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

FORM 10-Q

(Mark one)

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

For the quarterly period ended March 31, 2024

☐ **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: 001-38241

OPTINOSE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**42-1771610**
(State of other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

1020 Stony Hill Road, Suite 300
Yardley, Pennsylvania 19067
(Address of principal executive offices, including zip code)

(267) 364-3500
(Registrant's telephone number including area code)

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, par value $0.001 per share	OPTN	Nasdaq Global Select 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 Rule 12b-2 of the Act).Yes ☐ No ☒

The number of shares of the registrant's common stock outstanding at May 1, 2024 was 113,038,726 shares.

Unless the context otherwise requires, all references in this Form 10-Q to "Optinose," "Company," "we," "us," and "our" refer to OptiNose, Inc. and its subsidiaries.

Trademark Notice

OPTINOSE®, XHANCE®, EDS® and EXHALATION DELIVERY SYSTEM™ are trademarks of ours in the United States. All other trademarks, trade names and service marks appearing in this Form 10-Q are the property of their respective owners. We do not intend our use or display of other companies' trademarks, trade names or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 10-Q contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, among others, statements relating to:

- the potential uses for and advantages of XHANCE®, the Exhalation Delivery System™ (also referred to as, the EDS®) and related technologies;
- the potential benefits of the recent FDA approval of XHANCE for the treatment of chronic rhinosinusitis without nasal polyps;
- our commercial plans and expectations for XHANCE;
- the potential to expand promotion of XHANCE into the primary care segment and our plans to seek a partner for such expansion;
- our belief that the current practice of postoperative intranasal steroid (INS) use could support XHANCE’s adoption as a maintenance therapy to improve outcomes following sinus surgery;
- the potential for XHANCE to be the standard of care for the treatment of chronic rhinosinusitis with and without nasal polyps;
- the potential for direct-to-consumer (DTC) advertising to be a future driver of XHANCE prescription growth;
- the potential benefits of our patient affordability programs (including recent changes we made to the XHANCE co-pay assistance program) and their potential effect on XHANCE demand and financial results;
- our expectation for XHANCE prescriptions to be impacted by the seasonality observed in the INS market and the seasonal variation in patient visits with their doctor;
- our expectation for XHANCE prescriptions and average net revenue per prescription to be adversely impacted by the annual resetting of patient healthcare insurance plan deductibles and changes in individual patients' healthcare insurance coverage, both of which often occur in January;
- our expectation that research and development expenses in 2024 will be less than 2023;
- our expectations relating to the impact on average net product revenues per prescription resulting from changes we made to the XHANCE co-pay support program and disruptions that occurred at Change Healthcare, the claims processor for our vendor that administers the XHANCE co-pay support program;
- XHANCE prescription, net revenue, prescriber and other business trends;
- the potential for payor utilization management criteria to negatively impact XHANCE prescription volumes;
- the rate and degree of market acceptance and market opportunity of XHANCE;
- our expectation that our operating expenses (consisting of selling, general & administrative expenses and research & development expenses) in 2024 will be between $95.0 million and $101.0 million and that our non-cash stock-based compensation expense will be approximately $6.0 million;
- our expectation that XHANCE net product revenues for the full year of 2024 will be between $85.0 million and $95.0 million
- our expectation that the average net product revenue per prescription for XHANCE for the full year of 2024 will exceed $230
- our expectation that the net proceeds from the registered direct offering completed on May 10, 2024 will be approximately $55 million;
- our belief that our existing cash and cash equivalents plus the net proceeds from the May 2024 registered direct offering will be sufficient to fund our operations and debt service obligations through 2025;

- our expectations and the accuracy of our estimates regarding our future expenses, revenue, capital requirements, potential sources of capital and consequences of failing to obtain additional capital;

as well as other statements relating to our future operations, financial performance and financial condition, prospects, strategies, objectives or other future events. Forward-looking statements appear primarily in the sections of this Form 10-Q entitled “Item 1. Financial Statements,” and “Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.” In some cases, you can identify forward-looking statements by words such as “may,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” "target," “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “ongoing,” “scheduled” and similar expressions, although not all forward-looking statements contain these identifying words.

Forward-looking statements are based upon our current expectations and assumptions and are subject to a number of known and unknown risks, uncertainties and other factors that could cause actual results to differ materially and adversely from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this Form 10-Q and in our annual report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission (SEC), and in particular, the risks and uncertainties discussed therein under the caption “Risk Factors”. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. As a result, you should not place undue reliance on forward-looking statements.

Additionally, the forward-looking statements contained in this Form 10-Q represent our views only as of the date of this Form 10-Q (or any earlier date indicated in such statement). While we may update certain forward-looking statements from time to time, we specifically disclaim any obligation to do so, even if new information becomes available in the future. However, you are advised to consult any further disclosures we make on related subjects in the reports that we file with the SEC.

The foregoing cautionary statements are intended to qualify all forward-looking statements wherever they may appear in this Form 10-Q. For all forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

MARKET, INDUSTRY AND OTHER DATA

This Form 10-Q contains estimates, projections, market research and other information concerning our industry, our business, markets for XHANCE and the size of those markets, the prevalence of certain medical conditions, XHANCE market access, prescription data and other physician, patient and payor data. Unless otherwise expressly stated, we obtain this information from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources as well as from our own internal estimates and research and from publications, research, surveys and studies conducted by third parties on our behalf. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are reflected in this information. As a result, you are cautioned not to give undue weight to such information.

PART I

ITEM 1. FINANCIAL STATEMENTS

OptiNose, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	March 31, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 51,644	$ 73,684
Accounts receivable, net	14,227	19,926
Inventory	10,315	8,052
Prepaid expenses and other current assets	4,936	3,671
Total current assets	81,122	105,333
Property and equipment, net	754	815
Other assets	1,831	1,581
Total assets	$ 83,707	$ 107,729
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 1,912	$ 3,886
Accrued expenses and other current liabilities	30,793	42,411
Short term debt, net	—	130,227
Total current liabilities	32,705	176,524
Long term debt, net	130,653	—
Warrant liability	18,500	17,200
Other liabilities	1,065	611
Total liabilities	182,923	194,335
Stockholders' deficit		
Preferred stock, no par value; 5,000,000 shares authorized; no shares issued in 2024 or 2023	—	—
Common stock, $0.001 par value; 350,000,000 shares authorized; 113,038,726 and 112,399,495 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively.	113	112
Additional paid-in capital	635,198	633,742
Accumulated deficit	(734,443)	(720,376)
Accumulated other comprehensive loss	(84)	(84)
Total stockholders' deficit	(99,216)	(86,606)
Total liabilities and stockholders' deficit	$ 83,707	$ 107,729

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See accompanying notes to unaudited interim consolidated financial statements.

OptiNose, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Revenues:		
Net product revenues	$ 14,880	$ 11,846
Total revenues	14,880	11,846
Costs and expenses:		
Cost of product sales	1,231	1,706
Research and development	1,206	1,785
Selling, general and administrative	20,518	22,723
Total costs and expenses	22,955	26,214
Loss from operations	(8,075)	(14,368)
Other (income) expense:		
Unrealized loss on fair value of warrants	1,300	510
Interest income	(296)	(705)
Interest expense	4,970	4,672
Foreign currency loss	18	2
Net loss	$ (14,067)	$ (18,847)
Net loss per share of common stock, basic and diluted	$ (0.12)	$ (0.17)
Weighted average common shares outstanding, basic and diluted	112,594,852	111,774,425

See accompanying notes to unaudited interim consolidated financial statements.

OptiNose, Inc.
Consolidated Statements of Comprehensive Loss
(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Net loss	$ (14,067)	$ (18,847)
Other comprehensive income (loss):		
Foreign currency translation adjustment	—	—
Comprehensive loss	$ (14,067)	$ (18,847)

See accompanying notes to unaudited interim consolidated financial statements.

OptiNose, Inc.
Consolidated Statements of Changes in Stockholders' Deficit
(in thousands, except share data)
(unaudited)

Three months ended March 31, 2024

	Stockholders' Equity (Deficit)					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2023	112,399,495	$ 112	$ 633,742	$ (720,376)	$ (84)	$ (86,606)
Stock compensation expense	—	—	1,456	—	—	1,456
Vesting of restricted stock units	478,520	1	—	—	—	1
Issuance of common stock under employee stock purchase plan	160,711	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	—
Net loss	—	—	—	(14,067)		(14,067)
Balance at March 31, 2024	113,038,726	$ 113	$ 635,198	$ (734,443)	$ (84)	$ (99,216)

Three Months Ended March 31, 2023

	Stockholders' Equity (Deficit)					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2022	111,492,791	$ 111	$ 628,242	$ (684,893)	$ (84)	$ (56,624)
Stock compensation expense	—	—	1,520	—	—	1,520
Vesting of restricted stock units	343,406	1				1
Issuance of common stock under employee stock purchase plan	119,727	—	164	—	—	164
Foreign currency translation adjustment	—	—	—	—	—	—
Net loss	—	—	—	(18,847)	—	(18,847)
Balance at March 31, 2023	111,955,924	$ 112	$ 629,926	$ (703,740)	$ (84)	$ (73,786)

See accompanying notes to unaudited interim consolidated financial statements.

OptiNose, Inc.
Consolidated Statements of Cash Flows
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Operating activities:		
Net loss	$ (14,067)	$ (18,847)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	83	72
Stock-based compensation	1,456	1,523
Change in fair value of warrant liability	1,300	510
Amortization of debt discount and issuance costs	419	405
Changes in operating assets and liabilities:		
Accounts receivable	5,590	16,953
Prepaid expenses and other assets	(1,048)	874
Inventory	(2,263)	1,118
Accounts payable	(1,973)	953
Accrued expenses and other liabilities	(11,522)	(14,039)
Cash used in operating activities	(22,025)	(10,478)
Investing activities:		
Purchases of property and equipment	(22)	—
Cash used in investing activities	(22)	—
Financing activities:		
Proceeds from issuance of common stock under employee stock purchase plan	—	162
Cash paid for financing costs	7	—
Cash provided by financing activities	7	162
Net decrease in cash, cash equivalents and restricted cash	(22,040)	(10,316)
Cash, cash equivalents and restricted cash at beginning of period	73,684	94,244
Cash, cash equivalents and restricted cash at end of period	$ 51,644	$ 83,928
Supplemental disclosure of cash flow information:		
Cash paid for interest	9,218	4,255
Supplemental disclosure of noncash activities:		
Recognition of right-of-use assets and lease liabilities	$ 359	$ 37

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Notes to Unaudited Interim Consolidated Financial Statements
(in thousands, except share and per share data)

1. Organization and Description of Business

OptiNose, Inc. (the Company) was incorporated in Delaware in May 2010 (inception) and has facilities in Yardley, Pennsylvania and Ewing, New Jersey. The Company's predecessor entity, OptiNose AS, was formed under the laws of Norway in September 2000. In 2010, OptiNose AS became a wholly-owned subsidiary of the Company as part of an internal reorganization. Optinose AS was liquidated in October 2023. During 2022, the Company's board of directors also approved the liquidation of Optinose UK, which is expected to be completed in 2024, in order to simplify the corporate structure.

The Company is a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat (ENT) and allergy specialists. The Company's first commercial product, XHANCE® (fluticasone propionate) nasal spray, 93 microgram (mcg), is a therapeutic utilizing the Company's proprietary Exhalation Delivery System (EDS) that delivers a topically-acting corticosteroid for the treatment of chronic rhinosinusitis with and without nasal polyps.

2. Liquidity

Since inception, the Company's operations have focused on organization and staffing, business planning, raising capital, establishing an intellectual property portfolio, conducting preclinical studies and clinical trials, pursuing regulatory approvals and commercializing XHANCE in the US. As of March 31, 2024, the Company had cash and cash equivalents of $51,644 and working capital of $48,417.

On May 10, 2024, the Company completed a registered direct offering pursuant to which it issued an aggregate of 31,800,000 shares of common stock at a purchase price of $1.00 per share and, in lieu of shares of common stock to certain investors, pre-funded warrants to purchase an aggregate of 23,700,000 shares of common stock at a price of $0.999 per pre-funded warrant, which represents the per share offering price for common stock less the $0.0001 per share exercise price for each such pre-funded warrant. The aggregate net proceeds from the offering are expected to be approximately $55,000.

The Company’s continuation as a going concern is dependent on its ability to maintain compliance with the covenants under the A&R Note Purchase Agreement (Note 8) and its ability to generate sufficient cash flows from operations or other sources to meet its obligations as they come due. The Company follows the provisions of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 205-40, Presentation of Financial Statements—Going Concern, which requires management to assess the Company’s ability to continue as a going concern within one year after the date the financial statements are issued. At December 31, 2023, Management identified conditions and events that raised substantial doubt about the Company’s ability to continue as a going concern as management believed it was unlikely, without additional capital, that the Company would maintain compliance with certain covenants in the A&R Note Purchase Agreement in which case the lender could accelerate all amounts due under the agreement. As noted above, the Company completed a registered direct offering on May 10, 2024. The aggregate net proceeds from the offering are expected to be approximately $55,000. The Company believes that its cash and cash equivalents on hand as of March 31, 2024, along with the proceeds from the offering, will be sufficient to fund it operations and debt service obligations and maintain compliance with the liquidity covenant under the A&R Note Purchase Agreement for at least next twelve months from the issuance of these financial statements.

The Company will likely require additional capital in the future secured through equity or debt financings, partnerships, collaborations, or other sources in order to meet its debt service obligations, including repayment, under the Company's outstanding senior secured notes, and to carry out the Company's planned development and commercial activities. The terms of the outstanding senior secured notes, including applicable covenants, are described in Note 8. If additional capital is not obtained when required, the Company may need to delay or curtail its operations until additional funding is received.

The Company is subject to a number of risks similar to other life sciences companies, including, but not limited to, successful discovery, development and commercialization of its products and product candidates, raising additional capital, the development by its competitors of new technological innovations, protection of proprietary technology and market acceptance of the Company's products.

3. Basis of Presentation and Summary of Significant Accounting Policies

The accompanying unaudited interim consolidated financial statements have been prepared in conformity with US generally accepted accounting principles (GAAP). Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB).

In the opinion of management, the accompanying unaudited interim financial statements include all normal and recurring adjustments (which consist primarily of accruals and estimates that impact the financial statements) considered necessary to present fairly the Company's financial position as of March 31, 2024 and its results of operations for the three months ended March 31, 2024 and 2023 and cash flows for the three months ended March 31, 2024 and 2023. Operating results for the three months ended March 31, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024. The unaudited interim financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial statements. The accompanying unaudited interim financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2023 contained in the Company's annual report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 7, 2024.

Use of estimates

The preparation of the unaudited interim consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited interim consolidated financial statements and reported amounts of expenses during the reporting period. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the unaudited interim consolidated financial statements, actual results may materially vary from these estimates. Estimates and assumptions are periodically reviewed and the effects of revisions are reflected in the unaudited interim consolidated financial statements in the period they are determined to be necessary.

Concentration of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk are primarily cash and accounts receivable. The Company generally invests its cash in deposits with high credit quality financial institutions. Additionally, the Company performs periodic evaluations of the relative credit standing of these financial institutions.

Customer and supplier concentration

The Company has exposure to credit risk in accounts receivable from sales of product. XHANCE is sold to wholesale pharmaceutical distributors and preferred pharmacy network (PPN) partners, who, in turn, sell XHANCE to pharmacies, hospitals and other customers. Five customers represented approximately 86% and 58% of the Company's accounts receivable at March 31, 2024 and 2023, respectively. Five customers represented approximately 66% and 39% of the Company's net product sales for the three months ended March 31, 2024 and 2023, respectively.

The Company purchases XHANCE and its components from several third-party suppliers and manufacturing partners, certain of which are only available through a single source. Although the Company could obtain each of these components from alternative third-party suppliers, it would need to qualify and obtain FDA approval for another supplier as a source for each such component.

Fair value of financial instruments

The Company measures certain assets and liabilities at fair value, which is defined as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. The FASB accounting guidance outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value, the Company uses quoted prices and observable inputs. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources. The fair value hierarchy is broken down into three levels based on the source of the inputs as follows:

- Level 1 — Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2 — Valuations based on observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

At March 31, 2024 and December 31, 2023, the Company's financial instruments included cash and cash equivalents, accounts receivable, accounts payable, accrued expenses and certain liability classified warrants. The carrying amounts reported in the Company's financial statements for cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximates their respective fair values because of the short-term nature of these instruments. In addition, at March 31, 2024, the Company believed the carrying value of debt approximates fair value as the interest rates were reflective of the rate the Company could obtain on debt with similar terms and conditions. At March 31, 2024, there were no financial assets or liabilities measured at fair value on a recurring basis other than the liability classified warrants.

In November 2022, the Company issued warrants in connection with a public offering. Pursuant to the terms of the warrant agreement, the Company could be required to settle the warrants in cash in the event of an acquisition of the Company and, as a result, the warrants are required to be measured at fair value and reported as liability in the consolidated balance sheet. The Company recorded the fair value of the warrants upon issuance using a Monte Carlo simulation and is required to revalue the warrants at each reporting date with any changes in fair value recorded on our statement of operations. The valuation of the warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. The change in the fair value of the Level 3 warrants liabilities is reflected in the statement of operations for the three months ended March 31, 2024.

Net product revenues

The Company accounts for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* (ASC 606), which the Company adopted on January 1, 2018. The Company recognizes revenue from XHANCE sales at the point customers obtain control of the product, which generally occurs upon delivery. The transaction price that is recognized as revenue for products includes an estimate of variable consideration. The Company’s estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of its anticipated performance and all information (historical, current and forecasted) that is reasonably available. The components of the Company’s variable consideration include the following:

Provider Chargebacks and Discounts. Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified

healthcare providers. These components of variable consideration are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable.

Trade Discounts and Allowances. The Company generally provides customers with discounts that include incentive fees which are explicitly stated in the Company's contracts. These discounts are recorded as a reduction of revenue and accounts receivable in the period in which the related product revenue is recognized.

Product Returns. Consistent with industry practice, the Company has a product returns policy that provides customers a right of return for product purchased within a specified period prior to and subsequent to the product's expiration date. The Company estimates the amount of its product that may be returned and presents this amount as a reduction of revenue in the period the related product revenue is recognized, in addition to establishing a liability. The Company considers several factors in the estimation process, including expiration dates of product shipped to customers, inventory levels within the distribution channel, product shelf life, prescription trends and other relevant factors.

Government Rebates. The Company is subject to discount obligations under state Medicaid programs and Medicare. Reserves related to these discount obligations are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. The Company's liability for these rebates consists of estimates of claims for the current quarter and estimated future claims that will be made for product that has been recognized as revenue but remains in the distribution channel inventories at the end of the reporting period.

Payor Rebates. The Company contracts with certain third-party payors, primarily health insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. These rebates are based on contractual percentages applied to the amount of product prescribed to patients who are covered by the plan or the organization with which it contracts. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Patient Assistance. Other programs that the Company offers include voluntary co-pay patient assistance programs intended to provide financial assistance to eligible patients with prescription drug co-payments required by payors and coupon programs for cash payors. The calculation of the current liability for this assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period.

Distribution and Other Fees. The Company pays distribution and other fees to certain customers in connection with the sales of its products. The Company records distribution and other fees paid to its customers as a reduction of revenue, unless the payment is for a distinct good or service from the customer and the Company can reasonably estimate the fair value of the goods or services received. If both conditions are met, the Company records the consideration paid to the customer as an operating expense. These costs are typically known at the time of sale, resulting in minimal adjustments subsequent to the period of sale

Net income (loss) per common share

Basic net income (loss) per common share is determined by dividing net income (loss) applicable to common stockholders by the weighted average common shares outstanding during the period. For the three months ended March 31, 2024 and 2023, the outstanding common stock options, restricted stock units, common stock warrants and shares to be issued under the Company's 2017 Employee Stock Purchase Plan have been excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted net loss per share are the same.

(in thousands, except share and per share data)

Diluted net loss per common share for the periods presented do not reflect the following potential common shares, as the effect would be antidilutive:

	March 31,	
	2024	2023
Stock options	9,289,484	10,489,593
Restricted stock units	4,927,069	2,691,174
Common stock warrants	32,768,000	32,768,000
Total	46,984,553	45,948,767

Income taxes

In accordance with ASC 270, *Interim Reporting*, and ASC 740, *Income Taxes*, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three months ended March 31, 2024 and 2023, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. As of March 31, 2024 and December 31, 2023, the Company concluded that a full valuation allowance would be necessary for all of its net deferred tax assets. The Company had no amounts recorded for uncertain tax positions, interest or penalties in the accompanying consolidated financial statements.

