

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 June 30, 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 or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification Number)

777 Township Line 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 July 31, 2024 was 150,776,811 shares.

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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

XHANCE, EDS, EXHALATION DELIVERY SYSTEM, OPTINOSE and the OptiNose logo 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 including, among other things, the launch of XHANCE for its new indication;
- 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 changes made to the XHANCE co-pay assistance program) and their potential effect on XHANCE demand and financial results;
- the potential benefits of, and impact of transitioning XHANCE business to, a Hub model;
- 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 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 \$90.0 million;
- our expectation that the average net product revenue per prescription for XHANCE for the full year of 2024 will exceed \$250;
- our belief that our existing cash and cash equivalents 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.

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PART I

ITEM 1. FINANCIAL STATEMENTS

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

	June 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 91,358	\$ 73,684
Accounts receivable, net	20,819	19,926
Inventory	11,407	8,052
Prepaid expenses and other current assets	5,346	3,671
Total current assets	<u>128,930</u>	<u>105,333</u>
Property and equipment, net	714	815
Other assets	2,228	1,581
Total assets	<u><u>\$ 131,872</u></u>	<u><u>\$ 107,729</u></u>
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 1,733	\$ 3,886
Accrued expenses and other current liabilities	30,967	42,411
Short term debt, net	—	130,227
Total current liabilities	<u>32,700</u>	<u>176,524</u>
Long term debt, net	125,293	—
Warrant liability	15,400	17,200
Other liabilities	1,332	611
Total liabilities	<u>174,725</u>	<u>194,335</u>
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; 149,678,410 and 112,399,495 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively.	150	112
Additional paid-in capital	699,105	633,742
Accumulated deficit	(742,024)	(720,376)
Accumulated other comprehensive loss	(84)	(84)
Total stockholders' deficit	<u>(42,853)</u>	<u>(86,606)</u>
Total liabilities and stockholders' deficit	<u><u>\$ 131,872</u></u>	<u><u>\$ 107,729</u></u>

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues:				
Net product revenues	\$ 20,490	\$ 19,454	\$ 35,370	\$ 31,299
Total revenues	20,490	19,454	35,370	31,299
Costs and expenses:				
Cost of product sales	1,981	2,571	3,212	4,277
Research and development	928	951	2,134	2,736
Selling, general and administrative	24,129	20,104	44,647	42,828
Total costs and expenses	27,038	23,626	49,993	49,841
Loss from operations	(6,548)	(4,172)	(14,623)	(18,542)
Other (income) expense:				
Unrealized gain on fair value of warrants	(3,100)	(10,900)	(1,800)	(10,390)
Interest income	(809)	(725)	(1,105)	(1,429)
Interest expense	4,947	4,824	9,918	9,496
Foreign currency (gain) loss	(5)	3	13	5
Net (loss) income	\$ (7,581)	\$ 2,626	\$ (21,649)	\$ (16,224)
Less: undistributed earnings to participating shareholders	—	(53)	—	—
Net (loss) income - basic	\$ (7,581)	\$ 2,573	\$ (21,649)	\$ (16,224)
Net (loss) income per share of common stock, basic	\$ (0.05)	\$ 0.02	\$ (0.17)	\$ (0.15)
Weighted average common shares outstanding, basic	147,455,374	111,979,778	130,025,113	111,877,669
Net (loss) income - basic	\$ (7,581)	\$ 2,573	\$ (21,649)	\$ (16,224)
Add: Unrealized gain on fair value of warrants	(3,100)	—	(1,800)	—
Net (loss) income - diluted	\$ (10,681)	\$ 2,573	\$ (23,449)	\$ (16,224)
Net income (loss) per share of common stock - diluted	\$ (0.07)	\$ 0.02	\$ (0.17)	\$ (0.15)
Weighted average common shares outstanding - diluted	150,698,374	112,042,097	136,918,539	111,877,669

See accompanying notes to unaudited interim consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
(Net loss) income	\$ (7,581)	\$ 2,626	\$ (21,649)	\$ (16,224)
Other comprehensive income (loss):				
Foreign currency translation adjustment	—	—	—	—
Comprehensive loss	\$ (7,581)	\$ 2,626	\$ (21,649)	\$ (16,224)

See accompanying notes to unaudited interim consolidated financial statements.

