UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

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

For the quarterly period ended March 31, 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

TALPHERA, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

TALPHERA, INC.

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

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Unless the context indicates otherwise, the terms "Talphera," "we," "us" and "our" refer to Talphera, Inc., and its consolidated subsidiary. "Niyad" and "Fedsyra" are trademarks, and "Zalviso" are registered trademarks, all owned by Talphera, Inc. This 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;
- 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 estimates of the existence of and commercial potential for markets for our 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, 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

Talphera, Inc.

Condensed Consolidated Balance Sheets

(Unaudited)
(In thousands, except share and per share data)

	March 31, 2024	December 31, 2023[1]
Assets		
Current Assets:		
Cash and cash equivalents	$ 12,122	$ 5,721
Short-term investments	6,462	3,660
Prepaid expenses and other current assets	1,369	2,195
Total current assets	19,953	11,576
In-process research and development asset	8,819	8,819
Total assets	$ 28,772	$ 20,395
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,274	$ 1,336
Accrued and other liabilities	1,340	2,445
Liabilities of discontinued operations, current portion	730	731
Total current liabilities	3,344	4,512
Warrant liability	2,780	1,778
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 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	464,497	458,314
Accumulated deficit	(448,180)	(444,226)
Total stockholders' equity	16,334	14,105
Total Liabilities and Stockholders' Equity	$ 28,772	$ 20,395

(1) The condensed consolidated balance sheet as of 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, 2023.

See notes to condensed consolidated financial statements.

Talphera, Inc.

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

	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

See notes to condensed consolidated financial statements.

Talphera, Inc.

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of January 1, 2024	16,952,519	$ 17	$ 458,314	$ (444,226)	$ 14,105
Stock-based compensation	—	—	302	—	302
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	23,952	—	(17)	—	(17)
Net proceeds from issuance of pre-funded warrants in connection with equity financing	—	—	5,884	—	5,884
Issuance of common stock upon ESPP purchase	16,255	—	14	—	14
Net loss	—	—	—	(3,954)	(3,954)
Balance as of March 31, 2024	16,992,726	$ 17	$ 464,497	$ (448,180)	$ 16,334

	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.

Talphera, Inc.

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

	Three Months Ended March 31,	
	2024	**2023**
Cash flows from operating activities:		
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	—	262
Non-cash interest expense related to debt financing	—	38
Stock-based compensation	302	569
Revaluation of warrant liability	1,002	(5,311)
Impairment of net assets held for sale	—	7,007
Impairment of fixed assets	—	1,065
Gain on termination of lease liabilities	—	(1,098)
Gain on extinguishment of debt liability	—	(400)
Other	(72)	(15)
Changes in operating assets and liabilities:		
Inventories	—	61
Prepaid expenses and other assets	826	1,583
Accounts payable	(62)	100
Accrued liabilities	(1,106)	(960)
Operating lease liabilities	—	30
Deferred revenue	—	(29)
Net cash used in operating activities	(2,883)	(5,250)
Cash flows from investing activities:		
Purchase of property and equipment	—	(100)
Purchase of investments	(4,230)	—
Proceeds from maturities of investments	1,500	500
Net cash (used in) provided by investing activities	(2,730)	400
Cash flows from financing activities:		
Payment of long-term debt	—	(2,083)
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	(3)	9
Net cash provided by (used in) financing activities	12,014	(2,072)
Net change in cash, cash equivalents and restricted cash	6,401	(6,922)
Cash, cash equivalents and restricted cash—Beginning of period	5,721	20,275
Cash, cash equivalents and restricted cash—End of period	$ 12,122	$ 13,353
NONCASH FINANCING ACTIVITIES:		
Equity issuance costs from warrant modification	251	—

See notes to condensed consolidated financial statements.

1. Organization and Summary of Significant Accounting Policies

The Company

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

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

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

On January 7, 2022, the Company acquired Lowell Therapeutics, Inc., or Lowell, a privately held company (see Note 4, "Asset Acquisition" to the consolidated financial statements in the Company's 2023 Annual Report on Form 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, a nafamostat formulation for direct IV infusion, that it intends to develop for the treatment of one or more of the following indications: ARDS, DIC, acute pancreatitis or as an anti-viral agent.

On July 14, 2021, the Company entered into a License and Commercialization Agreement, or the PFS Agreement, with Aguettant, pursuant to which the Company obtained the exclusive right to develop and, subject to FDA approval, commercialize in the United States an ephedrine pre-filled syringe for injection, and (ii) a phenylephrine PFS for injection. Aguettant will supply the Company with the products for use in commercialization, if they are approved in the U.S. 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 condensed consolidated financial statements for the three months ended 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. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Considering the Company's current cash resources and its current and expected levels of operating expenses for the next twelve months, management expects to need additional capital to fund its planned operations prior to the 12-month anniversary of the date this Quarterly Report on Form 10-Q is filed with the United States Securities and Exchange Commission, or the SEC.

Management may seek to raise such additional capital through public or private equity offerings, including under the Controlled Equity Offering℠ Sales Agreement, or the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, debt securities, a new debt facility, monetizing or securitizing certain assets, entering into product development, license or distribution agreements with third parties, or divesting any of the Company's remaining product candidates. While management believes its plans to raise additional funds will alleviate the conditions that raise substantial doubt about the Company's ability to continue as a going concern, these plans are not entirely within the Company's control and cannot be assessed as being probable of occurring.

Additional funds may not be available when the Company needs them on terms that are acceptable to the Company, or at all. If adequate funds are not available, the Company may be required to further reduce its workforce or delay the development of its regulatory filing plans for its product candidates in advance of the date on which the Company's cash resources are exhausted to ensure that the Company has sufficient capital to meet its obligations and continue on a path designed to preserve stockholder value. In addition, if additional funds are raised through collaborations, strategic alliances or licensing arrangements with third parties, the Company may have to relinquish rights to its technologies, future revenue streams or product candidates, or to grant licenses on terms that may not be favorable to the Company.

Basis of Presentation

The preparation of financial statements in conformity with accounting principles generally accepted in the United States, or GAAP, requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and the accompanying notes. Actual results could differ from those estimates.

Reclassifications

Certain prior year amounts in the condensed consolidated financial statements have been reclassified to conform to the 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 condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the 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.

Significant Accounting Policies

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

Sale of Future Payments

On January 12, 2024, the Company entered into the Purchase Agreement with XOMA to monetize a portion of its future payments for commercial sales of DSUVIA and services performed by the Company to support sales of DSUVIA to the Department of Defense, or 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 Company recorded approximately $6.1 million, net of $0.5 million in issuance costs, of the $8.0 million proceeds as a liability, as this portion of the proceeds represents a sale of future revenues under ASC 470 for which the Company has continuing involvement in the generation of cash flows. The Company recorded approximately $1.2 million, net of $0.2 million in issuance costs, of the $8.0 million proceeds as other income, as this portion of proceeds represents the sale of all of the Company's interest in future payments related to commercial sales of DSUVIA for which the Company is no longer entitled to receive such payments and has no further continuing involvement. The Company utilized internal estimates to develop a cash flow model based on business assumptions to determine the allocation of the 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.

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

2. Investments and Fair Value Measurement

Investments

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

As of March 31, 2024, and 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 March 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash, cash equivalents and restricted cash:				
Cash	$ 585	$ —	$ —	$ 585
Money market funds	1,283	—	—	1,283
U.S. government agency securities	5,478	—	—	5,478
Commercial paper	4,776	—	—	4,776
Total cash and cash equivalents	12,122	—	—	12,122
Short-term investments:				
U.S. government agency securities	4,779	—	—	4,779
Commercial paper	1,683	—	—	1,683
Total short-term investments	6,462	—	—	6,462
Total cash, cash equivalents, and short-term investments	$ 18,584	$ —	$ —	$ 18,584