Recent accounting pronouncements

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. FASB is issuing the amendments in this Update to enhance the transparency and decision usefulness of income tax disclosures. Investors, lenders, creditors, and other allocators of capital (collectively, “investors”) indicated that the existing income tax disclosures should be enhanced to provide information to better assess how an entity’s operations and related tax risks and tax planning and operational opportunities affect its tax rate and prospects for future cash flows. Investors currently rely on the rate reconciliation table and other disclosures, including total income taxes paid, to evaluate income tax risks and opportunities. While investors find these disclosures helpful, they suggested possible enhancements to better (1) understand an entity’s exposure to potential changes in jurisdictional tax legislation and the ensuing risks and opportunities, (2) assess income tax information that affects cash flow forecasts and capital allocation decisions, and (3) identify potential opportunities to increase future cash flows. The amendments in this Update address investor requests for more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. This Update also includes certain other amendments to improve the effectiveness of income tax disclosures. The new standard is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating ASU No. 2023-09 and its impact on results of operations, financial position and cash flows and related disclosures.

4. Fair Value Measurements

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The Company applies the guidance in ASC 820, *Fair Value Measurements*, to account for financial assets and liabilities measured on a recurring basis. Fair value is measured as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability.

The Company uses a fair value hierarchy, which distinguishes between assumptions based on market data (observable inputs) and an entity's own assumptions (unobservable inputs). The guidance requires that fair value measurements be classified and disclosed in one of the following 3 categories:

Level I: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices in markets that are not active or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level I, 2 and 3 during the three months ended March 31, 2024.

The table below presents the liabilities (in thousands) measured and recorded in the financial statements at fair value on a recurring basis at March 31, 2024 categorized by the level of inputs used in the valuation of each liability.

	March 31, 2024			
	Total	Level 1	Level 2	Level 3
Liabilities				
Warrant Liability	$ 18,500	$ —	$ —	$ 18,500
Total Liabilities	$ 18,500	$ —	$ —	$ 18,500

	December 31, 2023			
Liabilities				
Warrant Liability	$ 17,200	$ —	$ —	$ 17,200
Total Liabilities	$ 17,200	$ —	$ —	$ 17,200

Changes in Level 3 Liabilities Measured at Fair Value on a Recurring Basis

Warrant Liability

The reconciliation of the Company's warrant liability measured at fair value on a recurring basis using unobservable inputs (Level 3) is as follows (in thousands):

	Warrant Liability
Balance, December 31, 2023	$ 17,200
Warrants issued	—
Change in fair value of liability	1,300
Balance, March 31, 2024	$ 18,500

Assumptions Used in Determining Fair Value of Liability-Classified Warrants

The Company issued warrants to purchase 30,268,000 shares of Common Stock at a public offering price of $0.01 per warrant (the Warrants). Each Warrant has an exercise price of $2.565 per share of common stock and is exercisable until the expiration date, which is the fifth anniversary of the date of issuance (November 23, 2027). After such date, any unexercised Warrants will expire and have no further value. If the Company issues or sells, or is deemed pursuant to the terms of the Warrants to have issued or sold, any shares of common stock (which includes, among other things, options and securities convertible into shares of common stock), subject to certain exceptions and excluding certain issuances defined in the Warrants as "excluded issuances, for a price per share less than the exercise price of the Warrants in effect immediately prior to such issuance or sale or deemed issuance

(in thousands, except share and per share data)

or sale (such event, a dilutive issuance), then immediately after such dilutive issuance the exercise price then in effect of the Warrants shall be reduced to the price of the shares of common stock issued or sold or deemed to be issued or sold in the dilutive issuance in the manner set forth in the Warrant.

A holder of Warrants will not have the right to exercise any portion of a Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or on election of such holder, prior to the issuance of any Warrants, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants; provided, however, such holder may increase or decrease such percentage to any other percentage not in excess of 19.00%, provided that any increase in such percentage shall not be effective until 61 days after such notice is delivered to the Company.

Pursuant to the terms of the Warrant, the Company could be required to settle the Warrants in cash in the event of a "fundamental transaction" as defined in the Warrant (which includes, among other things, an acquisition of the Company) and, as a result, the Warrants are required to be measured at fair value and reported as liability in the consolidated balance sheet.

The Company utilizes a Monte Carlo simulation valuation model which incorporates assumptions as to the stock price volatility, the expected life of the warrants, a risk-free interest rate, as well as timing and probability of equity financing. The Company values the warrant liability at each reporting period, with changes in fair value recognized in the consolidated statements of operations. The estimated fair value of the warrant liability is determined using Level 3 inputs. The inputs and values were as follows:

	March 31, 2024	December 31, 2023
Stock price	$ 1.46	$ 1.29
Strike price	$ 2.57	$ 2.57
Expected volatility	55.0 %	60.0 %
Risk-free interest rate	4.2 %	3.9 %
Expected dividend yield	— %	— %
Expected life (years)	3.6	3.9
Fair value per warrant	$ 0.61	$ 0.57

On May 10, 2024, the Company completed a registered direct offering which resulted in the exercise price of the Warrants being reduced from $2.565 to $1.00 (which was the offering price of each share sold in the registered direct offering) pursuant to the anti-dilution price protection provisions of such Warrants. All other terms of the Warrants remain unchanged.

5. Inventory

Inventory consisted of the following:

	March 31, 2024	December 31, 2023
Raw materials	$ 2,580	$ 2,400
Work-in-process	4,966	3,281
Finished goods	2,769	2,371
Total inventory	$ 10,315	$ 8,052

Inventories are stated at the lower of cost or net realizable value, as determined on a first-in, first-out, basis.

(in thousands, except share and per share data)

6. Property and Equipment

Property and equipment, net, consisted of the following:

	March 31, 2024	December 31, 2023
Computer equipment and software	$ 1,465	$ 1,443
Furniture and fixtures	366	366
Machinery and equipment	3,146	3,146
Leasehold improvements	609	609
Construction in process	115	115
	5,701	5,679
Less: accumulated depreciation	(4,947)	(4,864)
	$ 754	$ 815

Depreciation expense was $83 and $72 for the three months ended March 31, 2024 and 2023, respectively.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of:

	March 31, 2024	December 31, 2023
Accrued expenses:		
Product revenue allowances	$ 16,751	$ 20,145
Selling, general and administrative expenses	4,868	6,229
Research and development expenses	334	644
Payroll expenses	5,280	6,801
Accrued interest	—	4,666
Other	2,835	3,015
Total accrued expenses	$ 30,068	$ 41,500
Other current liabilities:		
Lease liability	$ 725	$ 911
Total other current liabilities	725	911
Total accrued expenses and other current liabilities	$ 30,793	$ 42,411

8. Debt

On September 12, 2019 (the Closing Date), the Company entered into a Note Purchase Agreement with funds managed by Pharmakon Advisors, LP (Pharmakon), the investment manager of BioPharma Credit Funds (BioPharma). The Note Purchase Agreement provided the Company with $130,000 in debt financing, of which $80,000 of senior secured notes (the Pharmakon Senior Secured Notes) was issued on the Closing Date, $30,000 was issued on February 13, 2020 and $20,000 was issued on December 1, 2020.

On November 23, 2022, the Company amended and restated the Note Purchase Agreement, initially entered into on September 12, 2019 and amended through November 9, 2022, among the Company, its subsidiaries, OptiNose US, Inc., OptiNose AS and OptiNose UK, Ltd., and BioPharma Credit PLC, as collateral agent, and the purchasers party thereto from time to time (the A&R Note Purchase Agreement). Pursuant to the A&R Note Purchase Agreement, certain modifications to the affirmative and negative covenants, events of default and other provisions were made, including, without limitation, (i) the requirement for the Company to deliver quarterly and annual financial statements that, commencing with the Company's consolidated financial statements for the year ending December 31, 2023 and subject to certain exceptions, are not subject to a “going concern” statement (the Going Concern Covenant) and (ii) the removal of certain exceptions to the negative covenants which previously permitted the Company to enter into certain transactions without the consent of the holders of the Pharmakon Senior Secured Notes, including permitted acquisitions, swap contracts, convertible bonds and revolving credit facilities. The

financial covenants requiring the Company to achieve minimum trailing twelve-month consolidated XHANCE net product sales and royalties were amended to be pushed back to March 31, 2024.

The A&R Note Purchase Agreement extended the maturity date of the Pharmakon Senior Secured Notes from September 12, 2024 to June 30, 2027 (New Maturity Date), extended the interest-only period from September 2023 to September 2025, after which principal repayments will commence starting on September 30, 2025 and will be made in eight equal quarterly installments of principal and interest through the New Maturity Date. As part of the A&R Note Purchase Agreement the Pharmakon Senior Secured Notes now bear an amended interest rate through the New Maturity Date equal to the 3-month Secured Overnight Financing Rate (subject to a 2.50% floor), determined as of the date that is two business days prior to the commencement of each quarter, plus 8.50% per annum, which interest rate shall be increased by an additional 3.00% per annum upon the occurrence and during the continuation of any event of default. The effective interest rate as of March 31, 2024 is 14.80%.

As an inducement for the holders of the Pharmakon Senior Secured Notes to enter into the A&R Note Purchase Agreement, the Company was required to pay the holders of the Pharmakon Senior Secured Notes an amendment fee of $3,900 (representing 3.00% of the then outstanding principal balance of such notes) due on the New Maturity Date or the earlier repayment of the Pharmakon Senior Secured Notes, which amendment fee shall reduced to $2,600 in the event that the Company repays the Pharmakon Senior Secured Notes in full on or after the one-year anniversary of the date of the A&R Note Purchase Agreement and prior to second anniversary of the date of the A&R Note Purchase Agreement. Additionally, the $1,300 fee payable under the Fourth Amendment to the Note Purchase Agreement that the Company entered into on November 9, 2022 will be credited against the amendment fee payable in connection with the A&R Note Purchase Agreement.

On March 5, 2024, the Company entered into a first amendment and waiver (the First Amendment) to the A&R note Purchase Agreement. The First Amendment provided for a waiver of Going Concern Covenant for the audited financial statements for the year ended December 31, 2023 and unaudited quarterly financial statements for the quarter ending March 31, 2024.

On March 8, 2024, the Company entered into a second amendment (the Second Amendment) to the A&R Note Purchase Agreement. Pursuant to the Second Amendment, the financial covenants requiring the Company to achieve minimum trailing twelve-month consolidated XHANCE net product sales and royalties was modified as follows (amounts in thousands):

Trailing Twelve-Months Ending	As Revised Pursuant to Second Amendment
March 31, 2024	$70,000
June 30, 2024	$70,000
September 30, 2024	$72,500
December 31, 2024	$75,000
March 31, 2025	$80,000
June 30, 2025	$87,500
September 30, 2025	$95,000
December 31, 2025	$105,500
March 31, 2026	$120,000
June 30, 2026	$130,000
September 30, 2026	$145,000
December 31, 2026	$150,000
March 31, 2027	$155,000
June 30, 2027	$160,000

In addition, the "make-whole" premium payment due in connection with any principal prepayments (whether mandatory or voluntary) was modified as part of the Second Amendment to provide that the Company will be required to pay a make-whole premium in the amount of (i) for any prepayment occurring up to and including November 21, 2024 (which represents the 24th-month anniversary of the effective date of the A&R Note Purchase Agreement), the sum of all interest that would have accrued on the principal amount of the notes prepaid or required to be prepaid from the date of such prepayment through and including the 18th-month anniversary of such prepayment date; and (b) for any prepayment occurring after November 21, 2024 (which represents the 24th-month anniversary of the effective date of the A&R Note Purchase Agreement) but prior to May 21, 2026 (which represents the 42nd-month anniversary of the effective date of the A&R Note Purchase Agreement), the sum of all interest that would have accrued on the principal amount of the notes prepaid or required to be prepaid from the date of such prepayment through and including May 21, 2026 (which represents the 42nd-month anniversary of the effective date of the A&R Note Purchase Agreement); provided, however, that in no event shall all make-whole amounts payable by the Company exceed $24,000 in the aggregate.

On May 8, 2024, the Company entered into a third amendment (the Third Amendment) to the A&R Note Purchase Agreement. The Third Amendment provided for a further waiver of the Going Concern Covenant for the Company's quarterly and annual financial statements through the fiscal quarter ending September 30, 2025. The Going Concern Covenant will continue to apply to the Company's financial statements for the fiscal year ending December 31, 2025 and each fiscal quarter and fiscal year thereafter. In addition, pursuant to the Third Amendment the minimum amount of cash and cash equivalents that the Company is required to maintain at all times under the A&R Note Purchase Agreement (the Liquidity Covenant) will be reduced from $30,000 to $20,000 following the date of the first quarterly payment of principal due on September 30, 2025.

As part of the Third Amendment, the Company issued an aggregate of 4,680,000 shares of common stock to the holders of the Pharmakon Senior Secured Notes in satisfaction of $4,680 of outstanding amendment and waiver fees owed under the A&R Note Purchase Agreement for prior amendments and waivers, which shares were calculated based on the offering price of each share of common stock sold in the registered direct offering completed on May 10, 2024. Additionally, the common stock warrants, dated November 18, 2021, issued to the holders of the Pharmakon Senior Secured Notes for the purchase of an aggregate of 2,500,000 shares of Company common stock (the Pharmakon Warrants) were amended to (i) reduce the exercise price of the Pharmakon Warrants from $1.60 per share to $1.00, which is the offering price of each share of common stock sold in the registered direct offering completed by the Company on May 10, 2024, and (ii) extend the expiration date of the Pharmakon Warrants from November 18, 2024 to November 18, 2026.

The Pharmakon Senior Secured Notes are secured by a pledge of substantially all of the assets of the Company and the Guarantors and the A&R Note Purchase Agreement contains affirmative and negative covenants customary for financings of this type, including limitations on the Company's and its subsidiaries' ability, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, repay junior indebtedness, incur a material adverse change and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the A&R Note Purchase Agreement contains financial covenants requiring the Company to maintain certain minimum trailing twelve-month consolidated XHANCE net sales and royalties, tested on a quarterly basis, and to maintain compliance with the Liquidity Covenant. As of March 31, 2024, the Company was in compliance with the covenants. The A&R Note Purchase Agreement also includes events of default customary for financings of this type, in certain cases subject to customary periods to cure, following which the holders of the Pharmakon Senior Secured Notes may accelerate all amounts outstanding under such notes.

The Company recorded interest expense of $4,970 and $4,672 during the three months ended March 31, 2024 and 2023, respectively. Interest expense included total coupon interest and the amortization of debt issuance costs.

(in thousands, except share and per share data)

The Pharmakon debt balance is comprised of the following:

	March 31, 2024	December 31, 2023
Face amount	$ 130,000	$ 130,000
Front end fees	(479)	(518)
Debt issuance costs	(4,848)	(5,235)
Back end fees	5,980	5,980
Debt, net	$ 130,653	$ 130,227

The Company classified the Pharmakon debt as a current liability at December 31, 2023 as it believed that, without additional capital, it was unlikely to comply with certain covenants in the A&R Note Purchase Agreement. The Pharmakon debt has been classified as long-term at March 31, 2024 as principal payments do not commence until the third quarter of 2025 and with the additional capital received from the May 10, 2024 registered direct offering (Note 2), the Company now expects to be in compliance with the Pharmakon debt covenants for at least the next 12 months.

9. Commitments and Contingencies

The Company has a manufacturing agreement (the Hikma Agreement) for the purchase of product with Hikma Pharmaceuticals USA Inc. (Hikma) which expires on December 31, 2026. Either the Company or Hikma may terminate the Hikma Agreement for uncured material breach by or insolvency of the other party. Additionally, the Company may terminate the Hikma Agreement if, among other things, any intellectual property of any third party is reasonably alleged by a third party to be infringed, misappropriated or otherwise violated by the manufacture, import, use, sale or distribution of XHANCE or if any regulatory authority requires the Company to cease production of the sale of XHANCE. As part of the Hikma Agreement, the Company has agreed to make minimum purchases of product of $1,688 in 2024, and $2,251 million in both 2025 and 2026. If the Company fails to achieve the minimum purchase commitments, the Company must pay Hikma 50% of the amount of any shortfall and must reimburse Hikma for certain non-cancellable costs and expenses. The Company's minimum purchase commitments are subject to certain exceptions and reductions. The Company has made $428 in purchases during the three months ended March 31, 2024 under the Hikma Agreement.

10. Employee Benefit Plans

For US employees, the Company maintains a defined contribution 401(k) retirement plan. As of March 31, 2024 and 2023, $183 and $61 respectively, were recorded in accrued liabilities related to the Company match. The Company's contributions are made in cash.

The Company also maintains a severance benefit plan for employees that is governed by the Employee Retirement Income Security Act of 1974. The severance benefit plan provides severance benefits to eligible employees who are involuntarily terminated from their jobs for reasons other than cause, disability, or death.

11. Stockholders' Equity

As of March 31, 2024, the Company had the following warrants outstanding to purchase shares of Common Stock:

Number of warrants	Classification	Exercise Price Per Share	Expiration Date
2,500,000	Equity	$1.60	November 18, 2024
30,268,000	Liability	$2.565	November 23, 2027

(in thousands, except share and per share data)

On May 10, 2024, the Company completed a registered direct offering pursuant to which it issued an aggregate of 31,800,000 shares of common stock at a purchase price of $1.00 per share and, in lieu of shares of common stock to certain investors, pre-funded warrants to purchase an aggregate of 23,700,000 shares of common stock at a price of $0.999 per pre-funded warrant, which represents the per share offering price for common stock less the $0.0001 per share exercise price for each such pre-funded warrant.

Upon the completion of the registered direct offering on May 10, 2024, the exercise price of the the 30,268,000 liability classified warrants was reduced from $2.565 to $1.00 (which was the offering price of each share sold in the registered direct offering) pursuant to the anti-dilution price protection provisions of such warrants. All other terms of the liability classified warrants remained unchanged.

Additionally, on May 10, 2024, pursuant to the Third Amendment to the A&R Note Purchase Agreement, the 2,500,000 equity classified common stock warrants listed above were amended to reduce the exercise price from $1.60 per share to $1.00 per share, and to extend the expiration date from November 18, 2024 to November 18. 2026.

12. Stock-based Compensation

The Company recorded total stock-based compensation expense related to stock options, restricted stock units and it's employee stock purchase plan awarded under the Company's 2010 Stock Incentive Plan, as amended and restated effective as of October 12, 20217 (the 2010 Plan), 2017 Employee Stock Purchase Plan (2017 Plan) and grants made pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4) in the following expense categories in the accompanying consolidated statements of operations as follows:

	Three Months Ended March 31,	
	2024	2023
Cost of product sales	$ 17	$ 6
Research and development	57	155
General and administrative	1,382	1,361
	$ 1,456	$ 1,522

Stock Options

The Company issues stock-based awards pursuant to the 2010 Plan. The Company has issued service-based, performance-based, and market-based stock options that generally have a contractual life of up to 10 years and may be exercisable in cash or as otherwise determined by the Company's board of directors or committee thereof. Vesting generally occurs over a period of not greater than four years. Performance-based options may vest upon the achievement of certain milestones. As of March 31, 2024, all of the performance conditions related to performance-based stock options issued by the Company had been achieved. Market-based options may vest upon the achievement of certain market-based objectives relating to the trading price of the Company's common stock.

OptiNose, Inc.
Notes to Unaudited Interim Consolidated Financial Statements
(in thousands, except share and per share data)

The following table summarizes the activity related to stock option grants to employees and non-employees for the three months ended March 31, 2024:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Outstanding at December 31, 2023	8,527,626	$ 5.03	6.55
Granted	1,139,601	1.81	
Exercised	—	—	
Expired	(20,838)	2.27	
Forfeited	(351,905)	4.93	
Outstanding at March31, 2024	9,294,484	$ 4.64	7.02
Exercisable at March 31, 2024	4,781,043	$ 7.34	5.34

During the three months ended March 31, 2024, service-based stock options to purchase 1,139,601 shares of common stock were granted to employees and generally vest over four years. The stock options had an estimated weighted average grant date fair value of $1.24. The grant date fair value of each service-based and performance-based option grant was estimated at the time of grant using the Black-Scholes option-pricing model. The grant date fair value of each market-based stock option grant was estimated at the time of grant using a Monte Carlo simulation.

The aggregate intrinsic value of stock options outstanding and stock options exercisable, other than market-based stock options, as of March 31, 2024 was $193 and $10, respectively. At March 31, 2024, the unrecognized compensation cost related to unvested stock options, other than market-based stock options, expected to vest was $4,370. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.91 years.