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

Six months ended June 30, 2024

	Stockholders' Equity (Deficit)						Total Stockholders' Equity (Deficit)	
	Common Stock		Additional Paid-in Capital		Accumulated Deficit			
	# of Shares	Par Amount \$				Other Comprehensive Loss		
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	—	—	—	—	—	—	
Net loss	—	—	—	(14,067)	—	—	(14,067)	
Balance at March 31, 2024	113,038,726	\$ 113	\$ 635,198	\$ (734,443)	\$ (84)	\$ (99,216)		
Issuance of stock per amended debt agreement	4,680,000	\$ 5	5,745	—	\$ —	—	5,750	
Proceeds from sales of common stock and warrants, net	31,800,000	\$ 32	55,262	—	\$ —	—	55,294	
Stock compensation expense	—	—	2,735	—	\$ —	—	2,735	
Vesting of restricted stock units	159,684	—	—	—	—	—	0	
Issuance of common stock under employee stock purchase plan	—	—	165	—	—	—	—	
Net loss	—	—	—	(7,581)	—	—	(7,581)	
Balance at June 30, 2024	149,678,410	\$ 150	\$ 699,105	\$ (742,024)	\$ (84)	\$ (42,853)		

Six Months Ended June 30, 2023

	Stockholders' Equity (Deficit)						Total Stockholders' Equity (Deficit)	
	Common Stock		Additional Paid-in Capital		Accumulated Deficit			
	Shares	Par Amount \$				Other Comprehensive Loss		
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	\$ 629,927	\$ (703,740)	\$ (84)	\$ (73,785)		
Stock compensation expense	—	—	1,499	—	—	—	1,499	
Vesting of restricted stock units	135,840	—	—	—	—	—	—	
Issuance of common stock under employee stock purchase plan	—	—	—	—	—	—	—	
Net income	—	—	—	2,626	—	—	2,626	
Balance at June 30, 2023	112,091,764	\$ 112	\$ 631,426	\$ (701,114)	\$ (84)	\$ (69,660)		

See accompanying notes to unaudited interim consolidated financial statements.

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

	Six Months Ended	
	June 30,	
	2024	2023
Operating activities:		
Net loss	\$ (21,649)	\$ (16,224)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	153	179
Stock-based compensation	4,191	3,024
Change in fair value of warrant liability	(1,800)	(10,390)
Amortization of debt discount and issuance costs	832	825
Changes in operating assets and liabilities:		
Accounts receivable	(1,069)	11,804
Prepaid expenses and other assets	(746)	1,856
Inventory	(3,356)	1,672
Accounts payable	(2,153)	1,191
Accrued expenses and other liabilities	(12,122)	(16,953)
Cash used in operating activities	<u>(37,719)</u>	<u>(23,016)</u>
Investing activities:		
Purchases of property and equipment	(51)	(79)
Cash used in investing activities	<u>(51)</u>	<u>(79)</u>
Financing activities:		
Proceeds from sale of common stock and warrants	55,476	—
Proceeds from issuance of common stock under employee stock purchase plan	165	164
Cash paid for financing costs	(198)	(3)
Cash provided by financing activities	<u>55,443</u>	<u>161</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	17,673	(22,934)
Cash and cash equivalents at beginning of period	73,684	94,244
Cash and cash equivalents at end of period	<u>\$ 91,358</u>	<u>\$ 71,310</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 13,745	\$ 8,656
Supplemental disclosure of noncash activities:		
Recognition of right-of-use assets and lease liabilities	\$ 1,402	\$ 221

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, in order to simplify the corporate structure. Optinose UK was liquidated in July 2024.

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 June 30, 2024, the Company had cash and cash equivalents of \$ 91,358 and working capital of \$ 96,230 .

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 net proceeds from the offering were \$ 55.3 million.

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. The Company believes that its cash and cash equivalents on hand as of June 30, 2024 will be sufficient to fund its 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 June 30, 2024 and its results of operations for the three and six months ended June 30, 2024 and 2023 and cash flows for the six months ended June 30, 2024 and 2023. Operating results for the three and six months ended June 30, 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 89 % and 64 % of the Company's accounts receivable at June 30, 2024 and 2023, respectively. Five customers represented approximately 80 % and 42 % of the Company's net product sales for the three months ended June 30, 2024 and 2023, respectively. Five customers represented approximately 72 % and 34 % of the Company's net product sales for the six months ended June 30, 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 June 30, 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 June 30, 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 June 30, 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.