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

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. Impairment is assessed at the individual security level. Factors considered in determining whether a loss resulted from a credit loss or other factors include the Company's intent and ability to hold the investment until the recovery of its amortized cost basis, the extent to which the fair value is less than the amortized cost basis, the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, any historical failure of the issuer to make scheduled interest or principal payments, any changes to the rating of the security by a rating agency, any adverse legal or regulatory events affecting the issuer or issuer's industry, any significant deterioration in economic conditions. There were no material realized or unrealized gains or losses on marketable securities for the three months ended March 31, 2024 or the twelve months ended December 31, 2023. As such, the Company did not record a credit allowance for the three months ended 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 pricing services in developing fair value measurements where fair value is based on valuation methodologies such as models using observable market inputs, including benchmark yields, reported trades, broker/dealer quotes, bids, offers and other reference data. Such Level II instruments typically include U.S. Treasury, U.S. government agency securities and commercial paper. As of March 31, 2024 and December 31, 2023, the Company held, in addition to Level II assets, a warrant liability related to the December 2022 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. 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 change in fair value of warrant liability in the 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 March 31, 2024			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 1,283	$ 1,283	$ —	$ —
U.S. government agency securities	10,257	—	10,257	—
Commercial paper	6,459	—	6,459	—
Total assets measured at fair value	$ 17,999	$ 1,283	$ 16,716	$ —
Liabilities				
Warrant liability	$ 2,780	$ —	$ —	$ 2,780
Total liabilities measured at fair value	$ 2,780	$ —	$ —	$ 2,780

	As of December 31, 2023			
	Fair Value	Level I	Level II	Level III
Assets				
Money market funds	$ 90	$ 90	$ —	$ —
U.S. government agency securities	5,258	—	5,258	—
Commercial paper	2,691	—	2,691	—
Total assets measured at fair value	$ 8,039	$ 90	$ 7,949	$ —
Liabilities				
Warrant liability	$ 1,778	$ —	$ —	$ 1,778
Total liabilities measured at fair value	$ 1,778	$ —	$ —	$ 1,778

The following tables set forth a summary of the changes in the fair value of the Company's Level III warrant liability for the three months ended March 31, 2024 (in thousands):

	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Fair value—beginning of period	$ 1,778	$ 7,098
Change in fair value of December 2022 Common Stock Warrants liability	1,002	(5,311)
Fair value—end of period	$ 2,780	$ 1,787

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 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 0% expected dividend yield.

There were no transfers between Level I, Level II or Level III of the fair value hierarchy during the three months ended March 31, 2024 and the year ended December 31, 2023.

3. Discontinued Operations

On March 12, 2023, the Company entered into the Asset Purchase Agreement with Alora for Alora's acquisition of all assets related to DSUVIA, including inventories, equipment and intellectual property in exchange for consideration at closing of $1.1 million, a 15% payment on commercial sales of DSUVIA, 75% payment on sales of DSUVIA to the Department of Defense and up to $116.5 million in sales-based milestones. The transaction closed on April 3, 2023 (see Note 3, "Discontinued Operations" to the consolidated financial statements in the Company's 2023 Annual Report on Form 10-K for additional information).

The following table presents the results of the discontinued operations for the three-month period ended March 31, 2024 and March 31, 2023 (in thousands):

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

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

	March 31, 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):

	Three months ended March 31,	
	2024	2023
Cash flows from operating activities:		
Depreciation and amortization	$ —	$ 215
Stock-based compensation	—	19
Impairment of net assets held for sale	—	7,007
Impairment of fixed assets	—	1,065
Gain on termination of lease liabilities	—	(1,098)
Gain on extinguishment of debt	—	(400)
Purchases of property and equipment	—	(100)

4. Sale of Future Payments

In January 2024, the Company and XOMA entered into the Purchase Agreement for the sale by the Company to XOMA, in exchange for $8.0 million, of the Company's right, title and interest in and to certain amounts payable to the Company, or collectively, the Purchased Receivables, pursuant to the DSUVIA Agreement in respect of net sales of the Product, excluding sales of the Product by Aguettant.

The Purchased Receivables include:

(i) 100% of certain payments based on net sales of the Product and potential sales-based milestone payments of up to $116.5 million in respect of net sales of the Product, in each case made on and after January 1, 2024 and excluding sales of the Product by Aguettant, and of certain associated license and acquisition payments relating to the Product, until XOMA has received $20.0 million of payments in respect of the foregoing, or the 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 the United States Department of Defense, or DoD and (B) 50% of each of the following: (a) payments based on net sales of the Product to the DoD, (b) potential sales-based milestone payments in respect of net sales of the Product, and (c) certain associated license and acquisition payments relating to the Product.

The Company has retained its right, title and interest in and to, following the Stepdown Date, 50% of each of the following: (a) payments based on net sales of the Product to the DoD, (b) potential sales-based milestone payments in respect of net sales of the Product, and (c) of certain associated license and acquisition payments relating to the Product.

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

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 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	6,133
Payments to XOMA	—
Non-cash interest expense recognized	181
Liability related to sale of future payments as of March 31, 2024	$ 6,314

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.

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, a securities class action complaint was filed in the U.S. District Court for the Northern District of California against the Company and two of its officers. The plaintiff is a purported stockholder of the Company. The complaint alleged that defendants violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by making false and misleading statements and omissions of material fact about the Company's disclosure controls and procedures with respect to its marketing of DSUVIA. The complaint sought unspecified damages, interest, attorneys' fees, and other costs. On December 16, 2021, the Court appointed co-lead plaintiffs. Plaintiffs' amended complaint was filed on March 7, 2022. The amended complaint named the Company and three of its officers and continued to allege that defendants violated Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 by making false and misleading statements and omissions of material fact about the Company's disclosure controls and procedures with respect to its marketing of DSUVIA. The amended complaint also asserted a violation of Section 20A of the Exchange Act against the individual defendants for alleged insider trading. The amended complaint sought unspecified damages, interest, attorneys' fees, and other costs. On September 1, 2022, the Court held oral hearings on the Company's motion to dismiss the amended complaint with prejudice that was filed on July 21, 2022. On September 28, 2022, the Court issued a formal written opinion, or the First Opinion, dismissing all of the plaintiff's claims against the Company and the named defendants with leave for plaintiffs to amend their complaint. On November 28, 2022, the plaintiffs filed their second amended complaint. On July 7, 2023, the Court issued a formal written opinion, or the Second Opinion, dismissing all of the plaintiff's claims against the Company and the named defendants with leave for plaintiffs to amend their complaint in part and without leave to amend in part. On September 5, 2023, the plaintiffs filed a third amended complaint. On 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, a purported shareholder derivative complaint was filed in the U.S. District Court for the Northern District of California. The complaint names ten of the Company's officers and directors and asserts state and federal claims based on the same alleged misstatements as the securities class action complaint. On September 30, 2021, October 26, 2021, and November 17, 2021, three additional purported shareholder derivative complaints were filed in the U.S. District Court for the Northern District of California. The complaints name nine of the Company's officers and directors and also assert state and federal claims based on the same alleged misstatements as the securities class action complaint. All four complaints seek unspecified damages, attorneys' fees, and other costs. On December 6, 2021, the Court entered an order consolidating all four actions and staying the consolidated action pending the outcome of any motion to dismiss the securities class action.

On February 16, 2024, another purported shareholder derivative complaint was filed in the Court of Chancery of the State of Delaware, 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.

7. Stockholders' Equity

Common Stock

January 2024 Private Placement

On January 17, 2024, the Company entered into a private placement with certain institutional investors for aggregate gross proceeds of $6.0 million upfront, an additional $10.0 million committed upon the announcement of positive clinical trial results for the Company's NEPHRO 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, or the Private Placement, to purchase shares of the Company's Common Stock, at a purchase price of $0.769 per share and an exercise price of $0.001 per share, or the January 2024 Pre-Funded 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 3,676,473 shares of Common Stock and (ii) Series B common stock purchase warrants to purchase up to 3,676,473 shares of Common Stock (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 each the Series A common stock purchase warrants and Series B common stock purchase warrants outstanding, by reducing their exercise price from $1.11 to $0.77 per share. Pursuant to ASU 2021-04, the Company remeasured the fair value of the amended and restated Prior Warrants as of the modification date based on the modified terms and recorded the increase in fair value of $0.3 million as equity issuance costs, all of which was allocated to additional paid in capital. The fair value assumptions related to the modification of these 5,882,356 amended and restated Prior Warrants as of January 17, 2024 were as follows: exercise price of $0.77 per share, stock price of $0.769 per share, expected life of 4.5 years, volatility of 96.91%, a risk-free rate of 4.02% and 0% expected dividend yield.