Included in the table above are 569,345 market-based options outstanding granted in 2022. These options generally become eligible to vest over four years, subject to the achievement of certain market-based objectives relating to the trading price of the common stock. Stock-based compensation for these awards is recognized over the derived service period of approximately 2 years. The grant date fair value of each stock option grant, as well as the derived service period for these awards, was estimated at the time of grant using a Monte Carlo simulation. During the three months ended March 31, 2024, no market-based options vested upon the achievement of certain market-based objectives relating to the trading price of the Company's common stock.

Included in the table above are 711,500 options outstanding granted outside the 2010 Plan. The grants were made pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4).

The Company calculated the fair value of the stock option grants using the following weighted average assumptions:

	Three Months Ended March 31,	
	2024	2023
Risk free interest rate	4.30 %	4.02 %
Expected term (in years)	6.08	6.08
Expected volatility	74.13 %	75.28 %
Annual dividend yield	0.00 %	0.00 %

(in thousands, except share and per share data)

Restricted Stock Units

The Company has issued service-based and performance-based restricted stock units (RSUs). Vesting generally occurs over a period not greater than four years. Vesting of the performance-based RSUs is subject to the achievement of certain milestones in connection with the Company's development programs.

The following table summarizes the activity related to RSUs granted to employees for the three months ended March 31, 2024:

	Shares
Balance at December 31, 2023	1,897,421
Granted	3,574,200
Vested and settled	(478,520)
Expired/forfeited/canceled	(66,032)
Balance at March 31, 2024	4,927,069
Expected to vest at March 31, 2024	4,927,069

During the three months ended March 31, 2024, the Company granted 3,574,200 RSUs at a weighted-average grant date fair value of $1.82, all of which were service-based RSUs. No performance-based RSUs were granted in the three months ended March 31, 2024. As of December 31, 2023, the milestone associated with the previously granted performance based-RSUs was achieved. At March 31, 2024, the unrecognized compensation cost related to unvested service-based RSUs expected to vest was $8,760, to be recognized over an estimated weighted-average amortization period of 3.09 years. The unrecognized compensation cost related to unvested performance-based RSUs was $80, which will be recognized over the remaining service period.

Included in the table above are 60,000 RSUs granted outside the 2010 Plan. The grants were made pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4).

2017 Employee Stock Purchase Plan

Under the 2017 Plan, shares of Common Stock may be purchased by eligible employees who elect to participate in the 2017 Plan at 85% of the lower of the fair market value of Common Stock on the first or last day of designated offering periods. During the three months ended March 31, 2024, the Company issued 160,711 shares of Common Stock to employees.

The Company calculated the fair value of each grant under the 2017 Employee Stock Purchase Plan using the following weighted average assumptions:

	Three Months Ended March 31,	
	2024	2023
Risk free interest rate	0.05 %	0.05 %
Expected term (in years)	0.5	0.5
Expected volatility	65.06 %	71.43 %
Annual dividend yield	— %	— %

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read this section in conjunction with our unaudited interim consolidated financial statements and related notes included in Part I. Item 1 of this Form 10-Q and our audited consolidated financial statements and related notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission (SEC) on March 7, 2024. In addition to historical information, some of the information contained in this discussion and analysis includes forward-looking statements that involve risks and uncertainties. As a result of many factors, our actual results could differ materially from the results described in or implied by such forward-looking statements. Please refer to the "Cautionary Note Regarding Forward-Looking Statements" section of this Form 10-Q for additional information.

Company Overview

We are a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat (ENT) and allergy specialists. Our first commercial product, XHANCE® (fluticasone propionate) nasal spray, 93 micrograms (mcg), is a therapeutic utilizing our proprietary Exhalation Delivery System™ (EDS®) that delivers a topically-acting corticosteroid for the treatment of chronic rhinosinusitis with and without nasal polyps. Chronic rhinosinusitis is a serious nasal inflammatory disease that is treated using therapies, such as intranasal steroids (INS), which have significant limitations. We believe XHANCE has a differentiated clinical profile with the potential to become part of the standard of care for this disease because it is able to deliver medication to the primary site of inflammation high and deep in the nasal passages in regions not adequately reached by conventional INS. Additionally, we believe the current practice of postoperative INS use could support XHANCE's adoption as a maintenance therapy to improve outcomes following sinus surgery.

XHANCE was approved by the United States (US) Food and Drug Administration (FDA) in September 2017 for the treatment of nasal polyps in patients 18 years of age or older (which indication statement was subsequently changed to "chronic rhinosinusitis with nasal polyps" in patients 18 years of age or older to reflect new FDA labeling terminology and not based on new XHANCE clinical trial data). We made XHANCE widely available through commercial channels in April 2018. On March 15, 2024, the FDA approved XHANCE for the treatment of chronic rhinosinusitis without nasal polyps in patients 18 years of age and older. XHANCE is the first and only drug therapy approved by the FDA for the treatment of chronic rhinosinusitis without nasal polyps.

We are relaunching XHANCE to focus on the comparatively larger market opportunity that we believe is created by the new indication. We plan to continue to focus our commercial efforts primarily to the ENT and allergy specialist audience while seeking partnerships to extend the commercialization of XHANCE into primary care. We realigned our 75 sales territories at the start of 2024 in order to optimize the chronic sinusitis prescribing potential within the called on specialist audience. As a result of the realignment, approximately 40% of targets in the called on specialist audience are new to our territory managers. We completed training with our territory managers on new promotional materials during a national sales meeting the week of April 8, 2024 and deployed those to the field starting the week of April 15, 2024.

In accordance with the Pediatric Research Equity Act, and as part of its approval of XHANCE for the treatment of chronic rhinosinusitis without nasal polyps in patients 18 years of age and older, the FDA required that we conduct a randomized, double-blind, placebo controlled, parallel group clinical study in children and adolescents 12 to 17 years of age with chronic rhinosinusitis without nasal polyps to assess the safety, efficacy, and pharmacokinetics of XHANCE using a Bayesian borrowing approach to evaluate efficacy in this population. We submitted our draft protocol to the FDA with respect to the pediatric study in March 2024 as required, and we are required to complete the study by March 2028 and submit a final report with respect to the study by October 2028.

The medical community and payers generally use the terms "chronic sinusitis" and "chronic rhinosinusitis" interchangeably. FDA uses the term "chronic rhinosinusitis" and recognizes two distinct indications "chronic rhinosinusitis with nasal polyps" and "chronic rhinosinusitis without nasal polyps". It is our view that variations in terminology are synonymous from a promotional perspective. In this Quarterly Report on Form 10-Q, we generally use the terms "chronic sinusitis" and "chronic rhinosinusitis without nasal polyps" as being synonymous.

XHANCE Business Update

We track and report metrics that we believe are an important part of assessing our progress in key strategic areas including:

- XHANCE Net Product Revenues per Prescription. We calculate average net product revenues per prescription, one metric that we use to gauge the profitability of XHANCE, by dividing net product revenues for the quarter by the estimated number of XHANCE prescriptions dispensed during the quarter. Average XHANCE net product revenues per prescription were $227 in the first quarter of 2024 which represents a 63% increase when compared to the $139 average XHANCE net product revenues per prescription in the first quarter of 2023. The increase in average net product revenues per prescription is primarily the result of changes we made to our co-pay saving program intended to reduce the number of prescriptions filled by patients in commercial insurance plans that either do not cover XHANCE or are in commercial insurance plans that have high deductibles. In addition, we believe the disruption in services at Change Healthcare, the claims processor for our vendor that administers the XHANCE co-pay support program, hindered access to our co-pay benefit for uncovered patients. We believe this disruption had a favorable effect on XHANCE net revenue per prescription and expect it to be isolated to first quarter 2024.

  During the second half of 2023 we began to modify our co-pay assistance program to reduce the amount co-pay assistance available to patients that do not have coverage for XHANCE or have high out of pocket costs. These changes were intended to increase average net revenue per prescription by decreasing the amount we pay in co-pay assistance for these prescriptions and decreasing the number of these prescriptions that are filled because they have limited or no profitability. We have continued to make changes through the first quarter of 2024 and in the future may make additional changes to our co-pay assistance program designed to increase average net revenue per prescription.

- XHANCE Prescriptions. Based on third-party inventory and prescription data as well as data from our hub and PPN partners, the total estimated number of XHANCE prescriptions in the first quarter of 2024 was 65,500, which represents a 23% decrease for total prescriptions when compared to estimated first quarter 2023 prescriptions of 85,200. We believe the first quarter 2024 decrease in prescriptions was primarily driven by changes we made to our co-pay saving program intended to reduce the number of prescriptions filled by patients in commercial insurance plans that either do not cover XHANCE or are in commercial insurance plans that have high deductibles.

  A seasonal effect has historically been observed in both the INS and XHANCE prescription markets in which market volume generally peaks near the middle of the second quarter and declines into the early part of the third quarter of each calendar year.

  Although the underlying disease that we are treating is chronic and causes symptoms year-round, we believe the variation in patient flow through the offices of relevant physician specialists, and seasonality in disease flare-ups, has an impact on the number of patients that present themselves and who are therefore available to receive a new prescription for XHANCE.

  Additionally, we believe that first quarter prescription demand and average net revenue per prescription for XHANCE is adversely impacted by the annual resetting of patient healthcare insurance plan deductibles and changes in individual patients' healthcare insurance coverage, both of which often occur in January.

- XHANCE New and Refill Prescriptions. The underlying disease that we are treating is chronic and, as a result, many patients may fill multiple prescriptions per year. We monitor new prescriptions as they create the potential for future refill prescriptions. As noted above, we believe the first quarter 2024 decrease in prescriptions (including both new and refill prescriptions) was primarily driven by changes we made to our co-pay saving program intended to reduce the number of prescriptions filled by patients in commercial insurance plans that either do not cover XHANCE or are in commercial insurance plans that have high deductibles. Based on third-party inventory and prescription data as well as data from or hub and PPN partners, the total estimated number of XHANCE new prescriptions in the first quarter of 2024 was 24,700, which represents a 19% decrease for new prescriptions when compared to estimated first quarter 2023 new prescriptions of 30,400.

  We track refill prescriptions and provide patient co-pay assistance to support refill programs that are administered by our hub or PPN partners. Based on third-party inventory and prescription data as well as data from our hub and PPN partners, the total estimated number of XHANCE refill prescriptions in the first quarter of 2024 was 40,800, which represents a 26% decrease for new prescriptions when compared to estimated first quarter 2023 new prescriptions of 54,800.

- Prescribing Breadth and Depth. We track the number of physicians who prescribe XHANCE in a time period to evaluate the breadth of prescribing. We do not distinguish profitable and unprofitable prescribing in this

metric. Based on third-party inventory and prescription data as well as data from our hub and PPN partners, the total estimated number of physicians who had at least one patient fill a prescription for XHANCE in the first quarter of 2024 was 8,451, which represents a 1% decrease when compared to the estimated 8,545 physicians who had at least one patient fill a prescription for XHANCE in the first quarter of 2023. In addition, the total estimated number of physicians who had at least one patient fill a prescription for XHANCE was 8,624 in the second quarter of 2023, 8,427 in the third quarter of 2023, and 8,478 in the fourth quarter of 2023.

We also track the number of prescriptions filled by a prescribing physician's patients in a time period to evaluate depth of prescribing. We do not distinguish profitable and unprofitable prescribing in this metric. Based on third-party prescription data as well as data from our hub and PPN partners, the total estimated number of physicians who had more than 15 XHANCE prescriptions filled by their patients in the first quarter of 2024 was 1,023, which represents a 26% decrease when compared to the estimated 1,391 physicians who had more than 15 XHANCE prescriptions filled by their patients in the first quarter of 2023. In addition, the total estimated number of physicians who had more than 15 XHANCE prescriptions filled by their patients was 1,428 in the second quarter of 2023, 1,346 in the third quarter of 2023, and 1,229 in the fourth quarter of 2023.

- Market Access. We believe that as of March 31, 2024, approximately 70% of insured lives were in a plan that covers XHANCE. However, payors generally impose restrictions on access to or usage of XHANCE, such as by requiring prior authorizations or "step-edits". For example, insurers may require that a physician attest that they are treating a patient for an FDA-approved indication prior to becoming eligible for coverage for XHANCE. We believe that approximately half of the covered lives as of March 31, 2024 are in a plan that requires a prior authorization and most of those prior authorizations request information regarding both prior use of standard-delivery nasal steroid, and patient diagnosis for an indication for which XHANCE has been approved by the FDA. In some cases, patients do not meet the payors' utilization management criteria or the patient's healthcare provider may not complete the burdensome administrative process required to demonstrate or document that the patients for whom XHANCE has been prescribed meet the payors' utilization management criteria (i.e., prior authorizations or step-edits) and, as a result, patients may not gain access to XHANCE treatment. The approval of XHANCE in March 2024 as a treatment for chronic sinusitis could make the prior authorization process easier for physicians to attest because chronic sinusitis is a more common clinical diagnosis and a diagnosis made by many types of physician, including those who do not have routine in-office ability to perform nasal endoscopy to ascertain the presence of nasal polyps. Payors can elect to change utilization management criteria to be more or less restrictive at any time, and changes in utilization management criteria or increasing rates of enforcement of utilization management criteria in the future could have a negative effect on prescription volume.

Financial Operations Overview

The following discussion sets forth certain components of our consolidated statements of operations as well as factors that impact those items.

Net product revenues

Sales of XHANCE generated $14.9 million and $11.8 million in net product revenues for the three months ended March 31, 2024 and 2023, respectively. In accordance with GAAP, we determine net product revenues for XHANCE, with specific assumptions for variable consideration components including but not limited to trade discounts and allowances, co-pay assistance programs and payor rebates.

Based on available XHANCE prescription data purchased from third parties and data from our hub and PPN partners, our average XHANCE net product revenues per prescription were $227 in the first quarter of 2024 which represents a 63% increase compared to the $139 average XHANCE net product revenues per prescription in the first quarter of 2023. The increase in average net product revenues per prescription is primarily the result of changes we made to our co-pay saving program intended to reduce the number of prescriptions filled by patients in commercial insurance plans that either do not cover XHANCE or are in commercial insurance plans that have high deductibles. In addition, we believe the disruption in services at Change Healthcare, the claims processor for our vendor that administers the XHANCE co-pay support program, hindered access to our co-pay benefit for uncovered patients. We believe this disruption had a favorable effect on XHANCE net revenue per prescription and expect it to be isolated to first quarter 2024.

We calculate average net product revenues per prescription, one metric that we use to gauge the profitability of XHANCE, by dividing net product revenues for the quarter by the estimated number of XHANCE prescriptions dispensed during the quarter. As a result, average net product revenues per prescription is subject to variability. That variability is impacted by factors that do not necessarily reflect a change in the price that is paid for an individual unit of XHANCE, including but not limited to ordering patterns and inventory levels for our wholesale customers, hub and PPN partners, patient utilization rates of our co-pay assistance and other affordability programs and the proportion of patients acquiring XHANCE through an insurance benefit. There is also the potential for variability that results from changes in estimation methodology by us and the third parties that we rely upon to provide certain prescription and inventory data which may lead to revisions of historical estimates of prescription volumes and our calculated average net product revenues per prescription.

We expect full year 2024 net product revenues will be between $85.0 to $95.0 million. For the full year 2024, we believe average net product revenues per prescription will exceed $230. We expect average net product revenues per prescription to increase in 2024, primarily as a result of revisions that we made to our co-pay assistance program in 2023 and early 2024 intended to enhance average net revenue per prescription by reducing co-pay support to, and thus prescriptions filled by, patients in commercial insurance plans that either do not cover XHANCE or are in commercial insurance plans that have high deductibles as these prescriptions have limited or no profitability.

Costs of product sales

Costs of product sales includes the cost of inventory sold, which includes direct and indirect manufacturing and supply chain costs.

Research and development expense

Research and development expense consists primarily of expenses incurred to prepare for, initiate and conduct our planned clinical trials, research efforts for new products and device improvements. We expense research and development costs as incurred. These expenses include:

- personnel expenses, including salaries, benefits and stock-based compensation expense;
- costs of funding clinical development performed by third parties, including pursuant to agreements with contract research organizations (CROs), as well as investigative sites and consultants that conduct or support our nonclinical studies and clinical trials;
- expenses associated with the continued development of the Exhalation Delivery System;
- expenses related to the continued development of our product portfolio;
- expenses incurred under agreements with contract manufacturing organizations (CMOs), including manufacturing scale-up expenses prior to regulatory approval of products for commercial sale and the cost of acquiring and manufacturing preclinical study and clinical trial materials;
- consultant fees and expenses associated with outsourced professional scientific development services;
- expenses for regulatory activities, including filing fees paid to regulatory agencies and costs incurred to compile and respond to filings with the FDA; and
- allocated expenses for facility costs, including rent, utilities, depreciation and maintenance.

We typically use our employee, consultant and infrastructure resources across our research and development programs. Although we track certain outsourced development costs by product candidate, we do not allocate personnel costs or other internal costs to specific product candidates.

We expect research and development expenses in 2024 to be lower than those in 2023.

Selling, general and administrative expense

General and administrative expense consists primarily of personnel expenses, including salaries, benefits and stock-based compensation expense, for employees in executive, finance, accounting, business development, information technology, legal and human resource functions. General and administrative expense also includes corporate facility costs, including rent, utilities, depreciation and maintenance, not otherwise included in research and development expense, as well as regulatory fees and professional fees for legal, patent, accounting and other consulting services.

Sales and marketing expenses include our sales team and supporting promotional materials, digital promotion, peer-to-peer education, congresses / conventions, product samples, and marketing activities such as direct-to-patient / direct-to-consumer initiatives. Additionally, sales and marketing-related expenses include fees paid to our hub and PPN partners for services unrelated to traditional distribution functions, such as patient services fees, data fees, benefit claims adjudication and program management fees.

Warrant Liability

In November 2022, we issued warrants in connection with a public offering. These warrants are required to be measured at fair value and reported as a liability in the consolidated balance sheet. We recorded the fair value of the warrants upon issuance using a Monte Carlo simulation and are required to revalue the warrants at each reporting date with any changes in fair value recorded on our statement of operations. The valuation of the warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. The change in the fair value of the Level 3 warrants liabilities is reflected in the statement of operations for the three months ended March 31, 2024 and 2023.

Interest (income) expense

Interest (income) expense consists of interest earned on our cash and cash equivalents held with institutional banks and interest expense is primarily related to the Pharmakon Senior Secured Notes.

Other (income) expense

Other (income) expense consists primarily of unrealized gains and losses on our warrant liability, as well as foreign currency (income) losses due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency.

Consolidated Results of Operations

Comparison of three months ended March 31, 2024 and 2023

The following table sets forth our selected consolidated statements of operations data for the periods indicated (in thousands):

	Three Months Ended March 31,	
	2024	2023
Revenues:		
Net product revenues	$ 14,880	$ 11,846
Total revenues	14,880	11,846
Costs and expenses:		
Cost of product sales	1,231	1,706
Research and development	1,206	1,785
Selling, general and administrative	20,518	22,723
Total operating expenses	22,955	26,214
Loss from operations	(8,075)	(14,368)
Other (income) expense:		
Interest (income) expense, net	4,674	3,967
Other losses	1,318	512
Total other expense	5,992	4,479
Net loss	$ (14,067)	$ (18,847)

Net product revenues

Net product revenues related to sales of XHANCE were $14.9 million and $11.8 million for the three months ended March 31, 2024 and 2023, respectively. The year-over-year increase in net product revenues is attributable primarily to revisions that we made to our co-pay assistance program in the second half of 2023 as well as in January of 2024 intended to enhance average net revenue per prescription.

Cost of product sales

Cost of product sales related to XHANCE were $1.2 million and $1.7 million for the three months ended March 31, 2024 and 2023, respectively. The decrease of $0.5 million can be attributed to an a lower number of units sold in 2024.

Research and development expense

Research and development expense was $1.2 million and $1.8 million for the three months ended March 31, 2024 and 2023, respectively. The $0.6 million decrease is attributable to a decrease in costs related to the preparation and filing of our supplemental new drug application for XHANCE for the treatment of chronic sinusitis.

Selling, general and administrative expense

Selling, general and administrative expense was $20.5 million and $22.7 million for the three months ended March 31, 2024 and 2023, respectively. The $2.2 million decrease was due primarily to decrease in sales, marketing and administrative costs as well as $1.1 million of severance costs recognized in 2023.