Net product revenues

The Company accounts for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* (ASC 606). 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 and diluted net income (loss) per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities, which include restricted stock units. Under the two-class method, net income (loss) is allocated to common stock and each restricted stock unit to the extent that each restricted stock unit may share in earnings as if all of the earnings for the period had been distributed. The two-class method is not applicable during periods with a net loss, as is the case in the quarter ended, June 30, 2024, and the six month periods ended June 30, 2023 and 2024.

Basic net income (loss) per share of common stock, (Basic), is computed by dividing net income (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding during each period. In the 2024 periods presented, the Basic weighted average share calculation also includes the weighted average of the pre-funded warrants to purchase shares of common stock at \$ 0.0001 per share that were issued in

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the registered direct offering on May 10, 2024. Diluted income (loss) per common share, (Diluted), also includes the weighted average of common stock equivalents, if the inclusion of such common stock equivalents would be dilutive. Dilutive common stock equivalents potentially include warrants, stock options and non-vested restricted stock awards using the treasury stock method. As occurred in the three and six month periods ended June 30, 2024 the Diluted calculation was further adjusted by the unrealized gains on the liability classified warrants under the assumption that the gains would not have been recorded if the warrants had been exercised.

The following table sets forth the computation of basic and diluted income (loss) for the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Basic net income (loss) per common share calculation:				
Net income (loss)	\$ (7,581)	2,626	\$ (21,649)	\$ (16,224)
Less: undistributed earnings to participating shareholders	—	(53)	—	—
Net income (loss) – basic	(7,581)	2,573	(21,649)	(16,224)
Weighted-average shares of common stock outstanding – basic	147,455,374	111,979,778	130,025,113	111,877,669
Net income (loss) per share of common stock - basic	<u><u>\$ (0.05)</u></u>	<u><u>\$ 0.02</u></u>	<u><u>\$ (0.17)</u></u>	<u><u>\$ (0.15)</u></u>
Diluted net income (loss) per common share calculation:				
Net income (loss) – basic	\$ (7,581)	\$ 2,573	\$ (21,649)	\$ (16,224)
Add: Unrealized gain on fair value of warrants	(3,100)	—	(1,800)	—
Net (loss) income - diluted	<u><u>\$ (10,681)</u></u>	<u><u>\$ 2,573</u></u>	<u><u>\$ (23,449)</u></u>	<u><u>\$ (16,224)</u></u>
Weighted average shares of common stock outstanding - diluted	150,698,374	112,042,097	136,918,539	111,877,669
Net income (loss) per share of common stock - diluted	<u><u>\$ (0.07)</u></u>	<u><u>\$ 0.02</u></u>	<u><u>\$ (0.17)</u></u>	<u><u>\$ (0.15)</u></u>
Computation of basic and diluted shares:				
Weighted average shares of common stock outstanding - basic	147,455,374	111,979,778	130,025,113	111,877,669
Potential common shares:				
Stock options	—	1,212	—	—
Restricted stock units	—	29,399	—	—
Employee stock purchase plan	—	31,708	—	—
Dilutive warrants	3,243,000	—	6,893,426	—
Weighted average shares of common stock outstanding - diluted	150,698,374	112,042,097	136,918,539	111,877,669

Diluted net loss per share for these periods presented on the statement of operations do not reflect the potential common shares noted below as their effect would be antidilutive.

	June 30,	
	2024	2023
Stock options	9,298,311	10,634,934
Restricted stock units	4,737,875	2,429,266
Common stock warrants	25,874,574	32,768,000
Total	<u><u>39,910,760</u></u>	<u><u>45,832,200</u></u>

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 six months ended June 30, 2024 and 2023, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. As of June 30, 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 1: 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).

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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 1, 2 and 3 during the three months ended June 30, 2024.

The table below presents the liabilities (in thousands) measured and recorded in the financial statements at fair value on a recurring basis at June 30, 2024 categorized by the level of inputs used in the valuation of each liability.

	June 30, 2024			
	Total	Level 1	Level 2	Level 3
Liabilities				
Warrant Liability	\$ 15,400	\$ —	\$ —	\$ 15,400
Total Liabilities	\$ 15,400	\$ —	\$ —	\$ 15,400
 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	(1,800)
Balance, June 30, 2024	<u><u>\$ 15,400</u></u>

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 \$ 1.00 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 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.

