Escrow Agent" means The Bank of New York Mellon, as escrow agent under the Escrow Agreement, or its successor.

"Escrow Agreement" means an Escrow Agreement to be entered into by and among Seller, Buyer, and The Bank of New York Mellon, in form and content acceptable to Seller and Buyer, as may be amended, amended and restated or otherwise modified from time to time.

"Exchange Act" means the Securities Exchange Act of 1934, as amended.

"Excluded Assets" is defined in Section 2.2.

"Excluded Liabilities and Obligations" is defined in Section 2.3.

"Financing Statements" is defined in Section 2.4.

"Fundamental Representations" means the Seller Fundamental Representations and the Buyer Fundamental Representations.

"Governmental Authority" means the government of the United States, any other nation or any political subdivision thereof, whether state or local, and any agency, authority (including supranational authority), branch, commission, instrumentality, regulatory body, court, tribunal or arbitral or judicial body or other Person exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government.

"Indemnified Party" is defined in Section 8.2(a).

- "Confidentiality Indemnified Tax" means any withholding tax or increased withholding tax imposed by any Governmental Authority in any jurisdiction that would not have been required to be withheld but for any action of Seller, including (a) a redomiciliation of Seller to another jurisdiction or (b) an assignment by Seller pursuant to Section 10.5, in each case after the Closing Date and in each case without regard to whether such tax is a Permitted Reduction. Notwithstanding anything to the contrary herein, no tax shall constitute an Indemnified Tax for purposes of this Agreement to the extent such tax (i) is imposed as a result of (A) an assignment by Buyer as permitted under Section 10.5, (B) a redomiciliation of Buyer to another jurisdiction, or (C) a change in Buyer's tax classification for U.S. federal income tax purposes or (ii) is attributable to a failure by Buyer to provide an Applicable Withholding Certificate.

"Indemnifying Party" is defined in Section 8.2(a).

"Initial Economics" means \$20,000,000.

"IP Agreement" means the Mutual Confidentiality that certain Intellectual Property Agreement, dated August 1, 2022 as of April 3, 2023, by and between Seller and Acella Pharmaceuticals, LLC, Vertical, as may be amended, amended and restated or otherwise modified from time to time.

- "Contract Consents IP Assignment Agreement" has the meaning set forth means that certain Intellectual Property Assignment Agreement, dated as of April 3, 2023, by and between Seller and Vertical, as may be amended, amended and restated or otherwise modified from time to time.

"IP Confidential Information" is defined in Section 3.8(a) 6.1(b).

"Judgment" means any judgment, order, writ, stipulation, consent order, injunction, or decree.

"Knowledge of Seller" means [***].

"Contracts Losses" 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, is defined in Section 8.1(a).

"Control" or "Controlled Marketing Agreement" means with respect that certain Marketing Agreement, dated April 3, 2023, between Vertical and Seller, as may be amended, amended and restated or otherwise modified from time 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, time.

"Copyrights Modification" 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 is defined in any works of authorship (including copyrights in computer software and code), whether published or unpublished, Section 7.5.

"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 Net Sales" has the meaning set forth in the Sale Agreement.

"Non-Warranting Parties" is defined in Section 8.3(a) 10.3(a).

"Direct Claim Notifying Party" is defined in Section 7.6(c)(iii).

"Permitted Reduction" means [***].

"Person" means any individual, firm, corporation, partnership, limited liability company, trust, joint venture, association, unincorporated organization, Governmental Authority or other entity or organization.

"Post Stepdown Date Enforcement Costs" is defined in Section 7.6(c)(iii).

"Post Stepdown Date Enforcement Costs Notice" is defined in Section 7.6(c)(iii).

"Pre/At Stepdown Date Enforcement Costs" is defined in Section 7.6(c)(ii).

"Pre/At Stepdown Date Enforcement Costs Notice" is defined in Section 7.6(c)(ii).

"Product" has the meaning set forth in Section 8.3(a), the Sale Agreement.

“Discussion Period Program” has the meaning set forth in the Sale Agreement.

“Purchase Price” is defined in Section 8.3(a) 2.1(b).

“Purchased Receivables” means, without duplication:

(a) following the Closing Date and on or prior to the Stepdown Date:

(i) 100% of any and all payments or amounts payable to Seller under Sections 2.11, 2.12, 2.13 and 2.14 of the Sale Agreement and Section 5.a of the Marketing Agreement (for clarity, after giving effect to all Permitted Reductions but excluding any Vertical Setoff) (and in the case of payments or amounts payable to Seller under Sections 2.11, 2.12 and 2.13 of the Sale Agreement and Section 5.a of the Marketing Agreement, payments or amounts payable to Seller only in respect of Net Sales (A) made during the fourth calendar quarter of 2023 in an amount for such payments or amounts payable equal to \$[***] and (B) made on and after January 1, 2024, and in each case (except with respect to payments or amounts payable to Seller under Section 2.12 of the Sale Agreement) subject to the Stepdown Adjustment);

(ii) any and all payments or amounts payable to Seller under the Sale Agreement or Marketing Agreement in lieu of such payments of the foregoing clause (i) (including, for purposes of clarity, pursuant to the last sentence of Section 2.15 of the Sale Agreement and the last sentence of Section 5.f of the Marketing Agreement, in each case, solely to the extent related to payments or amounts payable under the foregoing clause (i));

(iii) any and all payments or amounts payable to Seller under Section 2.18 of the Sale Agreement and Section 5.d of the Marketing Agreement (in each case, solely to the extent related to payments or amounts payable under the foregoing clause (i)); and

(iv) any interest payments to Seller under the Sale Agreement or the Marketing Agreement assessed on any payments or amounts payable described in the foregoing clauses (i), (ii), or (iii); and

(b) following the Stepdown Date:

(i) 50% of any and all payments or amounts payable to Seller under Section 2.11 of the Sale Agreement, 100% of any and all payments or amounts payable to Seller under Section 2.12 of the Sale Agreement, 50% of any and all payments or amounts payable to Seller under Section 2.13 of the Sale Agreement and Section 5.a of the Marketing Agreement, and 50% of any and all payments or amounts payable to Seller under Section 2.14 of the Sale Agreement (for clarity, after giving effect to all Permitted Reductions but excluding any Vertical Setoff) (and in each case (except with respect to payments or amounts payable to Seller under Section 2.12 of the Sale Agreement) subject to the Change of Control Adjustment);

(ii) any and all payments or amounts payable to Seller under the Sale Agreement or the Marketing Agreement in lieu of such payments of the foregoing clause (i) (including, for purposes of clarity, pursuant to the last sentence of Section 2.15 of the Sale Agreement and the last sentence of Section 5.f of the Marketing Agreement, in each case, solely to the extent related to payments or amounts payable under the foregoing clause (i));

(iii) any and all payments or amounts payable to Seller under Section 2.18 of the Sale Agreement and Section 5.d of the Marketing Agreement (in each case, solely to the extent related to payments or amounts payable under the foregoing clause (i)); and

(iv) any interest payments to Seller under the Sale Agreement or the Marketing Agreement assessed on any payments or amounts payable described in the foregoing clauses (i), (ii), or (iii).

“Effective Date Receivables” has means the meaning set forth in Purchased Receivables and the Preamble. Retained Interests.

“Encumbrance Receiving Party” 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) is defined in Section 6.1(a).

“EU Recipient Confidentiality Breach” 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 defined 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 2.26.1(a).

"Excluded Liabilities Recoupment Instruction" is defined in Section 7.4(b)(iv).

"Reimbursing Party" is defined in Section 7.6(c)(iii).

"Related Agreements" means, all Liabilities collectively, (a) the Sale Agreement, (b) the Marketing Agreement, (c) the IP Agreement, (d) the IP Assignment Agreement and (e) the Vertical TSA.

"Relevant Obligations" means confidentiality obligations of Seller Disclosing Party or any of its Affiliates other than under any agreement with a third party (including, without limitation, the Assumed Liabilities. For clarity, Sale Agreement and the Excluded Liabilities shall explicitly include, but shall not be limited Marketing Agreement) to which any Confidential Information is subject.

"Representatives" means, collectively, with respect to any Liabilities for, relating to Person, any directors, officers, employees, agents, advisors or arising from: (i) other representatives (including attorneys, accountants, consultants, scientists and financial advisors) of such Person.

"Retained Interests" means, without duplication, [***] ending on or prior Seller's right, title and interest in and 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) [***] following, from and after the Closing pursuant to [***], other than any Liability arising out Stepdown Date:

(a) 50% of [***] following the Closing Date; and (vii) any and all Liabilities payments or amounts payable to Seller under Section 2.11 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 Sale Agreement, 50% of any and all Liabilities arising out payments or amounts payable to Seller under Section 2.13 of [***] prior to the Closing Date, Sale Agreement and Section 5.a of the Marketing Agreement and 50% of any and all Liabilities arising out payments or amounts payable to Seller under Section 2.14 of or relating the Sale Agreement (for clarity, after giving effect to all Permitted Reductions but excluding any Vertical Setoff), in each case subject to the [***] prior Change of Control Adjustment;

(b) any and all payments or amounts payable to Seller under the Sale Agreement or the Marketing Agreement in lieu of such payments of the foregoing clause (a) (including, for purposes of clarity, pursuant to the Closing Date. Except as provided last sentence of Section 2.15 of the Sale Agreement and the last sentence of Section 5.f of the Marketing Agreement, in Section 2.3, where Buyer expressly assumes the Assumed Liabilities, and notwithstanding anything each case, solely to the contrary, Buyer shall not assume, in connection with extent related to payments or amounts payable under the Transaction foregoing clause (a));

(c) any and all payments or amounts payable to Seller under Section 2.18 of the Sale Agreement and Section 5.d of the Marketing Agreement (in each case, solely to the extent related to payments or amounts payable under the foregoing clause (a)); and

(d) any interest payments to Seller under the Sale Agreement or the transactions contemplated by the Ancillary Agreements, Marketing Agreement assessed on any additional Liability of Seller whatsoever, whether known payments 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 amounts payable described in the United States.

"FDA Fraud Policy" has the meaning set forth in Section 3.12(d) foregoing clauses (a), (b), or (c).

"FDCA Reverse Merger" 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 is defined in the making of the representations and warranties set forth in this Agreement, Section 7.8.

"GAAP Sale Agreement" means United States generally accepted accounting principles is defined in effect from time to time, the recitals.

"General Assignment SEC" means the U.S. Securities and Assumption Agreement Exchange Commission.

"SEC Documents" has means all reports, schedules, forms, statements, and other documents (including exhibits (including without limitation this Agreement) and all other information incorporated therein) required to be filed by Seller or Buyer with the meaning set forth SEC.

"Seller" is defined in the preamble.

"Seller Fundamental Representations" means the representations and warranties contained in Section 4.1 (Organization); Section 4.2 (Authorization); Section 4.3 (Enforceability); Section 4.4 (Absence of Conflicts); Section 4.8 (Brokers' Fees); [***]; Section 2.9(a)4.10 (Title to Purchased Receivables); and Section 4.11 (UCC Matters).

"Generic Equivalent Seller Indemnified Party" shall mean, with respect to a Product and country is defined 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)8.1(b).

"Government Entity Seller Material Adverse Effect" means any:

any one or more of: (a) nation, state, county, city, town, borough, village, district a material adverse effect on (i) the ability of Seller to consummate the transactions contemplated by the Transaction Documents and perform its obligations under any of the Transaction Documents or other jurisdiction;

(b) federal, state, local, municipal, foreign the Sale Agreement, (ii) the legality, validity 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 enforceability of any of the foregoing. Transaction Documents or the Sale Agreement, (iii) the rights or remedies of Buyer under any of the Transaction Documents, (iv) the rights or remedies of Seller under the Sale Agreement, or (v) the legal obligations of Vertical to pay the Purchased Receivables under the Sale Agreement; or (b) an adverse effect in any respect on the timing, amount or duration of the Purchased Receivables, or the timing, amount or duration of the payments to be made to Buyer in respect of any portion of the Purchased Receivables or the right of Buyer to receive such payments.

"Seller Participated Audit" is defined in Section 7.4(b)(i).

"Solvent" means, with respect to any Person on any date of determination, that on such date (a) the fair value of the property of such Person is greater than the total amount of liabilities, including contingent liabilities, of such Person, (b) the present fair salable value of the assets of such

Person is not less than the amount that will be required to pay the probable liability of such Person on its debts as they become absolute and matured, (c) such Person does not intend to, and does not believe that it will, incur debts or liabilities beyond such Person's ability to pay such debts and liabilities as they mature, (d) such Person is not engaged in business or a transaction, and is not about to engage in business or a transaction, for which such Person's property would constitute an unreasonably small capital and (e) such Person is able to pay its debts and liabilities, contingent obligations and other commitments as they mature in the ordinary course of business. For purposes of the definition of "Solvent," (i) "debt" means liability on a "claim," (ii) "claim" means any right to payment, whether or not such a right is reduced to judgment, liquidated, unliquidated, fixed, contingent, matured, unmatured, disputed, undisputed, legal, equitable, secured or unsecured and (iii) the amount of contingent liabilities at any time shall be computed as the amount that, in the light of all the facts and circumstances existing at such time, represents the amount that can reasonably be expected to become an actual or matured liability.

"**Governmental Authorizations Stepdown Adjustment**" means an adjustment to clause (a)(i) of the definition of Purchased Receivables, such that to the extent that as of the Stepdown Date there are any amounts accrued and payable to Seller but not yet paid under (a) Section 2.11 of the Sale Agreement, (b) Section 2.13 of the Sale Agreement and Section 5.a of the Marketing Agreement, or (c) Section 2.14 of the Sale Agreement, in each case as determined based on the date and timing of when the applicable Net Sales or event or events giving rise to amounts payable under Section 2.14 of the Sale Agreement occur (collectively, the "**Accrued Amounts Payable**"), then, effective as of the Stepdown Date, clause (a)(i) of the definition of Purchased Receivables shall mean 50% of any and all **licenses, permits, certificates, registrations** **Accrued Amounts Payable**.

As an example:

1. Assume that Buyer receives its Initial Economics (\$[***]) on January 31, 2026, at the time the Q4 2025 payment under Sections 2.11, 2.12 and **other authorizations, consents, waivers** 2.13 of the Sale Agreement and **approvals issued by or obtained from** Section 5.a of the Marketing Agreement is made. So, the Stepdown Date is January 31, 2026.
2. Assume that for Q1 2026, the only amount payable under Section 2.11 of the Sale Agreement, Section 2.13 of the Sale Agreement, Section 5.a of the Marketing Agreement and Section 2.14 of the Sale Agreement is a **Government Entity, including a Regulatory Authority**, total of \$[***], payable to Seller under Section 2.13 of the Sale Agreement and Section 5.a of the Marketing Agreement, and of that \$[***] is payable based on Net Sales made during the period January 1 – January 31, 2026 (the "**Example Accrued Amount Payable**").
3. Because the Stepdown Date is January 31, 2026, the Example Accrued Amount Payable that will have accrued as of the Stepdown Date but be paid in April 2026 (after the Stepdown Date) shall be subject to the Stepdown Adjustment and be calculated at 50% for purposes of clause (a)(i) of the definition of Purchased Receivables, such that \$[***] of the Example Accrued Amount Payable will be Purchased Receivables and \$[***] of the Example Accrued Amount Payable will be Retained Interests.

"**Gross Profit Stepdown Date**" means the date upon which Buyer has received the Initial Economics in respect of the Purchased Receivables.

"**Third Party Claim**" is defined in Section 8.2(a).

"**Transaction Documents**" means this Agreement, the Bill of Sale, the Escrow Agreement, the Vertical Notice and Waiver, and the Vertical Instruction Letter.

"**UCC**" means the Uniform Commercial Code as in effect in the State of New York; provided, that, if, with respect to any **calendar quarter**, **an amount equal** financing statement or by reason of any provisions of Applicable Law, the perfection or the effect of perfection or non-perfection of the back-up security interest or any portion thereof granted pursuant to (a) Section 2.4 is governed by the **Net Sales of Products sold or otherwise disposed of to DoD Uniform Commercial Code as in such calendar quarter, minus** (b) the Cost of Goods Sold for such Products sold or otherwise disposed of to DoD effect 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 a jurisdiction of the United States other than the State of New York, then "UCC" means the Uniform Commercial Code as in effect from time to time in such other jurisdiction for purposes of the **Physician Self-Referral Law, commonly known as the "Stark Law" (42 U.S.C. §§1395nn provisions of this Agreement and 1396b), the False Statements Relating any financing statement 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 such perfection or effect of "Laws" as defined below, perfection or non-perfection.**

"IND Vertical" means an investigational new drug application (as is 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. recitals.

"Knowledge Vertical Instruction Letter" or any similar phrase, with respect to a party, means [***]. is defined in Section 6.5.

"Law Vertical Notice and Waiver" 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 the notice to Vertical of common law, license or decree enacted, issued, promulgated, enforced or entered the transactions contemplated hereby under the Marketing Agreement and waiver by a Government Entity. Vertical of its right to receive 30 days' prior written notice under Section 12 of the Marketing Agreement, substantially in the form of Exhibit C attached hereto.