Interest (income) expense, net

Interest (income) expense, net, was $4.7 million and $4.0 million for the three months ended March 31, 2024 and 2023, respectively, which was primarily comprised of interest expense on the Pharmakon Senior Secured Notes during both periods. The increase was due primarily to lower interest income generated in 2024 as a result of lower cash balances.

Other losses

In November 2022, we issued warrants in connection with a public offering. These warrants are required to be measured at fair value and reported as a liability in the consolidated balance sheet. We recorded the fair value of the warrants upon issuance using a Monte Carlo simulation and are required to revalue the warrants at each reporting date with any changes in fair value recorded on our statement of operations. The valuation of the warrants

is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. The change in the fair value of the Level 3 warrants liabilities is reflected in the statement of operations for the quarter ended March 31, 2024.

Other losses includes primarily $1.3 million and $0.5 million for the three months ended March 31, 2024 and 2023, respectively of unrealized losses on the fair value of warrants.

Liquidity and Capital Resources

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. We incurred net losses of $14.1 million and $18.8 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $734.4 million. We have funded our operations primarily through the sale and issuance of stock and debt, as well as through sales of XHANCE and licensing revenues. As of March 31, 2024, we had $51.6 million in cash and cash equivalents.

The following table shows a summary of our cash flows for the periods indicated (in thousands):

	Three Months Ended March 31,	
	2024	2023
Net cash used in operating activities	$ (22,025)	$ (10,478)
Net cash used in investing activities	(22)	—
Net cash provided by financing activities	7	162
Net decrease in cash, cash equivalents and restricted cash	$ (22,040)	$ (10,316)

Operating activities

Cash used in operating activities increased by $11.5 million, from $10.5 million for the three months ended March 31, 2023 to $22.0 million for the three months ended March 31, 2024. The increase in cash used in operating activities was attributable to a decrease in accounts receivable, partially offset by a decrease in accrued expenses, and a lower net loss for the three months ended March 31, 2024.

Investing activities

Cash used in investing activities increased from the three months ended March 31, 2023 to the three months ended March 31, 2024 due to an increase in equipment and software purchases during the three months ended March 31, 2024.

Financing activities

Cash provided by financing activities decreased from the three months ended March 31, 2023 to the three months ended March 31, 2024 due to a decrease in proceeds from the issuance of common stock under our employee stock purchase plan.

Projected 2024 operating expenses

We expect that our total GAAP operating expenses, consisting of selling, general & administrative expenses and research & development expenses, for 2024 will be between $95million and $101 million of which approximately $6 million is expected to be stock-based compensation expense. As a result, our total operating expenses (consisting of selling, general & administrative expenses and research & development expenses) excluding approximately $6 million of expected stock-based compensation expense are expected to be between $89 million and $95 million. The $89 million to $95 million range is approximately a $9 million increase compared to 2023. The increase in selling, general, & administrative expenses from 2023 to 2024 is anticipated as we invest in the launch of XHANCE for the treatment of patients with chronic sinusitis.

Registered Direct Offering
On May 10, 2024, we completed a registered direct offering pursuant to which it issued an aggregate of 31,800,000 shares of common stock at a purchase price of $1.00 per share and, in lieu of shares of common stock to certain investors, pre-funded warrants to purchase an aggregate of 23,700,000 shares of common stock at a price of $0.999 per prefunded warrant which represents the per share offering price for common stock less the $0.0001 per share exercise price for each such pre-funded warrant. The aggregate net proceeds from the offering are expected to be approximately $55,000.

A&R Note Purchase Agreement

The principal balance of the Pharmakon Senior Secured Notes outstanding under the A&R Note Purchase Agreement was $130,000 at March 31, 2024. See Note 8 of our unaudited consolidated financial statements for a description of terms of the Pharmakon Senior Secured Notes and A&R Note Purchase Agreement, including repayment terms and applicable covenants.

Future funding requirements

We expect to continue to incur significant expenses in connection with our ongoing activities, particularly as we:

- continue advertising and other promotional activities to support the commercialization of XHANCE;
- continue to provide co-pay and other patient affordability programs for XHANCE;
- continue clinical development activities for XHANCE, including studies mandated under the Pediatric Research Equity Act;
- evaluate product candidates;
- continue to contract to manufacture XHANCE;
- maintain and protect our patent portfolio;
- service our debt obligations under the Pharmakon Senior Secured Notes;
- maintain infrastructure necessary to operate as a publicly-traded, commercial-stage company; and
- hire additional staff and add operational, financial and information systems to execute our business plan.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the success of our commercialization of XHANCE for the treatment of chronic rhinosinusitis with nasal polyps and chronic sinusitis including, among other things, continued patient and physician adoption of XHANCE and our ability to maintain adequate insurance coverage and reimbursement for XHANCE;
- our clinical development plans for XHANCE, including the outcome, timing and cost of studies mandated under the Pediatric Research Equity Act;
- the cost of commercialization activities for XHANCE, including product manufacturing, distribution, marketing and sales;
- net product revenues received from sales of XHANCE;
- the level of co-pay assistance and other patient affordability programs offered for XHANCE;
- the costs involved in preparing, filing and prosecuting patent applications and annuity fees relating to issued patents;
- the cost of maintaining and enforcing our intellectual property rights, as well as the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the initiation, progress, timing, costs and results of clinical trials and other research and development related to additional product candidates,
- the extent to which we in-license, acquire or otherwise partner in development or commercialization of other products, product candidates or technologies; and
- our ability to maintain compliance with the financial covenants (including the requirement for us to achieve certain minimum trailing twelve-month consolidated XHANCE net sales and royalties thresholds and the requirement for us to maintain at least a minimum level of cash and cash equivalents at all times), and the other provisions under the A&R Note Purchase Agreement.

Commencing on September 30, 2025, we will be required to begin making principal repayments on our debt in eight quarterly installments of $16.3 million each through maturity in June 2027.

Although it is difficult to predict our future liquidity requirements, we will likely require additional capital in the future secured through equity or debt financings, partnerships, collaborations, or other sources in order to meet the debt

service obligations under the Pharmakon Senior Secured Notes, including repayment, and to carry out our planned development and commercial activities. We believe that our existing cash and cash equivalents as of March 31, 2024, together with the net proceeds from the registered direct offering completed on May 10, 2024, will be sufficient to fund our operations and debt service obligations through 2025. Additional capital, secured in the future through equity or debt financings, partnerships, collaborations, or other sources, will likely be required, and may not be available on a timely basis, on favorable terms, or at all, and such capital, if raised, may not be sufficient to meet our debt service obligations, including repayment, or enable us to continue to implement our long-term business strategy. If additional capital is not secured when required, we may need to delay or curtail our operations until such funding is received. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected and we may need to delay or curtail our operations until such funding is received. Additionally, we may fail to satisfy our debt covenants, may never become profitable, or if we do, may not be able to sustain profitability on a recurring basis.

Critical accounting policies

The Critical Accounting Policies and Significant Judgments and Estimates included in our annual report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on March 7, 2024, have not materially changed.

Recent accounting pronouncements

See Note 3 to our unaudited interim consolidated financial statements of this Form 10-Q for a description of recent accounting pronouncements applicable to our consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act), refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Our Chief Executive Officer and our Principal Financial Officer evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2024.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the three months ended March 31, 2024 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

ITEM 5. OTHER INFORMATION

On February 28, 2024, each of Ramy Mahmoud, the Company's Chief Executive Officer and member of the board of directors, Anthony Krick, the Company's VP Finance and Chief Accounting Officer, Michael Marino, the Company's Chief Legal Officer, and Paul Spence, the Company's Chief Commercial Officer, were granted restricted stock units ("RSUs"). In accordance with the applicable RSU award agreements relating to such RSU grants, each of these executive officers entered into "sell-to-cover" arrangements that constitute "non-Rule 10b5-1 trading arrangements" (as defined in Item 408 of Regulation S-K), mandatorily requiring the pre-arranged sale of shares to satisfy tax withholding obligations arising solely from the vesting of the RSUs and the related issuance of shares. The amount of shares to be sold to satisfy the tax withholding obligations under these arrangements is dependent on the trading price of the Company's common stock at the time of the vesting of the RSUs. The duration of each these arrangements is until the final vesting date of the applicable RSUs or the earlier forfeiture of unvested RSUs as set forth in the grant agreement.

ITEM 6. EXHIBITS

The following is a list of exhibits filed as part of this Quarterly Report on Form 10-Q. Where so indicated, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

INDEX TO EXHIBITS

Exhibit Number		Exhibit Description
3.1		Fourth Amended and Restated Certificate of Incorporation of OptiNose, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with the SEC on October 18, 2017).
3.2		Amended and Restated Bylaws of OptiNose, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with the SEC on October 18, 2017).
3.3		Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of OptiNose, Inc. (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 10-Q (File No. 001-38241), as filed with the SEC on August 10, 2023).
10.1		First Amendment and Waiver to the Amended and Restated Note Purchase Agreement, dated March 5, 2024, among OptiNose US, Inc., OptiNose, Inc., BioPharma Credit PLC, and the purchasers from time to time party thereto (incorporated by reference to Exhibit 10.25 to the Company's Annual Report on Form 10-K (File No. 001-38241), as filed with the SEC on March 7, 2024.
10.2		Second Amendment to the Amended and Restated Note Purchase Agreement, dated March 8, 2024, among OptiNose US, Inc., OptiNose, Inc., BioPharma Credit PLC and the purchasers from time to time party thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with the SEC on March 8, 2024.
10.3	* †	Manufacture and Supply Agreement, dated December 11, 2020, by and between OptiNose US, Inc. and Hikma Pharmaceuticals USA, Inc.
31.1	*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.
31.2	*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act
32.1	**	Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer.
32.2	**	Certification Pursuant to 18 U.S.C. Section 1350 of principal financial officer.
101.SCH		Inline XBRL Taxonomy Extension Schema Document.
101.CAL		Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF		Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB		Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE		Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104		Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

† Portions of this exhibit (indicated by asterisks) have been omitted in compliance with Item 601 of Regulation S-K.

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

OPTINOSE, INC.

By: /s/ ANTHONY J. KRICK

Name: Anthony J. Krick

Title: *Vice President, Finance & Chief Accounting Officer*

(Principal Financial and Accounting Officer)

MANUFACTURE AND SUPPLY AGREEMENT

This **MANUFACTURE AND SUPPLY AGREEMENT** (the "**Agreement**") is made as of December 11, 2020 (the "**Effective Date**") by and between OptiNose US, Inc., duly organized and existing under the laws of Delaware and having offices located at 1020 Stony Hill Road, Suite 300, Yardley, PA 19067 ("**OptiNose**"), and Hikma Pharmaceuticals USA Inc., a Delaware corporation, having offices at 1809 Wilson Road, Columbus, OH 43228 (referred to herein as "**Hikma**"). OptiNose and Hikma are each a "**Party**" and together constitute the "**Parties**" under this Agreement.

WHEREAS, Hikma is a pharmaceutical company that, among other activities, manufactures and supplies pharmaceutical products to third party companies; and

WHEREAS, OptiNose desires that Hikma manufacture and supply finished dose forms of the Product (as defined below) appropriate for marketing, sampling, commercial sale, and distribution in accordance with the requirements of this Agreement.

NOW, **THEREFORE** in consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

The following capitalized terms, whether used in the singular or plural, shall have the meanings assigned to them below for purposes of this Agreement and all Exhibits and Schedules hereto:

1.1 "**Affiliate(s)**" means any corporation, firm, partnership or other entity that controls, is controlled by or is under common control with a Party. For purposes of this definition, "control" shall mean the ownership of at least fifty percent (50%) of the voting share capital of such entity or any other comparable equity or ownership interest, or the power to direct the management and policies of such person, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise.

1.2 "**ANDA/NDA**" means any abbreviated new drug application (ANDA) or new drug application (NDA) required to manufacture, market and sell finished dosage forms of the

Products in the Territory (as defined herein) filed by OptiNose with the FDA, and any supplements and amendments thereto which may be filed by OptiNose from time to time.

1.3 "**Annual Minimum**" means binding Purchase Orders placed for at least **[***]** Product units per Calendar Year, which includes **[***]**.

1.4 "**API"** means the active pharmaceutical ingredient, fluticasone propionate required for the Product.

1.5 "**Applicable Laws**" shall mean all laws, statutes, rules, regulations, and ordinances of any multi-national, federal, state, local or municipal subdivision, including laws and regulations promulgated by any supranational, national, federal, provincial, state, local, domestic or foreign government or any judicial, legislative, executive, administrative or regulatory agency or department or other governmental authority thereof, in each instance relating to the development, manufacture, testing and/or commercialization of pharmaceutical products.

1.1 "**Bailment Agreement**" means the Bailment Agreement to be entered into by the Parties in connection with an agreement to be entered into by the Parties for the transfer of OptiNose Equipment to a Facility.

1.2 "**Batch Records**" shall have the meaning set forth in Section 6.1.

1.3 "**Binding Period**" shall have the meaning set forth in Section 2.3.

1.4 "**Calendar Year**" shall mean the period from January 1 through December 31.

1.5 "**Capacity**" means the Facility space, equipment, utilities, maintenance capabilities, infrastructure, human capital, and other capabilities sufficient to manufacture the Product.

1.6 "**Claim**" shall have the meaning set forth in Section 11.4.2(b).

1.7 "**Competing Product**" shall mean

1.7.1 **[***]**

1.7.2 **[***]**

1.7.3 **[***]**

(a) **[***]**

(b) **[***]**

(i) **[***]**

(ii) **[***]**.

1.8 "**Confidential Information**" shall have the meaning set forth in Section 8.2.

1.9 "**Data**" shall refer to all data, materials, plans, reports, test results and other information developed by or for OptiNose in connection with the Manufacture of the Product.

1.10 "**Defective Product**" means any Product that contains a Patent Defect or Latent Defect.

1.11 "**Deliver**", "**Delivery**", or "**Delivered**" means delivery of Product after Release, packed for shipment pursuant to this Agreement, Ex-Works (Incoterms 2020) Hikma's loading dock at its Facility located at 2130 Rohr Road, Lockbourne, OH 43137 or such other Facility designated by Hikma upon prior written approval from OptiNose, which approval shall not be unreasonably withheld, conditioned, or delayed.

1.12 "**Effective Date**" means the date set forth in the preamble of this Agreement.

1.13 "**Facility**" means (a) for manufacturing and testing purposes, Hikma's manufacturing facility located at 1809 Wilson Road, Columbus, OH 43228 or any other Hikma-controlled facility approved in writing by OptiNose (such approval not to be unreasonably delayed, conditioned, or withheld); and (b) for warehousing and distribution purposes, Hikma's storage and distribution facility located at 2130 Rohr Road, Lockbourne, OH 43137 or any other Hikma-controlled facility approved in writing by OptiNose (such approval not to be unreasonably delayed, conditioned, or withheld).

1.14 "**FDA**" means the United States Food and Drug Administration and any successor bodies.

1.15 "**FD&C Act**" means the Federal Food, Drug, and Cosmetic Act, as amended, and includes the rules, and regulations and guidances promulgated thereunder.

1.16 "**Final Approval**" means the approvals received on the Final Approval Date.

1.17 "**Final Approval Date**" means the date all regulatory approvals are obtained for the manufacture of the Product at the Facility.

1.18 "**Force Majeure**" shall have the meaning set forth in Section 11.5.

1.19 "**Hikma Indemnitees**" shall have the meaning set forth in Section 9.2.

1.20 "**Indemnitee Party**" shall have the meaning set forth in Section 9.3.

1.21 "**Indemnitor Party**" shall have the meaning set forth in Section 9.3.

1.22 "**Initial Term**" shall have the meaning set forth in Section 11.1.

1.23 "**Intellectual Property**" means any and all of the following, and rights in, arising out of, or associated therewith: U.S. and non-U.S.

1.23.1 patents, utility models, supplementary protection certificates and applications thereof (including provisional applications, invention disclosures, certificates of invention and applications for certificates of invention) and divisionals, continuations, continuations-in-part, reissues, renewals, extensions, re-examinations, and equivalents thereof;

1.23.2 trade secrets, know-how, proprietary information, inventions, discoveries, improvements, technology, technical Data, and research and development, whether or not patentable;

1.23.3 trademarks, service marks, trade dress, trade names, and equivalents thereof; and

1.23.4 copyrights, mask works, registrations and applications thereof, and any equivalents thereof.

1.24 "**Latent Defect**" means any instance where a Product fails to conform to the Specifications, Applicable Laws or the Quality Agreement due to any act or omission of Hikma, which shall include, without limitation, Hikma's failure to confirm that the OptiNose Components conform to the Specifications, Applicable Laws and the Quality Agreement and any failure to conform arising from any other Raw Materials, which is not a Quantitative Defect or Patent Defect.

1.25 "**Losses**" shall have the meaning set forth in Section 9.1.

1.26 "**Manufacture(d)**" or "**Manufacturing**" means the compounding, filling, manufacture, assembly, bulk-packaging, and testing of the OptiNose Components and Raw Materials to produce the Product, in each case, in accordance with the Specifications, Applicable Laws, the Quality Agreement and the terms and conditions set forth in this Agreement.

1.27 "**Master Services Agreement**" means that certain Master Services Agreement dated **[***]** entered into between the Parties (or any Affiliates of the Parties).

1.28 "**Notice(s)**" shall have the meaning set forth in Article 13.

1.29 "**OptiNose Components**" shall have the meaning set forth in Section 2.1.5(b).

1.30 "**OptiNose-Designated Components**" shall have the meaning set forth in Section 2.1.5(c).

1.31 "**OptiNose-Designated Vendors**" shall have the meaning set forth in Section 2.1.5(c).

1.32 **"OptiNose Equipment"** shall mean OptiNose Equipment as shall be defined in the Bailment Agreement.

1.33 "**OptiNose Indemnitees**" shall have the meaning set forth in Section 9.1.

1.34 "**OptiNose Vendors**" shall have the meaning set forth in Section 2.1.5(b).

1.35 "**Packaged Product**" means the full saleable or sample Product unit of XHANCE® (fluticasone propionate) nasal spray, including without limitation active ingredient, delivery system, container closure system, and market package.

1.36 "**Patent Defect**" shall mean any instance where a Product fails to conform to the Specifications, Applicable Laws or the Quality Agreement due to any act or omission of Hikma (which shall include, without limitation, Hikma's failure to confirm that the OptiNose Components conform to the Specifications, Applicable Laws and the Quality Agreement and any failure to conform arising from any other Raw Materials), where such failure is discovered upon actual inspection, if any, upon receipt by OptiNose or its designee.

1.37 "**Product**" means the container closure system of XHANCE® including without limitation active ingredient, delivery system, cap (provided OptiNose does not request its exclusion, at its sole discretion), vial base (to the extent directed to be included by OptiNose at its sole discretion) and container closure system, but excluding the market package.

1.38 "**Purchase Order(s)**" shall have the meaning set forth in Section 2.5.

1.39 "**Purchase Price**" shall have the meaning set forth in Section 4.1.1.

1.40 "**Quality Agreement**" shall mean that quality agreement to be entered between the Parties related to production of the Product.

1.41 "**Quantitative Defect**" means any instance in which Hikma has Delivered a quantity of Product that is at least **[***]** less than the quantity stated in any invoice or bill of lading.

1.42 "**Raw Material**" means all raw materials, including API, supplies, components and packaging components and material necessary to manufacture and ship the Product in accordance with the Specifications, Applicable Laws, and the Quality Agreement.

1.43 "**Regulatory Authority**" means any governmental authority within the Territory or applicable to any Facility (including, but not limited to, the FDA) involved in regulating any aspect of the development, manufacture, testing, packaging, storage, handling, market approval, sale, distribution, Delivery or use of the Products in accordance with Applicable Laws.

1.44 **"Release"** shall mean the release of the Batch Records, such release to be as set forth in the Quality Agreement.

1.45 "**Renewal Term**" shall have the meaning set forth in Section 11.1.

1.46 "**Required Change**" shall have the meaning set forth in Section 2.2.2.

1.47 "**Rolling Forecast**" shall have the meaning set forth in Section 2.3.

1.48 "**Safety Stock**" shall have the meaning set forth in Section 2.4.

1.49 "**Specifications**" means the procedures, requirements, standards, quality control testing and other Data and requirements for the Product set forth in Exhibit A as such Exhibit may be amended in accordance with Section 2.2 of this Agreement.

1.50 "**Supply Failure**" has the meaning provided in Section 2.10.

1.51 "**Term**" shall have the meaning set forth in Section 11.1.

1.52 "**Territory**" means the United States of America, its territories, possessions, commonwealths, and any other country which the Parties agree in writing to add to this definition of Territory in an amendment to this Agreement.