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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 19.99 %, 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:

	June 30, 2024	December 31, 2023
Stock price	\$ 1.04	\$ 1.29
Strike price	\$ 1.00	\$ 2.57
Expected volatility	57.5 %	60.0 %
Risk-free interest rate	4.4 %	3.9 %
Expected dividend yield	— %	— %
Expected life (years)	3.4	3.9
Fair value per warrant	\$ 0.51	\$ 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:

	June 30, 2024	December 31, 2023
Raw materials	\$ 3,698	\$ 2,400
Work-in-process	4,430	3,281
Finished goods	3,279	2,371
Total inventory	<u><u>\$ 11,407</u></u>	<u><u>\$ 8,052</u></u>

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

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6. Property and Equipment

Property and equipment, net, consisted of the following:

	June 30, 2024	December 31, 2023
Computer equipment and software	\$ 1,465	\$ 1,443
Furniture and fixtures	366	366
Machinery and equipment	3,150	3,146
Leasehold improvements	622	609
Construction in process	128	115
	5,731	5,679
Less: accumulated depreciation	(5,017)	(4,864)
	<u>\$ 714</u>	<u>\$ 815</u>

Depreciation expense was \$ 83 and \$ 72 for the three months ended June 30, 2024 and 2023, respectively. Depreciation expense was \$ 152 and \$ 178 for the six months ended June 30, 2024 and 2023, respectively.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of:

	June 30, 2024	December 31, 2023
Accrued expenses:		
Product revenue allowances	\$ 17,376	\$ 20,145
Selling, general and administrative expenses	5,130	6,229
Research and development expenses	221	644
Payroll expenses	6,316	6,801
Accrued interest	—	4,666
Other	1,059	3,015
Total accrued expenses	<u>\$ 30,102</u>	<u>\$ 41,500</u>
Other current liabilities:		
Lease liability	\$ 865	\$ 911
Total other current liabilities	<u>865</u>	<u>911</u>
Total accrued expenses and other current liabilities	<u><u>\$ 30,967</u></u>	<u><u>\$ 42,411</u></u>

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

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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 June 30, 2024 is 14.53%.

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 be 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 24 th-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 18 th-month anniversary of such prepayment date; and (b) for any prepayment occurring after November 21, 2024 (which represents the 24 th-month anniversary of the effective date of the A&R Note Purchase Agreement) but prior to May 21, 2026 (which represents the 42 nd-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 June 30, 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 \$ 4,947 and \$ 4,824 during the three months ended June 30, 2024 and 2023, respectively. The Company recorded interest expense of \$ 9,918 and \$ 9,496 during the six months ended June 30, 2024 and 2023, respectively. Interest expense included total coupon interest and the amortization of debt issuance costs.

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The Pharmakon debt balance is comprised of the following:

	June 30, 2024	December 31, 2023
Face amount	\$ 130,000	\$ 130,000
Front end fees	(540)	(518)
Debt issuance costs	(5,467)	(5,235)
Back end fees	1,300	5,980
Debt, net	<u>\$ 125,293</u>	<u>\$ 130,227</u>

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 June 30, 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 is a party to a manufacture and supply agreement pursuant to which it has agreed to make minimum purchases of finished XHANCE units of \$ 2.0 million in 2024, and \$ 2.4 million in both 2025 and 2026. If the Company fails to achieve the minimum purchase commitments, the Company must pay the supplier 50 % of the amount of any shortfall and must reimburse the supplier for certain non-cancellable costs and expenses. The Company's minimum purchase commitments are subject to certain exceptions and reductions. The Company has made \$ 0.8 million in purchases during the six months ended June 30, 2024 under the Supply Agreement.

10. Employee Benefit Plans

For US employees, the Company maintains a defined contribution 401(k) retirement plan. As of June 30, 2024 and 2023, \$ 82 and \$ 83 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 June 30, 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	\$ 1.00	November 18, 2026
30,268,000	Liability	\$ 1.00	November 23, 2027
23,700,000	Equity	\$ 0.0001	No Expiration

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 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

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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 its employee stock purchase plan awarded under the Company's 2010 Stock Incentive Plan, as amended and restated effective as of October 12, 2017 (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) (the "Nasdaq Inducement Grant Exception") in the following expense categories in the accompanying consolidated statements of operations as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Cost of product sales	\$ 33	\$ 12	\$ 50	\$ 18
Research and development	5	126	62	281
General and administrative	2,697	1,365	4,079	2,726
	<u>\$ 2,735</u>	<u>\$ 1,503</u>	<u>\$ 4,191</u>	<u>\$ 3,025</u>

Stock Options

The Company issues stock-based awards pursuant to the 2010 Plan and the Nasdaq Inducement Grant Exception. 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 June 30, 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.