"Liabilities Vertical Reports" 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 collectively, (a) the same would be Payments Reports (as defined in the Sale Agreement) required by GAAP to be reflected in financial statements or disclosed delivered by Vertical to Seller pursuant to Section 2.12(c) of the Sale Agreement, (b) the DoD Payments Report (as defined 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 Marketing Agreement) required to be performed delivered 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 Vertical to Seller pursuant to Section 5.b of the Transferred Assets to a Third Party, whether received at Marketing Agreement, (c) 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 Reports (as defined in the Sale Agreement) required to be delivered by Buyer Vertical to Seller pursuant to Section 2.14(b) of the Sale Agreement, and its Affiliates (d) any notices and equityholders (a) from a Licensee that is allocable supporting documentation delivered by Vertical 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 Seller in respect of the Transferred Assets or any Product events specified in Sections 2.11-2.15 of the Sale Agreement and not solely for, or allocable to, any other assets purchased by such Third Party that are not related to any Product. [***]. Section 5 of the Marketing Agreement.

"License and Acquisition Income Payments Vertical Setoff" means any right of set-off, counterclaim, credit, reduction or deduction, in each case by contract or otherwise, including with respect to any amounts owed by Seller to Vertical, other than a Permitted Reduction. For purposes of clarity, the potential payments payable parties acknowledge and agree that (a) no adjustments or credits in the calculations pursuant to Section 2.14(a). 2.11(a) of the Sale Agreement for determining whether an amount is payable under Section 2.11 of the Sale Agreement will be a Vertical Setoff for purposes of this Agreement and (b) no deduction taken by Vertical in calculating Net Sales in accordance with the definition of Net Sales in the Sale Agreement will be a Vertical Setoff for purposes of this Agreement.

"License Vertical TSA" means that certain Transition Services Agreement, dated as of April 3, 2023, by and Acquisition Income Report between Seller and Vertical, as may be amended, amended and restated or otherwise modified from time to time.

"Waiver Expiration Date" means January 25, 2024.

In the event a capitalized term used herein is defined in both this Agreement and the Sale Agreement, the meaning given to such term in this Agreement shall control.

Section 1.2 Certain Interpretations. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement:

(a) an accounting term not otherwise defined has the meaning set forth assigned to it in Section 2.14(b). accordance with GAAP;

"Licensed Intellectual Property" means (b) unless otherwise defined, all terms that are defined in the Transferred Intellectual Property that is licensed to Seller or any of its Affiliates from a Third Party. UCC shall have the meanings stated in the UCC;

"Licensee" has (c) words of the meaning set forth in masculine, feminine or neuter gender shall mean and include the definition correlative words of "License and Acquisition Income".

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

"Marks" means all United States (d) the definitions of terms shall apply equally to the singular 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 plural forms of commercial source or origin, whether registered or not, used solely the terms defined;

(e) references to the term "or" will be interpreted in or intended to be used solely in connection the inclusive sense commonly associated with the Product, together with the goodwill associated with any of the foregoing, and all applications, registrations and renewals thereof. term "and/or";

"Material Adverse Effect(f) "include," 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 "includes" 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 "including" shall be deemed to be sold exclusively for money at followed by the average sales price during the applicable reporting period generally achieved for such Product in the same country, words "without limitation";

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 (g) references to a Third Party shall be included within the computation of Net Sales. Any free-of-charge disposal Person are also to its permitted successors and assigns (subject to any restrictions on assignment, transfer 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 trueed-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 **delegation** set forth in **Section 2.20(a)**.

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

"Organizational Documents" means (a) the certificate **herein** 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). **Transaction Documents**;

"Patent Files" means, with regard (h) the word "will" shall be construed to a Program Patent: (i) have the complete file histories for such Program Patent; **same meaning** 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, **effect as the word "shall"**;

"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) (i) **the words "hereof"**, 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) **"herein"**, 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 **"hereunder"** 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) materialmen's, 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 hereof, and "Article," "Section" "Exhibit" or "Schedule" refer to an Article or Section of, or an Exhibit or Schedule to, this Agreement; Agreement, unless otherwise specified;

(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 (j) except as otherwise set forth in this Agreement, it in the computation of a period of time from a specified date to a later specified date, the word "from" means "from and including" and each of the words "to" and "until" means "to but excluding";

(k) references to "\$" or otherwise to dollar amounts refer to the lawful currency of the United States;

(l) where any payment is to be made, any funds are to be applied or any calculation is to be made under this Agreement on a day that is not a Business Day, unless this Agreement otherwise provides, such payment shall be deemed made, such funds shall be applied and such calculation shall be made on the succeeding Business Day, and payments shall be adjusted accordingly;

(m) references to be followed by an Applicable Law include any amendment or modification to such Applicable Law and any rules and regulations issued thereunder, whether such amendment or modification is made, or issuance of such rules and regulations occurs, before, on or after the words "without limitation;" date of this Agreement; and

(f) (n) references to this "Agreement" shall include a reference to all Schedules and Exhibits attached to this Agreement (including the Disclosure Schedules), all of which constitute a part of this Agreement and are incorporated herein to any gender include each other gender, for all purposes.

ARTICLE II

PURCHASE AND SALE; LICENSE TO SELLER SALE OF PURCHASED RECEIVABLES

Section 2.1 **Purchase and Sale of Assets Purchased Receivables.** On

(a) **Purchase and Sale.** Upon the terms and subject to the conditions set forth herein, of this Agreement, at the Closing, Seller shall sell, convey, transfer, assign and deliver convey to Buyer, and Buyer shall purchase, acquire and acquire accept from Seller, free and clear of all liens and encumbrances, 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 or of 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 [Section 2.14\(a\)](#) shall not apply to a Change of Control Transaction (and any consideration received thereunder) involving Buyer or its Affiliates. **Purchased Receivables.**

(b) **License Purchase Price.** In full consideration for the sale, transfer, assignment and Acquisition Income Reports conveyance of the **Purchased Receivables**, 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 **subject** to the Transferred Assets if any License **terms** 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, **conditions set forth herein**, Buyer shall provide Seller with **make** 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 one-time payment to Seller on a reasonable and timely basis following such payment. To the extent Closing Date of \$8,000,000 (the "Purchase Price"), by wire transfer of immediately available funds as directed by Seller.

Section 2.2 Excluded Assets. Buyer does not, by purchase, acquisition or acceptance of the rights, title or interest granted hereunder or otherwise pursuant to any such Taxes are so deducted of the Transaction Documents, purchase, acquire or withheld and properly remitted to accept any assets or contract rights of Seller (including, for clarity, the appropriate Taxing Authority, such Taxes shall be treated for all purposes under this Agreement as having been paid to Retained Interests) other than the Person in respect of which such deduction or withholding was made. Purchased Receivables (the "Excluded Assets").

Section 2.3 No Obligations Transferred. Notwithstanding anything to the contrary contained herein, if in this Agreement, (a) the sale, transfer, assignment and conveyance to 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 the Purchased Receivables pursuant to this Agreement shall not in any way subject Buyer to, or transfer, affect or modify, any obligation or liability of Seller or Seller's Affiliates of whatever nature, whether presently in existence or arising or asserted hereafter, whether known or unknown (the "Excluded Liabilities and if Obligations") and (b) Buyer expressly does not assume or agree to become responsible for any of the Excluded Liabilities and Obligations. All Excluded Liabilities and Obligations shall be retained by and remain liabilities and obligations of Seller or Seller's Affiliates, as the case may be.

Section 2.4 True Sale. It is the intention of the parties hereto that the sale, transfer, assignment and conveyance contemplated by this Agreement be, and is, a true, complete absolute and irrevocable sale, transfer, assignment and conveyance by Seller to Buyer of all of Seller's right, title and interest in and to the Purchased Receivables. Neither Seller nor Buyer intends the transactions contemplated by this Agreement to be, or for any purpose characterized as, a loan from Buyer to Seller or a pledge, a security interest, a financing transaction or a borrowing. Each of Seller and Buyer hereby waives, to the maximum extent permitted by Applicable Law, any right to contest or otherwise assert that this Agreement does not constitute a true, complete, absolute and irrevocable sale, transfer, assignment and conveyance by Seller to Buyer of all of Seller's right, title and interest in and to the Purchased Receivables under Applicable Law, which waiver shall, to the maximum extent permitted by Applicable Law, be enforceable against Seller and Buyer in any bankruptcy or insolvency proceeding relating to Seller. Accordingly, each of Seller and Buyer agrees to account for the sale, transfer, assignment and conveyance of the Purchased Receivables as sales of "accounts" or "payment intangibles" (as appropriate) in accordance with the UCC (except to the extent generally accepted accounting principles in the United States require such obligation arises transaction to be accounted for as a liability or is increased a derivative in Seller's consolidated financial statements) and Seller hereby authorizes Buyer, from and after the Closing, to file financing statements (and continuation statements with respect to such financing statements when applicable) (the "Financing Statements") naming Seller as the seller and/or debtor and Buyer as the buyer and/or secured party in respect of the Purchased Receivables; provided, in each case that such Financing Statements shall not describe as collateral anything other than the Purchased Receivables and any "proceeds" (as defined in the UCC) thereof, and shall not contain an "all asset" (or words of similar effect) collateral description. Notwithstanding the statement of the intention of the parties hereto, and solely as a result precaution to protect to Buyer's interests hereunder if, notwithstanding the intention of the parties hereto, the sale, transfer, assignment and conveyance contemplated hereby is hereafter held not to be a true sale of the Purchased Receivables by Seller to Buyer or such sale is for any action by Buyer (or any of its Affiliates reason deemed ineffective or assignees) after the Closing Date, including, without limitation, any assignment of unenforceable, this Agreement by shall constitute a security agreement under the UCC and Seller does hereby grant to Buyer, any change in as security for all of Seller's obligations hereunder, including the tax residency payment to Buyer 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 Purchased Receivables as they become due and payable, a first priority security interest in and to all right, title and interest of Seller in, to and under the Purchased Receivables and any "proceeds" (as such Withholding Tax Action occurred, term is defined in the UCC) thereof, and Seller does hereby authorize Buyer to file such Financing Statements in such manner and such jurisdiction as may be necessary or appropriate to perfect such security interests.

Section 2.16 2.5 Diligence; Reversion Right Payments.

(a) Buyer shall, and shall cause each Selling Party Any payments 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 be made 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 party hereto shall be made by wire transfer of immediately available funds to the other party in accordance with written instructions provided from time to time by such other party. A late fee of [***]% over the prime rate published by the *Wall Street Journal*, from time to time, as the prime rate shall accrue on all unpaid undisputed amounts on an annualized basis with respect to any late payment under this Agreement beginning [***] after such payment is due.

ARTICLE III

CLOSING; DELIVERABLES

Section 3.1 Closing. The closing of the purchase and sale of the Purchased Receivables (the "Closing") shall take place within one Business Day of the satisfaction or waiver of the conditions set forth in Section 3.3, at the offices of Gibson, Dunn & Crutcher, LLP, One Embarcadero Center, Suite 2600, San Francisco, California 94111, or on such other date, at such other time or at such other place, in each case as the parties mutually agree (such date, the "Closing Date").

Section 3.2 Payment of Purchase Price. At the Closing, Buyer shall deliver to Seller payment of the Purchase Price by wire transfer of immediately available funds as directed by Seller.

Section 3.3 Conditions to Closing.

(a) The obligation of Buyer to consummate the transactions contemplated hereby on the Closing Date is subject to the satisfaction or waiver at or prior to the Closing of the following conditions:

(i) Seller shall have delivered to Buyer a bank duly executed counterpart to the Bill of Sale, evidencing the sale and account designated in writing assignment to Buyer of the Purchased Receivables.

(ii) Seller shall have delivered to Buyer a certificate of an executive officer of Seller, dated as of the Closing, certifying as to the (A) attached copies of the organizational documents of Seller and resolutions of the governing body of Seller authorizing and approving the execution, delivery and performance by Seller at least two (2) Business Days prior to applicable payment date, unless otherwise specified in writing by Seller, of the Transaction Documents and the transactions contemplated thereby and (B) the incumbency of the officer or officers of Seller who have executed and delivered the Transaction Documents, including therein a signature specimen of each such officer or officers.

Section 2.18 Audit. For a period of [***] following (iii) (A) The representations and warranties (other than the end of Seller Fundamental Representations) set forth in Article IV (without giving effect to any materiality or Seller Material Adverse Effect qualifiers contained therein) shall be true and correct in all respects on the calendar quarter date hereof and true and correct in all material respects on the Closing Date as though made on such date, (B) the Seller Fundamental Representations (without giving effect to which they pertain, Buyer any materiality or Seller Material Adverse Effect qualifiers contained therein) shall be true and shall require each Selling Party to, keep complete correct in all respects on the date hereof and accurate records pertaining to on the Sale or other disposition of Products and License and Acquisition Income in sufficient detail to permit Closing Date as though made on such date, (C) 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 performed and complied in all material respects with 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 agreements and conditions required 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 to have been performed or the Marketing Agreement, complied with by it prior to 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 and (D) there shall not have occurred a Seller Material Adverse Effect since the date hereof.

(iv) Seller shall have delivered to Buyer a certificate of an executive officer of Seller, dated as of the Closing, certifying that pursuant the conditions set forth in Section 3.3(a)(iii) have been fulfilled.

(v) The Related Agreements remain in full force and effect.

(vi) Seller shall have delivered to Buyer an Applicable Withholding Certificate.

(vii) Seller shall have delivered to Buyer the Vertical Notice and Waiver duly executed by Vertical, unless the Waiver Expiration Date has occurred.

(viii) Cooley LLP, as counsel to Seller, shall have delivered to Buyer a duly executed legal opinion in substantially the form of Exhibit E attached hereto.

(ix) Seller shall have delivered to Buyer an electronic copy of all of the information and documents posted to the provisions virtual data room established by Seller as of the date hereof and made available to Buyer for archival purposes only.

(x) There shall not have been issued and be in effect any judgment, order, writ, injunction, citation, award or decree of any Governmental Authority enjoining, preventing or restricting the consummation of the transactions contemplated by this Agreement, were required Agreement.

(xi) There shall not have been instituted or be pending any action or proceeding by any Governmental Authority or any other Person (A) challenging or seeking to be transferred (the "Nontransferred Assets"). To make illegal, to delay materially or otherwise directly or indirectly to restrain or prohibit the extent any Nontransferred Assets are identified, Seller shall promptly take all actions to transfer such Nontransferred Assets to Buyer. In consummation of the event Seller is required transactions contemplated hereby, (B) seeking to obtain material damages in connection with the consent of any Person prior transactions contemplated hereby or (C) seeking 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 restrain 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 prohibit Buyer's purchase 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. Purchased Receivables.

(c) All returned Products that were sold by (b) The obligation of Seller to consummate the transactions contemplated hereby on the Closing Date is subject to the satisfaction or waiver at or prior to the Closing Date of the following conditions:

(i) Buyer shall have delivered a duly executed counterpart to the Bill of Sale, evidencing the sale and assignment to Buyer of the Purchased Receivables.

(ii) Buyer shall have delivered to Seller a certificate of an executive officer or other authorized signatory of Buyer, dated as of the Closing, certifying as to the incumbency of the officer or officers of Buyer who have executed and delivered the Transaction Documents, including therein a signature specimen of each such officer or officers.

(iii) (A) The representations and warranties (other than the Buyer Fundamental Representations) set forth in Article V (without giving effect to any materiality or Buyer Material Adverse Effect qualifiers contained therein) shall be true and correct in all respects on the responsibility of Buyer, and/or its successors date hereof and assigns; provided that to the extent Buyer incurs payments to wholesalers true and correct 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 all material respects on the Closing Date as though made on such date, (B) the Buyer Fundamental Representations (without giving effect to any materiality or Buyer Material Adverse Effect qualifiers contained therein) shall be true and correct in all respects on the responsibility of date hereof and on the Closing Date as though made on such date, and (C) Buyer shall have performed and shall be sent to Buyer. Returns will be processed by Seller complied in accordance all material respects with the current returned goods policy provided agreements and conditions required by this Agreement to Buyer have been performed or complied with by it prior to the Closing. Returns will be processed by Buyer in accordance with the returned goods policy provided to Seller prior to or at the Closing.

(d) (iv) Buyer shall be responsible for processing all Chargebacks related have delivered to the Product sold by Seller prior to Closing and shall bear 100% a certificate of an executive officer of Buyer, dated as of the cost Closing, certifying that the conditions set forth in Section 3.3(b)(iii) have been fulfilled.

(v) Buyer shall have delivered to Seller an Applicable Withholding Certificate.

(vi) There shall not have been issued and be in effect any judgment, order, writ, injunction, citation, award or decree of any such Chargebacks; provided that Governmental Authority enjoining, preventing or restricting the consummation of the transactions contemplated by this Agreement.

(vii) There shall not have been instituted or be pending any action or proceeding by any Governmental Authority or any other Person (A) challenging or seeking to make illegal, to delay materially or otherwise directly or indirectly to restrain or prohibit the extent Buyer incurs payments consummation of the transactions contemplated hereby, (B) seeking to obtain material damages 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 transactions contemplated hereby or (C) seeking to the Product sold on restrain or after Closing and shall bear 100% prohibit Buyer's purchase of the cost of any such Chargebacks. Purchased Receivables.