ARTICLE 2
MANUFACTURE AND SUPPLY

2.1 Purchase and Supply of Product.

2.1.1 Supply. From and after the Final Approval Date and during the Term hereof, OptiNose may purchase Product from Hikma in accordance with the terms and conditions hereof, and Hikma shall Manufacture the Product at the Facility in accordance with the Specifications, Applicable Laws the Quality Agreement and the terms and conditions of this Agreement.

2.1.2 Labeling. OptiNose shall provide Hikma with all artwork, copy or other materials necessary for the Product labels that are in compliance with Hikma's technical data and labeling guidelines, other than in connection bulk-packaging which shall be Hikma's sole obligation. Hikma shall accurately implement copy changes as reasonably required by OptiNose, and Hikma shall not make any changes to the artwork, copy or other materials without the prior written approval of OptiNose, which shall not be unreasonably withheld, conditioned, or delayed; provided that any changes in Hikma's technical data and labeling guidelines after the Effective Date, other than changes to comply with regulatory requirements, that require OptiNose to make any changes to its Product label shall be at Hikma's sole cost and expense. Hikma shall ensure that all Product is assembled with labeling affixed in accordance with the Specifications, Applicable Laws and the Quality Agreement before Delivery of any such Product.

2.1.3 Annual Minimum. If OptiNose fails to issue Purchase Orders to Hikma for the Annual Minimum for a particular Calendar Year, then as OptiNose's sole and exclusive liability and Hikma's sole and exclusive remedy, **[***]**. For clarity, the Annual Minimum shall be measured based on the date and number of Products set forth in a Purchase Order issued by OptiNose, not the date Hikma Delivers such Product.

2.1.4 Raw Material Procurement. OptiNose, at its sole cost and expense, is responsible for the purchase of all OptiNose Components, and Hikma is responsible for the purchase of all other Raw Materials. Hikma is responsible for the receipt, storage, sampling, testing and release for use of all Raw Materials, including without limitation the OptiNose Components, according to Specifications, the Quality Agreement and Applicable Laws. For some Raw Materials, OptiNose may instruct Hikma to use specific suppliers to leverage existing contracts and, in such scenarios **[***]**. Other than as may otherwise be part of the Purchase Price, Hikma shall not be entitled to any additional administration or other pass-through fees or expenses in connection with the Raw Materials procured by Hikma from any third party; provided, however, that **[***]**.

2.1.5 Selected Vendors.

(a) Hikma shall only purchase Raw Materials (other than OptiNose Components which OptiNose shall purchase) from those vendors as reviewed and approved, in writing, by OptiNose. Any changes to such vendors shall require OptiNose's prior written consent.

(b) Unless otherwise instructed by OptiNose at a subsequent date, OptiNose shall order the OptiNose Components identified in Schedule 1 attached hereto from those third party suppliers identified thereon (the "**OptiNose Vendors**"), as such Schedule may be amended from time to time by written Notice from OptiNose. Raw Materials to be supplied by such OptiNose Vendors are collectively referred to as the "**OptiNose Components**", **[***]**.

(c) OptiNose may reasonably require Hikma from time to time, in writing, to have a direct commercial relationship for the purposes of this Agreement with certain vendors (each such vendor, an "**OptiNose-Designated Vendor**") and obtain from such OptiNose-Designated Vendors components necessary for the Manufacture of the Product (the "**OptiNose-Designated Components**"). Hikma shall use its commercially reasonable efforts to source the OptiNose-Designated Components and ensure that the OptiNose-Designated Vendors provide reasonable warranties for such OptiNose-Designated Components. Hikma shall inspect and use OptiNose-Designated Components as it does any other Raw Materials it sources for this Agreement or otherwise in the ordinary course of its business. **[***]**. OptiNose-Designated Vendors and OptiNose-Designated Components are identified in Schedule 1 attached hereto, as such Schedule 1 may be amended from time to time by written Notice from OptiNose to Hikma.

(d) With each of the OptiNose Vendors, OptiNose shall enter into supply agreements. Further, (i) Hikma shall be allowed to instruct OptiNose as to the reasonable time and destination for shipments of the relevant Raw Material from each such OptiNose Vendor, (ii) Hikma shall be required by the terms of this Agreement to inspect and ensure that Raw Material provided by each such OptiNose Vendor and OptiNose-Designated Vendor meets the applicable Specifications and, to the extent not prohibited by OptiNose's contracts with the OptiNose Vendors and to the extent authorized by the Quality Agreement, have the right to take any action as Hikma may deem reasonably appropriate regarding Latent Defects or Patent Defects associated with the OptiNose Components in coordination with OptiNose, and (iii) Hikma shall be allowed to audit such OptiNose Vendors and OptiNose-Designated Vendors (**[***]**) during the ordinary course of business and, as required, for-cause (provided, if OptiNose's contracts with an OptiNose Vendor restricts Hikma's ability to audit such OptiNose Vendor, OptiNose shall ensure that Hikma is timely provided with the most recently available audit report, **[***]**). Further, Hikma may enter into quality agreements with such OptiNose Vendors and shall enter into quality agreements with such OptiNose-Designated Vendors, in each instance in

consultation with OptiNose (including reasonably considering OptiNose's comments on such quality agreements), requiring such vendors to comply with Applicable Laws, quality standards and processes and to supply their respective Raw Material in a manner that enables Hikma to Manufacture and supply the Product in compliance with the Specifications, Applicable Law and the Quality Agreement. By mutual written agreement, OptiNose and Hikma may decide to adjust responsibility for Raw Material procurement. If such audits by Hikma result in Hikma determining that such vendors are not in compliance with such quality agreements, Hikma shall inform OptiNose of Hikma's audit findings and OptiNose shall have the sole right to negotiate to resolve disputes regarding any right, obligation, duty or liability which may arise between Hikma and the OptiNose Vendor under the quality agreement, provided it is understood and agreed that Hikma shall, upon request by OptiNose, assist OptiNose in any such investigations and dispute resolution at OptiNose's reasonable cost and expense. Hikma shall be solely responsible to resolve all matters with the OptiNose-Designated Vendors, using its commercially reasonable efforts to resolve such matters in a way that minimizes interruption to OptiNose and the Products to be Manufactured hereunder. **[***]**. Notwithstanding anything to the contrary in this Agreement and/or in the quality agreements between Hikma and the OptiNose Vendors and/or the Quality Agreement between Hikma and OptiNose, resolution of any quality issues and/or performance of Raw Materials received by Hikma from the OptiNose Vendors (other than confirmation by Hikma that such Raw Materials conform to the Specifications, Applicable Laws, and the Quality Agreement) **[***]**.

(e) Upon Hikma's receipt of OptiNose Components and OptiNose-Designated Components, Hikma shall inspect such OptiNose Components and OptiNose-Designated Components and ensure that such OptiNose Components and OptiNose-Designated Components provided by such OptiNose Vendor or OptiNose-Designated Vendor, as applicable, meets the applicable specifications for such OptiNose Components and OptiNose-Designated Components and that no Patent Defects or quantitative defects exist. With respect to OptiNose Components, Hikma shall do all such inspections for patent defects and quantitative defects (**[***]**) and notify OptiNose of any failure(s) and/or issue(s) identified from such inspection within **[***]** days from Hikma's receipt of OptiNose Components; provided Hikma shall have **[***]** days from its receipt of such OptiNose Components to do the manual activity inspections and **[***]** testing related to inspecting for Patent Defects (as such inspection and testing shall be set forth in the Specifications and/or Quality Agreement), and notify OptiNose of any failure(s) and/or issue(s) identified from such inspections and/or testing. In the event Hikma notifies OptiNose in advance of the expiry of the above-indicated timeframes under this Section 2.1.5 that it requires additional time to complete its inspections, OptiNose shall reasonably accommodate such request on the understanding that Hikma will need to promptly complete such inspections and provide OptiNose with a 'no later than' deadline for completion of such inspections; provided, Hikma shall use its best efforts to limit the number of instances of such notifications and requests for an extension.

2.1.6 Back-Up Supplier Support. It is expressly understood and agreed that Hikma shall provide reasonable support, **[***]**, should OptiNose want to add any additional supplier(s) of Product (an "**Additional Supplier(s)**") and that OptiNose may purchase Product from such Additional Supplier. Hikma agrees to promptly, and in any event within **[***]** days, transfer to any Additional Supplier(s) all documentation related to the processes, protocols, procedures, methods and tests relating to the Manufacturing of Product in accordance with the Specifications, Applicable Law, and the Quality Agreement. In all instances, Hikma shall provide OptiNose a list of all suppliers of Raw Materials and any other components used in connection with the manufacture of the Product. OptiNose shall reimburse Hikma for any and all costs reasonably incurred by Hikma in such transfer to an Additional Supplier. The obligations of Hikma under this Section 2.1.6 shall survive for **[***]** days after the expiration or termination of this Agreement.

2.2 Product Information.

2.2.1 Source/License. Subject to the terms of this Agreement, including but not limited to the warranties and representations of Hikma set forth in Article 7 and the obligations of Hikma set forth in Article 8, OptiNose shall provide to Hikma, and hereby grants Hikma a limited (as set forth in the next sentence hereof) license to use all Specifications, formulas, processes, analytical methods, Data, regulatory approvals, technology, Confidential Information and Intellectual Property of OptiNose solely to the extent necessary for the Manufacture of the Product in accordance with this Agreement (including, but not limited to, Hikma's full compliance with the confidentiality and Intellectual Property obligations hereof). The license granted to Hikma pursuant to this Section 2.2.1 shall be a non-exclusive, fully paid-up, and royalty-free license (without the right to grant sublicenses) limited to Hikma's use during the Term and for a period of **[***]** days thereafter, unless a longer period is otherwise required by Hikma (in consultation with OptiNose) to fulfil its obligations under this Agreement, in all instances solely for purposes of Hikma fulfilling its obligations to OptiNose under, or otherwise effectuating, this Agreement.

2.2.2 Specifications. All Specifications shall be provided by OptiNose to Hikma, or created by Hikma or a third party and approved by OptiNose and Hikma. Any changes in the Specifications agreed to by the Parties from time to time shall be in writing, dated and signed by the Parties, or as otherwise may be specifically set forth in the Quality Agreement. Except as provided in this subsection 2.2.2, no change in the Specifications, Manufacturing process, or Facility (other than changes to the Facility that are not prohibited under the Quality Agreement and do not materially and adversely impact the Manufacture of the Product), shall be implemented by Hikma until the Parties have agreed in writing to such change, the implementation date of such change, any regulatory implications, and any increase or decrease in costs, expenses, or fees associated with such change. Hikma shall respond promptly to any

request made by OptiNose for a change in the Specifications, and both Parties shall use commercially reasonable, good faith efforts to agree to the terms of such change in a timely manner. Changes resulting in reduction in cost of goods initiated by OptiNose, following reimbursement or recapture of costs incurred by Hikma to effect such reduction in costs, shall be discussed by the Parties in good faith and promptly agreed to before the change is implemented in order to determine the amount to be passed on to OptiNose in the form of a reduction in the Purchase Price. Hikma shall provide documentation of the changes in any such costs upon OptiNose's request. Notwithstanding the foregoing, the Parties shall promptly notify each other of any change in Specifications or Manufacturing process requested or required by a Regulatory Authority or an Applicable Law (a "**Required Change**"), and the Parties shall thereafter work in good faith to agree in writing upon the change in Specification or process, its effective date and the Purchase Price, costs, expenses and fees associated with such Required Change (which, Hikma shall in any event use commercially reasonable efforts to limit to the reasonable and necessary costs of effecting such Required Change) and to effect a corresponding written amendment to this Agreement reflecting same. However, it is understood and agreed that, if the Parties fail to agree upon the change in Specification or process to be made in response to a Required Change, OptiNose shall have the right to terminate this Agreement upon not less than **[***]** days prior written notice to Hikma, and if OptiNose does not so terminate this Agreement, Hikma shall make each Required Change that OptiNose requests in writing, while the Parties continue negotiations in good faith as to costs, expenses and fees; **[***]**.

2.3 Forecasts. Commencing on the Final Approval Date or such earlier date as may be agreed to between the Parties, OptiNose shall provide Hikma each month with non-binding, rolling **[***]** forecast of its Product requirements ("**Rolling Forecast**"). OptiNose shall be obligated to purchase the unit quantity of Products for the **[***]** of any Rolling Forecast that was requested in the Rolling Forecast for that **[***]** period (a "**Binding Period**"). During the first business week of each calendar month, OptiNose will issue a new Rolling Forecast which shall be updated monthly by OptiNose no later than the fifth (5^{th}) business day of each calendar month with the Binding Period updated with each Rolling Forecast to include the new **[***]** of the going forward **[***]** Rolling Forecast. Hikma shall participate in periodic sales and operations planning meetings with OptiNose and other suppliers as both Parties reasonably deem appropriate or as OptiNose may reasonably request. Notwithstanding any other provision of this Agreement, for Rolling Forecasts issued prior to Final Approval Date, OptiNose shall not be required to place any Purchase Order for quantities that otherwise would be applicable for any Binding Period, and OptiNose may, in its sole discretion, cancel or modify any Purchase Order placed prior to the Final Approval Date; provided, however, that OptiNose will reimburse Hikma for any out-of-pocket costs reasonably incurred in order for Hikma to be prepared to supply Product for such Purchase Orders (including, without limitation, the cost of Raw Materials purchased by Hikma based on such Rolling Forecasts that cannot otherwise be reasonably used by Hikma or its customers) and any other costs agreed to by the Parties. The Parties will work

collaboratively together regarding planning of production of initial Product in anticipation of the Final Approval Date. During the Term of this Agreement, Hikma shall ensure that, subject to utilization of OptiNose Equipment, it has the Capacity to meet all of OptiNose's requirements for Product in a timely manner based on the applicable Rolling Forecast under this Agreement and subject to the Product's standard lead time pursuant to Section 2.5; provided that if new or additional OptiNose Equipment is required, Hikma will inform OptiNose with sufficient lead time for such OptiNose Equipment to be acquired and qualified for use under this Agreement.

2.4 Reliance on Forecasts. Hikma may order those Raw Materials necessary or appropriate to fulfill the forecasted Product requirements for the Rolling Forecast, taking into account necessary lead times, agreed upon order policies, and **[***]**. In no case shall Hikma maintain less than **[***]** supply of Raw Materials based on the then existing Rolling Forecast ("**Safety Stock**") without OptiNose's prior written consent. If the Purchase Orders for the corresponding period from OptiNose are for a quantity less than would reasonably support the amount of Raw Materials that Hikma purchased in good faith in accordance with the preceding sentence, **[***]**.

2.5 Purchase Orders. OptiNose shall submit written Purchase Orders on its standard form for Product specifying: (a) the number of units of Product to be purchased, (b) the Purchase Price (determined in accordance with Exhibit B hereto) and (c) the expected date of Delivery ("**Purchase Order(s)**"). For Delivery of each Product, unless agreed with Hikma under the circumstances, a Purchase Order shall not request a date of Delivery sooner than **[***]** days from the date of the Purchase Order. Hikma shall confirm Purchase Orders and projected dates of Delivery within **[***]** days of receiving a Purchase Order, and Hikma may only reject such a Purchase Order if permitted under Section 2.7 of this Agreement or in the event of Force Majeure. Subject to Sections 2.7 and 11.5 (provided Hikma has provided written notice to OptiNose of a Force Majeure and such Force Majeure is ongoing at the time of, or happens within the **[***]** day period following, Hikma's receipt of such Purchase Order), Hikma's failure to confirm any Purchase Order within the **[***]** day period shall be deemed to be acceptance of such Purchase Order.

2.6 Terms of Sale. ANY ADDITIONAL OR INCONSISTENT TERMS OR CONDITIONS OF ANY STANDARDIZED FORM OF EITHER PARTY, INCLUDING WITHOUT LIMITATION, ANY PURCHASE ORDER, INVOICE, CONFIRMATION, OR ACKNOWLEDGMENT GIVEN OR RECEIVED PURSUANT TO THIS AGREEMENT WILL HAVE NO EFFECT AND SUCH TERMS AND CONDITIONS ARE HEREBY EXCLUDED.

2.7 Purchase Orders for the Binding Period. OptiNose shall issue Purchase Orders for unit quantities of Product that are equal to or greater than the amount set forth in the Rolling Forecast for the applicable Binding Period, and Hikma shall accept all such Purchase Orders except to the extent such Purchase Orders are for unit quantities of Product greater than **[***]** of the amount

set forth in the Rolling Forecast for such Binding Period (rounding such calculation up to the nearest batch size). In the event OptiNose issues Purchase Orders for unit quantities in excess of such **[***]** of the Rolling Forecast for an applicable Binding Period (rounding such calculation up to the nearest batch size) or requests a change to a Purchase Order to increase unit quantities, Hikma shall make a determination, in its sole discretion, whether to accept (wholly or in part) or reject such Purchase Orders for additional quantities or requested increases. Within **[***]** days of receipt of a Purchase Order for unit quantities in excess of **[***]** of the Rolling Forecast for an applicable Binding Period (rounding such calculation up to the nearest batch size) or request for a change to a Purchase Order to increase unit quantities, Hikma shall (subject to its obligations pursuant to the foregoing sentence) notify OptiNose whether it can accept, wholly or in part, or reject such Purchase Order or requested increase, and for all amounts that Hikma accepts Hikma shall be obligated to supply such excess quantities as if it was a part of the original Purchase Order governed by the terms of this Agreement. In the case of a partial acceptance, Hikma shall specify quantities and/or the date of projected Delivery. OptiNose shall not decrease the quantity of Product ordered in a Purchase Order. Notwithstanding the foregoing, Hikma's failure to accept the increased quantity of Product as a result of a change to a Purchase Order in excess of the original amount ordered within **[***]** days shall not be a breach of this Agreement but such failure shall be deemed to be a rejection of such Purchase Order reflecting the increased quantity of Product.

2.8 Order Cancellation; Order Change. Subject to the other provisions of this Agreement, in the event that OptiNose cancels or defers any Purchase Order issued by OptiNose and confirmed by Hikma, OptiNose shall be bound to purchase **[***]** of Product ordered against such Purchase Order. Notwithstanding the foregoing, OptiNose shall have the right to request Hikma to adjust the priority and related Delivery date with respect to outstanding Purchase Orders (e.g., such that one Purchase Order date is to be Delivered earlier while another is delayed) or to change a SKU (as defined below in Section 4.1.1), and Hikma shall use its best efforts to effectuate such request(s) and to do so without any additional fees or costs to OptiNose, with the understanding that any changes in the Delivery date for Product that is yet to be Manufactured by Hikma to extend the Delivery date in excess of **[***]** days shall be subject to any applicable storage fees and handling fees as set forth in Section 4.2, and Hikma may assess as well **[***]**; further, any delays to the Delivery of a Product already Manufactured by Hikma shall be subject to the provisions of Section 4.2.

2.9 Non- or late Deliveries. In the event that Hikma reasonably determines that it may be unable to provide Delivery of the Product on or before a date of Delivery specified in the applicable Purchase Order, Hikma shall promptly notify OptiNose of such potential delay and shall, if necessary, promptly provide a revised date for Delivery. **[***]**. However, if Hikma fails, for any reason other than Force Majeure, to Deliver Product pursuant to an accepted

Purchase Order within **[***]** days of the date specified in such Purchase Order, such failure shall constitute a Supply Failure pursuant to Section 2.10 and **[***]**.

2.10 Supply Failure.

2.10.1 In the event that:

(a) the Facility fails an inspection or suffers a hold or disciplinary action by the FDA or any other government authority that prevents Hikma from its ability to Deliver Product and Hikma fails to cure such inspection shortcoming, or remove or resolve such hold or disciplinary action in such a manner that the Facility passes re-inspection by the FDA or applicable government authority and/or is free of the hold or disciplinary action, in good standing with FDA or such other applicable government authority, and is lawfully able to and does resume timely and conforming manufacture and Delivery of OptiNose's Product requirements in accordance with this Agreement within **[***]** days of such original inspection, or imposition of the hold or disciplinary action;

(b) Hikma breaches its obligations or requirements under this Agreement related to the Manufacture and Delivery of the Product, other than for a Quantitative Defect, and fails to cure such breach within **[***]** days from Hikma's receipt of a Notice of breach from OptiNose;

(c) should Hikma have more than **[***]**; or

(d) this Agreement is terminated by OptiNose pursuant to Section 11.4.1;

(each instance of 2.10.1(a) – (d), a "**Supply Failure**"), OptiNose shall have the right (at no cost or expense to OptiNose) to terminate the portion of the applicable Purchase Order(s) subject to the Supply Failure on the understanding that OptiNose shall be required to purchase whatever conforming Product Hikma can supply under such Purchase Order(s) and that the non-conforming portion(s) of such Purchase Order(s) shall count against the applicable Annual Minimum for the Calendar Year in question without any obligation on OptiNose to ultimately purchase a replacement amount for such non-conforming Product. Further, OptiNose shall have the right to terminate any Purchase Order(s) outstanding during a Supply Failure, any Purchase Order(s) for any Binding Period that would have become binding during a Supply Failure, or any other Purchase Order that OptiNose may have intended to be issued during any instance of an outstanding Supply Failure, in all instances (i) such termination right shall exist up to the date Hikma has cured any outstanding Supply Failure(s) and provides written notice to OptiNose that Hikma has cured such outstanding Supply Failure(s) and (ii) the amount of Product ordered or

that would have been ordered under such terminated Purchase Orders(s) shall count against the applicable Annual Minimum.