The following table summarizes the activity related to stock option grants to employees and non-employees for the six months ended June 30, 2024:

	Shares	Weighted	Weighted
		average	average
		exercise price	remaining
		per share	contractual life
Outstanding at December 31, 2023	8,527,626	\$ 5.03	6.55
Granted	1,685,601	1.56	
Exercised	—	—	
Expired	(846,640)	9.73	
Forfeited	(68,276)	1.90	
Outstanding at June 30, 2024	<u>9,298,311</u>	<u>\$ 4.00</u>	<u>7.34</u>
Exercisable at June 30, 2024	<u>4,926,384</u>	<u>\$ 3.97</u>	<u>6.07</u>

During the six months ended June 30, 2024, service-based stock options to purchase 1,685,601 shares of common stock were granted to employees and generally vest over four years. The stock options had an estimated weighted

[Table of Contents](#)**OptiNose, Inc.****Notes to Unaudited Interim Consolidated Financial Statements**
(in thousands, except share and per share data)

average grant date fair value of \$ 1.06 . 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 June 30, 2024 was \$ 0 and \$ 0 , respectively. At June 30, 2024, the unrecognized compensation cost related to unvested stock options, other than market-based stock options, expected to vest was \$ 4,209 . This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.6 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 six months ended June 30, 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.

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

	Six Months Ended June 30,	
	2024	2023
Risk free interest rate	4.26 %	3.97 %
Expected term (in years)	5.9	6.08
Expected volatility	75.02 %	75.31 %
Annual dividend yield	0.00 %	0.00 %

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 six months ended June 30, 2024:

	Shares
Balance at December 31, 2023	1,897,421
Granted	3,574,200
Vested and settled	(638,204)
Expired/forfeited/canceled	(95,542)
Balance at June 30, 2024	4,737,875
Expected to vest at June 30, 2024	<u>4,737,875</u>

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

During the six months ended June 30, 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, provided, that, in the event certain financial metrics are achieved any then unvested RSUs shall become fully-vested subject to the recipients continued service through such date. No performance-based RSUs were granted in the six months ended June 30, 2024. As of December 31, 2023, the milestone associated with the previously granted performance based-RSUs was achieved. At June 30, 2024, the unrecognized compensation cost related to unvested service-based RSUs expected to vest was \$ 6,612 , to be recognized over an estimated weighted-average amortization period of 3.33 years.

Included in the table above are 41,250 RSUs granted outside the 2010 Plan. The grants were made pursuant to the Nasdaq Inducement Grant Exception.

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 six months ended June 30, 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:

	Six Months Ended June 30,	
	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 and the new indication, 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 the second quarter of 2024, more than half of our territory manager sales calls were to targets who are new to our territory managers or have historically prescribed XHANCE infrequently. Successfully growing XHANCE prescribing in this audience, as well as our existing prescribing base, will be important to achieving our near and long term financial objectives.

In the first quarter of 2024 we launched a central in-take pharmacy model (commonly referred to as, a "Hub") to prepare for the growth we expect from XHANCE's new indication. In addition to offering the necessary scalability for our anticipated growth, we believe the Hub has the potential to provide improved protections for business continuity and more comprehensive and consistent patient support and prescription fulfillment services than our historical preferred pharmacy network. During the second quarter we transitioned a significant proportion of the XHANCE business from our historical preferred pharmacy network to the Hub. Although we may experience initial inefficiencies as a result of this transition, we believe we will begin to realize the benefits of the Hub model as we continue to optimize processes at the Hub and physician offices become familiar with working with the Hub.

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 \$309 in the second quarter of 2024 which represents a 44% increase when compared to the \$214 average XHANCE net product revenues per prescription in the second 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 in the first quarter 2024, and was resolved in the second 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 made additional changes to our co-pay assistance program in the first quarter of 2024 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 second quarter of 2024 was 66,200, which represents a 27% decrease for total prescriptions when compared to estimated second quarter 2023 prescriptions of 90,700. We believe the second 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 second quarter of 2024 was

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25,300, which represents a 18% decrease for new prescriptions when compared to estimated second quarter 2023 new prescriptions of 30,900.

We track refill prescriptions and provide patient co-pay assistance to support refill programs that are administered by our hub and 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 second quarter of 2024 was 40,900, which represents a 32% decrease for new prescriptions when compared to estimated second quarter 2023 new prescriptions of 59,800.