ARTICLE III IV

SELLER'S REPRESENTATIONS AND WARRANTIES OF SELLER

Except as set forth in the Disclosure Schedules, Seller hereby represents and warrants to Buyer as of the Effective Date date hereof 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: Date:

Section 3.1 4.1 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 licensed or qualified to do business and is in corporate good standing in each jurisdiction in which the nature of the business conducted by it or the character or location of the properties and assets owned, leased or operated by it makes such licensing or qualification necessary, except where the ownership or operation of the Transferred Assets or the conduct of the Program requires the Seller failure to be so licensed or qualified and is in corporate good standing has not and would not reasonably be expected to have, either individually or in good standing, as the case may be. aggregate, a Seller Material Adverse Effect.

Section 3.2 4.2 Corporate Authorization. Seller has full the requisite corporate power and authority to execute, and deliver this Agreement and the Ancillary Agreements and to perform its obligations hereunder and thereunder, under the Transaction Documents and to consummate the Transaction. transactions contemplated thereby. The execution, delivery and performance by Seller of this Agreement and the Ancillary Agreements, the performance by Seller of its obligations hereunder and thereunder, Transaction Documents, and the consummation of the Transaction and the transactions contemplated by the Ancillary Agreements thereby, 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 Seller.

Section 4.3 Enforceability. Each 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 obligation of Seller, enforceable against Seller in accordance with its terms. terms, except as may be limited by general principles of equity (regardless of whether considered in a proceeding at law or in equity) and by applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws of general application relating to or affecting creditors' rights generally, general equitable principles and principles of public policy.

Section 4.4 Absence of Conflicts. The Person(s) signing this execution, delivery and performance by Seller of the Transaction Documents and the consummation of the transactions contemplated thereby do not and shall not (a) conflict with, or constitute a breach of or default under, any provision of (i) the certificate of incorporation or bylaws of Seller or (ii) the Sale Agreement or the Marketing Agreement, or (b) conflict with, or constitute a material breach

of or material default under, any provision of any (i) Applicable Law or Judgment, in each case existing as of the date hereof or (ii) any Contract (other than the Sale Agreement and the Marketing Agreement) to which Seller is a party or by which Seller is bound.

Section 4.5 Consents. No notice to, or Consent of, any Governmental Authority or any other Ancillary Agreements Person is required, or will be required, by or with respect to Seller in connection with the execution and delivery by Seller of the Transaction Documents, the performance by Seller of its obligations under the Transaction Documents or the consummation by Seller of the transactions contemplated by the Transaction Documents, except for (a) such Consents as shall have been obtained on behalf of or prior to the date hereof, (b) the Vertical Instruction Letter, (c) the Vertical Notice and Waiver and (d) a Current Report on Form 8-K by Seller has been duly authorized to execute with the U.S. Securities and deliver this Agreement and the other Ancillary Agreements. Exchange Commission.

Section 3.3 4.6 Title Litigation. No action, suit, proceeding, claim, demand, citation, summons, subpoena, inquiry, investigation or other proceeding (whether civil, criminal, administrative, regulatory, investigative or informal), including by or before any Governmental Authority, is pending, or, to and Sufficiency the Knowledge of Transferred Assets Seller, threatened, by or against Seller, at law or in equity, that, individually or in the aggregate would reasonably be expected to result in a Seller Material Adverse Effect or which questions the validity of this Agreement or the transactions contemplated hereby or any action taken or to be taken pursuant hereto.

Section 4.7 Compliance with Laws. Seller has good (a) not violated, is not in violation of, has not been given written notice that it has violated, and, marketable title to or a valid leasehold interest in, the Transferred Assets, free Knowledge of Seller, Seller is not under investigation with respect to its violation of, and, clear to the Knowledge of Seller, has not been threatened to be charged with any violation of, any Encumbrances (other than Permitted Encumbrances). Other than the Excluded Assets, the Transferred Assets include all tangible Applicable Law or any Judgment of any Governmental Authority, and intangible property and assets owned or, (b) is not subject to any Judgment of any Governmental Authority; in the each case of Licensed Intellectual Property, in-licensed clauses (a) and (b) that would reasonably be expected to result in a Seller Material Adverse Effect.

Section 4.8 Brokers' Fees. There is no investment banker, broker, finder, financial advisor or other intermediary who has been retained by or is authorized to act on behalf of Seller that who is entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

Section 4.9 Sale Agreement and Marketing Agreement.

(a) **Sale Agreement and Marketing Agreement; Vertical Reports.** Attached hereto as Exhibit F are (a) necessary true, correct and sufficient for complete copies of the continued conduct of Seller's business as it relates to the Product Sale Agreement and the Program after Closing in Marketing Agreement. Seller has made available to Buyer true, correct and complete copies of: (i) 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 Related Agreements (other than the Licensed Intellectual Property) Sale Agreement and the Marketing Agreement), free (ii) all Vertical Reports that have been received by Seller prior to the date hereof; and clear (iii) all material written notices delivered to Vertical by Seller, or by Vertical to Seller pursuant to the Sale Agreement or the Marketing Agreement.

(b) **Validity and Enforceability of any Encumbrances (other than Permitted Encumbrances).** Except as set forth on Schedule 3.3 Sale Agreement and Marketing Agreement, there are no assets. Each of the Sale Agreement and the Marketing Agreement is a valid and binding obligation of Seller or any other Person used in and, to the Program or necessary for Knowledge of Seller, of Vertical, enforceable against each of Seller and, to the Product as in existence as Knowledge 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 Vertical, in accordance with all United States manufacturing practices. No item its terms, except as may be limited by general principles of Inventory has been misbranded equity (regardless of whether considered in a proceeding at law or adulterated within the meaning in equity) and by applicable bankruptcy.

insolvency, reorganization, moratorium or other similar laws of general application relating to or affecting creditors' rights generally, general equitable principles and principles of public policy. Each of the FDCA.

Section 3.5 No Conflict. The execution and delivery of this Sale Agreement and the Ancillary Agreements by Seller do not, Marketing Agreement will continue to be valid, binding and enforceable on identical terms immediately following the consummation of the Transaction and the transactions contemplated by the Ancillary Agreements will Transaction Documents. Seller has not directly received any written notice from Vertical challenging the validity, enforceability, or indirectly, with or without notice or lapse interpretation of time: (a) conflict with or violate any provision of the Organizational Documents Sale Agreement or the Marketing Agreement or any obligation of Seller; (b) conflict with Vertical to pay the Receivables thereunder.

(c) **Other Agreements.** The Sale Agreement and the Marketing Agreement are the only agreements, instruments, arrangements, waivers or violate understandings (other than the other Related Agreements) between Seller (or any Law applicable Affiliate thereof) and Vertical (or any Affiliate thereof) relating to the subject matter thereof, and other than the Related Agreements and except as set forth in the Disclosure Schedules, there are no other agreements, instruments, arrangements, waivers or understandings between Seller (or any Affiliate thereof) and Vertical (or any Affiliate thereof) that relate to the Sale Agreement, the Marketing Agreement or the Receivables, or that would reasonably be expected to result in a Seller Material Adverse Effect. Other than the Sale Agreement and the Marketing Agreement, there is no contract, agreement or other arrangement (whether written or oral) to which Seller is a party or by which any of the Transferred Assets its assets or Seller properties is bound or affected; (c) contravene, conflict with committed (i) that creates a lien on the Purchased Receivables; (ii) that materially affects the Purchased Receivables or result in any (iii) for which breach of thereof, nonperformance thereof, cancellation thereof or failure to renew would reasonably be expected to result in a default (or an Seller Material Adverse Effect.

(d) **No Termination, Force Majeure, etc.** Seller has not (i) given Vertical any notice of termination pursuant to Section 9.1 of the Sale Agreement or Section 7 of the Marketing Agreement or (ii) received from Vertical any written notice of termination pursuant to Section 9.1 of the Sale Agreement or Section 7 of the Marketing Agreement. To the Knowledge of Seller, no event which with the giving of has occurred that upon notice or lapse the passage of time, or both, would reasonably be expected to become a default give Seller or Vertical the right to terminate, or delay any of its obligations under, the Sale Agreement or the Marketing Agreement, or cease or delay paying the Receivables.

(e) **No Breaches.** There is and has been no material breach of any provision of the Sale Agreement or the Marketing Agreement by Seller, and no event has occurred that upon notice or the passage of time, or both, would reasonably be expected to give rise to others any right such material breach by Seller. To the Knowledge of termination, amendment, acceleration Seller, there is and has been no material breach of any provision of the Sale Agreement or cancellation the Marketing Agreement by Vertical, and, to the Knowledge of Seller, no event has occurred that, upon notice or modification the passage of time, or both, would reasonably be expected to give rise to any such material breach by Vertical. Seller has not received any notice that Seller or Vertical is in default of, or of an intention by Vertical to breach, any provision of the exercise Sale Agreement or the Marketing Agreement.

(f) **No Payments.** Except as set forth in the Disclosure Schedules, as 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 the date of this Agreement, Vertical has not made, and Seller has not received, any rights payments with respect to the Receivables.

(g) **No Waivers, Releases or Amendments.** Seller has not granted any material waiver under the Sale Agreement or the performance Marketing Agreement or released Vertical, in whole or in part, from any of which is guaranteed its material obligations under the Sale Agreement or the Marketing Agreement. There have been no oral waivers or modifications (or pending requests therefor) in respect of the Sale Agreement or the Marketing Agreement by Seller or result Vertical. Seller has not received from Vertical any proposal, and has not made any proposal to Vertical, to amend or waive any provision of the Sale Agreement or the Marketing Agreement.

(h) **No Sublicenses.** To the Knowledge of Seller, there are no licenses or sublicenses entered into by Vertical or any other Person (or any predecessor or Affiliate thereof) in respect of the creation Product, the Sale Agreement, or the Marketing Agreement. Seller has not received any notice from Vertical relating to any prospective licenses or sublicenses in respect of the Product, the Sale Agreement, or the Marketing Agreement.

(i) **Audits.** Seller has not requested access to or conducted an Encumbrance on audit of, pursuant to Section 2.18 of the Sale Agreement or Section 5.d of the Marketing Agreement, the books of account or records of Vertical or disputed the amount of any Receivables payable pursuant to the Sale Agreement or the Marketing Agreement.

(j) **Vertical Setoffs.** Vertical is not owed any amount by Seller, under any of the Transferred Assets Related Agreements or Assigned Contracts (other than Permitted Encumbrances); otherwise, that would permit Vertical to exercise any Vertical Setoff against the Receivables or (d) contravene, conflict with or result in a violation of any other amounts payable to Seller under any of the terms Related Agreements. Vertical has not in the past exercised, and, to the Knowledge of Seller, no event has occurred and no facts or requirements circumstances exist that would reasonably be

expected to give rise to a right of Vertical to exercise any Vertical Setoff against the Receivables or give any Government Entity other amounts payable to Seller under any of the Related Agreements.

(k) Sale Agreement and Marketing Agreement Representations. To the Knowledge of Seller, all representations and warranties of Seller in the Sale Agreement and the Marketing Agreement were true and correct in all material respects when made.

(l) No Indemnity Claims. As of the date of this Agreement, neither Seller nor Vertical has made or provided any notice of an indemnity claim under the Sale Agreement or the Marketing Agreement.

(m) No Assignments. Seller has not consented to, and Seller has not been notified of, any assignment or other transfer by Vertical of the Sale Agreement or the Marketing Agreement or any of Vertical's rights or obligations under the Sale Agreement or the Marketing Agreement. To the Knowledge of Seller, Vertical has not assigned or otherwise transferred the Sale Agreement or the Marketing Agreement or any of Vertical's rights or obligations under the Sale Agreement or the Marketing Agreement to any Person. Seller has not assigned or otherwise transferred, in whole or in part, the Sale Agreement or the Marketing Agreement or any of Seller's right, title or interest in and to the Purchased Receivables to any Person.

(n) Freedom-to-operate. No written legal opinion concerning or with respect to any third party intellectual property rights relating to the Product, including any freedom-to-operate, product clearance, patentability or right-to-use opinion, has been delivered to Seller or, to the Knowledge of Seller, to Vertical. To the Knowledge of Seller, there is no patent owned or exclusively controlled by a third party which Vertical does not have the right to revoke, withdraw, suspend, cancel, terminate or modify, any filing, permit, authorization, consent, approval, right or Order use and that is would be infringed by Vertical's sale of the Product.

Section 4.10 Title to Purchased Receivables. Seller has good and valid title to the Purchased Receivables, free and clear of all liens and encumbrances (other than those contemplated to be included granted by Seller to Buyer in respect of the Purchased Receivables pursuant to Section 2.4). Upon payment of the Purchase Price by Buyer, Buyer will have acquired, subject to the terms and conditions set forth in this Agreement, good and valid title to the Purchased Receivables, free and clear of all liens and encumbrances (other than those contemplated to be granted by Seller to Buyer in respect of the Purchased Receivables pursuant to Section 2.4). Upon the filing by Buyer of the Financing Statements with the Secretary of State of the State of Delaware and to the extent that, despite the intent of the parties hereto, the sale, transfer, assignment and conveyance of the Purchased Receivables by Seller to Buyer pursuant to this Agreement is hereafter held not to be a sale, the security interest in the Transferred Assets or is held Purchased Receivables granted by Seller to Buyer pursuant to Section 2.4 shall be a perfected first priority security interest in and relates to the Transferred Assets. Purchased Receivables to the extent that such security interest can be perfected under the UCC by the filing of the Financing Statements in such filing office.

Section 3.6 4.11 Required Filings and Consents UCC Matters. The execution Seller's exact legal name is, and delivery since January 9, 2024 has been Talphera, Inc. Seller was originally incorporated as "SuRx, Inc." on July 13, 2005, and between August 13, 2006 and January 9, 2024, was "AcelRx Pharmaceuticals, Inc." Seller's jurisdiction of this Agreement organization is, and since its organization has been, the Ancillary Agreements by Seller do not, and the consummation State of the Transaction and the transactions contemplated by the Ancillary Agreements will not, require any consent, approval, authorization or permit Delaware. Seller's principal place 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 business since August 2023, is located in Section 5.10(a), San Mateo, California.

Section 3.7 4.12 Intellectual Property.

(a) Disclosure and Ownership of Program Patents Taxes. 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 No deduction or withholding for or 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 account of any basis for tax has been or was required to be made from any inventorship challenge, interference, invalidity or unenforceability with respect payment by Vertical 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), **Sale Agreement**. Seller has not received written notice of, and has no Knowledge from Vertical of any intent intention to effect, withhold or deduct any tax from future payments under the acceleration, cancellation, modification or termination of any Assigned Contract. True, correct **Sale Agreement**. Seller has filed (or caused to be filed) all material tax returns 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 material tax reports required to be filed by Seller with respect to the Program or the Transferred Assets have been timely filed under Applicable Law and such Tax Returns are true and correct in has paid 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 taxes required to be withheld paid by Seller (including, in respect of payments arising each case, in connection with the Program or the Transferred Assets to its capacity as a withholding agent), except for 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 taxes that 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 faith by appropriate proceedings and for which adequate reserves have been established in accordance with the generally accepted accounting principles applicable to Seller. There are no existing liens for taxes on the Purchased Receivables (or 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)) portion thereof).

Section 3.10 4.13 **Compliance with Laws Solvency**. Seller is, not in conflict individually and together 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 its subsidiaries on a consolidated basis, Solvent, and will be Solvent immediately after giving effect 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. Agreement.

Section 3.13 4.14 Product Financial Information Disclosure. 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 fact (other than general economic or industry conditions) that would reasonably be expected to materially and between Seller and adversely affect 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 Purchased Receivables 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 Aguetant, 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 V

BUYER'S REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer hereby represents and warrants to Seller that as of the Effective Date date hereof and as of the Closing Date as follows: Date:

Section 4.1.5.1 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 4.2.5.2 Corporate Authorization. Buyer has full corporate the requisite organizational power and authority to execute, deliver and deliver this Agreement and perform the Ancillary Agreements and to perform its obligations hereunder and thereunder, Transaction Documents and to consummate the Transaction, transactions contemplated thereby. The execution, delivery and performance by Buyer of this Agreement and the Ancillary Agreements, the performance by Buyer of its obligations hereunder and thereunder, Transaction Documents, and the consummation of the Transaction and the transactions contemplated by the Ancillary Agreements thereby, 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 4.3.5.3 **No Conflict Enforceability.** Each of the Transaction Documents has been duly executed and delivered by Buyer, and constitutes a valid and binding obligation of Buyer, enforceable against Buyer in accordance with its terms, except as may be limited by general principles of equity (regardless of whether considered in a proceeding at law or in equity) and by applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws of general application relating to or affecting creditors' rights generally, general equitable principles and principles of public policy.

Section 5.4 **Absence of Conflicts.** The execution, delivery 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 performance by Buyer of the Transaction Documents and the consummation of the transactions contemplated by the Ancillary Agreements, thereby do not and will not: shall not (a) conflict with, or violate constitute a breach of or default under, any provision of Organizational Documents the certificate of Buyer; incorporation or bylaws of Buyer, or (b) conflict with, or violate constitute a material breach of or material default under, any provision of any (i) Applicable Law or Order applicable to Buyer; (c) conflict with, result Judgment 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 each case existing as of the performance required by, date hereof or require (ii) any consent, authorization, or approval under, any material Contract to which Buyer is a party or by which it Buyer 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. bound.