9. Stock-Based Compensation

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

	March 31, 2024	March 31, 2023
Research and development	$ 107	$ 93
Selling, general and administrative	195	457
Discontinued operations	—	19
Total	$ 302	$ 569

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

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Restricted stock units outstanding, January 1, 2024	86,232	$ 7.57
Granted	131,724	1.03
Vested	(39,293)	12.06
Forfeited	—	—
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 15,090 shares of common stock underlying vested RSUs that were withheld during the quarter ended 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)
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 quarter ended March 31, 2024 was estimated at $0.84 per share on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	Three months ended March 31, 2024
Expected term (in years)	6.5
Risk-free interest rate	4.26%
Expected volatility	98%
Expected dividend rate	0%

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

10. Net Loss per Share of Common Stock

The Company's basic net loss per share of common stock is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. The diluted net loss per share of common stock is computed by giving effect to all potential common stock equivalents outstanding for the period determined using the treasury stock method. For purposes of this calculation, options to purchase common stock, RSUs, and warrants to purchase common stock were considered to be common stock equivalents. In periods with a reported net loss, common stock equivalents are excluded from the calculation of diluted net loss per share of common stock if their effect is antidilutive. 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 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 outstanding shares of common stock equivalents were excluded from the computation of diluted net loss per share of common stock for the periods presented because including them would have been antidilutive:

	Three Months Ended March 31,	
	2024	2023
RSUs, stock options and ESPP to purchase common stock	1,850,012	989,011
Common stock warrants	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.

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

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q, or Form 10-Q, and with the audited Consolidated Financial Statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2023, or Annual Report.

About 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 nafamostat product candidates and pre-filled syringe product candidates, as further described below.

In January 2022, we acquired Lowell Therapeutics, Inc., or Lowell, a privately held company, pursuant to the Agreement and Plan of Merger, dated as of November 14, 2021, or the Merger Agreement, in a transaction for consideration of approximately $32.5 million plus net cash acquired and certain other adjustments, and which includes up to approximately $26.0 million of contingent consideration payable in cash or stock at our option, upon the achievement of regulatory and sales-based milestones, or the Merger Agreement. In connection with the Merger Agreement, we acquired Niyad™ and LTX-608 (lyophilized vials of nafamostat for injection into the extracorporeal circuit or direct IV infusion to the patient, respectively), an in-process research and development, or IPR&D, asset. For additional information regarding the Merger Agreement, see Note 4, "Asset Acquisition" to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2023 for additional information.

Nafamostat Product Candidates

Product/Product Candidate	Description	Target Use	Status
Niyad	Lyophilized vial containing nafamostat for injection	Regional anticoagulant for injection into the extracorporeal circuit	Received an investigational device exemption, or IDE, and Breakthrough Device Designation from the United States Food and Drug Administration, or FDA. Plan to begin enrollment in a registrational trial in the 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.

The Niyad NEPHRO CRRT Study, which has received both IDE approval from the FDA and central Institutional Review Board, or IRB, approval, is designed as a prospective, double-blinded trial to be conducted at up to 10 U.S. hospital intensive care units. NEPHRO CRRT stands for 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 evaluate 166 adult patients undergoing renal replacement therapy, who cannot tolerate heparin or are at risk for bleeding. The primary endpoint of the study is mean post-filter activated clotting time using Niyad versus placebo over the first 24 hours. Key secondary endpoints include filter lifespan, number of filter changes over 72 hours, number of transfusions over 72 hours and dialysis efficacy (based on urea concentration) over the first 24 hours. We believe that decades of nafamostat studies on anticoagulation of the extracorporeal circuit can help guide and support our Niyad development efforts.

LTX-608

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

Pre-filled Syringe (PFS) Product Candidates

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

Fedsyra and Phenylephrine

The PFS product candidates are ready-to-use formulations of active ingredients that are currently approved in the United States in concentrated formulations that must be diluted prior to administration to patients, and more recently in ready-to-use vial, and in the case of ephedrine, ready-to-use pre-filled syringe formulations. Hospitals currently purchase ready-to-use, pre-filled syringe presentations of these active ingredients mainly from compounding facilities that have not obtained FDA approval for the products, or manually dilute the products in-house. There have been two recently FDA-approved pre-filled ephedrine syringe products made available on the market. Our product candidates have been developed in a ready-to-use strength and pre-filled into syringes that can be immediately administered to patients, eliminating the need for calculations and additional dilution and filling steps. Aguettant pre-filled syringes are focused on delivering commonly used medicines safely and efficiently. Perioperative medication errors continue, and pre-filled syringes are preferred for improving safety while containing costs. We believe that, if approved, our pre-filled syringe products may offer significant benefits to hospitals and surgery centers and avoid potential disadvantages of the currently available compounded products. We are currently evaluating the timing of submitting the NDA for our ephedrine pre-filled syringe given the two other FDA-approved products recently made available on the market.

Our Strategy

Our strategy is focused on developing, obtaining approval, and commercializing our product candidates, first and 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, 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. We have no plans to further develop or commercialize any of our other sufentanil sublingual products that were previously our product candidates. As described below, 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 DSUVIA to the 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 payments earned on sales to the Department of Defense, milestones and other payments from Alora (see Note 4, "Sale of Future Payments" to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional 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, global events have impacted our global supply chain and we may face further disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products. Such supply disruptions may adversely impact our ability to continue development of our product candidates and ultimately generate sales of and revenues from any approved products, and our business, financial condition, results of operations and growth prospects could be adversely affected.

Inflation

We do not believe that inflation has had a material impact on our business or operating results during the periods presented. However, inflation, led by supply chain constraints, federal stimulus funding, increases to household savings, and the sudden macroeconomic shift in activity levels arising from the loosening or removal of many government restrictions, has had, and may continue to have, an impact on overhead costs and transportation costs and may in the future adversely affect our operating results. In addition, increased inflation has had, and may continue to have, an effect on interest rates. Increased interest rates may adversely affect our borrowing rate and our ability to obtain, or the terms under which we can obtain, any potential additional funding.

Recent Developments

In January 2024, we entered into the XOMA Agreement pursuant to which we sold to XOMA our right to amounts payable to us by Alora under the DSUVIA Agreement in exchange for $8.0 million in order to monetize certain future payments for services performed to support sales of DSUVIA to 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 right, after XOMA has received $20.0 million of payments in respect of such 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 (see Note 4, "Sale of Future Payments" to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information).

Financial Overview

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

Our net loss for the three months ended March 31, 2024 and 2023 was $4.0 million and $8.2 million, respectively. As of March 31, 2024, we had an accumulated deficit of $448.2 million. As of March 31, 2024, we had cash, cash equivalents and short-term investments totaling $18.6 million compared to $9.4 million as of 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 months ended 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 do not believe other recently issued but not yet effective accounting standards, if currently adopted, would have a material effect on our consolidated financial statements.

Results of Operations

Our unaudited condensed consolidated results of operations are presented for the three months ended March 31, 2024 and 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 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 Months Ended March 31, 2024 and 2023

Research and Development Expenses

Research and development expenses included the following:

- expenses incurred under agreements with contract research organizations and clinical trial sites;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- payments to third party pharmaceutical and engineering development contractors;
- payments to third party manufacturers;
- depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and equipment and laboratory and other supply costs; and
- costs for equipment and laboratory and other supplies.

We expect to incur future research and development expenditures to support the FDA regulatory review of our product candidates and anticipated activities required for the development of our nafamostat product candidates.

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

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

	Three Months Ended March 31,		$ Change	% Change
	2024	2023	2024 vs. 2023	2024 vs. 2023
Niyad	$ 424	$ 472	$ (48)	(10)%
Overhead	1,009	575	434	75%
Total research and development expenses	$ 1,433	$ 1,047	$ 386	37%

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

Selling, General and Administrative Expenses

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

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

	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 March 31, 2024, as compared to the three months ended March 31, 2023, primarily due to the divestment of DSUVIA. More specifically, the decrease was attributed to a $0.4 million reduction in employee compensation and related expenses due to a reduction in headcount, a $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 $0.3 million.

Other Income (Expense), Net

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

	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. 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, net, for the three months ended March 31, 2024 and 2023, primarily consisted of 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, as compared to a $5.3 million decrease in the fair value for the first quarter of 2023.

The non-cash interest expense on the liability related to the sale of future payments is attributable to the XOMA Purchase Agreement. Please refer to Note 4, “Sale of Future Payments” to the unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information.

Discontinued Operations

For the three months ended March 31, 2023, we recognized an impairment on net assets held for sale of $7.0 million and a loss from discontinued operations of $1.2 million. 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

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 2024 and may incur significant losses and negative cash flows from operations in the future. Although we raised additional capital in January 2024 as discussed below, considering our current cash resources and current and expected levels of operating expenses for the next twelve months, we expect to need additional capital to fund our planned operations prior to the twelve-month anniversary of the filing date of this Quarterly Report on Form 10-Q.

We may seek to raise such additional capital through public or private equity offerings, the issuance of debt securities, a new debt facility, or entering into product development, license or distribution agreements with third parties. Our existing capital resources will not be sufficient to fund our operations until such time as we may be able to generate sufficient revenues to sustain our operations.