- **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 second quarter of 2024 was 8,561, which represents a 1% decrease when compared to the estimated 8,624 physicians who had at least one patient fill a prescription for XHANCE in the second quarter of 2023. In addition, the total estimated number of physicians who had at least one patient fill a prescription for XHANCE was 8,427 in the third quarter of 2023, 8,478 in the fourth quarter of 2023, and 8,451 in the first quarter of 2024.

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 second quarter of 2024 was 1,056, which represents a 26% decrease when compared to the estimated 1,428 physicians who had more than 15 XHANCE prescriptions filled by their patients in the second quarter of 2023. In addition, the total estimated number of physicians who had more than 15 XHANCE prescriptions filled by their patients was 1,346 in the third quarter of 2023, 1,229 in the fourth quarter of 2023, and 1,023 in the first quarter of 2024.

- **Market Access.** We believe that as of June 30, 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 June 30, 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 \$20.5 million and \$19.5 million in net product revenues for the three months ended June 30, 2024 and 2023, respectively, and \$35.4 million and \$31.3 million for the six months ended June 30, 2024 and 2023, respectively. In accordance with GAAP, we determine net product revenues for XHANCE, with specific

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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 \$309 in the second quarter of 2024 which represents a 44% increase when compared to the \$214 average XHANCE net product revenues per prescription in the second 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.

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.

The magnitude of the benefit derived as a result of the revisions that we made to our co-pay assistance program was greater than we expected in the first half of 2024, which led us to increase our expected average net product revenues per prescription for full year 2024 while narrowing our expected range for full year 2024 XHANCE net revenues. The narrowing of the guidance range for full year 2024 XHANCE net revenues is primarily driven by our expectation for less net revenue from prescriptions that have limited or no profitability, for which we have intentionally reduced the level of copay support. For the full year 2024, we believe average net product revenues per prescription will exceed \$250. Previously, we believed that average net revenues per prescription would exceed \$230. We expect full year 2024 net product revenues will be between \$85.0 to \$90.0 million. Previously, we expected full year 2024 net product revenues to be between \$85.0 to \$95.0 million.

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 and 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.

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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.

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 and six months ended June 30, 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 June 30, 2024 and 2023**

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

	Three Months Ended June 30,	
	2024	2023
Revenues:		
Net product revenues	\$ 20,490	\$ 19,454
Total revenues	<u>20,490</u>	<u>19,454</u>
Costs and expenses:		
Cost of product sales	1,981	2,571
Research and development	928	951
Selling, general and administrative	24,129	20,104
Total operating expenses	<u>27,038</u>	<u>23,626</u>
Loss from operations	<u>(6,548)</u>	<u>(4,172)</u>
Other (income) expense:		
Interest (income) expense, net	4,138	4,099
Other income	(3,105)	(10,897)
Total other expense (income)	<u>1,033</u>	<u>(6,798)</u>
Net loss	<u><u>\$ (7,581)</u></u>	<u><u>\$ 2,626</u></u>

Net product revenues

Net product revenues related to sales of XHANCE were \$20.5 million and \$19.5 million for the three months ended June 30, 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 \$2.0 million and \$2.6 million for the three months ended June 30, 2024 and 2023, respectively. The decrease of \$0.6 million can be primarily attributed to an a lower number of units sold in 2024.

Research and development expense

Research and development expense was \$0.9 million and \$1.0 million for the three months ended June 30, 2024 and 2023, respectively. The \$0.1 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 rhinosinusitis without nasal polyps.

Selling, general and administrative expense

Selling, general and administrative expense was \$24.1 million and \$20.1 million for the three months ended June 30, 2024 and 2023, respectively. The \$4.0 million increase was due primarily to an increase in sales and marketing costs related to our launch of XHANCE for the treatment of chronic sinusitis, as well as higher stock based compensation expense in 2024.

Interest (income) expense, net

Interest (income) expense, net, was \$4.1 million and \$4.1 million for the three months ended June 30, 2024 and 2023, respectively, which was primarily comprised of interest expense on the Pharmakon Senior Secured Notes during both periods.

Other income

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

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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 June 30, 2024.

Other income includes primarily \$3.1 million and \$10.9 million for the three months ended June 30, 2024 and 2023, respectively of unrealized gains on the fair value of warrants.