2.10.2 The rights set forth in Section 2.10.1 regarding OptiNose's ability to terminate Purchase Order(s) and have such Product count against the Annual Minimum shall apply if a Force Majeure event occurs or is ongoing that prevents Hikma from timely Manufacture and Delivery of Product; provided that such adjustment of the Annual Minimum shall only apply for the duration of such Force Majeure event and it being understood that such Force Majeure shall not be considered a Supply Failure; provided, however, that the Parties agree that the Annual Minimum shall be **[***]**.

2.10.3 Additionally, the Annual Minimum shall, where applicable, be modified from and after Hikma's resumption of supplying the Product to OptiNose after a Supply Failure for the remainder of the Term, as provided in the definition of Annual Minimum.

2.11 Delivery. All Products provided for Delivery by Hikma under this Agreement shall be:

2.11.1 suitably packed by Hikma for Delivery in accordance with good commercial practice and the Specifications, Applicable Laws and the Quality Agreement, as well as any reasonable instructions provided to Hikma by OptiNose with respect to protection of such Product during transportation;

2.11.2 marked for shipment to OptiNose or such other party as OptiNose may designate;

2.11.3 accompanied by a certificate of analysis, certificate of compliance, import/export documents (if applicable), and other documents as necessary and appropriate; and

2.11.4 in accordance with the terms of the Quality Agreement.

2.12 Competitive Products. Provided that in so doing, no Confidential Information or Intellectual Property of OptiNose or OptiNose Equipment is in any manner infringed by, used, or disclosed by or on behalf of Hikma to any third party (other than its Affiliates performing services hereunder within the Territory who have a need to know for purposes of providing the Product in accordance with the terms of this Agreement), Hikma shall have the right to manufacture, package, and/or supply products to third parties which may compete with the Packaged Product and which may or may not contain the same active ingredient or ingredients as the Packaged Product; provided, however, that:

2.12.1 **[***]**, neither Hikma nor any of its Affiliates shall directly or indirectly (whether for itself or a third party), Manufacture, import, export, develop, obtain regulatory approval for,

or commercialize, market, sell, offer for sale, package or distribute a Competing Product within the Territory other than as required pursuant to this Agreement (including with respect to any Additional Supplier);

2.12.2 **[***]**, neither Hikma nor any of its Affiliates performing services hereunder and/or incorporated within the Territory shall directly or indirectly (whether for itself or a third party), develop a Competing Product for the Territory or any jurisdiction listed under Schedule 2; and

2.12.3 **[***]**, neither Hikma nor its Affiliates shall rely on or use any information or data developed by any Hikma Affiliate for the purpose of developing, obtaining regulatory approval for, or commercializing, marketing, selling, offering for sale, packaging, or distributing a Competing Product within the Territory.

For purposes of clarity, this Section 2.12 shall not prohibit Hikma from **[***]**; provided further that Hikma is not otherwise in breach of Article 8 or any other applicable terms of this Agreement.

2.13 Meeting. At least annually, the Parties shall meet at such places as agreed by the Parties to have a business review whereby the Parties shall discuss (and come prepared to discuss), amongst other matters:

2.13.1 business updates;

2.13.2 technical discussions;

2.13.3 review of supply (Rolling Forecast review, Safety Stock review, and Capacity planning), OptiNose-Designated Vendors, and OptiNose Vendors;

2.13.4 Packaged Product supply and related metrics;

2.13.5 quality matters (to be discussed by the relevant quality personnel); and

2.13.6 optimization opportunities.

2.14 Reporting. At such times as OptiNose may request (**[***]**), Hikma shall provide OptiNose within **[***]** days of such request with such information (other than what is provided for under Section 2.13) as may reasonably be requested by OptiNose; provided however, that within **[***]** days from the end of each calendar month, Hikma shall provide OptiNose a written report noting the following (in such form as reasonably agreed to between the Parties):

2.14.1 inventory on-hand; and

2.14.2 inventory usage.

ARTICLE 3
OPTINOSE EQUIPMENT

3.1 OptiNose Equipment; Bailment Agreements; Financing Agreements. OptiNose and Hikma shall negotiate in good faith and enter a Bailment Agreement with respect to the OptiNose Equipment to be maintained by Hikma at its Facility. The Parties further agree that the term of the Bailment Agreement shall align with the Agreement's Term and that such Bailment Agreement is be co-terminus with the termination of this Agreement. Any additional OptiNose equipment not covered by the Bailment Agreement shall be added to the appropriate schedule of the Bailment Agreement. Hikma further agrees to promptly respond to all requests for documentation related to any financing transactions OptiNose may enter into or may have previously entered into with a third party, and Hikma shall take all action as may be reasonably requested (including, but not limited to, entering into any consent and acknowledgement agreements, bailment agreements, or any other agreements) in connection with any such OptiNose financing transaction on the understanding that under no circumstance shall Hikma be considered a guarantor of or liable for any obligations under any such financing transactions or arrangements associated with the equipment subject of the Bailment Agreement.

ARTICLE 4
PRICES AND PAYMENT

4.1 Price and Continuous Efficiencies Pass Through.

4.1.1 Price. OptiNose shall pay Hikma the unit price set forth in Exhibit B for all Product Manufactured by Hikma hereunder ("**Purchase Price**"). The Parties expressly acknowledge and agree that the Purchase Price specified in Exhibit B is predicated upon the batch size designated therein. The Parties agree to continue ongoing discussions and negotiate in good faith what the impact may be of a smaller or larger batch size. Prior to the Manufacture of such smaller or larger batch size, Hikma shall advise OptiNose of the proposed adjustment to the Purchase Price, as applicable, to reflect the commercially reasonable impact of the batch size change, including the reasons for the adjustment, including but not limited to process and/or packaging validation, claimed to be applicable. The Parties shall agree on such adjusted Purchase Price prior to the Manufacture of such smaller or larger batch size. The Parties also acknowledge and agree that, subject to Hikma's sole discretion and approval (not to be unreasonably withheld, conditioned or delayed), the entire batch may be filled into more than a

single stock keeping unit ("**SKU**") if OptiNose requests that a batch be split into two or more SKUs, and Hikma shall implement that request; provided that the maximum number of splits in any particular batch is no more than three (3). For each split batch supplied by Hikma, OptiNose shall **[***]**.

4.1.2 Scrap Adjustment. Hikma hereby agrees that Hikma's scrap rate (i.e., the percentage of materials that are discarded in the ordinary course of Manufacturing the Product, provided that particular batch of Product is still otherwise capable of being Delivered) with respect to the OptiNose Components in connection with Hikma's Manufacturing provided hereunder for the validation batches shall not exceed **[***]**. If Hikma scraps more than **[***]** of the OptiNose Components in connection with foregoing sentence, Hikma shall credit OptiNose for OptiNose's costs and expenses for all such scrapped OptiNose Components. Starting from **[***]**, the scrap rate set forth in the preceding sentences shall hereby be reduced to **[***]** and Hikma shall credit OptiNose for OptiNose's costs and expenses for all such scrapped OptiNose Components above such **[***]**.

4.1.3 Cost Reduction Plan. Should Hikma Manufacture or the Parties desire to Manufacture the Product in a batch size larger than **[***]**, the Parties shall meet to seek initiatives to improve quality of the Product and/or to reduce material, labor and other costs, and the Parties shall work to implement such initiatives and work to reduce the Purchase Price, which shall be as set forth in an amendment agreed to by the Parties. For each such initiative, the following shall be subject to mutual agreement: the capital and expense to implement the initiative, the Party to provide funds for such capital and expense, and the expected cost savings to result.

4.1.4 Raw Material Price Increase. Upon advance written notice to OptiNose in each instance, Hikma shall be entitled to an immediate adjustment to the Purchase Price for a Product by the amount of the increase in Raw Materials cost where any increase in Raw Material costs increase the total Purchase Price per unit of Product by **[***]**. Hikma shall provide reasonable documentation to support any Purchase Price adjustment in accordance with this Section 4.1.4. Upon any reduction(s) in Raw Materials cost thereafter, which Hikma shall use it best efforts thereafter to implement any such cost reduction(s), **[***]**.

4.2 Payment Terms. All undisputed amounts payable under this Agreement shall be expressed in United States Dollars and shall be due and payable by OptiNose to Hikma within **[***]** days from the date of OptiNose's receipt of Hikma's invoice for Product, subject to the terms of this Agreement. Hikma may not issue to OptiNose an invoice for Product until after Delivery of such Product. However, Hikma shall not be required to store Product for more than **[***]** days after Release and may charge OptiNose a daily storage fee should OptiNose not take Delivery of the Product within such **[***]** day timeframe; provided that such storage and

handling fee shall be [***] or part thereof. All invoices shall reference the applicable Purchase Order, be sent to the address specified in the applicable Purchase Order, and state the Purchase Price for Product in a given shipment, plus any taxes that are applicable. All payments shall be made in United States dollars by check to Hikma or by electronic payment in accordance with written instructions given by Hikma from time to time.

4.3 Importer of Record. Hikma shall be the importer of record for the Raw Materials received by Hikma and if so identified in Schedule 1, to the extent reasonably requested in writing by OptiNose.

ARTICLE 5
PRODUCT CONFORMITY TO SPECIFICATIONS

1.1 Notification of Defective Product.

1.1.1 OptiNose or its designee shall notify Hikma within:

(a) [***] days after taking Delivery of Product if it determines that such shipment contains a Quantitative Defect,

(b) [***] days after taking Delivery of Product if it determines that such shipment contains a Patent Defect, and

(c) [***] days after OptiNose becomes aware of a Latent Defect.

5.1.2 OptiNose shall provide Hikma a sample of what it alleges contains a Latent Defect or Patent Defect. Subject to compliance with the foregoing notice requirements and the provisions of Section 5.2, below, OptiNose shall have the right to reject any batch of Product having a Patent Defect or Latent Defect, provided that (other than with respect to an indemnity obligation under Section 9), in the case of any Latent Defect, notice of the defect by OptiNose must also be made prior to [***]. Any Product that is not rejected within the applicable period indicated in Section 5.1.1 above shall be deemed accepted by OptiNose; provided that OptiNose shall accept that portion of a batch that it receives with respect to a batch that has a Quantitative Defect (with the terms of Section 2.9 and 2.10 still applying to the full Purchase Order), while awaiting Hikma's Delivery of the remaining portion of such batch.

5.2 Resolution of Defective Product.

5.2.1 Patent Defect or Latent Defect. Subject to, and without waiver or limitation of OptiNose's and/or Hikma's rights and remedies hereunder, at law and/or in equity, if OptiNose believes that a Product or shipment has a Patent Defect or Latent Defect, OptiNose shall, in

consultation with Hikma but at OptiNose's reasonable discretion, request Hikma to replace the Defective Product or shipment with Product that is not Defective Product, or credit or repay the full amount of any payments, including actual shipping costs, made by OptiNose for such Product. If Hikma does not agree with OptiNose's determination that such Product or shipment has a Latent Defect or Patent Defect, then after reasonable efforts to resolve the disagreement, and subject to, and without waiver or limitation of OptiNose's and/or Hikma's rights and remedies hereunder, at law and/or in equity, either Party may submit a sample of such Product to a mutually agreed upon independent third party testing laboratory which is an expert in the industry and which will expertly and objectively apply the agreed upon testing protocol in order to determine whether the Product constitutes Defective Product. The independent party's results shall be final and binding for purposes of determining whether payment is owed (but not for purposes of any pending or potential product liability litigation which shall be governed by Article 9 hereof). If such results indicate that the Product was Defective Product, then in addition to, and without waiver or limitation of OptiNose's or Hikma's rights and remedies hereunder, at law and/or in equity, OptiNose shall be entitled, at its option, to demand that Hikma replace the Defective Product shipment with Product that is not Defective Product or that Hikma credit or repay (at OptiNose's sole discretion) the full amount of any payments, including shipping costs, made by OptiNose for such Product. If the independent party's results indicate the Product was not a Defective Product, OptiNose shall pay the Purchase Price for such Product (if not already paid), the Purchase Price of any replacement Product and the shipping costs for the delivery and/or return, as applicable, of the Product and replacement Product, if any. Unless otherwise agreed to by the Parties in writing, the costs associated with testing and review of a Product by such independent third-party laboratory pursuant to this Section 5.2.1 shall be borne by the non-prevailing Party.

5.2.2 Quantitative Defect. Subject to, and without waiver or limitation of OptiNose's and/or Hikma's rights and remedies hereunder, at law and/or in equity, if OptiNose believes that a shipment has a Quantitative Defect, OptiNose shall notify Hikma within the applicable period. If Hikma agrees with such Quantitative Defect, Hikma will, in consultation with OptiNose and at OptiNose's reasonable discretion, either (a) promptly and as soon as practicable, and in no event more than **[***]**, ship sufficient Product at OptiNose's direction to remedy such Quantitative Defect (which such shipment shall be subject to the terms of Section 2.9 hereof and all other applicable provisions of this Agreement); or (b) promptly credit or refund (at OptiNose's sole discretion) OptiNose for the amount of such Quantitative Defect. If Hikma does not agree with OptiNose's determination that such shipment has a Quantitative Defect, then after reasonable efforts to resolve the disagreement, and subject to and without waiver or limitation of OptiNose's and/or Hikma's rights and remedies hereunder, at law and/or in equity, Hikma may require a mutually agreed upon independent third party to determine whether the shipment had a Quantitative Defect. The independent party's results shall be final and binding for purposes of determining whether Hikma is obligated to ship additional Product, and the costs of such

independent third party shall be borne by the non-prevailing Party. If such results indicate that the shipment had a Quantitative Defect, then OptiNose shall be entitled to require that Hikma promptly and as soon as practicable, and in no event more than **[***]** from such determination, make available and pay for expedited shipping Product at OptiNose's direction to remedy such Quantitative Defect, with no additional costs or charges due or payable from OptiNose with respect to such additional shipment and Product therein, and if OptiNose has already paid in connection with the original Purchase Order, to require that Hikma credit any amounts due to OptiNose pursuant to Section 2.9 as it relates to the Product supplied to remedy the Quantitative Defect; provided that if no payments are due by OptiNose to Hikma then Hikma shall promptly refund such amount to OptiNose within **[***]** days of Hikma's receipt of an invoice from OptiNose for same. Notwithstanding anything to the contrary and subject to Sections 2.9 and 2.10, the remedies under this Section 5.2.2 are **[***]**.

5.2.3 All Products with a Patent Defect, Latent Defect or Quantitative Defect shall count against the Annual Minimum without any obligation on OptiNose to ultimately purchase such Product.

ARTICLE 6
RECORDS AND REGULATORY MATTERS

6.1 Batch Records and Data. Prior to Delivery of the first and each subsequent batch of each Product, Hikma shall provide OptiNose with properly completed and accurate copies of manufacturing work orders, packaging work orders, certificates of analysis, and certificates of compliance, and any other documents properly associated with the Product batch Release (for example, without limitation, documents relating to any investigations concerning the batch Release) ("**Batch Records**"). OptiNose shall have **[***]** days after receipt of all Batch Records to either provide Hikma with comments or corrections to be addressed or incorporated in such documents or with a Release letter authorizing Hikma to provide Delivery of the Product.

6.2 Recordkeeping. Hikma shall maintain true and accurate books, records, test and laboratory data, reports and all other information relating to Manufacturing under this Agreement, including all information required to be maintained by all Applicable Laws. Such information shall be maintained for a period of at least **[***]** from the relevant finished Product expiration date or longer if required under Applicable Laws. Hikma shall provide monthly inventory reports of OptiNose Components and all other Raw Material inventoried by Hikma solely for the manufacture of Product.

6.3 Regulatory Compliance. Except as provided in the following sentence, OptiNose shall be solely responsible for obtaining and maintaining all permits and licenses required by any Regulatory Authority with respect to the Product, the NDA and any other marketing

authorizations in the Territory and other jurisdictions, as applicable, including any Product licenses, applications and amendments in connection therewith. Hikma will be responsible for obtaining and maintaining all permits and licenses required by any Applicable Law with respect to the Facility, its equipment, and the Manufacture and Delivery of the Product. Hikma will also maintain the Specifications, subject to Section 2.2.2, in accordance with the written instructions from OptiNose. Hikma will Manufacture and provide Delivery of the Product in accordance with the requirements of this Agreement, Specifications, Applicable Laws and the Quality Agreement. In addition, during the Term of this Agreement, at OptiNose's request and at OptiNose's expense, Hikma will reasonably assist OptiNose with all regulatory matters related to Manufacturing under this Agreement. Each Party intends and commits to cooperate to satisfy all Applicable Laws within the scope of its respective responsibilities under this Agreement.

6.4 Regulatory Correspondence. Hikma shall notify OptiNose immediately (**[***]**) of any correspondence, any inspections, and the result of any inspection(s) with the FDA or any Regulatory Authority related to the Product. Hikma shall send a draft to OptiNose of all correspondence related to the Product that Hikma intends to send to any Regulatory Authority. All correspondence with a Regulatory Authority related to the Product shall be subject to OptiNose's review and comment. OptiNose shall have **[***]** days to review the draft correspondence and provide its comments. Hikma shall, acting reasonably, determine whether to incorporate such comments into the final correspondence. If OptiNose fails to review and/or provide comments to such correspondence within **[***]** days, OptiNose shall be deemed to have no comments to the correspondence. In no event shall OptiNose cause Hikma to be late in responding to any Regulatory Authority. With respect to all correspondence and reports provided to OptiNose pursuant to this Section 6.4, Hikma shall be entitled to redact any information that is specific to its customers other than OptiNose or that is not directly related to the Product, and OptiNose agrees that such correspondence and reports shall constitute Confidential Information of Hikma.

6.5 Governmental Inspections and Requests. Hikma and OptiNose shall as soon as reasonably practicable (**[***]**) inform each other in writing of any inspection, application for inspection, and other regulatory action, by any regulatory agency material to the Product or the manufacture of Product and/or, in the case of the Facility, material to Hikma's manufacturing, packaging, testing and storage of the Product, so that the other Party has as much advance notice as reasonably possible to enable it to, as applicable and relevant, participate in preparation and/or strategy regarding and/or attend the inspection. Each Party will permit the other's representatives to be present during any such inspection related directly to the Product, and in the case of OptiNose, Hikma will, where Hikma reasonably deems it appropriate or as otherwise agreed to between the Parties under the Quality Agreement, also permit OptiNose to be present at any inspection of the Facility to the extent such inspection is directly related to Hikma's manufacturing, packaging, testing or storage of the Product, provided that in such case, it is

understood and agreed by OptiNose that all communication with the Regulatory Authority shall be directly between Hikma and the Regulatory Authority unless the FDA requests to communicate with OptiNose. Each Party will provide the other with the results of all regulatory inspection or audits directly related to the Product within **[***]** days after such Party's receipt of such results.

6.6 Recall. In the event Hikma believes a recall, field alert, Product withdrawal or field correction may be necessary with respect to any Product provided under this Agreement, Hikma shall as soon as reasonably practicable (**[***]**) notify OptiNose in writing. Hikma will not act to initiate a recall, field alert, Product withdrawal or field correction. In the event OptiNose believes a recall, field alert, Product withdrawal or field correction may be necessary with respect to any Product provided under this Agreement, OptiNose shall immediately notify Hikma in writing and Hikma shall provide all reasonably necessary cooperation and assistance to OptiNose. The cost of any recall, field alert, Product withdrawal or field correction, and any assistance in connection therewith, shall be borne by **[***]**. For avoidance of doubt, OptiNose shall have the ultimate and final authority to initiate a recall and is responsible (as it deems appropriate) for initiating any recall, field alert, Product withdrawal or field correction.