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

XOMA Purchase Agreement

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

January 2024 Private Placement

In January 2024, we entered into securities purchase agreements with institutional investors, relating to the issuance and sale of pre-funded warrants to the purchasers in a two-tranche private placement to purchase shares of Common Stock at a purchase price of $0.769 per share and an exercise price of $0.001 per share. The pre-funded warrants are exercisable immediately and have an unlimited term. The terms of the private placement included:

- the first tranche of the private placement, which closed in January 2024, resulted in the aggregate gross proceeds of approximately $6.0 million excluding the proceeds, if any, from the exercise of the pre-funded warrants issued in such tranche. 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 the private placement, we agreed to amend and restate a portion of the outstanding warrants issued in connection with the July 2023 private placement (Refer to Note 9, “Stockholders’ Equity” and Note 10, “Warrants” to the consolidated financial statements in 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 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 determined by market conditions at the time of any offering. Our ability to sell such securities will be limited until we are no longer subject to the SEC's "baby shelf" limitations.

Cantor Controlled Equity Offering℠ Sales Agreement

In June 2016, we entered into a Controlled Equity Offering℠ Sales Agreement, as amended, the ATM Agreement, with Cantor Fitzgerald & Co., or Cantor, as agent, pursuant to which we may offer and sell, from time to time through Cantor, shares of our common stock. There were no sales under the ATM Agreement for the three months ended March 31, 2024 or 2023. As of March 31, 2024, approximately $35.6 million of our common stock remained available for sale and issuance under the ATM Agreement. As of March 31, 2024, we had the ability to sell approximately $35.6 million of our common stock under the ATM Agreement, subject to the filing of a prospectus supplement with the SEC to our registration statement on Form S-3. Our ability to sell such shares will be limited until we are no longer subject to the SEC's "baby shelf" limitations.

Cash Flows

	Three Months Ended March 31,	
	2024	**2023**
Net cash used in operating activities	$ (2,883)	$ (5,250)
Net cash (used in) provided by investing activities	(2,730)	400
Net cash provided by (used in) financing activities	12,014	(2,072)

The discussion of our cash flows that follows includes the impact of discontinued operations. For additional information, see Note 3, "Discontinued Operations" to the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Cash Flows from Operating Activities

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

Cash used in operating activities of $2.9 million during the three months ended March 31, 2024, reflected a net loss of $4.0 million, partially offset by aggregate non-cash charges of $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 $0.8 million net change in our operating assets and liabilities. Non-cash adjustments included an impairment charge of $7.0 million on our net assets held for sale in connection with our divestment of DSUVIA, an impairment charge of $1.1 million on fixed assets, a gain of $1.1 million related to the termination of lease liabilities, a $5.3 million decrease in the fair value of our warrant liability and $0.6 million in stock-based compensation expense, a $0.4 million gain on extinguishment of debt, and $0.3 million in depreciation and amortization expense. The net change in our operating assets and liabilities included a $1.6 million decrease in prepaid expenses and other assets and a $1.0 million decrease in accrued liabilities.

Cash Flows from Investing Activities

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

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

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, including the sale of future payments.

During the three months ended March 31, 2024, cash provided by financing activities of $12.0 million was primarily due to net proceeds from the XOMA Purchase Agreement of $6.1 million, and $5.9 million in net proceeds from the January 2024 private placement.

During the three months ended March 31, 2023, cash used in financing activities of $2.1 million was primarily due to long-term debt payments under the Loan Agreement with Oxford. 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. Our operating plan includes anticipated activities required for the development and supply of our nafamostat product candidates. These assumptions may change as a result of many factors. We will continue to evaluate the work necessary to gain approval of our product candidates in the United States and intend to update our cash forecasts accordingly. Considering our current cash resources and current and expected levels of operating expenses for the next twelve months, we expect to need additional capital to fund our planned operations for at least the next twelve months.

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

- the ability to successfully initiate and complete our clinical trial for the Niyad product candidate.
- the outcome, timing and cost of the development of our other nafamostat product candidates;
- expenditures related to drafting and submission of new drug or device regulatory applications with the FDA for our developmental product candidates and payment of statutory filing fees and related application prosecution costs arising from such submissions;
- costs associated with business development activities and licensing transactions;
- the outcome and timing of the regulatory submissions for our product candidates, including our two in-licensed product candidates from Aguettant, and any approvals for our product candidates;
- expenditures related to the potential commercialization of our product candidates, if approved;
- the initiation, progress, timing and completion of any post-approval clinical trials for our product candidates, if approved;
- the ability to retain the listing of our common stock on Nasdaq;
- changes in the focus and direction of our business strategy and/or research and development programs;
- 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 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 Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Evaluation of disclosure controls and procedures. As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

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

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in legal proceedings relating to intellectual property, commercial, employment and other matters arising in the ordinary course of business. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position or cash flows. Please see the matters under the caption "Part I. Financial Information —Item 1. Financial Statements—Note 6, Commitments and Contingencies—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.
- 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 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.
- We rely on single sources of supply for the active pharmaceutical ingredients and finished product for our nafamostat-based product candidates and any disruptions in the chain of supply may cause a delay in developing our product candidates.

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

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. In addition, we have generated negative cash flows from operations and we expect to incur significant losses in 2024 and may incur significant losses and negative cash flows from operations in the future. These conditions raise substantial doubt about our ability to continue as a going concern.

We have devoted most of our financial resources to research and development, including our non-clinical development activities and clinical trials. To date, we have financed our operations primarily through the issuance of equity securities, borrowings, payments from Grünenthal GmbH, or Grünenthal, the monetization of certain future royalties and commercial sales milestones from the European sales of Zalviso by Grünenthal, funding from the Department of Defense, or DoD, with revenues from sales of DSUVIA, 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 Aguettant. 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 the required development activities associated with those products can be time consuming and costly. We expect to incur significant expenditures in connection with supporting our research and development activities for our product candidates.

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

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

The unaudited condensed consolidated financial statements for the quarterly period ended March 31, 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 ongoing military conflicts between Hamas and Israel, and between Russia and Ukraine and related sanctions imposed against Russia.

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

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

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

Our ability to generate revenue from commercial sales and/or royalties and achieve profitability depends on our ability, alone and with collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize our products. We do not anticipate generating significant near-term revenues from our product candidates, if approved, in the United States. Our ability to generate future revenues from product sales depends heavily on the success in:

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

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

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

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

Future sales of DSUVIA to the DoD are not predictable, may occur on an irregular basis and may not meet our expectations due to various U.S. government-related factors that are beyond our control and into which we have little to no visibility, including the timing and extent of future U.S. military deployments.

Under the DSUVIA Agreement, Alora is responsible for commercializing DSUVIA except that we retain the responsibility for driving the demand within the DoD, and, if the XOMA Threshold is achieved, we will be entitled to receive quarterly payments in an amount equal to one-half of the 75% of net DSUVIA sales to the DoD. Refer to Note 3, "Discontinued Operations" to the 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.

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 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.

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

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

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

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

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

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

Our development efforts might not generate successful product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Nafamostat is being developed for use in both medical devices and drug 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 are studying Niyad™ in the NEPHRO CRRT study under an investigational device exemption, or IDE. Niyad has received Breakthrough Device Designation from the FDA for regional anticoagulant for injection into the extracorporeal circuit and is expected to be used during renal replacement therapy for acute kidney injury patients in the hospital and for end-stage renal disease patients receiving dialysis in outpatient clinics. We expect that Niyad will require approval of a PMA application for commercialization in the U.S., and as a company we have never submitted nor received approval for a PMA.

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

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

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

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

- our partners may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical or regulatory results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- our contracts for collaborative arrangements are or may be terminable at will on written notice and may otherwise expire or terminate, and we may not have alternatives available to achieve the potential for our products in those territories or markets;
- our partners may choose to pursue alternative technologies, including those of our competitors;
- we may have disputes with a partner that could lead to litigation or arbitration, including in connection with any contractual breach notice;
- we have limited control over the decisions of our partners, and they may change the priority of our programs in a manner that would result in termination of the agreement or add significant delays to the partnered program;

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

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

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

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

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

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

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

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

The U.S. biotechnology and pharmaceutical industries are characterized by intense competition and cost pressure. Our Niyad product candidate, if approved in the U.S., may compete with currently available anticoagulants such as heparin and citrate. The LTX-608 nafamostat product candidates, if approved in the U.S., may compete with existing or emerging third party products. The PFS product candidates, if approved in the U.S., may compete with other ready-to-use formulations of ephedrine and phenylephrine.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. Aggregate reductions of Medicare payments to providers went into effect on April 1, 2013 and due to subsequent legislative amendments to the statute will stay in effect until 2032, unless Congressional action is taken. The American Taxpayer Relief Act further reduced Medicare payments to several providers, including hospitals. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, which began on January 1, 2024.