Comparison of six months ended June 30, 2024 and 2023

	Six Months Ended June 30,	
	2024	2023
Revenues:		
Net product revenues	\$ 35,370	\$ 31,299
Total revenues	<u>35,370</u>	<u>31,299</u>
Costs and expenses:		
Cost of product sales	3,212	4,277
Research and development	2,134	2,736
Selling, general and administrative	<u>44,647</u>	<u>42,828</u>
Total operating expenses	<u>49,993</u>	<u>49,841</u>
Loss from operations	<u>(14,623)</u>	<u>(18,542)</u>
Other (income) expense:		
Interest (income) expense, net	8,813	8,066
Other income	<u>(1,787)</u>	<u>(10,384)</u>
Total other expense	<u>7,026</u>	<u>(2,318)</u>
Net loss	<u><u>\$ (21,649)</u></u>	<u><u>\$ (16,224)</u></u>

Net product revenues

Net product revenues related to sales of XHANCE were \$35.4 million and \$31.3 million for the six months ended June 30, 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 \$3.2 million and \$4.3 million for the six months ended June 30, 2024 and 2023, respectively. The decrease of \$1.1 million can be primarily attributed to an a lower number of units sold in 2024.

Research and development expense

Research and development expense was \$2.1 million and \$2.7 million for the six months ended June 30, 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 rhinosinusitis without nasal polyps.

Selling, general and administrative expense

Selling, general and administrative expense was \$44.6 million and \$42.8 million for the six months ended June 30, 2024 and 2023, respectively. The \$1.8 million increase was due primarily to an increase in sales and marketing costs related to our launch of XHANCE for the treatment of chronic sinusitis, as well as higher stock based compensation expense in 2024, which was partially offset by \$1.1 million of severance costs recognized in 2023.

Interest (income) expense, net

Interest (income) expense, net, was \$8.8 million and \$8.1 million for the six months ended June 30, 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 higher interest rates in 2024.

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Other income

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 June 30, 2024.

Other income includes primarily \$1.8 million and \$10.4 million for the six months ended June 30, 2024 and 2023, respectively of unrealized gains 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 \$21.6 million and \$16.2 million for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, we had an accumulated deficit of \$742.0 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 June 30, 2024, we had \$91.4 million in cash and cash equivalents.

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

	Six Months Ended June 30,	
	2024	2023
Net cash used in operating activities	\$ (37,719)	\$ (23,016)
Net cash used in investing activities	(51)	(79)
Net cash provided by financing activities	55,443	161
Net decrease in cash, cash equivalents and restricted cash	\$ 17,673	\$ (22,934)

Operating activities

Cash used in operating activities increased by \$14.7 million, from \$23.0 million for the six months ended June 30, 2023 to \$37.7 million for the six months ended June 30, 2024. The increase in cash used in operating activities was attributable to decrease in accounts payable and accrued expenses, and an increase in inventory and prepaid expenses, partially offset by a smaller loss from operations for the six months ended June 30, 2024.

Investing activities

Cash used in investing activities decreased from the six months ended June 30, 2023 to the six months ended June 30, 2024 due to a decrease in equipment and software purchases during the six months ended June 30, 2024.

Financing activities

Cash provided by financing activities increased from the six months ended June 30, 2023 to the six months ended June 30, 2024 due to the registered direct offering completed in May 2024.

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 \$95 million 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. This increase is the result of additional selling, general, & administrative expenses that we expect to incur in 2024 as we invest in the launch of XHANCE for the treatment of patients with chronic sinusitis.

Registered Direct Offering

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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 were \$55.3 million.

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 June 30, 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 June 30, 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.

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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 June 30, 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 June 30, 2024 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

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).
4.1	Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with the SEC on May 9, 2024).
10.1	Form of Securities Purchase Agreement, dated May 8, 2024 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-38241), as files with SEC on May 9, 2024).
10.2	Third Amendment to the Note Purchase Agreement, dated May 8, 2024, among OptiNose US, Inc., OptiNose, Inc., and Optinose AS, BioPharma Credit PLC, as collateral agent and the purchasers from time to time party thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K (File No. 001-38241), as files with SEC on May 9, 2024).
10.3	Amendment No. 2 to Manufacture and Supply Agreement, dated May 20, 2024, by and between OptiNose US, Inc. and Contract Pharmaceuticals Limited Canada (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 May 20, 2024).
10.4 *†	Amendment No. 1 to Manufacture and Supply Agreement, dated June 7, 2024, 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.

OPTINOSE, INC.