6.7 Inspections and Audits by OptiNose.

6.7.1 Representatives of OptiNose shall have the right to access to each Facility with reasonable notice, as more particularly described below, for the purpose of:

(a) conducting inspections of such Facility and Hikma's maintenance and usage of the equipment utilized in the Manufacture of the Products;

(b) performing quality control audits as provided for under the Quality Agreement;

(c) witnessing the Manufacture, storage of the Products or the Raw Materials related to or used in the Manufacture of the Products; or

(d) inventory count of OptiNose Components and audit of OptiNose Equipment at the Facility.

6.7.2 OptiNose shall have access to the results of any tests performed by Hikma relating to Products and the Raw Materials that Hikma purchases directly from a third party in the Manufacture of the Product. Hikma shall, to the extent practical and reasonable, endeavor (without the payment of any additional fees) to ensure that OptiNose has similar access to the facilities, data and records of Hikma's agents and suppliers. Further, Hikma will make available

to OptiNose written documentation verifying the current qualification status of the third parties and audit results from audits that Hikma conducts, or has conducted, regarding such third parties. Such inspections do not relieve Hikma of any of its obligations under this Agreement or create new obligations on the part of OptiNose.

6.7.3 It is expressly understood that with respect to Sections 6.7.1(a) and (b) above, OptiNose's right of inspection, audit, and witnessing can be exercised **[***]**, and subject to a written notice to Hikma given at least **[***]** days prior to the inspection, or as soon as reasonably practicable if for cause.

6.7.4 It is also expressly understood that with respect to Section 6.7.1(c) above, OptiNose's right of inspection shall be subject to a written notice to Hikma given at least **[***]** days prior to the inspection.

6.7.5 It is further expressly understood that with respect to Section 6.7.1(d) above, OptiNose's right may be exercised **[***]** (and as often as necessary for cause), subject to a written notice to Hikma given at least **[***]** days prior to the inspection, or at any time or more frequently for cause. Hikma shall permit such inspection during normal business hours at reasonable and mutually acceptable times.

6.7.6 At all times during any audit by OptiNose of a Facility, OptiNose's representatives shall be accompanied by Hikma personnel and will follow all site environmental health and safety policies of Hikma. Each inspection, audit and witnessing shall be subject, at all times, to Hikma's confidentiality and non-disclosure obligations to its other third-party customers.

ARTICLE 7
REPRESENTATIONS AND WARRANTIES

7.1 Hikma. Hikma hereby represents, warrants and covenants to OptiNose that:

7.1.1 All Product Delivered hereunder and its corresponding Raw Materials will conform to the Specifications, Applicable Laws, and the Quality Agreement, and such Product shall have been Manufactured, assembled, packaged, labeled, tested and Delivered in accordance with all Applicable Laws, including without limitation, current good manufacturing practices, and the Quality Agreement, and shall be free of any Latent Defect, Patent Defect, or Quantitative Defect;

7.1.2 Product Delivered hereunder shall not contain any material or be manufactured, handled or stored in any way that would cause the Product to be adulterated in any way within

the meaning of Section 501, or misbranded within the meaning of Section 502, of the FD&C Act, as amended from time to time;

7.1.3 As of the Effective Date and at all times during the Term, Hikma will ensure to have the Facility and all equipment utilized in the Manufacture of the Product in compliance with all Applicable Laws;

7.1.4 At all times during the Term, Hikma shall obtain OptiNose's written approval for the use of any third party contract laboratory for the testing and Release of Product, and shall be responsible to ensure that any such contractor is bound to and fully complies with all applicable terms and conditions of this Agreement, including but not limited to those regarding confidentiality and Intellectual Property, the Specifications, the Quality Agreement and the requirements of all Applicable Laws. It is understood that any delays beyond **[***]** days in OptiNose's responsiveness regarding Hikma's obligations under this Section 7.1.4, shall extend any applicable delivery dates *pari passu* under a Purchase Order and, in this regard, such delay shall *pari passu* extend the time by which it is determined whether it is a Supply Failure;

7.1.5 **[***]**, Hikma will not, and will instruct and ensure that its Affiliates do not:

(a) challenge, instruct a third party to challenge, or assist any third party in any challenge of the validity or enforceability of any of OptiNose's Intellectual Property rights within the Territory, including any claim of OptiNose's patents related to the Packaged Product, in any context, in any court or forum within the Territory, including but not limited to, any judicial, agency, Regulatory Authority, or USPTO (or equivalent) proceeding (including reexamination proceedings) and/or any efforts to initiate a declaratory judgment action with respect to any of OptiNose's Intellectual Property rights, or

(b) challenge, instruct a third party to challenge, or assist any third party in any challenge (provided, however, that performing general contract manufacturing services in the ordinary course at a third party's request or participating in a business partnership (so long as Hikma and its Affiliates do not make direct payment(s) for, opine on, or submit filing(s) as part of a challenge), in each instance to the extent not barred or otherwise restricted by this Agreement, shall not be deemed as "assist" for purposes of this Section 7.1.5(b)) of the validity or enforceability of any of OptiNose's Intellectual Property rights within such other countries/territories as set forth on Schedule 2, including any claim of OptiNose's patents related to the Packaged Product, in any context, in any court or forum within such countries/territories as set forth on Schedule 2, including but not limited to, any judicial, agency, regulatory authority, or USPTO (or equivalent) proceeding (including reexamination proceedings) and/or any efforts to initiate a declaratory judgment action with respect to any of OptiNose's Intellectual Property rights;

7.1.6 **[***]**, neither Hikma nor any of its Affiliates providing services under this Agreement will challenge, instruct a third party to challenge, or assist any third party in any challenge of the validity or enforceability of any of OptiNose's Intellectual Property rights within such other countries/territories as set forth on Schedule 2, including any claim of OptiNose's patents related to the Packaged Product, in any context, in any court or forum within such countries/territories as set forth on Schedule 2, including but not limited to, any judicial, agency, regulatory authority, or USPTO (or equivalent) proceeding (including reexamination proceedings) and/or any efforts to initiate a declaratory judgment action with respect to any of OptiNose's Intellectual Property rights;

7.1.7 To its knowledge, information and belief, Hikma warrants, represents and agrees that neither Hikma nor any of its employees has ever been: (a) debarred under Section 306 (a) or (b) of the Generic Drug Enforcement Act of 1992, (Article 306(a) or (b)); or (b) (i) convicted of a crime for which a person can be debarred, (ii) threatened to be debarred, or (iii) indicted for a crime or otherwise engaged in conduct for which a person can be debarred, in each case under Section 306 (a) or (b), provided, it is understood and agreed that the foregoing representations, warranties and agreements contained in this Section 7.1.6, the use of the phrase "to its knowledge" means that Hikma has made reasonable inquiries of its employees and has conducted searches of the FDA debarment list (available at: http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/ucm2005408.htm), the U.S. Department of Health & Human Services Office of Inspector General Exclusions Database (available at: https://exclusions.oig.hhs.gov), the U.S. Federal Government System for Award Management Records (available at: https://www.sam.gov) and http://www.ustreas.gov/offices/enforcement/ofac/ maintained by the U.S. Treasury Department's Office of Foreign Assets Control and as a result thereof no information has come to Hikma's attention which contradicts or is inconsistent with such facts or circumstances. OptiNose acknowledges and agrees that Hikma shall be entitled to assume the accuracy, currency and completeness of the records, indices and filing systems maintained at the public offices where such searches are conducted and the information and advice provided to Hikma by appropriate government, regulatory or other like officials with respect to such matters, and Hikma's reliance on such assumption shall be full compliance with Hikma's obligations under this Section. Hikma agrees to immediately notify OptiNose should any Regulatory Authority threaten any action that could possibly result in a breach of this Section 7.1.6;

7.1.8 Hikma shall be solely responsible, liable for, and shall indemnify OptiNose and its Affiliates, for any breach by or on behalf of Hikma's Affiliates of any obligations set forth herein;

7.1.9 Hikma shall review and approve all in-process and finished Product test results to ensure conformity of such results with the Specifications, Applicable Laws, and the Quality Agreement; and

7.1.10 Hikma will exert commercially reasonable efforts to ensure that the certificate of analysis and certificate of compliance, which will accompany each shipment of Product, and all other materials provided by Hikma hereunder shall be accurate, truthful and made in good faith; and

7.1.11 Hikma will comply with all Applicable Laws in the performance of its obligations under this Agreement.

7.2 OptiNose. OptiNose hereby represents, warrants and covenants to Hikma that:

7.2.1 To OptiNose's knowledge, the Specifications conform to all Applicable Laws, and during the Term, OptiNose will inform Hikma of any changes in Applicable Laws to which OptiNose becomes aware that are a Required Change pursuant to Section 2.2.2;

7.2.2 OptiNose will comply with all Applicable Laws in the performance of its obligations under this Agreement and its use of any materials or Product provided by Hikma under this Agreement;

7.2.3 OptiNose has all necessary authority and has requisite rights to OptiNose's Intellectual Property to be used with respect to each Product and any Purchase Order under this Agreement;

7.2.4 To its knowledge, information and belief, OptiNose warrants, represents and agrees that neither OptiNose nor any of its employees has ever been: (a) debarred under Section 306 (a) or (b) of the Generic Drug Enforcement Act of 1992, (Article 306(a) or (b)); or (b) (i) convicted of a crime for which a person can be debarred, (ii) threatened to be debarred, or (iii) indicted for a crime or otherwise engaged in conduct for which a person can be debarred, in each case under Section 306 (a) or (b), provided, it is understood and agreed that the foregoing representations, warranties and agreements contained in this Section 7.2.4, the use of the phrase "to its knowledge" means that OptiNose has made reasonable inquiries of its employees and has conducted searches of the FDA debarment list (available at: http://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/ucm2005408.htm), the U.S. Department of Health & Human Services Office of Inspector General Exclusions Database (available at: https://exclusions.oig.hhs.gov), the U.S. Federal Government System for Award Management Records (available at: https://www.sam.gov) and http://www.ustreas.gov/offices/enforcement/ofac/ maintained by the U.S. Treasury Department's Office of Foreign Assets Control and as a result

thereof no information has come to OptiNose's attention which contradicts or is inconsistent with such facts or circumstances. OptiNose acknowledges and agrees that OptiNose shall be entitled to assume the accuracy, currency and completeness of the records, indices and filing systems maintained at the public offices where such searches are conducted and the information and advice provided to OptiNose by appropriate government, regulatory or other like officials with respect to such matters, and OptiNose's reliance on such assumption shall be full compliance with OptiNose's obligations under this Section. OptiNose agrees to immediately notify OptiNose should any Regulatory Authority threaten any action that could possibly result in a breach of this Section 7.2.4; and

7.2.5 To the best of OptiNose's current knowledge, information and belief, Hikma's use, in accordance with the terms of this Agreement, of OptiNose's Intellectual Property, Confidential Information or other proprietary information of OptiNose, or Raw Materials supplied to Hikma by, or obtained by Hikma at the instruction of, OptiNose, in the manufacture, packaging, assembly, testing, Delivery, importing, exporting of Product or any other service provided by Hikma hereunder, does not infringe or misappropriate the Intellectual Property rights of any third party.

7.3 Mutual. Each Party hereby represents, warrants and covenants to the other Party that:

7.3.1. Existence and Power. Such Party: (a) is duly organized, validly existing and in good standing under the laws of the state or province in which it is organized, (b) has the power and authority and the legal right to own and operate its property and assets, and to carry on its business as it is now being conducted, and (c) is in compliance with all requirements of Applicable Laws.

7.3.2 Authorization and Enforcement of Obligations. Such Party: (a) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (b) has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder;

7.3.3 Execution and Delivery. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;

7.3.4 Consents. All necessary consents, approvals and authorizations of all Regulatory Authorities and other persons required to be obtained by such Party in connection with the Agreement have been obtained; and

7.3.5 No Conflict. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder: (a) do not conflict with or violate any requirement of Applicable Laws, and (b) do not materially conflict with, or constitute a material default or require any consent under, any current contractual obligation of such Party.

7.4 Disclaimer. EXCEPT AS PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES (EXPRESS, IMPLIED, STATUTORY OR OTHERWISE) WITH RESPECT TO THE SUBJECT MATTER HEREOF AND EACH PARTY EXPRESSLY DISCLAIMS ANY SUCH ADDITIONAL REPRESENTATIONS OR WARRANTIES.

ARTICLE 8
CONFIDENTIAL INFORMATION AND INTELLECTUAL PROPERTY

8.1 Mutual Obligation. Hikma and OptiNose agree that they will not use or disclose the other Party's Confidential Information (defined below) to any third party or its Affiliates without the prior written consent of the other Party except as required by law, regulation or court or administrative order; provided, however, that prior to making any such legally required disclosure, the Party making such disclosure shall, to the extent legally permitted, give the other Party as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances and cooperate with the reasonable efforts of such Party to obtain an appropriate protective order. Notwithstanding the foregoing, each Party may disclose the other Party's Confidential Information as necessary to fulfill its obligations under this Agreement to the extent the recipients of the Confidential Information:

8.1.1 need to know such Confidential Information for the purpose of performing under this Agreement;

8.1.2 are advised of the contents of this Article; and

8.1.3 are subject to confidentiality and non-use obligations no less restrictive than those set out under this Article 8.

8.2 Definition. As used in this Agreement, the term "**Confidential Information**" includes all proprietary information related to the Product furnished by Hikma or OptiNose, or any of their respective representatives or Affiliates, to the other or its representatives or Affiliates, as of October 24, 2019 and for the duration of the Term of this Agreement and furnished in any form, including but not limited to written, verbal, visual, electronic or in any other media or manner, and whether or not marked as "confidential". Confidential Information includes, among other things, all proprietary products, Raw Materials, components, Specifications, formulae, reports,

methods, drawings, tools, models, proprietary technologies whether commercial or developmental, Intellectual Property (including, but not limited to inventions, patents, patent applications, patent disclosures, trademarks, copyrights and know-how), regulatory, manufacturing, quality control or assurance, clinical, R&D, human resources, and/or compliance information, data or materials, analyses, compilations, business (including, but not limited to corporate structure, financial, accounting, strategy, plans, documents, contracts, practices, policies and procedures, software, tax, customer, supplier, marketing, sales, forecasting, distribution and/or shipping information, materials or data) or technical information, data and other materials prepared by either Party, or any of their respective representatives, containing or based in whole or in part on any such information furnished by the other Party or its representatives. Confidential Information also includes the existence of this Agreement and its terms, as well as the Confidentiality Agreement, and information provided thereunder, dated as of October 24th, 2019, which is hereby made a part of this Agreement.

8.3 Exclusions. Notwithstanding Section 8.2, Confidential Information does not include information that:

8.3.1 is or becomes generally available to the public or within the industry to which such information relates other than as a result of a breach of this Agreement;

8.3.2 is already known by the receiving Party at the time of disclosure as evidenced by the receiving Party's written records;

8.3.3 becomes available to the receiving Party on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis; or

8.3.4 was or is independently developed or discovered by or for the receiving Party without access or reference to the Confidential Information, as evidenced by the receiving Party's reasonable written records.

8.4 Return of Confidential Information. Upon termination of this Agreement, the receiving Party shall, upon request, promptly return within **[***]** days all such Confidential Information (to the extent reasonably accessible), including any copies thereof, and cease its use or, at the request of the disclosing Party, shall promptly destroy the same and certify such destruction to the disclosing Party; except for a single copy thereof, which may be retained for the sole purpose of complying with the scope of the obligations incurred under this Agreement. For the avoidance of doubt, retention of electronic copies of Confidential Information maintained pursuant to regular data archiving and record retention policies and practices shall not be deemed to be a violation of this Agreement; provided that the Party retaining such electronic copies

implement appropriate measures to ensure that it complies with the confidentiality and non-use obligations related to such Confidential Information.

8.5 Intellectual Property Rights and Disclosure and Ownership of Results.

8.5.1 All right, title and interest in and to, and ownership of and/or Intellectual Property rights in and to the Packaged Product, the Specifications, the Final Approval, any other regulatory approvals related to the Packaged Product (where such regulatory approvals are issued in the Territory or any jurisdiction listed under Schedule 2), the Manufacture, and the marketing, sale, offer for sale, import, export, components, testing, assembly, packaging and distribution associated with the Packaged Product is and at all times remains in OptiNose hereunder and nothing in this Agreement shall operate or be construed so as to grant any license or convey to or confer upon Hikma, whether expressly or by implication, any such rights to other than such limited, nonexclusive license (without right to sublicense) as is necessary to permit Hikma to Manufacture the Packaged Product and provide the Manufacturing to OptiNose on the terms and conditions of and for the periods and limited purposes contemplated in this Agreement.

8.5.2 Moreover, Hikma shall promptly and fully disclose to OptiNose in writing all findings, data, results, and conclusions and all inventions, discoveries, trade secrets, techniques, processes, materials, know-how, trademarks, copyrights and other Intellectual Property rights related thereto, that are prepared, made or discovered by Hikma, either alone or with others, that are solely or materially related to the performance of, or in connection with, the Manufacturing or which result from the use of OptiNose Confidential Information, data, materials, Intellectual Property, Specifications, Final Approval, or other OptiNose-owned or OptiNose-controlled property, during the Term (collectively, "**Inventions**"). In consideration of the promises made hereunder by OptiNose to Hikma, OptiNose shall own all rights, title and interest in and to all Inventions, including, without limitation, all Intellectual Property regarding formulation with respect to the Packaged Product, except to the extent constituting improvements to Hikma's then pre-existing or independently developed Intellectual Property (in each instance without the use or reliance upon any OptiNose Confidential Information or Inventions) (the "**Hikma Manufacturing Improvements**"). Hikma will own all rights, title and interest in and to the Hikma Manufacturing Improvements and hereby grants to OptiNose, in consideration of the promises made hereunder, a perpetual, non-terminable, worldwide, royalty-free, transferable and sublicensable (through multiple tiers) non-exclusive license to use the Hikma Manufacturing Improvements for any purpose related to the Packaged Product. Hikma, on behalf of itself, its Affiliates, and its and their respective directors, officers, employees and agents, hereby assigns, transfers and conveys all of their right, title and interest in and to any and all Inventions, other than the Hikma Manufacturing Improvements, to OptiNose. Any materials (including the information contained therein) produced by Hikma, either alone or with others, for OptiNose pursuant to the terms of this Agreement shall be the sole and exclusive property of OptiNose.

OptiNose hereby grants to Hikma a royalty-free, non-transferable, non-sublicensable, non-exclusive license to use any Inventions solely to the extent and for the duration necessary to enable Hikma to perform its obligations hereunder. Hikma shall not acquire any other right, title or interest in or to the Inventions as a result of its performance hereunder.

8.5.3 All materials subject to copyright protection prepared by or on behalf of Hikma in relation to the Packaged Product based on or relying upon OptiNose's Confidential Information or Inventions shall be "works made for hire," the entire right, title and interest of which shall vest and reside in OptiNose. To the extent any such works prepared by or on behalf of Hikma that are directly related to the Packaged Product or that are based on or rely upon OptiNose's Confidential Information or Inventions, may not be interpreted as "works made for hire," such works shall be subject to Hikma's granting to OptiNose an exclusive, non-royalty bearing, perpetual, non-terminable, worldwide, royalty-free license, with the right to assign and/or sub-license (including through multiple tiers) such works. OptiNose shall have the right to use all materials and other works subject to copyright protection prepared by or on behalf of Hikma directly related to the Packaged Product, and Hikma hereby grants to OptiNose, in consideration of the payments made hereunder, a perpetual, non-terminable, worldwide, royalty-free, transferable and sublicensable (through multiple tiers) non-exclusive license to use such materials for any purpose related to the Packaged Product.

8.5.4 Upon the request and at the expense of OptiNose, Hikma will execute and deliver any and all instruments and documents and take such other acts as may be necessary or desirable to document such transfer or to enable OptiNose or its Affiliates to prepare, file, apply for, prosecute, enforce and maintain patents, trademark registrations or copyrights associated with the Packaged Product.

8.5.5 For clarification, except as specifically provided herein all Intellectual Property rights and know-how owned by each Party before the Effective Date of this Agreement or developed independently of this Agreement during the Term and thereafter remain the property of the said Party.

8.6 Survival. The obligations of this Article 8 shall at all times survive the expiration or sooner termination of the Term of this Agreement.

ARTICLE 9
INDEMNIFICATION

9.1 Indemnification by Hikma.

9.1.1 Hikma shall defend (if requested), indemnify and hold harmless OptiNose, its Affiliates, and their respective directors, officers, employees and agents ("**OptiNose Indemnitees**") from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees) ("**Losses**") arising out of or resulting from:

(a) **[***]**;

(b) **[***]**;

(c) **[***]**;

(d) **[***]**; or

(e) **[***]**.