Section 4.4.5.5 **Required Filings and Consents.** The No Consent of any Governmental Authority or any other Person is required by or with respect to Buyer in connection with the execution and delivery of this Agreement by Buyer do not, and of the Transaction Documents, the performance by Buyer of its obligations hereunder and under the Transaction Documents or the consummation of the transactions contemplated by 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, Documents, except for (a) such Consents, the letters failure of which to be obtained or made, would not reasonably be expected to result in a Buyer Material Adverse Effect, and (b) such Consents as shall have been obtained on or prior to the applicable Regulatory Authorities set forth in Section 5.10(a), date hereof.

Section 4.5.5.6 **No Brokers Litigation.** No action, suit, proceeding or investigation before any Governmental Authority is pending, or, to the knowledge of Buyer, threatened, against Buyer that, individually or in the aggregate, would reasonably be expected to result in a Buyer Material Adverse Effect.

Section 5.7 **Brokers' Fees.** There is no investment banker, broker, finder, financial advisor or investment banker other intermediary who has been retained by or is authorized to act on behalf of Buyer who is entitled to any brokerage commission, finder's fee or similar payment commission in connection with the Transactions based upon arrangements made transactions contemplated by or on behalf of Buyer, this Agreement.

Section 4.6.5.8 **Legal Proceedings Financing.** There is no action, suit, claim Buyer has, and will have as of the Closing, sufficient cash on hand or counterclaim or legal, administrative or arbitral proceeding or investigation, pending or threatened against binding and enforceable commitments to provide it with funds sufficient to satisfy its obligations to pay the Purchase Price. Buyer acknowledges 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. contingent on obtaining financing.

ARTICLE VI

GENERAL COVENANTS

Section 4.10 6.1 No Implied Representations Confidentiality.

(a) Confidentiality. 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 Except as set forth in Section 6.1(c) below, each party ("Article III Receiving Party") shall keep confidential and not disclose to any Person (other than its Affiliates and its and its Affiliates' Representatives), and shall cause its Affiliates and its and its Affiliates' Representatives to keep confidential and not disclose to any Person, any Confidential Information. Receiving Party shall, and shall cause its Affiliates and its and its Affiliates' Representatives to, use the Confidential Information solely in connection with Receiving Party's administration of, and exercising of rights and performance of obligations under, the Transaction Documents (and not for any other purpose). The foregoing obligations shall continue until the later of (i) three years after the date of termination of this Agreement. Buyer acknowledges Agreement pursuant to Section 9.1, in the case of Confidential Information other than IP Confidential Information, (ii) five years after the date of termination of this Agreement pursuant to Section 9.1 in the case of IP Confidential Information and (iii) the date of expiration of the last to expire of the Relevant Obligations. The Receiving Party agrees that in determining to enter into this Agreement it shall be 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 remain responsible hereunder for any representation or warranty of failure by any kind, express or implied, made or purportedly made by Person who receives Confidential Information from or on behalf of the Receiving Party pursuant to this Section 6.1 (including the Receiving Party's Affiliates, Representatives, Affiliates' Representatives, and other permitted recipients under this Section 6.1) to treat such Confidential Information as required under this Section 6.1 (any such failure, a "Recipient Confidentiality Breach").

(b) Confidential Information. "Confidential Information" means, collectively, all information (whether written or oral, or in electronic or other form, and whether furnished before, on or after the date of this Agreement) (i) concerning, or relating in 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. way, directly or indirectly, to the other party ("Disclosing Party"), the Related Agreements, the Purchased Receivables or the Retained Interests, including any Vertical Reports, notices, requests, correspondence or other information furnished pursuant to this Agreement and any other reports, data, information, materials, notices, correspondence or documents of any kind relating in any way, directly or indirectly, to the Purchased Receivables or the Retained Interests, including any IP Confidential Information and (ii) disclosed by the parties hereto under the Confidentiality Agreement. "IP Confidential Information" means, collectively, (x) the terms and conditions of the IP Agreement and (y) any and all confidential or proprietary information disclosed by Vertical or any of its Affiliates to Seller or by Seller to Vertical or any of its Affiliates under the IP Agreement. Notwithstanding the

foregoing, no event "Confidential Information" shall this Section 4.10 limit not include any information that (A) was known by Receiving Party at the time such information was disclosed to Receiving Party, its Affiliates or its or its Affiliates' Representatives in any way Buyer from pursuing a claim of Fraud against any Person.

ARTICLE V

COVENANTS

Section 5.1 Access and Information. From accordance herewith or in accordance with the Effective Date until Confidentiality Agreement, as evidenced by its written records; (B) was or becomes generally available to the earlier public or part of the termination public domain (other than as a result of a disclosure by Receiving Party, its Affiliates or its or its Affiliates' Representatives in violation of this Agreement or the Closing, subject Confidentiality Agreement) prior to reasonable rules and policies any disclosure of Seller and any applicable Laws, Seller shall, upon reasonable advance notice: (i) afford Buyer such information by Receiving Party, its Affiliates or its or its Affiliates' Representatives; (C) becomes known to Receiving Party on a non-confidential basis from a source other than Disclosing Party and its Representatives reasonable access, during regular business hours, to the Transferred Assets and employees or consultants (and without any breach 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 the Confidentiality Agreement by Receiving Party, 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 Affiliates or 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 its Affiliates' Representatives); provided, 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 such source, to the other party's obligations hereunder, including securing as promptly as practicable all Authorizations required in connection with knowledge of Receiving Party, had the transactions contemplated hereby, right to disclose such information to Receiving Party (without breaching any legal, contractual or fiduciary obligation to Disclosing Party); or (D) is or has been independently developed by Receiving Party, its Affiliates or its or its Affiliates' Representatives without use of or reference to the Confidential Information (as evidenced by contemporaneous written records). The existence and terms of this Agreement shall be deemed the Confidential Information of both parties hereto. [***]

(c) Permitted Disclosures.

(i) In the event that Receiving Party or its Affiliates or any of its or its Affiliates' Representatives are requested by a Governmental Authority or required by Applicable Law (as reasonably determined by Receiving Party after consulting with legal counsel), legal process, or the regulations of a stock exchange or Governmental Authority or by the order or ruling of a court, administrative agency or other government body of competent jurisdiction to disclose any Confidential Information, Receiving Party shall promptly, and, in any event, use reasonable efforts to, promptly upon learning of such requirement, to the extent permitted by Applicable Law, notify Disclosing Party in writing of such requirement so that Disclosing Party may seek an appropriate protective order or other appropriate remedy (and if Disclosing Party seeks such an order or other remedy, Receiving Party will provide such cooperation, at Disclosing Party's expense, as Disclosing Party shall reasonably request). If no such protective order or other remedy is obtained or sought and Receiving Party or its Affiliates or its or its Affiliates' Representatives are, in the view of their respective counsel (which may include their respective internal counsel), legally compelled to disclose Confidential Information, Receiving Party or its Affiliates or its or its Affiliates' Representatives, as the case may be, shall only disclose that portion of the Confidential Information that their respective counsel advises that Receiving Party or its Affiliates or its or its Affiliates' Representatives, as the case may be, are compelled to disclose and will exercise reasonable efforts, at Disclosing Party's expense, to obtain reliable assurance that confidential treatment will be accorded

to that portion of the Confidential Information that is being disclosed. In any event, Receiving Party will not oppose action by Disclosing Party to obtain an appropriate protective order or other reliable assurance that confidential treatment will be accorded the Confidential Information.

(ii) Notwithstanding anything herein to the contrary, the Receiving Party may disclose Confidential Information with the prior written consent of the Disclosing Party or to the extent such disclosure is reasonably necessary in the following situations:

(A) prosecuting or defending litigation;

(B) for regulatory, tax or customs purposes;

(C) for audit purposes, provided that each recipient of Confidential Information must be bound by customary obligations of confidentiality and non-use prior to any such disclosure;

(D) to the extent such disclosure of this Agreement or the transactions contemplated hereby is required by Applicable Law or reasonably necessary to comply with the Securities Act of 1933, as amended, with the Exchange Act, or with any rule, regulation or legal process promulgated by the SEC or a stock exchange, provided that prior to the submission by the filing party to the SEC of any SEC Documents containing any Confidential Information of the other party or that contain information related to the existence or subject matter of this Agreement or the identity of the other party, to the extent practicable and permitted by Applicable Law, the filing party shall provide drafts of such SEC Documents to the other party within a reasonable period of time prior to the planned date of such submission (but in any event no less than [***] Business Days prior to the planned date of such submission), to review any redactions related thereto, and the filing party shall consider in good faith any comments by the other party thereto and cooperate in good faith with the other party to obtain confidential treatment with respect to the portions of this Agreement that the other party reasonably requests to be kept confidential and to redact any Confidential Information of the other party therein as requested by the other party, unless reasonably advised by counsel that such Confidential Information is required to be included by Applicable Law;

(E) disclosure to (i) its Affiliates and their Representatives on a need-to-know basis in order for such party to exercise its rights or fulfill its obligations under this Agreement and (ii) its Representatives; provided, that in the case of each of clause (i) and clause (ii) the recipient of Confidential Information agrees to be bound by the provisions of this Section 5.4.6.1, or are otherwise subject to confidentiality obligations no less restrictive than those set forth in this Agreement;

(F) disclosure to existing or prospective lenders, acquirors, investors, partners, assignees and other sources of funding, including underwriters, debt financing or co-investors, or direct or indirect beneficial owners, or limited partners, or potential partners or collaborators, and the Representatives of the foregoing, provided that the recipient of Confidential Information agrees to be bound by the provisions of this Section 6.1, or are otherwise subject to confidentiality obligations no less restrictive than those set forth in this Agreement (other than with respect to the duration of such confidentiality obligations, which shall be consistent with customary practice for the purpose but in any event having a duration of not less than [***] year from the date of disclosure of Confidential Information other than IP Confidential Information and a duration of not less than [***] years from the date of disclosure in the case of any IP Confidential Information); or

(G) as is necessary in connection with a permitted assignment pursuant to Section 10.5.

Notwithstanding anything to the contrary in Section 6.1(c)(ii)(D), a party making a filing with the SEC shall have no obligation to provide a draft of a proposed filing of an SEC Document or otherwise comply with Section 6.1(c)(ii)(D) with respect to a proposed filing of an SEC Document if the description of or reference to this Agreement or to the subject Confidential Information of the other party or the identity of the other party contained in, or attached as an exhibit to, the proposed SEC Document, has been included in any previous SEC Document filed by either party in accordance with Section 6.1(c)(ii)(D) or otherwise approved by the other party in writing.

(d) Termination of Confidentiality Agreement. Effective upon the date hereof, the Confidentiality Agreement, dated September 14, 2023 (the "Confidentiality Agreement"), between Buyer and Seller shall terminate and be of no further force or effect, and shall be superseded by the provisions of this Section 6.1.

Section 6.2 Taxes.

(a) Transfer Taxes Tax Treatment. All excise, sales, use, value added, transfer (including real property transfer or gains), stamp, documentary, filing, recordation For U.S. federal, state, local and other similar Taxes imposed or assessed as a result of the Transaction and/or non-U.S. tax purposes, Seller and Buyer shall treat (i) 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, Transaction Documents as and when due. To a sale of 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 Purchased Receivables and (ii) Buyer shall be entitled any and all amounts remitted by Seller 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 Buyer 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 Section 7.2(a) or otherwise under this Section 5.4(d).

(e) Purchase Price Allocation. The payments Agreement as having been received by Seller as agent 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 promulgated 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, Buyer, unless otherwise required pursuant to by a "determination" within the meaning of final determination as defined in Section 1313(a) of the Code (or or any analogous or similar corresponding provision of state, local, or foreign Law) non-U.S. Applicable Law. If there is an inquiry by any Governmental Authority of Seller or Buyer related to this Section 6.2, Seller and Buyer shall cooperate with each other in responding to such inquiry in a commercially reasonable manner consistent with this Section 6.2.

(b) Withholding Certificates. Each party hereto agrees (i) to notify the other party promptly in writing if (A) such party becomes ineligible to use or deliver any Applicable Withholding Certificate or other tax form previously delivered pursuant to this Agreement, or (B) any Applicable Withholding Certificate or other tax form previously delivered pursuant to this Agreement ceases to be accurate or complete, (ii) to provide (to the extent it is legally eligible to do so) an updated IRS Form W-9 to the other party whenever required in order for such party to have on file a duly completed and valid IRS Form W-9, and (iii) to provide any additional tax forms that the other party may reasonably request.

(c) Withholding. Buyer and Seller acknowledge and agree that, under Applicable Law in effect as of the date hereof, no taxes are expected to be deducted or withheld from payments under this Agreement provided the parties deliver the Withholding Certificates contemplated by Section 6.2(b). Buyer and Seller shall each be entitled to deduct and withhold (or cause to be deducted and withheld) from any amount payable under this Agreement (but for this sentence) any amounts that it is required to deduct or withhold under Applicable Law with respect thereto; provided that if Buyer or Seller shall be required to withhold or deduct any such tax, it shall remit (or cause to be remitted) any amount withheld or deducted pursuant to this Section 6.2 to the relevant taxing authority (and such amounts shall be treated for all purposes of this Agreement as having been paid to the Person to whom such amounts would otherwise have been paid). Notwithstanding the foregoing or anything to the contrary in this Agreement, if amounts are deducted or withheld from amounts payable to Buyer (or to Seller pursuant to Section 2.15 of the Sale Agreement or Section 5.f of the Marketing Agreement that result in a reduction of the Purchased Receivables) in respect of an Indemnified Tax, Seller shall make a payment to Buyer so that, after all such required deductions and withholdings in respect of any Indemnified Tax attributable to amounts payable or that would be payable to Buyer hereunder (including any

deductions and withholdings required with respect to any additional payments under this Section 6.2), Buyer receives an amount equal to the amount that it would have received had no deductions or withholdings on account of Indemnified Taxes been made. Buyer shall use commercially reasonable efforts to obtain a refund or credit in respect of any Indemnified Tax, and to the extent that the Buyer obtains such refund or tax credit that actually reduces cash taxes payable by Buyer (a "Cash Tax Savings") attributable to such Indemnified Tax in the year the relevant payment was made or in the immediately following year, Buyer shall reimburse Seller an amount equal to such refund or Cash Tax Savings (less reasonable expenses incurred in obtaining such refund or credit).

(f) (d) **Intended Tax Treatment Cooperation.** For applicable Tax purposes, (i) the Transaction Each of Buyer and Seller shall cooperate and provide, or cause to be treated as a taxable asset purchase and sale, (ii) the rights of Seller provided, to the Milestone Payments, other party such assistance as may reasonably be necessary to enable the Payments for DoD Marketing, applicable recipient party to claim any exemption or credit in respect of any amounts withheld pursuant to this Section 6.2. Each of Buyer and Seller shall furnish to the Quarterly Payments shall be treated as deferred contingent purchase price eligible for installment treatment under Section 453 other party proper evidence of the Code, and (iii) interest may be imputed taxes paid by it to the relevant taxing authority on such payments if required by Sections 483 or 1274 behalf of the Code, recipient party.

Section 5.5 6.3 **Notification Further Actions.** Between the Effective Date From and after the Closing, each of Buyer and Seller shall, promptly notify Buyer in writing if it becomes aware of: (i) any fact, circumstance, event or action at 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 expense 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 requesting party, execute and deliver such Person is or additional documents, certificates and instruments, and perform such additional acts, as may be required in connection with reasonably requested and necessary or appropriate to carry out all of the Transaction and/or provisions of this Agreement and to give full effect to and consummate the transactions contemplated by this Agreement, including to (a) perfect the Ancillary Agreements; (iii) sale, assignment, transfer and conveyance of the Purchased Receivables to Buyer pursuant to this Agreement, (b) create, evidence and perfect Buyer's security interest granted pursuant to Section 2.4 and (c) enable Buyer to exercise or enforce any notice or other communication from of Buyer's rights under any Government Entity Transaction Document to which Buyer is party (subject to, in connection with the Transaction and/or case of clause (c), [***]).

Section 6.4 **Escrow Agreement.** The parties agree to negotiate and enter into the transactions contemplated Escrow Agreement within [***] Business Days of the Closing Date.

Section 6.5 **Vertical Instruction Letter.** On the effective date of the Escrow Agreement, Seller shall deliver to Buyer and Vertical an instruction letter, in substantially the form of Exhibit D attached hereto (the "Vertical Instruction Letter"), duly executed by Seller, instructing Vertical to pay 100% of all payments due to Seller under the Ancillary Agreements; Sale Agreement and (iv) any Proceeding commenced or, the Marketing Agreement to Seller's Knowledge, threatened in writing against the Escrow Account (for purposes of clarity, Seller and directly involving Buyer agree to instruct the Transferred Assets, Escrow Agent that \$[***] of the Program or payments under Sections 2.12 and 2.13 of the Assumed Liabilities. Notwithstanding Sale Agreement and Section 5.a of the foregoing, except as otherwise explicitly set forth herein, Marketing Agreement payable to Seller in respect of Net Sales made during the fourth calendar quarter of 2023 shall be payable to Buyer out of the Escrow Account and the portion of such payments in excess of \$[***] shall be payable to Seller out of the Escrow Account). Prior to the termination of this Agreement pursuant to Section 9.1, Seller shall not, have the right without Buyer's prior written consent, deliver any further directions relating 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 payment of the conditions set forth in Section 6.2 Receivables 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. Vertical.