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

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

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

Risks Related to Our Reliance on Third Parties

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

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

- the inability to meet our product specifications and quality requirements consistently;
- the inability to procure raw materials in a timely fashion due to ongoing challenges in the global supply chain;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to maintain in good order our production and manufacturing equipment for our products;
- a failure to comply with cGMP and similar foreign standards;
- the inability to negotiate manufacturing or supply agreements with third parties under commercially reasonable terms;

- termination or nonrenewal of manufacturing or supply agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for essential product components or finished goods, such that if we are unable to secure a sufficient supply of these product components or finished goods, we will be unable to manufacture, supply and sell our products in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified secondary or backup suppliers for those essential components or finished goods that are currently purchased from a sole or single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, economic sanctions, or government orders related to pandemics;
- carrier disruptions due to international conflicts and/or increased costs that are beyond our control; and
- the failure to deliver our products under specified storage conditions and in a timely manner.

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

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

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

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 manufacturers, we are dependent on their continued adherence to cGMP manufacturing and acceptable changes to their processes. If our manufacturers do not meet the FDA or other foreign regulatory agency's strict regulatory requirements, they will not be able to secure FDA or other foreign regulatory agency approval for their manufacturing facilities. If the FDA or the relevant foreign regulatory agency does not approve these facilities for the commercial manufacture of Niyad, we will need to find alternative suppliers, which would result in significant delays in obtaining regulatory agency approval. These challenges may have a material adverse impact on our business, results of operations, financial condition and prospects.

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

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

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

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

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

Risks Related to Our Business Operations and Industry

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Business interruptions could delay our operations and sales efforts.

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have systems in place, including 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 filed a trademark application for TALPHERA in the United States and will file related trademark applications in other major foreign pharmaceutical jurisdictions of interest. In addition, we have obtained approval of our Niyad and Fedsyra marks in the United States and are awaiting our first use of those marks in commerce in order to secure our federal registrations. Although we are not currently aware of any oppositions to or cancellations of our registered trademarks or pending applications, it is possible that one or more of the applications and/or registrations could be subject to rejection, opposition or cancellation. In addition, we will need to seek FDA approval to use Niyad and other potential product trademarks as part of future potential applications for marketing approval of the relevant developmental products. The registrations will be subject to use and maintenance requirements. It is also possible that we have not yet registered all of our trademarks in all of our potential markets, and that there are names or symbols that may be protectable marks for which we have not sought registration, and failure to secure those registrations could adversely affect our business. Opposition or cancellation proceedings may be filed against our trademarks and our trademarks may not survive such proceedings.

Risks Related to Ownership of Our Common Stock

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

The trading price of our common stock has experienced significant volatility and is likely to be volatile in the future. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- failure to successfully develop and commercialize our product candidates in the United States;
- inability to obtain additional funding needed to conduct our planned business operations;
- the integration and performance of any assets or businesses we acquire;
- our inability to develop and commercialize products and product candidates that we in-license;
- the perception of limited market sizes or pricing for our products;
- safety issues;
- adverse results or delays in clinical trials;
- changes in laws or regulations applicable to our products;
- inability to obtain adequate product supply for our products, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- changes in the structure of the healthcare payment systems;
- introduction of new products, services or technologies by our competitors;

- failure to meet or exceed financial projections we provide to the public;
- failure to meet or exceed the estimates and projections of the investment community;
- decisions by our collaboration partners regarding market access, pricing, and commercialization efforts in countries where they have the right to commercialize our products;
- failure to maintain our existing collaborations or enter into new collaborations;
- the perception of the pharmaceutical industry generally, and of opioid manufacturers more specifically, by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures, or other significant transactions, including disposition transactions, or capital commitments by us or our competitors;
- disputes or other developments relating to employment matters, business development efforts, proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key management or scientific personnel;
- costs associated with potential governmental investigations, inquiries, regulatory actions or lawsuits that may be brought against us as a result of us being an opioid manufacturer;
- other types of significant lawsuits, including patent, stockholder, securities class action and derivative litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future;
- our ability to maintain compliance with Nasdaq listing requirements;
- liquidity of our common stock; and
- trading volume of our common stock.

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

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

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

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

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

Because we will continue to need additional capital in the future to continue to expand our business and our research and development activities, among other things, we may conduct additional equity offerings. Sales of a substantial number of shares of our common stock in the public market or our issuance of common stock warrants, or the perception that these sales or issuances might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants under our equity incentive plans. Grants under our equity incentive plans may also cause our stockholders to experience additional dilution, which could cause our stock price to fall. We may in the future issue additional shares of our common stock as consideration in mergers, acquisitions and other business development transactions. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. All of our shares of common stock outstanding are eligible for sale in the public market, subject in some cases to the volume limitations and manner of sale requirements of Rule 144 under the Securities Act. Sales of stock by our stockholders could have a material adverse effect on the trading price of our common stock.

We 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 award 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, 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 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, 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 expensive and diverts management's attention and our financial resources, which could harm our business. Additional lawsuits related to the pending litigation may follow. Moreover, if Talphera experiences a decline in its stock price, we could face additional securities class action lawsuits.

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

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

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

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

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

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
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	01/09/2024
3.3	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	06/25/2019
3.4	Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Registrant.	8-K	001-35068	3.1	10/25/2022
3.5	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.				
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).				

§ 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: May 14, 2024

Talphera, Inc.
(Registrant)

/s/ Raffi Asadorian

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

Exhibit 10.1

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.

PAYMENT INTEREST PURCHASE AGREEMENT

BY AND BETWEEN

TALPHERA, INC.

AND

XOMA (US) LLC

DATED AS OF JANUARY 12, 2024

List of Exhibits

PAYMENT INTEREST PURCHASE AGREEMENT

This Payment Interest Purchase Agreement is dated as of January 12, 2024 (this "Agreement"), by and between **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 ("Vertical"), 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, Seller desires to sell, transfer, assign and convey to Buyer, and Buyer desires to purchase, acquire and accept from Seller, all of Seller's right, title and interest in and to the 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 representations, warranties, covenants and agreements set forth herein and for good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, intending to be legally bound, Seller and Buyer hereby agree as follows:

ARTICLE I

DEFINITIONS; INTERPRETATION

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

"Affected Receivables" is defined in Section 7.8.

"Affiliate" means, with respect to any Person, any other Person that directly, or indirectly through one or more intermediaries, Controls, or is Controlled by, or is under common Control with, such Person.

"Agreed Amount" is defined in Section 8.3.

[***]

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

"Applicable Law" means, with respect to any Person, all laws, rules, regulations, codes and orders of Governmental Authorities applicable to such Person or any of its properties or assets.

"Applicable Withholding Certificate" means a valid and properly executed IRS Form W-9 (or any applicable successor form) certifying that the applicable party hereto (or its regarded owner, as applicable) is a "United States person" as defined in Section 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.

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

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

"Buyer" is defined in the 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 Party" is defined in Section 8.1(a).

"Buyer Material Adverse Effect" means any one or more of: (a) a material adverse effect on the ability of 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 the validity or enforceability of the Transaction Documents against Buyer or the rights of Seller thereunder.

"Buyer Participated Audit" is defined in Section 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" means, with respect to Seller, the consummation of any bona fide third party tender offer, merger, acquisition, consolidation or other similar transaction, in one transaction or a series of related transactions, the result of which 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 of the total voting power of the voting stock of Seller (or the surviving entity) or (b) all or substantially all of Seller's and its Affiliates' assets; but excluding any such transaction or series of transactions effected exclusively for bona fide equity financing purposes or any consolidation or merger transaction or series of transactions effected exclusively to change Seller's domicile.

"Change of Control Adjustment" is defined in Section 7.8.

"Claim Amount" is defined in Section 8.3.

"Claim Notice" is defined in Section 8.3.

"Claim Notice Response" is defined in Section 8.3.

"Closing" is defined in Section 3.1.

"Closing Date" is defined in Section 3.1.

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

"Commercially Reasonable Efforts" means the efforts Seller would reasonably be expected to expend if Seller had the sole right, title and interest in 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 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).

"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 that certain Intellectual Property 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 Assignment Agreement" 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 6.1(b).

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

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

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

"Marketing Agreement" means 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 time.