9.1.2 Hikma's obligation to OptiNose Indemnitees under this Section 9.1 shall (a) not apply where it is determined that the Losses incurred by OptiNose arise from **[***]**.

9.2 Indemnification by OptiNose.

9.2.1 OptiNose shall defend (if requested), indemnify and hold harmless Hikma, its Affiliates, and their respective directors, officers, employees and agents ("**Hikma Indemnitees**") from and against all Losses arising out of or resulting from:

(a) **[***]**;

(b) **[***]**;

(c) **[***]**;

(d) **[***]**; or

(e) **[***]**.

9.2.1 OptiNose's obligation to Hikma Indemnitees under this Section 9.2 shall not apply where it is determined that the Losses incurred by Hikma arise from **[***]**.

9.3 Indemnification Procedures. Upon becoming aware of a claim for which it believes it is entitled to indemnification, a Party (the "**Indemnitee Party**") shall: (i) provide the other Party

(the "**Indemnitor Party**") with prompt notice; (ii) reasonably cooperate with the Indemnitor Party in the defense of any such claim at the Indemnitor Party's expense; and (iii) at its sole election and discretion provide the Indemnitor Party with control of the defense and/or settlement of any such claim, provided that the Indemnitor Party shall not settle any claim admitting fault or liability of or imposing duties of performance or payment upon any Indemnitee Party (or any other OptiNose Indemnitees or Hikma Indemnitees) without the Indemnitee Party's prior written consent, not to be unreasonably withheld, conditioned, or delayed. The Indemnitee Party will have the right to participate in the defense of any claim (including by engaging separate counsel at its sole cost and expense) for which it seeks indemnification at its own expense, unless the Indemnitor Party is obligated to indemnify the Indemnitee Party for such expenses in accordance with this Section 9.3. If requested to defend the Indemnitee Party, the Indemnitor Party will engage counsel reasonably acceptable to the Indemnitee Party. For the avoidance of doubt, should the Indemnitee Party opt not to provide the Indemnitor Party with control of the defense and/or settlement of a claim, the Indemnitor Party shall remain responsible for indemnifying the Indemnitee Party for the reasonable costs and expenses associated with such defense and/or settlement, including reasonable attorneys' fees and costs, and the Indemnitee Party shall not settle any claim admitting fault or liability of or imposing duties of performance or payment upon the Indemnitor Party without the Indemnitor Party's prior written consent. The Indemnitee Party's failure to comply with its obligations under this Section will not relieve the Indemnitor Party of its obligations under this Section except to the extent that the Indemnitor Party has been materially and unreasonably prejudiced as a result of such failure.

ARTICLE 10
INSURANCE

10.1 Hikma Insurance. Hikma shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the Term of this Agreement:

10.1.1 Commercial General Liability Insurance;

10.1.2 Product Liability Insurance and Completed Operations Liability Insurance

10.1.3 Property Insurance (that shall cover the OptiNose Equipment and OptiNose Components while at the Facility); and

10.1.4 Professional Liability and/or Errors and Omissions Liability Insurance.

10.2 Each type of insurance identified under Section 10.1 shall have a per-occurrence and general aggregate limits of not less than **[***]**, and from and after the date of first commercial sale of a Product Manufactured pursuant to this Agreement, of not less than **[***]**. This

requirement may be satisfied through the use of an umbrella policy. Additionally, Hikma shall, at its own cost and expense, obtain and maintain in full force and effect, Worker's Compensation Insurance with employer's liability limits meeting statutory requirements. In the event that any of the required policies of insurance are written on a claims-made basis, then such policies shall be maintained during the entire Term of this Agreement and for a period of not less than **[***]**. Hikma's policies shall, upon OptiNose's request, be specifically endorsed to include OptiNose as an additional insured. Upon request, Hikma shall supply OptiNose with proof of insurance and forms as may be reasonably required.

10.3 OptiNose Insurance. OptiNose shall, at its own cost and expense, obtain and maintain in full force and effect the following insurance during the Term of this Agreement: (a) Commercial General Liability Insurance, and (b) Product Liability Insurance and Completed Operations Liability Insurance, in each case with per-occurrence and general aggregate limits of not less than **[***]**, and from and after the date of first commercial sale of a Product Manufactured pursuant to this Agreement, of not less than **[***]**. This requirement may be satisfied through the use of an umbrella policy. In the event that any of the required policies of insurance are written on a claims made basis, then such policies shall be maintained during the entire Term of this Agreement and for a period of not less than **[***]**. OptiNose's policies shall, upon Hikma's request, be specifically endorsed to include Hikma as an additional insured. Upon request, OptiNose shall supply Hikma with proof of insurance and forms as may be reasonably required.

10.4 For clarity, the insurance requirements of this Article 10 shall not be construed to create a limit of either Party's liability with respect to its indemnification obligations under Article 9 or otherwise relieve such Party of any of its other obligations under this Agreement.

ARTICLE 11
TERM AND TERMINATION

11.1 Term of Agreement. The Term of this Agreement shall commence as of the Effective Date and shall remain in effect until December 31, 2026 ("**Initial Term**"). This Agreement shall automatically expire at the end of the Initial Term. This Agreement may be renewed for additional **[***]** terms (each a "**Renewal Term**" and together with the Initial Term, the "**Term**") upon the Parties' written agreement at least **[***]** prior to the end of the Initial Term or the then current Term.

11.2 Default. If either Party at any time commits a material breach of the provisions of this Agreement, the Bailment Agreement or the Quality Agreement, the other Party shall have the right to terminate this Agreement upon **[***]** days' written notice, whereupon this Agreement shall terminate, unless the breach complained of is cured within the said notice period or if the breach cannot, using commercially reasonable efforts, be cured within such **[***]** day period but

is reasonably expected to be cured within an additional **[***]** day period, and the Party in default has promptly commenced to cure such breach within such **[***]** day period and exercises diligent efforts to effect such cure as soon as is reasonably practicable in the circumstances, and in any event such breach is cured within such additional **[***]** day period. Notwithstanding the foregoing, should a Party have **[***]** material breaches during a **[***]** or **[***]** material breaches during **[***]** (even if subsequently cured) (the "**Default Breach**"), the other Party shall have the right thereafter to terminate this Agreement by providing the defaulting Party with written notice within one (1) year from the date of the applicable Default Breach, which termination shall be no less than **[***]** days from the date of the notice.

11.3 Bankruptcy or Insolvency. If either Party shall:

11.3.1 become bankrupt or insolvent;

11.3.2 file for petition therefore;

11.3.3 make an assignment for the benefit of creditors; or

11.3.4 have a receiver appointed for its assets, which appointment shall not be vacated within **[***]** days after the filing,

then the other Party shall be entitled to terminate this Agreement forthwith by written notice to such Party.

11.4 Termination.

11.4.1 Termination by OptiNose.

(a) OptiNose shall have the right to terminate this Agreement immediately upon written notice if:

(i) any Intellectual Property of any third party is reasonably alleged by a third party to be infringed, misappropriated or otherwise violated by the Manufacture, import, use, sale or distribution of the Product;

(ii) any Regulatory Authority requires OptiNose to cease production or sale of Product(s); or

(iii) **[***]**.

(b) OptiNose agrees that in the event it exercises any right to terminate the Agreement pursuant to this Section 11.4.1, that OptiNose shall pay Hikma the Purchase Price for all finished Product and may reimburse Hikma for the costs of work in process inventory of all partially Manufactured by Hikma (as shall be negotiated in good faith between the Parties), in each case in accordance with this Agreement as of the date when OptiNose exercises such right; provided, however, that OptiNose shall be promptly reimbursed for any such Raw Materials that Hikma otherwise uses or sells to other customers without violation of the terms of this Agreement.

(c) Hikma will cooperate with OptiNose to return inventory where applicable and feasible, with freight and restocking fees to be at the expense of OptiNose. It is understood and agreed, however, that where Hikma is able to return inventory, OptiNose shall only be responsible for such freight charges, provided that Hikma has been reimbursed in full by vendor(s) for such returned inventory. In the event that Hikma has not been reimbursed in full by any vendor or by any other third party for any Raw Material, OptiNose shall pay to Hikma the difference between Hikma's cost and the reimbursement received by the vendor or such other third party. Subject to and without waiver or limitation of OptiNose's rights and remedies in Section 11.2 above, 11.6 below and elsewhere in this Agreement, at law and/or in equity, OptiNose shall make payment to Hikma for all amounts described in this Section 11.4, subject to and in accordance with the terms hereof, within **[***]** days from the invoice date.

1.1.2 Termination by Hikma. Hikma may terminate this Agreement:

(a) for convenience during the Initial Term and only after the Final Approval Date, for any or no reason **[***]**; or

(b) after the Final Approval Date, with **[***]** days' prior written notice to OptiNose if (i) Hikma is named in a third party claim, suit, action, or proceeding (each a "**Claim**") whereby such Claim states that Hikma's performance of its obligations under this Agreement, to the extent directed by OptiNose, infringes, misappropriates, or otherwise violates the Intellectual Property of any third party in the Territory; (ii) in the reasonable opinion of Hikma's external counsel (after discussions with and reasonable consideration of OptiNose's counsel's opinion), the Intellectual Property of such third party that is the subject of the Claim and that is material to the Packaged Product is reasonably determined to be infringed, misappropriated, or otherwise violated in the Territory by Hikma's performance of its obligations under this Agreement to the extent directed by OptiNose; and (iii) if OptiNose fails to cure such infringement, misappropriation, or violation within a timeframe reasonably agreed to between the Parties after OptiNose's receipt of a termination notice under this Section 11.4.2(b) (but in no event shall such timeframe be fewer than ninety (90) days). Notwithstanding the foregoing, the termination right set forth in this Section 11.4.2(b) shall not apply if OptiNose provides Hikma

with reasonable written assurances that OptiNose will satisfy its indemnification obligations to Hikma with respect to such Claim.

11.5 Force Majeure. Except as to payments required under this Agreement, if any default or delay occurs which prevents or materially impairs a Party's performance and is due to a cause beyond the Party's reasonable control, and provided that the default or delay is not caused by or the fault of such Party, including but not limited to an act of God, flood, fire, explosion, earthquake, casualty, accident, war, revolution, civil commotion, blockade, terrorism or embargo or failure of available supply of Raw Materials and/or packaging components not reasonably preventable (in each case **"Force Majeure**"), the affected Party shall promptly notify the other Party in writing of such cause and shall exercise diligent efforts to resume performance under this Agreement as soon as possible (which for Hikma shall include potentially using alternative sites, with OptiNose's written approval). Neither Party will be liable to the other Party for any loss or damage due to such cause, nor will the Term be extended thereby. A Party may terminate this Agreement because of a Force Majeure upon not less than **[***]** days' prior written notice to the other Party provided that the default or delay has already existed for **[***]** days at the time of such notice and is continuing at the end of such termination notice period (i.e., the Force Majeure need not be suffered by the other Party for more than **[***]** days).

11.6 Effect of Termination.

11.6.1 Expiration or termination of this Agreement on any basis shall be without prejudice to:

(a) any rights or obligations that accrued to the benefit of either Party prior to such expiration or termination; and

(b) any claims, remedies or other rights either Party may have at law, in equity or otherwise pursuant to or in connection with this Agreement.

11.6.2 The rights and obligations of the Parties shall continue under Article 1, Section 2.1.6, Articles 3, 5, 6, 7, 8, 9, and 10, Sections 11.4 and 11.6, Articles 12, 13, and 14 notwithstanding expiration or termination of this Agreement. Furthermore, the rights and obligations of the Parties under Section 2.12 shall continue until the end of the anticipated date hereunder of the Initial Term. In addition, any other provision required to interpret and to enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the observation and performance of the aforementioned surviving portions of this Agreement.

ARTICLE 12

LIMITATIONS OF LIABILITY

12.1 EXCEPT WHERE DUE TO **[***]**, SUCH PARTY SHALL NOT BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF THIS AGREEMENT, INCLUDING WITHOUT LIMITATION, LOSS OF REVENUES, PROFITS, DATA, OR BUSINESS OPPORTUNITY, WHETHER IN CONTRACT OR TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

12.2 NOTWITHSTANDING ANY OTHER PROVISION TO THE CONTRARY UNDER THIS AGREEMENT AND EXCEPT WITH RESPECT TO **[***]**, IT IS EXPRESSLY AGREED THAT A PARTY'S AGGREGATE LIABILITY TO THE OTHER PARTY UNDER THIS AGREEMENT SHALL NOT EXCEED **[***]**:

12.2.1 **[***]**

12.2.2 **[***]**

(a) **[***]**

(b) **[***]**

(c) **[***]**.

ARTICLE 13
NOTICE

13.1 Notices. All notices and other communications hereunder ("**Notices**") shall be in writing and shall be deemed given:

13.1.1 when delivered personally;

13.1.2 when received or refused, if mailed by registered or certified mail (return receipt requested), postage prepaid;

13.1.3 when delivered if sent by reliable express courier service with a confirmation, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof**);** or

13.1.4 when delivered by email followed up by registered or certified mail, return receipt requested.

13.2 Parties' Addresses. For the purposes of this Article 13, the Parties' addresses for Notices are set out below:

13.2.1 If to OptiNose:

OptiNose US, Inc.
1020 Stony Hill Road
Suite 300
Yardley, PA 19067
Attn: Chief Executive Officer

with copy to:

OptiNose US, Inc.
1020 Stony Hill Road
Suite 300
Yardley, PA 19067
Attn: Chief Legal Officer

13.2.2 If to Hikma:

Hikma Pharmaceuticals USA Inc.
200 Connell Drive
Berkeley Heights, NJ 07922
Attn: Legal Department

With a copy, which shall not constitute notice, to:

Hikma Pharmaceuticals USA Inc.
1809 Wilson Road
Columbus, OH 43228
Attn: Alliance Management

ARTICLE 14
MISCELLANEOUS

14.1 Entire Agreement; Amendments. This Agreement, the Quality Agreement, the Bailment Agreement, and any exhibits, schedules, attachments, and any amendments hereto or thereto, constitute the entire understanding between the Parties with respect to the specific subject matter hereof. No term of this Agreement may be amended except upon written agreement duly executed by both Parties, unless otherwise provided in this Agreement.

14.2 Recitals. The recitals are hereby incorporated in and made part of this Agreement.

14.3 Intentionally Omitted.

14.4 Further Assurances. The Parties agree to execute, acknowledge and deliver such further instruments and to take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

14.5 No Waiver. Failure by either Party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed to be a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

14.6 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect to the extent reasonably severable without altering the Parties' original intent. In such case, the Parties shall promptly undertake in good faith to negotiate a valid replacement provision for any such invalidated or severed provision that tracks as nearly as possible the Parties' original intent.

14.7 Independent Contractors. The relationship of the Parties is that of independent contractors, and neither Party will incur any debts or make any commitments for the other Party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the Parties the relationship of joint ventures, co-partners, employer/employee or principal and agent.

14.8 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the Parties, their successors and permitted assigns. Neither Party may assign this Agreement, in whole or in part, without the prior written consent of the other Party, except that either Party may, without the other Party's consent, assign this Agreement to an Affiliate or to an acquirer of or a successor to substantially all of the business or assets of the assigning Party. In the case of assignment to an Affiliate, where the assignee is not also the acquirer or successor to substantially all of the business or assets of the assigning Party (a "**Permitted Transferee**"), the following conditions apply:

14.8.1 the transferor is not in breach of its obligations under this Agreement;

14.8.2 the Permitted Transferee is, and remains, an Affiliate of the transferor; and

14.8.3 the Permitted Transferee has the reasonable wherewithal to and is reasonably capable of discharging the obligations of the transferor hereunder to the same extent as transferor, and the Permitted Transferee agrees to assume and be bound by and entitled to the benefits and obligations and rights under this Agreement to the extent and with the same effect as if such Permitted Transferee was the original Party to this Agreement and the Permitted Transferee and the transferor shall be jointly and severally liable to the other Party for the performance of the Permitted Transferee of the obligations of the transferor contained in this Agreement.

14.9 Intentionally Omitted.

14.10 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

14.11 Publicity. Neither Party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other Party's express prior written consent, except as required under Applicable Laws or by any governmental agency or stock exchange rule or regulation, in which case the Party required to make the press release or public disclosure shall inform the other Party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

14.12 Conflicting Terms. To the extent this Agreement and the Quality Agreement or Bailment Agreement have directly conflicting terms, this Agreement shall govern.

14.13 Currency. Wherever a currency is indicated throughout this Agreement, that currency shall be United States Dollars.

14.14 Intentionally Omitted.

14.15 Sophisticated Parties. Each Party to this Agreement is a sophisticated business party negotiating in good faith with the advice of legal counsel.

14.16 English Language. This Agreement has been negotiated and is written in the English language, and the English original shall prevail over any translation hereof.

14.17 Interpretations. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections, Schedules or Exhibits mean the particular Articles, Sections, Schedules or Exhibits to this Agreement and references to this Agreement include all Schedules and Exhibits hereto. Unless context clearly requires otherwise, whenever used in this Agreement: (i) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (ii) the word "or" shall have its inclusive meaning of "and/or;" (iii) the word "notice" shall require notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (iv) the words "hereof," "herein," "hereunder," "hereby" and derivative or similar words refer to this Agreement (including any Schedules and Exhibits); (v) provisions that require that a Party or the Parties "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing; (vi) words of any gender include the other gender; (vii) words using the singular or plural number also include the plural or singular number, respectively; and (viii) references to any specific law, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement thereof.

14.18 Dispute Resolution. The senior executives of the respective Parties shall use reasonable efforts to negotiate in good faith to resolve disputes regarding any right, obligation, duty or liability which may arise between the Parties under this Agreement. Subject to Section 5.2 hereof, in the event that the Parties are unable to resolve such dispute within a reasonable period of time, either Party may pursue appropriate legal and equitable relief, as provided by Applicable Law, consistent with Section 14.19, below.

14.19 Governing Law and Venue. This Agreement shall be governed by and construed in accordance with the laws (except for the laws governing choice of law) of and in the state and/or federal courts, should federal jurisdiction requirements exist, located within the State of Delaware, U.S.A, wherein jurisdiction and venue over the Parties and any dispute shall be exclusively had. THE PARTIES HEREBY IRREVOCABLY WAIVE THEIR RIGHT TO TRIAL BY JURY. The Parties expressly agree that the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused their duly authorized representatives to execute this Agreement.

HIKMA PHARMCEUTICALS USA INC.	**OPTINOSE US, INC.**
By: /s/ Brian Hoffmann	By: /s/ Ramy Mahmoud
Name: Brian Hoffmann	Name: Ramy Mahmoud
Its: President	Its: President

EXHIBIT A

PRODUCT SPECIFICATIONS

[***]

EXHIBIT B

PRICE

[***]

SCHEDULE 1
OPTINOSE COMPONENTS, OPTINOSE-DESIGNATED COMPONENTS, OPTINOSE-DESIGNATED VENDORS, AND OPTINOSE VENDORS

[***]

SCHEDULE 2
OTHER COUNTRIES/TERRITORIES

[***]

CERTIFICATION UNDER SECTION 302 OF THE

SARBANES-OXLEY ACT OF 2002

I, Ramy A. Mahmoud, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of OptiNose, 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 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)) 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 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/ Ramy A. Mahmoud
Ramy A. Mahmoud
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION UNDER SECTION 302 OF THE

SARBANES-OXLEY ACT OF 2002

I, Anthony J. Krick, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of OptiNose, 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 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)) 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 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/ Anthony J. Krick
Anthony J. Krick
Chief Accounting Officer
(Principal Financial and Accounting Officer)

CERTIFICATION UNDER SECTION 906 OF THE

SARBANES-OXLEY ACT OF 2002

I, Ramy A. Mahmoud, Chief Executive Officer of OptiNose, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Quarterly Report on Form 10-Q of the Company for the period ending March 31, 2024 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: May 14, 2024

/s/ Ramy A. Mahmoud
Ramy A. Mahmoud
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION UNDER SECTION 906 OF THE

SARBANES-OXLEY ACT OF 2002

I, Anthony J Krick, Chief Accounting Officer of OptiNose, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge

1. the Quarterly Report on Form 10-Q of the Company for the period ended March 31, 2024 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: May 13, 2024

/s/ Anthony J. Krick
Anthony J. Krick
Chief Accounting Officer
(Principal Financial and Accounting Officer)