Section 5.6.6 Further Assurances Public Announcements

. At Except (a) for a press release previously approved in form and substance by Seller and Buyer, or any time other public announcement using substantially the same text as such press release, and from time to time after (b) for a public disclosure in accordance with Section 6.1(c)(ii)(D) and the Closing, as and when requested by any party hereto and at such requesting party's expense, the other last paragraph of Section 6.1(c)(ii), neither party hereto shall, and each party hereto shall cause its Affiliates promptly not to, execute, acknowledge and deliver without the prior written consent of the other party (which consent shall not be unreasonably withheld or delayed), issue any press release or make any other assurances public disclosure with respect to this Agreement or documents any of the other Transaction Documents or instruments any of transfer reasonably requested the transactions contemplated hereby or thereby.

Section 6.7 Vertical Notice and Waiver. For a period of 30 days following receipt by Vertical of the requesting party hereto Vertical Notice and necessary for the requesting party to satisfy its obligations hereunder or Waiver delivered by Seller, Seller shall use commercially reasonable efforts to obtain the benefits of the Transaction. Vertical's duly authorized signature to such Vertical Notice and Waiver.

Section 5.7 Exclusivity ARTICLE VII. 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 COVENANTS RELATING TO THE SALE AGREEMENT AND MARKETING AGREEMENT 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 5.8.7.1 Transferred Intellectual Property. After the Closing Date, Seller shall not practice, license or otherwise exploit any Performance 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 Sale 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 Marketing 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 Aguetant 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 that it shall (i) comply in all material respects with its obligations under each of the Sale Agreement and acknowledges the Marketing Agreement, (ii) not take any action or forego any action that would reasonably be expected to constitute a material breach or default under the Sale Agreement or the Marketing Agreement and (iii) use Commercially Reasonable Efforts to cure any such breach by Seller is familiar with of the trade secrets and other information of a confidential Sale Agreement 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 Marketing Agreement, (iv) not forgive, release or compromise any of its Affiliates were to provide services amount owed to or otherwise participate in becoming owed to Seller under 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 Sale Agreement in respect of the Receivables, without the prior written consent of Buyer, and (v) not, without the Transferred Assets. prior written consent of Buyer, (A) exercise any right to offset the Receivables, or modify the Receivables or terminate the Sale Agreement or the Marketing Agreement, in whole or in part, (B) agree with Vertical to offset the Receivables, or modify the Receivables or terminate the Sale Agreement or Marketing Agreement, in whole or in part, or (C) take, or permit any Affiliate or sublicensee of Seller further agrees or Vertical to take, any action that would reasonably be expected to give Vertical the right to offset the Receivables, or modify the Receivables or terminate the Sale Agreement or Marketing Agreement, in whole or in part. Subject to the foregoing, promptly, 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 any event within [***] Business Days, following receipt by Seller of any written notice

of breach by Seller or of termination of the bargain set forth Sale Agreement or Marketing Agreement, Seller shall furnish a true, correct and complete copy of the same to Buyer.

(b) Seller shall not, without the prior written consent of Buyer, grant or withhold any consent, exercise or waive any right, obligation or option or fail to exercise any right, obligation or option in this respect of, affecting or relating to the Receivables, the Product, the Sale Agreement, as specifically negotiated by or the parties hereto if Marketing Agreement in any manner that would reasonably be expected (with or without the giving of notice or the passage of time, or both) to have a Seller Material Adverse Effect or its Affiliates breached any of conflict with, or cause a termination, breach or default under the Sale Agreement.

Section 7.2 Misdirected Payments; Setoffs.

(a) Misdirected Payments.

(i) If Seller shall, notwithstanding 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 Vertical Instruction Letter, receive any other obligation pursuant to this Agreement, Purchased Receivables, Seller shall not, directly or indirectly, either for Seller or its controlled Affiliates or for or through promptly, and in any other Person (other event no later 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 Business Days after such receipt, remit 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. Purchased Receivables.

(ii) Non-Disparagement. Make If Buyer shall receive any material public (including, for payment under 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 Sale Agreement or the Products.

(iii) For Marketing Agreement that does not consist entirely of Purchased Receivables, Buyer shall promptly, and in any event no later than *** Business Days after such receipt remit to Seller the avoidance portion, if any, of doubt, following the Closing, the performance of any duties under this Agreement or any Ancillary Agreement, in itself, shall such payment that does not be considered a breach of this Section 5.16. constitute Purchased Receivables.

(b) Additional Acknowledgments Vertical Setoffs. If Vertical exercises a Vertical Setoff against the Purchased Receivables, then Seller acknowledges shall promptly, and in any event no later than *** calendar days following the payment of the Purchased Receivables affected by such Vertical Setoff, make a true-up payment to Buyer pursuant to this Section 7.2(b) such that Buyer receives the full amount of the Purchased Receivables payment that would have been paid to Buyer had such Vertical Setoff not occurred. Notwithstanding anything to the contrary herein, to the extent Seller shall have made a true-up payment to Buyer pursuant to this Section 7.2(b) in respect of any Vertical Setoff, any subsequent payment received from Vertical in respect, and to the extent, of such Vertical Setoff shall not be included in the Purchased Receivables, such that the provisions of subsequent payment is included in the Excluded Assets. For all purposes hereunder, any true-up payment made pursuant to this Section 5.16 are in consideration of the direct and indirect benefits to 7.2(b) will 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 treated 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 paid with respect to subject matter, time period and geographical area. Because the protection Purchased Receivables for U.S. federal income tax purposes to the fullest extent permitted by Applicable Law. For the avoidance of doubt, withholding taxes (including any withholding taxes deducted by Vertical from payments under the Sale Agreement pursuant to 2.15 of the Confidential Information and the other legitimate business interests acquired by Buyer pursuant to the Sale Agreement Buyer and its respective Affiliates require that Seller and its Affiliates comply with the covenants in this or 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 5.f 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 Marketing Agreement) shall not be treated as a time period equal to the Restricted Period. Vertical Setoff.

(c) **Enforcement Remittances.** If, at the time of enforcement of All remittances pursuant to 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 7.2 shall be substituted for the stated period, scope made (i) without setoff 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 deduction of any kind (except as required by Applicable Law) and (ii) by wire transfer of immediately available funds to such account designated by Seller or Buyer, as applicable, for distributions under 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 Escrow Agreement or to enforce its provisions, such other account as Seller or Buyer, as applicable, may designate in addition writing (such designation to be made at least [***] Business Days prior to any other remedies available to Buyer or its Affiliates. Seller such payment), as the case may be.

(d) **Payments Held In Trust.** Each party hereto agrees that neither it nor its Affiliates will assert shall hold any amounts received by it to which the other party is entitled under this Agreement 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 trust 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 benefit of the provisions of this Agreement. other party and agrees that it shall have no right, title or interest whatsoever in such amounts.

Section 5.17 7.3 **Insurance Vertical Reports; Notices; Correspondence.** Until August 31, 2025, Seller shall maintain products liability insurance covering subject matter

(a) **Promptly,** and in amounts consistent with Seller's current policies.

Section 5.18 **Equipment Reimbursement.** Buyer will reimburse Seller for all costs reasonably incurred any event no later than [***] Business Days, following the receipt by Seller of (i) Vertical Reports required to be delivered pursuant to the Sale Agreement or the Marketing Agreement or (ii) any written notice or material written correspondence from or on behalf of Vertical or any of its Affiliates or the DoD relating to, or involving, the Purchased Receivables (including, for disassembling and crating the automated packaging line [***], up purposes of clarity, any written results of any audit delivered by Vertical to but not Seller pursuant 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 Section 2.18 of the crated automated packaging line equipment Sale Agreement or Section 5.d of the Marketing Agreement, as applicable) or that would reasonably be expected to result in a Seller Material Adverse Effect, or (iii) any written notice or material written correspondence from or on behalf of Vertical or any of its Affiliates or the Catalent Pharma Solutions, LLC location DoD relating to, or involving, the Sale Agreement or the Marketing Agreement, Seller shall furnish a location desired by true and correct copy of the same to Buyer.

ARTICLE VI

CONDITIONS TO CLOSING(b) Seller shall not send (i) any written notice or material written correspondence to Vertical or any of its Affiliates or the DoD relating to, or involving, the Purchased Receivables or that would reasonably be expected to result in a Seller Material Adverse Effect, or (ii) any written notice or material written correspondence to Vertical or any of its Affiliates or the DoD relating to, or involving, the Sale Agreement or the Marketing Agreement, in each case, pursuant to the Sale Agreement or the Marketing Agreement without the prior written consent of Buyer (such consent not to be

unreasonably withheld or delayed). Seller shall promptly, and in any event no later than [***] Business Days, provide to Buyer a copy of any notice or material correspondence sent by Seller to Vertical relating to, or involving, the Purchased Receivables, the Sale Agreement or the Marketing Agreement, or that would reasonably be expected to result in a Seller Material Adverse Effect, in each case, pursuant to the Sale Agreement or the Marketing Agreement. Seller shall use Commercially Reasonable Efforts to respond to any reasonable written inquiries of Buyer related to or involving the Purchased Receivables, which for purposes of clarity shall not require Seller to [***].

Section 6.1 7.4 Conditions to the Obligations Audits of Buyer Vertical. 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 Consultation. Seller and Warranties. No event or events Buyer shall have occurred since consult with each other regarding the effective date timing, manner and conduct of this Agreement which, individually or in (i) any audit of Vertical's books of accounts and other records with respect to 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 Purchased Receivables pursuant to Section 2.18 of the Effective Date and as Sale Agreement or Section 5.d of the Closing, as though made on Marketing Agreement and as of the Closing (except (ii) any dispute with respect to the extent expressly made as of an earlier date, in which case as of the earlier date). a Vertical Report.

(b) Covenants Audits.

(i) If requested in writing by Buyer, Seller shall cause an independent, certified public accountant reasonably acceptable to Vertical to audit Vertical's books of accounts and other records with respect to the Purchased Receivables pursuant to Section 2.18 of the Sale Agreement or Section 5.d of the Marketing Agreement, as applicable; provided, however, that Buyer shall not be entitled to request such an audit more frequently than [***], unless [***] is expressly permitted under the terms of Section 2.18 of the Sale Agreement or Section 5.d of the Marketing Agreement, as applicable. With respect to any such audit, Seller shall select such independent, certified public accountant as Buyer shall recommend for such purpose (as long as such independent, certified public accountant is reasonably acceptable to Seller and Vertical). Subject to the last sentence of this Section 7.4(b)(i), all of the expenses of any such audit requested by Buyer under this Section 7.4(b)(i) (including the fees and expenses of any independent, certified public accountant) that would otherwise be borne by Seller pursuant to the Sale Agreement or the Marketing Agreement shall instead be borne (as such expenses are incurred) by Buyer. If, following the completion of such an audit, Vertical is obligated to bear the costs of such audit pursuant to Section 2.18 of the Sale Agreement or Section 5.d of the Marketing Agreement, Buyer shall be entitled to 100% of the amounts received from Vertical for such costs (or 50% in the case of a Seller Participated Audit, with Seller being entitled to the other 50% in the case of a Seller Participated Audit). Notwithstanding the above, upon reasonable request of Seller, any audit initiated at the request of Buyer pursuant to this Section 7.4(b)(i) may include such additional matters as reasonably requested by Seller (such audit, a "Seller Participated Audit"); provided that half of the expenses of a Seller Participated Audit shall be borne by Seller (as such expenses are incurred).

(ii) Seller shall not request an audit under Section 2.18 of the Sale Agreement or Section 5.d of the Marketing Agreement without the prior written consent of Buyer. Subject to the last sentence of this Section 7.4(b)(ii), all of the expenses of any audit requested by Seller under this Section 7.4(b)(ii) (including the fees and expenses of such independent public accounting firm designated for such purpose) shall be borne by Seller (if and as such expenses are incurred). Notwithstanding the above, upon reasonable request of Buyer, any audit initiated at the request of Seller pursuant to this Section 7.4(b)(ii) may include such additional matters as reasonably requested by Buyer (such audit, a "Buyer Participated Audit"); provided that (A) half of the expenses of a Buyer Participated Audit shall be borne by Buyer (as such expenses are incurred) and (B) if, following the completion of such an audit, Vertical reimburses Seller for the costs of such audit pursuant to Section 2.18 of the Sale Agreement or Section 5.d of the Marketing Agreement, Buyer shall be entitled to [***] of the amount of such reimbursement received from Vertical.

(iii) If, following the completion of an audit of Vertical under Section 7.4(b)(i) or Section 7.4(b)(ii), as applicable, Vertical is required to pay for underpayment of the Receivables, such payment shall be first used to reimburse for all of the expenses as provided in Section 7.4(b)(i) or Section 7.4(b)(ii), as applicable, and the remainder shall be distributed as Purchased Receivables to Buyer and, if applicable, Retained Interests to Seller.

(iv) If, following the completion of an audit of Vertical under Section 7.4(b)(i) or Section 7.4(b)(ii), as applicable, Seller is required to reimburse Vertical for overpayment of Purchased Receivables and, if applicable, Retained Interests, then (A) Buyer shall promptly (and in any event within [***] Business Days following receipt of a request from Seller) pay to Seller for further distribution to Vertical the portion of such overpaid amount that was actually paid to Buyer, and Seller shall promptly (and in any event within [***] Business Days following receipt of such amount from Buyer)

pay such amount to Vertical in accordance with Section 2.18 of the Sale Agreement or Section 5.d of the Marketing Agreement, as applicable, and promptly (and in any event within [***] Business Days) after making such payment provide documentation to Buyer evidencing that such payment was made, and (B) if applicable, Seller shall promptly (and in any event within [***] Business Days following provision of such evidence) reimburse Vertical for the portion of such overpaid amount that was actually paid to Seller and shall promptly (and in any event within [***] Business Days) after making such payment provide documentation to Buyer evidencing that such payment was made. In the event that (1) Buyer fails to pay Seller for the portion of such overpaid amount that was actually paid to Buyer within the time specified in the preceding sentence and Seller subsequently pays such amount to Vertical on Buyer's behalf and provides documentation to Buyer evidencing that payment was made, Seller shall be entitled to recoup an amount equal to the amount not paid by Buyer, together with any late fee in respect thereof in accordance with Section 2.5, from the Purchased Receivables; or (2) Seller fails to reimburse Vertical for the portion of such overpaid amount that was actually paid to Seller within the time specified in the preceding sentence and Buyer subsequently pays such amount to Vertical on Seller's behalf and provides documentation to Seller evidencing that such payment was made, Buyer shall be entitled to recoup an amount equal to the amount not paid by Seller from the Retained Interests, in each case ((1) and (2)) by giving one or more unilateral written instructions to the Escrow Agent to deduct from amounts deposited into the Escrow Account that would otherwise be distributable to Buyer or Seller, respectively, in respect of the Purchased Receivables or Retained Interests, respectively (each, a "Recoupment Instruction"), an amount equal to the sum of such unpaid amount and any late fee in respect thereof calculated in accordance with Section 2.5, if applicable, and to cause the Escrow Agent to distribute such amount to Seller or Buyer, respectively.

Section 7.5 Amendment of Sale Agreement and Marketing Agreement. Seller shall have performed provide Buyer a copy of any proposed amendment, supplement, modification or waiver (a "Modification") of any provision of the Sale Agreement or the Marketing Agreement as soon as practicable and complied with all in any event not less than [***] Business Days prior to the date Seller proposes to execute such Modification. Seller shall not, without the prior written consent of its covenants contained Buyer (such consent not to be unreasonably withheld or delayed), execute or agree to execute any proposed Modification. Promptly, and in Article V at or before the Closing (to the extent that such covenants require performance any event within [***] Business Days, following receipt by Seller at of a fully executed Modification of the Sale Agreement 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.** Marketing Agreement, Seller shall have furnished furnish a true, correct, and complete copy of such Modification 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. Buyer.

Section 6.2 7.6 Conditions to the Obligations Enforcement of Seller Sale Agreement and Marketing Agreement. 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 Notice of Vertical Breaches.** Promptly, and Warranties. The representations and warranties in any event within [***] Business Days after Seller becoming aware of Buyer shall be true and correct on and as a breach of, or an alleged breach of, the Effective Date and as Sale Agreement or the Marketing Agreement by Vertical, or of the Closing, as though made on and as existence of any facts, circumstances or events that, alone or together with other facts, circumstances or events, would reasonably be expected (with or without the giving of notice or passage of time, or both) to give rise to a breach of the Closing (except Sale Agreement or the Marketing Agreement by Vertical or the right to terminate the extent expressly made as Sale Agreement or the Marketing Agreement (in whole or in part) by Seller, in each case Seller shall promptly (but in any event within [***] Business Days) provide notice of an earlier date, such breach or termination event to Buyer describing in which case as reasonable detail the relevant breach or termination event. In addition, Seller shall provide Buyer a copy of any written notice of breach or alleged breach of the earlier date). Sale Agreement or the Marketing Agreement as soon as practicable and in any event not less than [***] Business Days following such delivery.