"Modification" is defined in Section 7.5.

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

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

"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 the Sale Agreement.

"Program" has the meaning set forth in the Sale Agreement.

"Purchase Price" is defined in Section 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).

"Receivables" means the Purchased Receivables and the Retained Interests.

"Receiving Party" is defined in Section 6.1(a).

"Recipient Confidentiality Breach" is defined in Section 6.1(a).

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

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

"Related Agreements" means, 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 Disclosing Party or any of its Affiliates under any agreement with a third party (including, without limitation, the Sale Agreement and the Marketing Agreement) to which any Confidential Information is subject.

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

"Retained Interests" means, without duplication, Seller's right, title and interest in and to the following, from and after the Stepdown Date:

(a) 50% of any and all payments or amounts payable to Seller under Section 2.11 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), in each case subject to the 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 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 (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 Marketing Agreement assessed on any payments or amounts payable described in the foregoing clauses (a), (b), or (c).

"Reverse Merger" is defined in Section 7.8.

"Sale Agreement" is defined in the recitals.

"SEC" means the U.S. Securities and Exchange Commission.

"SEC Documents" 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 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 4.10 (Title to Purchased Receivables); and Section 4.11 (UCC Matters).

"Seller Indemnified Party" is defined in Section 8.1(b).

"Seller Material Adverse Effect" means any one or more of: (a) 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 the Sale Agreement, (ii) the legality, validity or enforceability of any of the 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.

"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 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 2.13 of the Sale Agreement and 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 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.

"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 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 Section 2.4 is governed by the Uniform Commercial Code as in effect in 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 provisions of this Agreement and any financing statement relating to such perfection or effect of perfection or non-perfection.

"Vertical" is defined in the recitals.

"Vertical Instruction Letter" is defined in Section 6.5.

"Vertical Notice and Waiver" means the notice to Vertical of the transactions contemplated hereby under the Marketing Agreement and waiver by 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.

"Vertical Reports" means, collectively, (a) the Payments Reports (as defined in the Sale Agreement) required to be delivered by Vertical to Seller pursuant to Section 2.12(c) of the Sale Agreement, (b) the DoD Payments Report (as defined in the Marketing Agreement) required to be delivered by Vertical to Seller pursuant to Section 5.b of the Marketing Agreement, (c) the License and Acquisition Income Reports (as defined in the Sale Agreement) required to be delivered by Vertical to Seller pursuant to Section 2.14(b) of the Sale Agreement, and (d) any notices and supporting documentation delivered by Vertical to Seller in respect of the events specified in Sections 2.11-2.15 of the Sale Agreement and Section 5 of the Marketing Agreement.

"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 parties acknowledge and agree that (a) no adjustments or credits in the calculations pursuant to Section 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.

"Vertical TSA" means that certain Transition Services 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.

"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 assigned to it in accordance with GAAP;

(b) unless otherwise defined, all terms that are defined in the UCC shall have the meanings stated in the UCC;

(c) words of the masculine, feminine or neuter gender shall mean and include the correlative words of other genders;

(d) the definitions of terms shall apply equally to the singular and plural forms of the terms defined;

(e) references to the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or";

(f) "include," "includes" and "including" shall be deemed to be followed by the words "without limitation";

(g) references to a Person are also to its permitted successors and assigns (subject to any restrictions on assignment, transfer or delegation set forth herein or in any of the other Transaction Documents);

(h) the word "will" shall be construed to have the same meaning and effect as the word "shall";

(i) the words "hereof", "herein", "hereunder" and similar terms 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, unless otherwise specified;

(j) except as otherwise set forth in this Agreement, 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 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 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 date of this Agreement; and

(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 for all purposes.

ARTICLE II

PURCHASE AND SALE OF PURCHASED RECEIVABLES

Section 2.1 Purchase and Sale of Purchased Receivables.

(a) Purchase and Sale. Upon the terms and subject to the conditions of this Agreement, at the Closing, Seller shall sell, transfer, assign and convey to Buyer, and Buyer shall purchase, acquire and accept from Seller, free and clear of all liens and encumbrances, all of Seller's right, title and interest in and to the Purchased Receivables.

(b) Purchase Price. In full consideration for the sale, transfer, assignment and conveyance of the Purchased Receivables, and subject to the terms and conditions set forth herein, Buyer shall make a one-time payment to Seller on the 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 of the Transaction Documents, purchase, acquire or accept any assets or contract rights of Seller (including, for clarity, the Retained Interests) other than the Purchased Receivables (the "Excluded Assets").

Section 2.3 No Obligations Transferred. Notwithstanding anything to the contrary contained in this Agreement, (a) the sale, transfer, assignment and conveyance to Buyer of 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 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 transaction to be accounted for as a liability or 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 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 reason deemed ineffective or unenforceable, this Agreement shall constitute a security agreement under the UCC and Seller does hereby grant to Buyer, as security for all of Seller's obligations hereunder, including the payment to Buyer of amounts equal to the 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 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 2.5 Payments. Any payments to be made by a 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 duly executed counterpart to the Bill of Sale, evidencing the sale and 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 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.

(iii) (A) The representations and warranties (other than the 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 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 any materiality or Seller Material Adverse Effect qualifiers contained therein) shall be true and correct in all respects on the date hereof and on the Closing Date as though made on such date, (C) Seller shall have performed and complied in all material respects with the agreements and conditions required by this Agreement to have been performed or complied with by it prior to or at the Closing, 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 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 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.

(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 make illegal, to delay materially or otherwise directly or indirectly to restrain or prohibit the consummation of the transactions contemplated hereby, (B) seeking to obtain material damages in connection with the transactions contemplated hereby or (C) seeking to restrain or prohibit Buyer's purchase of the Purchased Receivables.

(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 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 date hereof and true and correct in 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 date hereof and on the Closing Date as though made on such date, and (C) Buyer shall have performed and complied in all material respects with the agreements and conditions required by this Agreement to have been performed or complied with by it prior to or at the Closing.

(iv) Buyer shall have delivered to Seller a certificate of an executive officer of Buyer, dated as of the 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 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 consummation of the transactions contemplated hereby, (B) seeking to obtain material damages in connection with the transactions contemplated hereby or (C) seeking to restrain or prohibit Buyer’s purchase of the Purchased Receivables.

ARTICLE IV

SELLER'S REPRESENTATIONS AND WARRANTIES

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

Section 4.1 Organization. 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 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 the aggregate, a Seller Material Adverse Effect.

Section 4.2 Authorization. Seller has the requisite corporate power and authority to execute, deliver and perform its obligations under the Transaction Documents and to consummate the transactions contemplated thereby. The execution, delivery and performance of the Transaction Documents, and the consummation of the transactions contemplated thereby, have been duly authorized by Seller.

Section 4.3 Enforceability. Each of the Transaction Documents has been duly executed and delivered by Seller, and constitutes a valid and binding obligation of Seller, enforceable against Seller 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 4.4 Absence of Conflicts. The 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 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 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 with the U.S. Securities and Exchange Commission.

Section 4.6 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 the Knowledge of 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 (a) not violated, is not in violation of, has not been given written notice that it has violated, and, to the Knowledge of Seller, Seller is not under investigation with respect to its violation of, and, to the Knowledge of Seller, has not been threatened to be charged with any violation of, any Applicable Law or any Judgment of any Governmental Authority, and (b) is not subject to any Judgment of any Governmental Authority; in each case of 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 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 true, correct and complete copies of the Sale Agreement and the Marketing Agreement. Seller has made available to Buyer true, correct and complete copies of: (i) the Related Agreements (other than the Sale Agreement and the Marketing Agreement), (ii) all Vertical Reports that have been received by Seller prior to the date hereof; and (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 Sale Agreement and Marketing Agreement. Each of the Sale Agreement and the Marketing Agreement is a valid and binding obligation of Seller and, to the Knowledge of Seller, of Vertical, enforceable against each of Seller and, to the Knowledge of Seller, Vertical, 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. Each of the Sale Agreement and the Marketing Agreement will continue to be valid, binding and enforceable on identical terms immediately following the consummation of the transactions contemplated by the Transaction Documents. Seller has not received any written notice from Vertical challenging the validity, enforceability, or interpretation of any provision of the Sale Agreement or the Marketing Agreement or any obligation of Vertical to pay the Receivables thereunder.