Date: August 8, 2024

By: /s/ ANTHONY J. KRICK

Name: Anthony J. Krick

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

(Principal Financial and Accounting Officer)

FIRST AMENDMENT TO MANUFACTURE AND SUPPLY AGREEMENT

This **FIRST AMENDMENT TO MANUFACTURE AND SUPPLY AGREEMENT** (this "First Amendment") is made as of June 7, 2024 ("First Amendment Effective Date"), by and between:

HIKMA PHARMACEUTICALS USA INC., a Delaware corporation, having an address at 1809 Wilson Road, Columbus, OH 43228 (hereinafter "Hikma"); and

OPTINOSE US, INC., a Delaware corporation, having an address at 1020 Stony Hill Road, Suite 300, Yardley, PA 19067 (hereinafter "OptiNose").

Each of Hikma and OptiNose hereinafter are referred to as a **Party** or collectively as the **Parties**. Capitalized terms used herein and not otherwise defined herein shall have the meaning ascribed thereto in the Agreement as amended (as defined below).

RECITALS

WHEREAS, Hikma and OptiNose entered into that certain Manufacture and Supply Agreement dated December 11, 2020 (the "Agreement");

WHEREAS, Section 14.1 of the Agreement provides that the Agreement may not be amended or modified except by written agreement duly executed by both Parties;

WHEREAS, the Parties now wish to amend certain terms in the Agreement related to pricing and forecasts; and

WHEREAS, the Parties hereby enter into this First Amendment to amend such terms in accordance with Section 14.1 of the Agreement.

NOW THEREFORE, in consideration of the premises and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, the Parties hereby agree as follows:

1. Amendments to the Agreement

(a) **Section 2.3. Forecasts**. Effective as of the First Amendment Effective Date, Section 2.3, Forecasts, is hereby amended and restated in its entirety to read in full as follows:

"**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 shall submit to Hikma, on a monthly

basis, a new Rolling Forecast that sets forth the monthly quantity of Products by SKU that OptiNose has ordered, desires to order, or expects to order from Hikma within the upcoming [***] period, to be used for Hikma's capacity and sourcing planning purposes. In addition, on a quarterly basis, during the first business week of each calendar quarter, OptiNose shall submit to Hikma an [***] rolling forecast that sets forth the monthly quantity of Products by SKU for the[***] and the quarterly quantity of Products by SKU for the [***], which OptiNose has ordered, desires to order, or expects to order from Hikma. Hikma may not reject the Rolling Forecast received from OptiNose, nor may Hikma reject or alter the total quantity of Products contained in the Rolling Forecast. Notwithstanding the foregoing sentence, [***]. 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 o initial Product in anticipation o 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.

(b) Exhibit B to the Agreement. Effective as of the First Amendment Effective Date, Exhibit B to the Agreement is hereby deleted in its entirety and replaced with the new Exhibit B, Price, attached hereto as Attachment 1 to First Amendment and incorporated herein by reference.

Miscellaneous Provisions

2. This First Amendment may be executed simultaneously in multiple counterparts, each of which shall be deemed an original, and all of which taken together shall constitute one and the same instrument. Original signatures transmitted and received by means of facsimile or other electronic transmission of a scanned document, (e.g., pdf or similar format, including via

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY "[***]", HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

DocuSign) will constitute true and valid signatures for all purposes hereunder and will have the same force and effect as the delivery of an original.

3. The terms of this First Amendment are intended by the Parties to be the final expression of their agreement with respect to the subject matter hereof and may not be contradicted by evidence of any prior or contemporaneous agreement. The Parties further intend that this First Amendment constitute the complete and exclusive statement of its terms and shall supersede any prior agreement with respect to the subject matter hereof.
4. The heading references herein are for convenience purposes only, do not constitute a part of this First Amendment, and shall not be deemed to limit or affect any of the provisions hereof.
5. This First Amendment shall be governed by and construed in accordance with the substantive laws of the State of Delaware, U.S.A.
6. Except as expressly amended and modified by this First Amendment, the terms, conditions, and provisions of the Agreement shall remain in full force and effect.

[Signature Page Follows]

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY "[**]", HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

WHEREFORE, the Parties have caused this First Amendment to be executed by their duly authorized representatives effective as of the First Amendment Effective Date.

HIKMA PHARMACEUTICALS USA INC.

By: /s/ Hafrun Fridriksdottir

Name: Hafrun Fridriksdottir

Title: President

OPTINOSE US, INC.

By: /s/ Ramy Mahmoud

Name: Ramy Mahmoud

Title: Chief Executive Officer

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ATTACHMENT 1 to FIRST AMENDMENT

EXHIBIT B TO SUPPLY AGREEMENT

PRICE

[***]

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**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: August 8, 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: August 8, 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 June 30, 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: August 8, 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 June 30, 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: August 8, 2024

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