(b) **Covenants Enforcement of Sale Agreement and Marketing Agreement.** Seller shall consult with Buyer regarding the breach or termination event referred to in Section 7.6(a) and as to the timing, manner and conduct of any enforcement of Vertical's obligations under the Sale Agreement or the Marketing Agreement relating thereto. Following such consultation, Seller shall, as reasonably instructed by Buyer, exercise such rights and remedies relating to such breach as shall be available to Seller, whether under the Sale Agreement or the Marketing Agreement or by operation of Applicable Law, and use Commercially Reasonable Efforts to enforce compliance by Vertical with the relevant provisions of the Sale Agreement or the Marketing Agreement. In connection with any enforcement of Vertical's obligations under the Sale Agreement or the Marketing Agreement pursuant to this Section 7.6, Seller shall employ such counsel as Buyer shall have performed recommend for such purpose (as long as such counsel is reasonably acceptable to Seller), and complied shall provide Buyer with access to such counsel for such purpose. Seller agrees to keep Buyer reasonably informed of any such enforcement and to provide copies as soon as practicable, but in any event within [***] Business Days following Seller's receipt or delivery of any and 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). filings, notices and written communications relating thereto.

(c) **Certificate Allocation of Proceeds and Costs of Enforcement.**

(i) The proceeds from any enforcement of Vertical's obligations under the Sale Agreement or the Marketing Agreement pursuant to this Section 7.6, after deduction and reimbursement to Buyer and Seller of all costs and expenses (including reasonable and documented attorneys' fees and expenses) incurred by Buyer and Seller in connection with such enforcement, shall have received a certificate, signed by a duly authorized officer be, promptly (and in any event within [***] Business Days) following the receipt of such proceeds, allocated as follows: proceeds, to the extent relating to [***] shall be allocated to Buyer, and proceeds, to the extent relating to the [***] shall be allocated to Seller.

(ii) All costs and expenses (including reasonable and documented attorneys' fees and expenses) of Buyer and dated Seller of any enforcement by Seller of Vertical's obligations under the Closing Date, Sale Agreement or the Marketing Agreement pursuant to this Section 7.6 incurred on or prior to the effect that Stepdown Date ("Pre/At Stepdown Date Enforcement Costs") shall be borne [***]% by Buyer. Seller shall provide written notice to Buyer from time to time of any Pre/At Stepdown Date Enforcement Costs incurred by Seller, together with reasonable documentation evidencing such Pre/At Stepdown Date Enforcement Costs (each, and together with such documentation, a "Pre/At Stepdown Date Enforcement Costs Notice"). Buyer shall promptly (and in any event within ten Business Days) following Buyer's receipt of a Pre/At Stepdown Date Enforcement Costs Notice reimburse Seller for the conditions undisputed amount of Pre/At Stepdown Date Enforcement Costs set forth in Sections 6.2(a) such Pre/At Stepdown Date Enforcement Costs Notice. In the event that Buyer fails to pay Seller the undisputed amount of such Pre/At Stepdown Date Enforcement Costs within the time specified in the preceding sentence, Seller may issue a Recoupment Instruction to the Escrow Agent to recoup from amounts that would otherwise be distributable to Buyer in respect of the Purchased Receivables an amount equal to the sum of the undisputed, unpaid amount of such Pre/At Stepdown Enforcement Costs and 6.2(b), have been satisfied, any late fee in respect thereof calculated in accordance with Section 2.5, and cause the Escrow Agent to distribute such amount to Seller.

(d) (iii) All costs and expenses (including reasonable and documented attorneys' fees and expenses) of Buyer and Seller of any enforcement by Seller of Vertical's obligations under the Sale Agreement or the Marketing Agreement pursuant to this Section 7.6 incurred after the Stepdown Date ("Deliverables Post Stepdown Date Enforcement Costs") shall be borne [***]%. Following the Stepdown Date, Seller or Buyer, as applicable (the "Notifying Party") shall have furnished provide written notice to Seller all deliverables the other party (the "Reimbursing Party") from time to time of any Post Stepdown Date Enforcement Costs incurred by the Notifying Party, together with reasonable documentation evidencing such Post Stepdown Date Enforcement Costs (each, and together with such documentation, a "Post Stepdown Date Enforcement Costs Notice"). The Reimbursing Party shall promptly (and in any event within ten Business Days) following the Reimbursing Party's receipt of a Post Stepdown Date Enforcement Costs Notice reimburse the Notifying Party for the undisputed amount of that portion of the Post Stepdown Date Enforcement Costs set forth in such Post Stepdown Date Enforcement Costs Notice (the "Applicable Amount") as required so that, after giving effect to such payment (including any previous such payments and any Post Stepdown Date Enforcement Costs borne directly by the Reimbursing Party), the Notifying Party and the Reimbursing Party shall have [***]% of the aggregate Post Stepdown Date Enforcement Costs incurred by Buyer and Seller as of the date of such payment. In the event that the Reimbursing Party fails to pay the Notifying Party the undisputed Applicable Amount within the time specified in the preceding sentence, the Notifying Party may issue a Recoupment Instruction to the Escrow Agent to recoup from amounts that would otherwise be distributable to the Reimbursing Party in respect of the Purchased Receivables or Retained Interests, as applicable, an amount

equal to the sum of the undisputed, unpaid Applicable Amount and any late fee in respect thereof calculated in accordance with Section 2.9.2.5, and cause the Escrow Agent to distribute such amount to the Notifying Party.

(e) No Prohibition

In connection with the foregoing, the party receiving a Pre/At Stepdown Date Enforcement Costs Notice or Post Stepdown Date Enforcement Costs Notice shall have ten Business Days to deliver a written response to the other party disputing the amount of any Pre/At Stepdown Date Enforcement Costs or Post Stepdown Date Enforcement Costs included in such Pre/At Stepdown Date Enforcement Costs Notice or Post Stepdown Date Enforcement Costs Notice, as applicable. If no such written response is delivered to the party that delivered the Pre/At Stepdown Date Enforcement Costs Notice or Post Stepdown Date Enforcement Costs Notice, as applicable, within such ten Business Day period, the amount of such Pre/At Stepdown Date Enforcement Costs or Post Stepdown Date Enforcement Costs, as applicable, shall be deemed undisputed for the purposes of this Section 7.6(c). **No temporary restraining Order, preliminary** If a written response is delivered to the party that delivered the Pre/At Stepdown Date Enforcement Costs Notice or **permanent injunction or other Order preventing the consummation** Post Stepdown Date Enforcement Costs Notice, as applicable, within such ten Business Day period, any portion of the **Transaction and/** Pre/At Stepdown Date Enforcement Costs or Post Stepdown Date Enforcement Costs to which the **transactions contemplated** party delivering the written response has agreed in such written response shall be undisputed for purposes of this Section 7.6(c) and, as to any portion that is disputed by the **Ancillary Agreements** party delivering such written response, if such dispute has not been resolved within twenty Business Days following delivery of such written response, each party shall have **been issued by any** the right to submit such dispute to a court of competent jurisdiction **and remain in effect.** accordance with the provisions of Section 10.11.

ARTICLE VII

SURVIVAL Notwithstanding the foregoing, all costs and expenses (including reasonable and documented attorneys' fees and expenses) of Buyer and Seller of any enforcement by Seller of Vertical's obligations under the Sale Agreement or the Marketing Agreement pursuant to this Section 7.6 shall be borne 100% by Seller if such breach or termination event results from a breach of the Sale Agreement or the Marketing Agreement by Seller. Nothing contained herein shall limit Buyer from retaining, at its sole cost, separate outside counsel who shall be permitted, where reasonably practical, to consult with the lead counsel selected pursuant to Section 7.6(b) for such enforcement.

Section **7.1 7.7** **Survival Preservation of Rights; Assignments.** Seller shall not hereafter sell, transfer, hypothecate, delegate, assign or in any manner convey or mortgage, pledge or grant a security interest or other encumbrance of any kind in any of its rights, title or interest in and to, or duties under, all or any portion of the Sale Agreement or the Marketing Agreement without the prior written consent of Buyer (such consent not to be unreasonably withheld or delayed). Promptly, and in any event within [***] Business Days following receipt by Seller of a written request from Vertical for consent to assign or prior written notice of an assignment of the Sale Agreement or the Marketing Agreement (in whole or in part), Seller shall provide notice thereof to Buyer. Promptly (and in any event no later than [***] Business Days) following Seller's receipt of any fully executed assignment of the Sale Agreement or the Marketing Agreement by Vertical, Seller shall furnish a copy of such assignment to Buyer.

Section 7.8 **Change of Control.** In the event (a) either (i) Seller consummates a reverse merger or similar transaction whereby Seller issues a majority of its voting stock to the equityholders of a third party (which equityholders, in connection with such transaction, become the holders of a majority of the outstanding voting stock of Seller either at the closing of the merger or upon the subsequent conversion of securities issued in the merger) and such third party becomes a wholly-owned subsidiary of Seller or merges with the Seller (a "**Reverse Merger**") or (ii) immediately following a Change of Control, Seller or any of its Affiliates (excluding any acquiror of Seller, if applicable) is no longer the performing party under the Marketing Agreement, and (b) aggregate DoD Net Sales for the succeeding four calendar quarters (beginning with the first calendar quarter that begins following the calendar quarter in which the Reverse Merger or Change of Control, as applicable, occurs) are [***]% or more less than aggregate DoD Net Sales for the four calendar quarters ending on the last day of the calendar quarter in which the Reverse Merger or Change of Control, as applicable, occurs (or such shorter period from the time the first DoD Net Sales occurred to the last day of the calendar quarter in which the Reverse Merger or Change of Control, as applicable, occurs), then, following the Stepdown Date (x) clause (b)(i) of the definition of "Purchased Receivables" hereunder shall be deemed automatically modified, without any further action of the parties hereto, to replace each occurrence of "[***]" with "[***]"; and (y) clause (a) of the definition of "Retained Interests" hereunder shall be deemed automatically modified, without any further action of the parties hereto, to replace each occurrence of "[***]" with "[***]" (the "**Change of Control Adjustment**"). In addition, the parties agree that in the event that Buyer has received payments of Purchased Receivables and Seller has received payments of Retained Interests, in each case after the Stepdown Date but prior to the time when a Change of Control Adjustment is

determined to apply (collectively, the “Affected Receivables”), the parties agree to reconcile such Affected Receivables to the extent necessary to give effect to the Change of Control Adjustment as if it had been in effect as of the Stepdown Date by appropriately adjusting the amount of subsequent distributions from the Escrow Account of Purchased Receivables and Retained Interests.

As an example:

1. Change of Control (immediately following which, Seller or any of its Affiliates (excluding Seller's acquiror, if applicable) is no longer the performing party under the Marketing Agreement) occurs on February 1, 2025.

(a) All representations and warranties contained in this Agreement and all claims with respect thereto shall terminate eighteen (18) months after 2. During the Closing. Notwithstanding preceding four calendar quarters ending on 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 last day of the Closing, calendar quarter in which the Change of Control occurs (i.e., the four calendar quarters commencing April 1, 2024 and (ii) 30 days ending March 31, 2025), aggregate DoD Net Sales were \$[***].

3. During the four succeeding calendar quarters commencing with the first calendar quarter that begins following the expiration calendar quarter in which the Change of Control occurs (i.e., the applicable statute of limitations. Notwithstanding four calendar quarters commencing April 1, 2025 and ending March 31, 2026), aggregate DoD Net Sales were \$[***], which amount is determined on April 30, 2026, the foregoing, any Claims asserted in writing by notice from date that Vertical provides the Indemnified Person DoD Payment Report (as defined in Section 8.3(a)) seeking indemnification under the Marketing Agreement) for the calendar quarter ending March 31, 2026. Since the aggregate DoD Net Sales for the four succeeding calendar quarters of \$[***] is [***]% or more lower than the \$[***] of aggregate DoD Net Sales in the preceding four calendar quarters, the date of this Agreement determination, April 30, 2026, is the date that the Change of Control Adjustment is deemed to an Indemnifying Person (as defined in Section 8.3(a)) have occurred.

4. Stepdown Date occurred September 30, 2025.

5. Affected Receivables. Following the Stepdown Date (September 30, 2025) and prior to the expiration date time of the applicable survival period shall not thereafter be barred by the expiration Change of Control Adjustment (April 30, 2026), Buyer received Purchased Receivables of \$[***] and Seller received Retained Interests of \$[***], all of which (for sake of simplicity in this example) were payments under Section 2.13 of the relevant representation or warranty Sale Agreement and such claims shall survive until finally resolved.

(b) The respective agreements and covenants Section 5.a of the parties contained in this Marketing Agreement to (and so each of Buyer and Seller received [***]% of the extent to be performed total \$[***] of Affected Receivables for the period following September 30, 2025 and 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, April 30, 2026, in accordance with their terms clause (b)(i) of the definition of Purchased Receivables and clause (a) of the definition of Retained Interests). To give effect to the Change of Control Adjustment in respect of the Affected Receivables, Buyer should have received [***]% of the \$[***], or if no end date is provided, forever, \$[***] (i.e., Buyer should have received \$[***] more than it received) and Seller should have received [***]% of the \$[***], or \$[***] (i.e., Seller should have received \$[***] less than it received).

(c) 6. Reconciliation from Next Payment: For purposes the calendar quarter ended June 30, 2026 and the corresponding payment to be made on July 31, 2026, there is \$[***] paid to the Escrow Account and it is all (for sake of clarity, simplicity) payments under Section 2.13 of the survival periods set forth in Sale Agreement and Section 5.a of the Marketing Agreement. Giving effect to the Change of Control Adjustment for this Section 7.1 shall not apply quarter, the \$[***] is allocated [***]% to Fraud, Buyer (\$[***]) and [***]% to Seller (\$[***]). In addition, to reconcile for the Affected Receivables (i.e., to give effect to the Change of Control Adjustment for those Affected Receivables), the parties will instruct the Escrow Agent to deduct \$[***] from the amount that would have been paid to Seller and instead pay that amount to Buyer, so that, for this payment distribution, the Escrow Agent will distribute to Buyer a total of \$[***] and will distribute to Seller a total of \$[***].

7. For succeeding payments of Purchased Receivables and Retained Interests, the distributions will be made giving effect to the Change of Control Adjustment (i.e., the [***]% Buyer / [***]% Seller split with respect to the applicable payments under clause (b)(i) of the Purchased Receivables definition and clause (a) of the Retained Interests definition).

ARTICLE VIII

INDEMNIFICATION

Section 8.1 Indemnification by Seller Obligation of Parties to Indemnify.

(a) Indemnification by Seller. Subject to the terms and conditions of limitations set forth in 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 ("Representatives (each, a "Buyer Indemnified Persons Party)"), against and from, and will reimburse any Buyer Indemnified Persons for, any and all Damages which are suffered, paid, sustained losses, liabilities, expenses (including reasonable and documented attorneys' fees and expenses in connection with any third party action, suit or proceeding) and damages (collectively, "Losses") incurred directly by such Buyer Indemnified Party, to the extent arising or indirectly, by resulting from 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: following:

(i) any inaccuracy in or breach of any representation or warranty of made by Seller set forth in this Agreement or any Ancillary Agreement; the Transaction Documents;

(ii) any breach of any covenant or agreement of Seller contained in the Transaction Documents;

(iii) any Recipient Confidentiality Breach by any Person who receives Confidential Information from or obligation to be performed on behalf of Seller under this Agreement by Seller; (iii) Section 6.1; and

(iv) the Excluded Assets and the Excluded Liabilities and Obligations.

The foregoing shall exclude any Losses of any Buyer Indemnified Party to the extent resulting from (A) the bad faith, gross negligence, intentional misrepresentation, willful misconduct or fraud of any Buyer Indemnified Party, (B) any matter in respect of which any Seller Indemnified Party would be entitled to indemnification under Section 8.1(b), or (C) acts or omissions of Seller taken (or omitted to be taken) based upon the express written instructions from any Buyer Indemnified Party. Any amounts determined to be due to any Buyer Indemnified Party hereunder in accordance with and subject to the terms, conditions and procedures of this Article VIII shall (if not otherwise paid) be payable by Seller to such Buyer Indemnified Party within [***] Business Days following written demand delivered to Seller by such Buyer Indemnified Party.

(b) Indemnification by Buyer. Subject to the limitations set forth in this Article VIII, from and after the Closing, Buyer shall indemnify Seller, its Affiliates, and their Representatives (each, a "Seller Indemnified Party") against any and all Losses incurred by such Seller Indemnified Party, to the extent arising or resulting from any of the following:

(i) any breach of any representation or warranty made by Buyer in the Transaction Documents;

(ii) any breach of any covenant or agreement of Buyer contained in the Transaction Documents; and

(iii) any Recipient Confidentiality Breach by any Person who receives Confidential Information from or on behalf of Buyer under

Section 6.1.

The foregoing shall exclude any Losses of any Seller Indemnified Party to the extent resulting from (A) the bad faith, gross negligence, intentional misrepresentation, willful misconduct or fraud of any Seller Indemnified Party, (B) any matter in respect of which any Buyer Indemnified Party would be entitled to indemnification under Section 8.1(a), or (C) acts or omissions of Buyer taken (or omitted to be taken) based upon the express written instructions from any Seller Indemnified Party. Any amounts determined to be due to any Seller Indemnified Party hereunder in accordance with and subject to the terms, conditions and procedures of this Article VIII shall (if not otherwise paid) be payable by Buyer to such Seller Indemnified Party within [***] Business Days following written demand delivered to Buyer by such Seller Indemnified Party.