(c) Other Agreements. The Sale Agreement and the Marketing Agreement are the only agreements, instruments, arrangements, waivers or understandings (other than the other Related Agreements) between Seller (or any 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 its assets or properties is bound or committed (i) that creates a lien on the Purchased Receivables; (ii) that materially affects the Purchased Receivables or (iii) for which breach thereof, nonperformance thereof, cancellation thereof or failure to renew would reasonably be expected to result in a 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 has occurred that upon notice or the passage of time, or both, would reasonably be expected to 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 any such material breach by Seller. To the Knowledge of Seller, there is and has been no material breach of any provision of the Sale Agreement or the Marketing Agreement by Vertical, and, to the Knowledge of Seller, no event has occurred that, upon notice or 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 Sale Agreement or the Marketing Agreement.

(f) No Payments. Except as set forth in the Disclosure Schedules, as of the date of this Agreement, Vertical has not made, and Seller has not received, any 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 Marketing Agreement or released Vertical, in whole or in part, from any of 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 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 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 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 Related Agreements or otherwise, that would permit Vertical to exercise any Vertical Setoff against the Receivables or any other amounts payable to Seller under any of the Related Agreements. Vertical has not in the past exercised, and, to the Knowledge of Seller, no event has occurred and no facts or circumstances exist that would reasonably be expected to give rise to a right of Vertical to exercise any Vertical Setoff against the Receivables or any 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 use and that 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 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 Purchased Receivables granted by Seller to Buyer pursuant to Section 2.4 shall be a perfected first priority security interest in and to the 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 4.11 UCC Matters. Seller's exact legal name is, and 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 organization is, and since its organization has been, the State of Delaware. Seller's principal place of business since August 2023, is located in San Mateo, California.

Section 4.12 Taxes. No deduction or withholding for or on account of any tax has been or was required to be made from any payment by Vertical to Seller under the Sale Agreement. Seller has not received written notice from Vertical of any intention to withhold or deduct any tax from future payments under the Sale Agreement. Seller has filed (or caused to be filed) all material tax returns and material tax reports required to be filed under Applicable Law and has paid all material taxes required to be paid by Seller (including, in each case, in its capacity as a withholding agent), except for any such taxes that are being contested in good 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 portion thereof).

Section 4.13 Solvency. Seller is, individually and together with its subsidiaries on a consolidated basis, Solvent, and will be Solvent immediately after giving effect to the transactions contemplated by this Agreement.

Section 4.14 Disclosure. [***] to the Knowledge of Seller, there is no fact (other than general economic or industry conditions) that would reasonably be expected to materially and adversely affect the Purchased Receivables or the Product.

ARTICLE V

BUYER'S REPRESENTATIONS AND WARRANTIES

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

Section 5.1 Organization. Buyer is a limited liability company, duly organized, validly existing and in good standing under the laws of Delaware.

Section 5.2 Authorization. Buyer has the requisite organizational power and authority to execute, deliver and perform the Transaction Documents and to consummate the transactions contemplated thereby. The execution, delivery and performance of the Transaction Documents, and the consummation of the transactions contemplated thereby, have been duly authorized by Buyer.

Section 5.3 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 performance by Buyer 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 the certificate of incorporation or bylaws of Buyer, 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 to which Buyer is a party or by which Buyer is bound.

Section 5.5 Consents. 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 by Buyer of the Transaction Documents, the performance by Buyer of its obligations under the Transaction Documents or the consummation of the transactions contemplated by the Transaction Documents, except for (a) such Consents, the 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 date hereof.

Section 5.6 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 other intermediary who has been retained by or is authorized to act on behalf of Buyer who is entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

Section 5.8 Financing. Buyer has, and will have as of the Closing, sufficient cash on hand or binding and enforceable commitments to provide it with funds sufficient to satisfy its obligations to pay the Purchase Price. Buyer acknowledges that its obligations under this Agreement are not contingent on obtaining financing.

ARTICLE VI

GENERAL COVENANTS

Section 6.1 Confidentiality.

(a) Confidentiality. Except as set forth in Section 6.1(c) below, each party ("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 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 it shall be and remain responsible hereunder for any failure by any 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 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, "Confidential Information" shall 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 accordance herewith or in accordance with the Confidentiality Agreement, as evidenced by its written records; (B) was or becomes generally available to the public or part of the 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 Confidentiality Agreement) prior to any disclosure of 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 (and without any breach of this Agreement or the Confidentiality Agreement by Receiving Party, its Affiliates or its or its Affiliates' Representatives); provided, that such source, to the knowledge of Receiving Party, had the 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 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) Tax Treatment. For U.S. federal, state, local and non-U.S. tax purposes, Seller and Buyer shall treat (i) the transactions contemplated by the Transaction Documents as a sale of the Purchased Receivables and (ii) any and all amounts remitted by Seller to Buyer after the Closing Date pursuant to Section 7.2(a) or otherwise under this Agreement as having been received by Seller as agent for Buyer, unless otherwise required by a final determination as defined in Section 1313(a) of the Code or any corresponding provision of state, local, or 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).

(d) Cooperation. Each of Buyer and Seller shall cooperate and provide, or cause to be provided, to the other party such assistance as may reasonably be necessary to enable the 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 other party proper evidence of the taxes paid by it to the relevant taxing authority on behalf of the recipient party.

Section 6.3 Further Actions. From and after the Closing, each of Buyer and Seller shall, at the expense of the requesting party, execute and deliver such additional documents, certificates and instruments, and perform such additional acts, as may be reasonably requested and necessary or appropriate to carry out all of the provisions of this Agreement and to give full effect to and consummate the transactions contemplated by this Agreement, including to (a) perfect the 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 of Buyer's rights under any Transaction Document to which Buyer is party (subject to, in the case of clause (c), [***]).

Section 6.4 Escrow Agreement. The parties agree to negotiate and enter into the 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 Sale Agreement and the Marketing Agreement to the Escrow Account (for purposes of clarity, Seller and Buyer agree to instruct the Escrow Agent that $[***] of the payments under Sections 2.12 and 2.13 of the Sale Agreement and Section 5.a of the 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, without Buyer's prior written consent, deliver any further directions relating to payment of the Receivables to Vertical.

Section 6.6 Public Announcements

. Except (a) for a press release previously approved in form and substance by Seller and Buyer, or any other public announcement using substantially the same text as such press release, and (b) for a public disclosure in accordance with Section 6.1(c)(ii)(D) and the last paragraph of Section 6.1(c)(ii), neither party hereto shall, and each party hereto shall cause its Affiliates not to, 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 public disclosure with respect to this Agreement or any of the other Transaction Documents or any of 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 Vertical Notice and Waiver delivered by Seller, Seller shall use commercially reasonable efforts to obtain Vertical's duly authorized signature to such Vertical Notice and Waiver.

ARTICLE VII

COVENANTS RELATING TO THE SALE AGREEMENT AND MARKETING AGREEMENT

Section 7.1 Performance of Sale Agreement and Marketing Agreement.

(a) Seller agrees that it shall (i) comply in all material respects with its obligations under each of the Sale Agreement and 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 of the Sale Agreement or the Marketing Agreement, (iv) not forgive, release or compromise any amount owed to or becoming owed to Seller under the Sale Agreement in respect of the Receivables, without the prior written consent of Buyer, and (v) not, without the 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 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 in any event within [***] Business Days, following receipt by Seller of any written notice of breach by Seller or of termination of the 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 respect of, affecting or relating to the Receivables, the Product, the Sale Agreement, or the 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 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 the Vertical Instruction Letter, receive any Purchased Receivables, Seller shall promptly, and in any event no later than [***] Business Days after such receipt, remit to Buyer such Purchased Receivables.

(ii) If Buyer shall receive any payment under the Sale Agreement or the 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 portion, if any, of such payment that does not constitute Purchased Receivables.

(b) Vertical Setoffs. If Vertical exercises a Vertical Setoff against the Purchased Receivables, then Seller 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 subsequent payment is included in the Excluded Assets. For all purposes hereunder, any true-up payment made pursuant to this Section 7.2(b) will be treated as paid with respect to the 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 Sale Agreement or Section 5.f of the Marketing Agreement) shall not be treated as a Vertical Setoff.

(c) Remittances. All remittances pursuant to this Section 7.2 shall be made (i) without setoff or 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 Escrow Agreement or to such other account as Seller or Buyer, as applicable, may designate in writing (such designation to be made at least [***] Business Days prior to any such payment), as the case may be.

(d) Payments Held In Trust. Each party hereto agrees that it shall hold any amounts received by it to which the other party is entitled under this Agreement in trust for the benefit of the other party and agrees that it shall have no right, title or interest whatsoever in such amounts.

Section 7.3 Vertical Reports; Notices; Correspondence.