Section 8.2 Procedures Relating to Indemnification for Third Party Claims.

(a) Notice of Third Party Claim. In order for a party (an "Indemnified Party") to be entitled to any indemnification under this Article VIII in respect of Losses arising out of or involving a claim or demand made by any Person other than Buyer or Seller against a Buyer Indemnified Party or a Seller Indemnified Party, as applicable (a "Third Party Claim"), the Indemnified Party must notify the party from whom indemnification is sought under this Article VIII (the "Indemnifying Party") promptly in writing (including in such notice a brief description of the Third Party Claim, including any damages sought or estimated, to the extent actually known or reasonably capable of estimation by the Indemnified Party); provided, however, that the failure to satisfy, perform, promptly provide such notice shall not affect the indemnification provided under this Article VIII except to the extent that the Indemnifying Party has

been actually prejudiced as a result of such failure. Thereafter, the Indemnified Party shall deliver to the Indemnifying Party, promptly after the Indemnified Party's receipt thereof, copies of all documents (including court papers) received by the Indemnified Party relating to the Third Party Claim.

(b) Defense of Third Party Claims. The Indemnifying Party shall be entitled to participate in the defense of the Third Party Claim and, if it so chooses, to assume the defense thereof, at its own expense, with counsel selected by the Indemnifying Party; provided, that such counsel is not reasonably objected to by the Indemnified Party. If the Indemnifying Party elects to assume the defense of any Third Party Claim, the Indemnifying Party shall not be liable to the Indemnified Party for legal expenses subsequently incurred by the Indemnified Party in connection with the defense thereof, except that, if the Indemnifying Party and the Indemnified Party have conflicting interests or **discharge an Excluded Liability**; (iv) different defenses available with respect to such Third Party Claim, the Indemnified Party may hire its own separate counsel (provided that such counsel is not reasonably objected to by the Indemnifying Party) with respect to such Third Party Claim and the related action or suit, and the reasonable fees and expenses of such counsel shall be considered Losses for purposes of this Agreement. The Indemnifying Party shall permit the Indemnified Party to participate in, but not control, the defense of any **Excluded Asset**, such action or suit through counsel chosen by the Indemnified Party, provided that such counsel is not reasonably objected to by the Indemnifying Party and, **any Liabilities related thereto**; (v) **any claim** except in the circumstances described in the immediately preceding sentence, the fees and expenses of such counsel shall be borne by the Indemnified Party. The Indemnifying Party shall be liable for the reasonable fees and expenses of counsel employed by the Indemnified Party in the defense of a Third Party **based upon**, Claim (which shall all be considered Losses for purposes of this Agreement) for any period during which the Indemnifying Party has not assumed the defense thereof (other than during the period prior to the time the Indemnified Party shall have notified the Indemnifying Party of such Third Party Claim).

(c) Cooperation. The parties hereto shall cooperate in the defense or prosecution of any Third Party Claim, with such cooperation to include (i) the retention of and the provision to the Indemnifying Party of records and information that are reasonably relevant to such Third Party Claim and (ii) the making available of employees on a mutually convenient basis for providing additional information and explanation of any material provided hereunder. Neither the Indemnified Party nor the Indemnifying Party shall consent (such consent not to be unreasonably withheld or delayed) to the entry of any judgment, settlement, compromise or discharge of such Third Party Claim without the prior written consent of the other; provided that the consent of the Indemnified Party shall not be required if such judgment, settlement, compromise or discharge (A) does not involve any non-monetary penalties (other than customary and reasonable confidentiality obligations relating to such claim, judgment, settlement, compromise or discharge), (B) results in the complete and unconditional release of the Indemnified Party from all liabilities arising out of, relating to or in connection with such Third Party Claim and (C) does not involve a finding or admission of any fault, culpability, failure to act, violation of any law, rule, regulation or judgment, or the rights of any Person by the Indemnified Party, and has no effect on any other claims that may be made against the Indemnified Party.

Section 8.3 Procedures Relating to Indemnification for Other Claims. In order for an Indemnified Party to be entitled to any indemnification under this Article VIII in respect of Losses that do not arise out of or involve a Third Party Claim, the Indemnified Party must notify the Indemnifying Party promptly in writing (a "**Claim Notice**") (including in such notice a brief description of the claim for indemnification and the Loss, including damages sought or estimated, to the extent actually known or reasonably capable of estimation by the Indemnified Party (the "**Claim Amount**")); provided, however, that the failure to promptly provide such notice shall not affect the indemnification provided under this Article VIII except to the extent that the Indemnifying Party has been actually prejudiced as a result of such failure. Within **[***]** Business Days after delivery of a Claim Notice, the Indemnifying Party shall deliver to the Indemnified Party a written response (a "**Claim Notice Response**") in which the Indemnifying Party shall either (a) agree that the Indemnified Party is entitled to receive the Claim Amount (in which case such response shall be accompanied by a payment to the Indemnified Party of the Claim Amount by the Indemnifying Party by wire transfer of immediately available funds); (b) agree that the Indemnified Party is entitled to receive part, but not all, of the Claim Amount (the amount so agreed in (a) or (b), the "**Agreed Amount**") (in which case such response shall be accompanied by a payment to the Indemnified Party of the Agreed Amount by the Indemnifying Party by wire transfer of immediately available funds); or (c) contest that the Indemnified Party is entitled to receive any of the Claim Amount. If any such dispute described in clauses (b) or (c) of the preceding sentence is not resolved within **[***]** Business Days following the delivery by the Indemnifying Party of a Claim Notice Response, the Indemnifying Party and the Indemnified Party shall each have the right to submit such dispute to a court of competent jurisdiction in accordance with the provisions of Section 10.11. If the Indemnifying Party does not deliver a timely Claim Notice Response to the Indemnified Party in accordance with the preceding sentence notifying the Indemnified Party that the Indemnifying Party disputes its liability to the Indemnified Party with respect to the Claim Amount in whole or **resulting from** in part or delivers a timely Claim Notice Response that disputes its liability to the **Transferred Assets**, Indemnified Party with respect to the **Product, operations, properties, assets** Claim Amount only in part, in each case in accordance with this Section 8.3, such Claim Amount specified by the Indemnified Party in such Claim Notice, to the extent liability for such Claim Amount has not been timely disputed in a Claim Notice Response, shall be conclusively deemed a liability of the Indemnifying Party under Section 8.1(a) or **obligations** Section 8.1(b), as applicable, and the Indemnifying Party shall pay the amount of such undisputed liability to the Indemnified Party promptly upon request or, in the case of any Claim Notice in which the amount of the claim (or any portion thereof) is estimated, on such

later date when the amount of such claim (or such portion thereof) becomes finally determined. For all purposes of this Section 8.3, Seller shall be entitled to deliver Claim Notices to Buyer on behalf of the Seller Indemnified Parties, and Buyer shall be entitled to deliver Claim Notices to Seller on behalf of the Buyer Indemnified Parties.

Section 8.4 Limitations on Indemnification. Notwithstanding anything in this Agreement to the contrary, the aggregate amount of all Losses for which Seller or Buyer shall be liable hereunder pursuant to Section 8.1(a)(i) or Section 8.1(b)(i), respectively, shall not exceed an amount equal to the sum of: (a) [***]% of the Purchase Price, minus the Purchased Receivables actually received by Buyer, and (b) fees and expenses incurred by Buyer in enforcing its **Affiliates conducted, existing** rights hereunder to the extent such fees and expenses are indemnifiable Losses under Section 8.1(a); provided that the limitations set forth in this Section 8.4 shall not apply to (i) breaches of any Fundamental Representations or (ii) Losses arising out of any bad faith, gross negligence, fraud, intentional misrepresentation or willful misconduct.

Section 8.5 Survival of Representations and Warranties. The representations and warranties contained in this Agreement shall survive the Closing solely for purposes of Section 8.1 and shall terminate on the date that is [***] years following the Closing Date; provided, however, that the Fundamental Representations shall survive until [***] days following the expiration of all applicable statutes of limitations (giving effect to any waiver, mitigation or extension thereof). No party hereto shall have any liability or obligation of any nature with respect to any representation or warranty after the termination thereof, unless the other party hereto shall have delivered a notice to such party, pursuant to Section 8.2(a) or Section 8.3, claiming such a liability or obligation under Section 8.1, prior to the Closing Date; and (vi) each expiration of the **matters** applicable survival period set forth in the preceding sentence.

Section 8.6 Schedule 8.1(a)(vi) No Implied Representations and Warranties; Access to Information.

(a) BUYER ACKNOWLEDGES AND AGREES THAT, (I) OTHER THAN THE EXPRESS REPRESENTATIONS AND WARRANTIES OF SELLER SPECIFICALLY CONTAINED IN ARTICLE IV, THERE ARE NO REPRESENTATIONS OR WARRANTIES OF SELLER OR ANY OTHER PERSON EITHER EXPRESSED OR IMPLIED WITH RESPECT TO THE PURCHASED RECEIVABLES OR THE SALE AGREEMENT OR THE TRANSACTIONS CONTEMPLATED BY THE TRANSACTION DOCUMENTS OR OTHERWISE; (II) BUYER SHALL HAVE NO REMEDIES IN RESPECT OF, ANY REPRESENTATION OR WARRANTY NOT SPECIFICALLY SET FORTH IN ARTICLE IV; AND (III) ALL OTHER REPRESENTATIONS AND WARRANTIES, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE, INCLUDING WITH RESPECT TO IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE, OR THE PROSPECTS OR LIKELIHOOD OF COMMERCIAL SUCCESS OF THE PRODUCT, ARE HEREBY EXPRESSLY DISCLAIMED BY SELLER. SELLER MAKES NO REPRESENTATION OR WARRANTY THAT THE PRODUCT WILL BE COMMERCIALIZED IN ANY COUNTRY OR ACHIEVE ANY PARTICULAR SALES LEVEL, WHETHER IN ANY INDIVIDUAL COUNTRY OR CUMULATIVELY THROUGHOUT THE WORLD. BUYER FURTHER ACKNOWLEDGES AND AGREES THAT SELLER HAS NO RIGHTS OR RESPONSIBILITIES OF ANY KIND WITH RESPECT TO, AND BY VIRTUE OF THE TRANSACTIONS CONTEMPLATED BY THE TRANSACTION DOCUMENTS HAS NOT BECOME ENTITLED TO ANY RIGHTS OR ASSUMED ANY RESPONSIBILITIES OF ANY KIND WITH RESPECT TO, THE REGULATORY SUBMISSIONS FOR AND USE, SALE, DISTRIBUTION, MARKETING OR OTHER COMMERCIALIZATION ACTIVITIES WITH RESPECT TO THE PRODUCT, ALL OF THE RIGHTS AND RESPONSIBILITY FOR WHICH IS WITH VERTICAL, EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THE MARKETING AGREEMENT. BUYER FURTHER ACKNOWLEDGES AND AGREES THAT SELLER SHALL HAVE NO LIABILITY TO BUYER (EXCEPT AS OTHERWISE PROVIDED HEREUNDER) WITH RESPECT TO ANY ACT OR OMISSION OF VERTICAL RELATING TO SUCH REGULATORY SUBMISSIONS AND USE, SALE, DISTRIBUTION, MARKETING OR OTHER COMMERCIALIZATION ACTIVITIES.

(b) **No amount shall be payable and there shall be no liability for Seller for indemnification under** BUYER ACKNOWLEDGES AND AGREES THAT BUYER HAS MADE ITS OWN INVESTIGATION OF THE PURCHASED RECEIVABLES, THE SALE AGREEMENT, THE MARKETING AGREEMENT, THE OTHER RELATED AGREEMENTS AND THE TRANSACTIONS CONTEMPLATED BY THE TRANSACTION DOCUMENTS AND HAS HAD THE OPPORTUNITY TO ASK SUCH QUESTIONS OF, AND TO RECEIVE ANSWERS FROM, REPRESENTATIVES OF SELLER CONCERNING THE SALE AGREEMENT, THE MARKETING AGREEMENT, THE OTHER RELATED AGREEMENTS, THE TRANSACTION DOCUMENTS, THE PURCHASED RECEIVABLES AND THE TRANSACTIONS CONTEMPLATED BY THE TRANSACTION DOCUMENTS, IN EACH CASE AS IT DEEMED NECESSARY TO MAKE AN INFORMED DECISION TO PURCHASE THE PURCHASED RECEIVABLES IN ACCORDANCE WITH THE TERMS OF THIS AGREEMENT. BUYER ACKNOWLEDGES AND AGREES THAT (I) IT SHALL HAVE NO REMEDIES IN RESPECT OF, ANY IMPLIED WARRANTIES AND THAT NO REPRESENTATION OR WARRANTY IS MADE AS TO THE FUTURE AMOUNT OR POTENTIAL AMOUNT OF THE PURCHASED

RECEIVABLES, OR AS TO THE CREDITWORTHINESS OF VERTICAL (OR ANY OF ITS AFFILIATES) AND (II) EXCEPT AS EXPRESSLY SET FORTH IN ANY REPRESENTATION OR WARRANTY IN ARTICLE IV, BUYER SHALL HAVE NO CLAIM OR RIGHT REGARDING LOSSES PURSUANT TO THIS ARTICLE VIII (OR OTHERWISE) WITH RESPECT TO ANY INFORMATION, DOCUMENTS OR MATERIALS FURNISHED OR MADE AVAILABLE TO BUYER IN ANY DATA ROOM, PRESENTATION, INTERVIEW OR IN ANY OTHER FORM OR MANNER RELATING TO THE TRANSACTIONS CONTEMPLATED BY THE TRANSACTION DOCUMENTS, THE SALE AGREEMENT, THE MARKETING AGREEMENT OR THE OTHER RELATED AGREEMENTS. NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, CLAIMS FOR BAD FAITH, GROSS NEGLIGENCE, FRAUD, INTENTIONAL MISREPRESENTATION OR WILLFUL MISCONDUCT SHALL NOT BE WAIVED OR LIMITED BY THIS SECTION 8.6.

Section 8.7 Section 8.1(a)(i) Exclusive Remedy, unless the amount of Damages incurred by a Buyer Indemnified Person exceeds One Hundred Thousand Dollars (\$100,000). Except in the aggregate (the "Threshold Amount"), after which point case of (a) breaches or threatened breaches of Section 6.1, (b) the Threshold Amount shall be recoverable along with all other amounts parties' rights to recoupment under Section 7.4(b)(iv) and Section 7.6(c) and (c) Section 10.14 (including 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, avoidance of doubt, for purposes of determining whether there has been a breach Section 6.1), the parties hereto acknowledge and the amount of Damages agree 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 the indemnification afforded by this Article VIII shall indemnify be the sole and hold harmless Seller, its Affiliates and their respective officers, directors, managers, employees, agents, successors and permitted assigns ("Seller Indemnified Persons"), against and from exclusive remedy for any and all Damages which are suffered, sustained Losses awarded against or incurred or suffered by any of a party in connection with the foregoing Seller Indemnified Persons (regardless of whether or not such Damages relate transactions set forth in the Transaction Documents, including with respect 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 made by a party in any of Buyer set forth the Transaction Documents or any certificate delivered by a party to the other party in writing pursuant to this Agreement or any breach of or default under any covenant or agreement by a party pursuant to any Transaction Document, except that any claim or matter based upon bad faith, gross negligence, fraud, intentional misrepresentation or willful misconduct shall not be subject to or limited by this Article VIII.

Section 8.8 Limitations on Damages. Notwithstanding anything to the contrary in this Agreement or any Ancillary Agreement; (ii) other Transaction Document, in no event shall either party hereto be liable (including, without limitation, under Section 8.1) for any (a) special, indirect, incidental, exemplary, punitive, multiple or consequential damages or (b) loss of use, business interruption, loss of any contract or other business opportunity or good will, in each case, of the other party hereto (other than any such damages or losses included in Losses for Purchased Receivables that Buyer was entitled to receive but did not receive timely or at all due to indemnifiable events under this Agreement or occasioned by any breach of the covenants or agreements set forth in Section 6.1), whether or not caused by or resulting from the actions of such party or the breach of its covenants, agreements, representations or warranties under any covenant, agreement of the Transaction Documents (except as aforesaid) and whether in contract, tort or obligation breach of statutory duty or otherwise, even if such party has been advised of the possibility of such damages. In connection with the foregoing, the parties hereto acknowledge and agree that (i) Buyer's damages, if any, for any such action or claim will include Losses for Purchased Receivables that Buyer was entitled to be performed under receive or would have received absent such breach, in each case in respect of its ownership of the Purchased Receivables, as well as expenses incurred in connection with Buyer's enforcement of this Agreement by Buyer; (iii) related to such breach, and (ii) Buyer shall be entitled to make claims for all such missing, delayed or diminished Purchased Receivables as Losses hereunder, and such missing, delayed or diminished payments shall not be deemed (A) special, indirect, incidental, exemplary, punitive, multiple or consequential damages or (B) loss of use, business interruption, loss of any failure contract or other business opportunity or good will.

ARTICLE IX

TERMINATION

Section 9.1 Termination of Agreement.

(a) This Agreement may be terminated at any time prior 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 by Buyer upon the occurrence of a Seller Material Adverse Effect.

(b) Following the Closing, this Agreement shall continue in full force and effect until the date on which Buyer has received the last payment with respect to the Purchased Receivables, at which time this Agreement shall automatically terminate.

Section 9.2 Effect of Termination.

(a) Upon the termination of this Agreement pursuant to Section 9.1(a), this Agreement shall become void and of no further force and effect, except for any Liability arising out rights, obligations or claims of either party that have accrued prior to termination; provided, however, that (i) the Development, manufacture, commercialization or other exploitation provisions of Article I (Definitions; Interpretation), Section 6.1 (Confidentiality) (only for the period set forth in Section 6.1(a)), Section 6.6 (Public Announcements), this Section 9.2 (Effect of Termination) and Article X (Miscellaneous) shall survive such termination and shall remain in full force and effect and (ii) nothing contained in this Section 9.2 shall relieve either party from liability for any Product breach of this Agreement that occurs prior to termination.

(b) No amount Upon the termination of this Agreement pursuant to Section 9.1(b), this Agreement shall be become void and of no further force and effect, except for any rights, obligations or claims of either party that have accrued prior to termination; provided, however, that (i) the provisions of Article I (Definitions; Interpretation), Section 6.1 (Confidentiality) (only for the period set forth in Section 6.1(a)), Section 6.2 (Taxes), Section 6.6 (Public Announcements), Section 7.2(Misdirected Payments), Section 7.4(b) (Audits) (only until the date that is [***] years after the termination date), Article VIII (Indemnification), this Section 9.2 (Effect of Termination) and Article X (Miscellaneous) shall survive such termination and shall remain in full force and effect, (ii) if, upon the termination of this Agreement, any payments of the Purchased Receivables or other amounts are payable to Buyer hereunder, this Agreement shall remain in full force and there effect until any and all such payments have been made in full, and (except as provided in this Section 9.2) solely for that purpose, and (c) termination shall be no not relieve either party from liability for Buyer for indemnification under Section 8.2(a)(i), unless the amount any breach 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. this Agreement that occurs prior to termination.

(c) Buyer's maximum liabilityARTICLE X

MISCELLANEOUS

Section 10.1 Headings. The captions to the Articles, Sections and subsections hereof are not a part of this Agreement but are for convenience only and shall not be deemed to limit or otherwise affect the construction thereof.

Section 10.2 Notices. All notices and other communications under this Agreement for Damages incurred shall be in writing and shall be sent by Seller Indemnified Persons shall not exceed the Cap.

(d) Notwithstanding anything email with PDF attachment, courier or personal delivery to the contrary contained herein, the limitations set forth in this Section 8.2 shall not apply to Damages arising out of following addresses, 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 other addresses as shall be free designated from time 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 time 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 party hereto in accordance with this 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. 10.2.

If to:	Address:
Seller	<p>Talphera, Inc. 1850 Gateway Dr. #175 San Mateo, CA 94404 Attention: [***] Email: [***]</p>
with a copy to:	<p>Cooley LLP 10265 Science Center Drive San Diego, CA 92121 Attention: Matthew Browne Email: mbrowne@cooley.com</p>
Buyer	<p>XOMA (US) LLC 2200 Powell Street Suite 310 Emeryville, CA 94608 Attention: [***] Email: [***]</p>
with a copy to:	<p>Gibson, Dunn & Crutcher LLP One Embarcadero Center, Suite 2600 San Francisco, CA 94111 Attention: Ryan Murr; Todd Trattner Email: rmurr@gibsondunn.com; ttrattner@gibsondunn.com</p>

(b) If an Indemnified Person is entitled to indemnification All notices and communications under this Agreement shall be effective upon receipt by the addressee. Notwithstanding anything to the contrary in this Section 10.2, all notices and communications under Section 8.2(a) and Section 8.3 and all service of legal process shall be sent by courier or personal delivery.

Section 10.3 Article VIII No Personal Liability because a claim. It is filed or instituted expressly understood and agreed by any Third Party, including any Government Entity ("Third Party Claim" Seller and together with a Direct Claim, "Claims"), as soon as reasonably practicable after obtaining knowledge thereof, such Indemnified Person shall notify Buyer that:

(a) each of the Indemnifying Person representations, warranties, covenants and agreements in writing, and in reasonable detail, of such Third Party Claim (the "Claim Notice"). Any failure the Transaction Documents made on the part of an Indemnified Seller is made by Seller and is not intended to be nor is a personal representation, warranty, covenant or agreement of any other Person, including those Persons named in the definition of "Knowledge of Seller" and any other Representative of Seller or Seller's Affiliates (the "Non-Warranting Parties");

(b) other than Seller, no Person, including the Non-Warranting Parties, shall have any liability whatsoever for breach of any representation, warranty, covenant or agreement made in the Transaction Documents on the part of Seller or in respect of any claim or matter arising out of, relating to so notify or in connection with the Indemnifying Person shall not limit any Transaction Documents or the transactions contemplated thereby; and

(c) the provisions of this Section 10.3 are intended to benefit each and every one of the obligations Non-Warranting Parties and shall be enforceable by each and every one of them to the fullest extent permitted by Applicable Law.

Section 10.4 Expenses. Except as otherwise expressly provided in this Agreement or any Transaction Document, each of Seller and Buyer shall bear its own fees and expenses with respect to this Agreement and the Transaction Documents and the transactions contemplated by this Agreement and the Transaction Documents; provided, however, that (a) in the event of a termination pursuant to Section 9.1(a), Seller will reimburse Buyer for any reasonable and documented out-of-pocket fees and expenses regarding the transactions contemplated hereby by or on behalf of, or paid directly by, Buyer (the "Buyer Transaction Expenses") incurred prior to such termination up to \$[***]; or (b) on the Closing Date, Seller will reimburse Buyer for any Buyer Transaction Expenses up to \$[***], and in each case ((a) and (b)) Seller shall have the right to set-off the \$[***] deposit provided to Buyer upon the execution of the Indemnifying Person under Article VIII except term sheet, to the extent such failure deposit was 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. paid.

Section 8.610.5 Survival Periods Assignment. The parties acknowledge that the time periods set forth in Article VII for the survival and assertion provisions 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 Seller shall not be entitled to assign any of its obligations and rights under this Agreement express or implied, is intended to confer upon any non-Affiliate of Seller without: (a) the prior written consent of Buyer, such consent not to be unreasonably withheld, and (b) requiring any such non-Affiliate to agree in writing to be bound by the terms of this Agreement; provided, however, the consent of Buyer shall not be required for Seller to assign its rights and delegate its obligations under this Agreement to any Person into which Seller may merge, with which it may consolidate or to which it may sell all or substantially all of its assets. Seller may assign any of its obligations and rights under this Agreement to Seller's Affiliates, provided that Seller promptly thereafter notifies Buyer and any such assignee agrees in writing to be bound by the terms of this Agreement. Buyer may assign this Agreement and all of Buyer's rights, interests and obligations hereunder, in whole or in part, to any Person(s), provided that Buyer promptly thereafter notifies Seller and any such assignee agrees in writing to be bound by the terms of this Agreement, including, for clarity, the confidentiality and non-use obligations of Buyer pursuant to Section 6.1 (and, if such assignee is an Affiliate of Buyer's and the assignment is not in connection with a sale of all or substantially all of Buyer's business, by merger, sale of assets or otherwise, Buyer shall remain liable to Seller for its obligations to Seller hereunder (and Seller shall be entitled to seek recovery for any breach or default of an obligation hereunder from Buyer or from such Affiliate assignee)). Any purported assignment in violation of this Section 10.5 shall be null and void. For the avoidance of doubt, no assignment by Buyer will operate to expand the obligations of Seller under this Agreement, including with respect to Indemnified Taxes.

Section 10.6 Amendment and Waiver.

(a) This Agreement may be amended, modified or supplemented only in a writing signed by all of the parties hereto. Any provision of this Agreement may be waived only in a writing, which writing may be signed only by the party granting such waiver.

(b) No failure or delay on the part of any party hereto in exercising any right, power or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy preclude any other than Buyer, Seller, or further exercise thereof or the Buyer Indemnified Persons, exercise of any other right, power or remedy. No course of dealing between the Seller Indemnified Persons and their respective successors, legal Representatives and permitted assigns, parties hereto shall be effective to amend, modify, supplement or waive any legal or equitable right, remedy or claim under or by reason provision of this Agreement.

Section 10.4 10.7 Entire Agreement. This Agreement, (including all including the Exhibits and Schedules hereto) contains attached to this Agreement, sets forth the entire agreement and understanding between the parties hereto with respect as to the subject matter hereof. All express or implied agreements, promises, assurances, arrangements, representations, warranties and understandings as to the subject matter hereof, and supersedes all prior agreements and understandings, whether 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 heretofore made 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 superseded 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. Agreement.

Section 10.8 Bulk Sales Independent Contractors. The parties hereto recognize and agree that the relationship between Seller and Buyer agree to waive compliance is solely that of seller and buyer, each is operating as an independent contractor and not as an agent, partner or fiduciary of any other, and neither Seller nor Buyer has any fiduciary or other special relationship with Article 6 of the Uniform Commercial Code as adopted in each of the jurisdictions in which other party hereto or any of the Transferred Assets are located its Affiliates. Nothing contained in this Agreement or in any other Transaction Document shall be deemed for any purpose (including tax purposes) to the extent that such Article is applicable to the transactions contemplated hereby, constitute Seller and Buyer as a partnership, agency, an association, a joint venture or any other kind of entity or legal form.

Section 10.9 Governing Law No Third Party Beneficiaries. 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.

Except to the extent otherwise contemplated by Section 10.10 Intentionally Omitted.

Section 10.11 Assignment. Neither 10.3, this Agreement nor any of is for 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 Buyer and their respective permitted successors and assigns. Notwithstanding assigns, and nothing herein expressed or implied shall give or be construed to give to any Person, other than the foregoing, either parties hereto and such successors and assigns, any legal or equitable rights hereunder. For the avoidance of doubt, indemnification under Article VIII in respect of Losses incurred by a Buyer Indemnified Party or a Seller Indemnified Party may only be enforced by Buyer or Seller, respectively, and not by any other Person.

Section 10.10 Governing Law. This Agreement shall be governed exclusively by the laws of the State of New York, United States of America, without regard to any conflict of law provisions that would dictate the application of the law of another jurisdiction.

Section 10.11 Jurisdiction; Venue; Service Of Process; Waiver of Jury Trial. Each party may also grant a security interest hereto irrevocably submits to the exclusive jurisdiction of (a) state courts of the State of California sitting in the City of San Francisco and collaterally assign its rights under (b) the United States District Court for the Northern District of California for the purposes of any action, suit or other proceeding arising out of, relating to or in connection with this Agreement or any transaction contemplated hereby. Each party hereto agrees to one commence any action, suit or more other proceeding arising out of, such party's debt financing sources without relating to or in connection with this Agreement or any transaction contemplated hereby in the prior consent state courts of the State of California sitting in the City of San Francisco, or, if such action, suit or other proceeding may not be brought in such court for jurisdictional reasons, in the United States District Court for the Northern District of California. Each party hereto; provided, hereto further agrees that no such assignment shall relieve the assigning party service of any of its obligations hereunder; and provided further, that no such grant process, summons, notice or assignment document by courier or personal delivery in accordance with Section 10.2 shall be effective until immediately after the Closing. Nothing service of process for any action, suit or other proceeding in California with respect to any matters to which it has submitted to jurisdiction in this Section shall prohibit Buyer from licensing 10.11. Each party hereto irrevocably and unconditionally waives any objection to the laying of venue of any action, suit or other proceeding arising out of, relating to or in connection with this Agreement or any transaction contemplated hereby in (i) state courts of the Transferred Assets, State of California sitting in the City of San Francisco or (ii) the United States District Court for the Northern District of California, 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, hereby further irrevocably 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 unconditionally 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 assert by way of motion, defense, or otherwise, in any such action, suit or other proceeding, any claim that it is not subject personally to limit or affect any the jurisdiction of the provisions hereof.

Section 10.14 Severability. The provisions above-named courts, that its property is exempt or immune from attachment or execution, that such action, suit or other proceeding is brought in an inconvenient forum, that the venue of this Agreement shall be deemed severable and the invalidity such action, suit or unenforceability of any provision shall not affect the validity other proceeding is improper, or enforceability of the other provisions hereof. If any provision of that 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 transactions contemplated hereby 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 enforced in or by such invalidity or unenforceability, nor shall such invalidity or unenforceability affect any of the validity or enforceability of such provision, or the application thereof, in any other jurisdiction. above-named courts. EACH PARTY HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY ACTION DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT, OR THE TRANSACTIONS CONTEMPLATED HEREBY (WHETHER BASED ON CONTRACT, TORT, OR ANY OTHER THEORY). EACH PARTY (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF THE OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT THE OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE

FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTY HAVE BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 10.11.

Section 10.12 **Remedies; Severability.** If any term or provision of this Agreement is held to be invalid, illegal or unenforceable by a court or other Governmental Authority of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement, which shall remain in full force and effect, and the parties hereto shall replace such term or provision with a new term or provision permitted by Applicable Law and having an economic effect as close as possible to the invalid, illegal or unenforceable term or provision. The holding of a term or provision to be invalid, illegal or unenforceable in a jurisdiction shall not have any effect on the application of the term or provision in any other jurisdiction.

Section 10.13 **Counterparts.** This Agreement may be executed in any number of counterparts and by the parties hereto in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Copies of executed counterparts transmitted by email with PDF attachment shall be considered original executed counterparts.

Section 10.14 **Specific Performance.** The Each of the parties agree hereto acknowledges that irreparable damage the other party hereto may occur have no adequate remedy at law if it fails to perform any of its obligations under any of the Transaction Documents and may be damaged irreparably in the event that any of the provisions of this Agreement were (including, for clarity, Section 6.1) are not performed in accordance with their its specific terms or were otherwise are breached or violated (including, for clarity, any actual or threatened breach of Section 6.1 by Buyer or Seller, any of their respective Affiliates or any of their or their Affiliates' respective Representatives). In such event, the parties agree that the other party shall have the right, without posting bond or other undertaking, to be breached and that seek an award of money damages may be inadequate in such event. Accordingly, except as otherwise expressly provided in Article VIII, each injunction or injunctions to prevent breaches or violations of the parties hereto agrees that, provisions of this Agreement (including, in the case of Section 6.1, threatened breach) and to enforce specifically this Agreement and the terms and provisions hereof in any action instituted pursuant to Section 10.11, in addition to any other remedy to which such party it may be entitled, at law or in equity, they each shall be entitled to an injunction equity. Each party further agrees that, in the event of any action for specific performance in respect of such breach or injunctions or other equitable relief to prevent breaches violation (including, in the case of Section 6.1, threatened breach), it will not assert, and irrevocably waives the provisions of this Agreement and to enforce specifically this Agreement, the terms and provisions hereof, without the necessity of posting defense that a bond or other security or proving actual damages and without regard will be required. For the avoidance of doubt, such remedy shall not be deemed to be an exclusive remedy with respect to any of the adequacy of any remedy at law. A party's right breaches to specific performance which it relates but shall be in addition to all other legal or equitable rights and 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 Seller 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. Buyer (as applicable).

[Remainder of Signature Page Intentionally Left Blank] Follows]

IN WITNESS WHEREOF, IN WITNESS WHEREOF, THE PARTIES HERETO HAVE EXECUTED OR CAUSED THIS AGREEMENT TO BE EXECUTED BY THEIR RESPECTIVE REPRESENTATIVES THEREUNTO DULY AUTHORIZED AS OF THE DATE FIRST WRITTEN ABOVE, ABOVE WRITTEN.

SELLER: SELLER:

AcelRx Pharmaceuticals, Inc. TALPHERA, 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

SIGNATURE PAGE TO ASSET PURCHASE AGREEMENT

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 AceRx 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 "**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.

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:BUYER:

AcelRx Pharmaceuticals, Inc. XOMA (US) LLC

By: /s/ Bradley Sitko

Name:

Title:

Bradley Sitko

Title: Chief

Investment

Officer

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 EXHIBIT A

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. PAYMENT INTEREST PURCHASE AGREEMENT

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 **FORM OF BILL OF SALE**

[***]

EXHIBIT EXHIBIT B
TO PAYMENT INTEREST PURCHASE AGREEMENT

Marks

DISCLOSURE SCHEDULES

[***]

VERTICAL NOTICE AND WAIVER

[***]

VERTICAL INSTRUCTION LETTER

[***]

LEGAL OPINION

[***]

SALE AGREEMENT AND MARKETING AGREEMENT

[***]

Exhibit 31.1

CERTIFICATION

I, Vincent J. Angotti, certify that:

1. I have reviewed this quarterly report on Form 10-Q of **AcelRx Pharmaceuticals, Talphera, 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, subsidiaries**, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: November 14, 2023 May 14, 2024

/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, Talphera, 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, subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Date: November 14, 2023 May 14, 2024

/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, Talphera, 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 March 31, 2024, 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. May 2024.

/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, Talphera**, 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.

DISCLAIMER

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