(a) Promptly, and in 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 purposes of clarity, any written results of any audit delivered by Vertical to Seller pursuant to Section 2.18 of the 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 DoD relating to, or involving, the Sale Agreement or the Marketing Agreement, Seller shall furnish a true and correct copy of the same to Buyer.

(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 7.4 Audits of Vertical.

(a) Consultation. Seller and Buyer shall consult with each other regarding the timing, manner and conduct of (i) any audit of 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 and (ii) any dispute with respect to a Vertical Report.

(b) 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 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 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 Buyer (such consent not to be unreasonably withheld or delayed), execute or agree to execute any proposed Modification. Promptly, and in any event within [***] Business Days, following receipt by Seller of a fully executed Modification of the Sale Agreement or the Marketing Agreement, Seller shall furnish a true, correct, and complete copy of such Modification to Buyer.

Section 7.6 Enforcement of Sale Agreement and Marketing Agreement.

(a) Notice of Vertical Breaches. Promptly, and in any event within [***] Business Days after Seller becoming aware of a breach of, or an alleged breach of, the Sale Agreement or the Marketing Agreement by Vertical, or of the 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 Sale Agreement or the Marketing Agreement by Vertical or the right to terminate the 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 such breach or termination event to Buyer describing in 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 Sale Agreement or the Marketing Agreement as soon as practicable and in any event not less than [***] Business Days following such delivery.

(b) 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 recommend for such purpose (as long as such counsel is reasonably acceptable to Seller), and 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 filings, notices and written communications relating thereto.

(c) 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 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 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 on or prior to the 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 undisputed amount of Pre/At Stepdown Date Enforcement Costs set forth in 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 any late fee in respect thereof calculated in accordance with Section 2.5, and cause the Escrow Agent to distribute such amount to Seller.

(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 ("Post Stepdown Date Enforcement Costs") shall be borne [***]%. Following the Stepdown Date, Seller or Buyer, as applicable (the "Notifying Party") shall provide written notice to 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 2.5, and cause the Escrow Agent to distribute such amount to the Notifying Party.

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). If a 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, any portion of the Pre/At Stepdown Date Enforcement Costs or Post Stepdown Date Enforcement Costs to which the 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 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 the right to submit such dispute to a court of competent jurisdiction in accordance with the provisions of Section 10.11.

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 7.7 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.

2. During the preceding four calendar quarters ending on the last day of the calendar quarter in which the Change of Control occurs (i.e., the four calendar quarters commencing April 1, 2024 and 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 calendar quarter in which the Change of Control occurs (i.e., the 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 date that Vertical provides the DoD Payment Report (as defined in 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 determination, April 30, 2026, is the date that the Change of Control Adjustment is deemed to have occurred.

4. Stepdown Date occurred September 30, 2025.

5. Affected Receivables. Following the Stepdown Date (September 30, 2025) and prior to the time of the 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 Sale Agreement and Section 5.a of the Marketing Agreement (and so each of Buyer and Seller received [***]% of the total $[***] of Affected Receivables for the period following September 30, 2025 and prior to April 30, 2026, in accordance with 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 $[***] (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).

6. Reconciliation from Next Payment: For 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 simplicity) payments under Section 2.13 of the Sale Agreement and Section 5.a of the Marketing Agreement. Giving effect to the Change of Control Adjustment for this quarter, the $[***] is allocated [***]% to Buyer ($[***]) 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 Obligation of Parties to Indemnify.

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

(i) any breach of any representation or warranty made by Seller in 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 on behalf of Seller under 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 damages sought or estimated, to the extent actually known or reasonably capable of estimation by the Indemnified Party); 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. 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 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 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, 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 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 in part or delivers a timely Claim Notice Response that disputes its liability to the Indemnified Party with respect to the 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 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 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 expiration of the applicable survival period set forth in the preceding sentence.

Section 8.6 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) 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 Exclusive Remedy. Except in the case of (a) breaches or threatened breaches of Section 6.1, (b) the parties' rights to recoupment under Section 7.4(b)(iv) and Section 7.6(c) and (c) Section 10.14 (including for the avoidance of doubt, for purposes of Section 6.1), the parties hereto acknowledge and agree that, from and after the Closing, the indemnification afforded by this Article VIII shall be the sole and exclusive remedy for any and all Losses awarded against or incurred or suffered by a party in connection with the transactions set forth in the Transaction Documents, including with respect to any breach of any representation or warranty made by a party in any of 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 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 of the Transaction Documents (except as aforesaid) and whether in contract, tort or 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 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 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 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 the Closing Date 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 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 6.6 (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 breach of this Agreement that occurs prior to termination.

(b) Upon the termination of this Agreement pursuant to Section 9.1(b), this Agreement shall 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 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 not relieve either party from liability for any breach of this Agreement that occurs prior to termination.

ARTICLE 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 shall be in writing and shall be sent by email with PDF attachment, courier or personal delivery to the following addresses, or to such other addresses as shall be designated from time to time by a party hereto in accordance with this Section 10.2.

If to:	Address:
Seller	Talphera, Inc. 1850 Gateway Dr. #175 San Mateo, CA 94404 *Attention*: [***] Email: [***]
with a copy to:	Cooley LLP 10265 Science Center Drive San Diego, CA 92121 *Attention*: Matthew Browne Email: mbrowne@cooley.com
Buyer	XOMA (US) LLC 2200 Powell Street Suite 310 Emeryville, CA 94608 *Attention*: [***] Email: [***]
with a copy to:	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

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 No Personal Liability. It is expressly understood and agreed by Seller and Buyer that:

(a) each of the representations, warranties, covenants and agreements in the Transaction Documents made on the part of 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 or in connection with the 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 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 term sheet, to the extent such deposit was actually paid.

Section 10.5 Assignment. The provisions of this Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns. Seller shall not be entitled to assign any of its obligations and rights under this Agreement to 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 or further exercise thereof or the exercise of any other right, power or remedy. No course of dealing between the parties hereto shall be effective to amend, modify, supplement or waive any provision of this Agreement.

Section 10.7 Entire Agreement. This Agreement, including the Exhibits and Schedules attached to this Agreement, sets forth the entire agreement and understanding between the parties hereto as to the subject matter hereof. All express or implied agreements, promises, assurances, arrangements, representations, warranties and understandings as to the subject matter hereof, whether oral or written, heretofore made are superseded by this Agreement.

Section 10.8 Independent Contractors. The parties hereto recognize and agree that the relationship between Seller and Buyer 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 the other party hereto or any of its Affiliates. Nothing contained in this Agreement or in any other Transaction Document shall be deemed for any purpose (including tax purposes) to 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 No Third Party Beneficiaries. Except to the extent otherwise contemplated by Section 10.3, this Agreement is for the sole benefit of Seller and Buyer and their respective permitted successors and assigns, and nothing herein expressed or implied shall give or be construed to give to any Person, other than the 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 hereto irrevocably submits to the exclusive jurisdiction of (a) state courts of the State of California sitting in the City of San Francisco and (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 commence any action, suit or other proceeding arising out of, relating to or in connection with this Agreement or any transaction contemplated hereby in the 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 further agrees that service of any process, summons, notice or document by courier or personal delivery in accordance with Section 10.2 shall be effective 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 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 State of California sitting in the City of San Francisco or (ii) the United States District Court for the Northern District of California, and hereby further irrevocably and unconditionally waives, and shall not 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 the jurisdiction of the 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 such action, suit or other proceeding is improper, or that this Agreement or the transactions contemplated hereby may not be enforced in or by any of the 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 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. Each of the parties hereto acknowledges that the other party hereto may 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 any of the provisions of this Agreement (including, for clarity, Section 6.1) are not performed in accordance with its specific terms or 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 seek an injunction or injunctions to prevent breaches or violations of the 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 it may be entitled, at law or in equity. Each party further agrees that, in the event of any action for specific performance in respect of such breach or violation (including, in the case of Section 6.1, threatened breach), it will not assert, and irrevocably waives the defense that a bond or other security 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 breaches to which it relates but shall be in addition to all other rights and remedies available at law or equity to Seller or Buyer (as applicable).

[*Signature Page Follows*]

In Witness Whereof, the parties hereto have caused this Agreement to be executed by their respective representatives thereunto duly authorized as of the date first above written.

SELLER:

TALPHERA, INC.

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

BUYER:

XOMA (US) LLC

By: /s/ Bradley Sitko
Name: Bradley Sitko
Title: Chief Investment Officer

FORM OF BILL OF SALE

[***]

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 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 subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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

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

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

Date: May 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 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 subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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

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

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

Date: May 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 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 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 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 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.