

**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 **September 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

(State or other jurisdiction of incorporation or organization)

42-1771610

(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

Non-accelerated filer

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 October 31, 2024 was 150,829,507 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 belief that an inflection in new prescriptions commenced in September and continued through the week ended October 25, 2024 (which is the most recent week for which a full prescription data set was available prior to the filing of this Form 10-Q);
- our expectation that our operating expenses (consisting of selling, general & administrative expenses and research & development expenses) in 2024 will be between \$90.0 million and \$93.0 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 \$75.0 million and \$79.0 million;
- our expectation that the average net product revenue per prescription for XHANCE for the full year of 2024 will be approximately \$270;

- our potential non-compliance with certain covenants of the A&R Note Purchase Agreement, the consequences of failing to achieve compliance with such covenants and our plans to seek to mitigate such risks;
- our belief that our existing cash and cash equivalents will be sufficient to fund our operations and debt service obligations for at least the next 12 months if we are able to maintain compliance with or obtain a waiver or modification of the financial and other covenants under A&R Note Purchase Agreement;
- 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;
- our ability to continue as a going concern;

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

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

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

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

MARKET, INDUSTRY AND OTHER DATA

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

PART I

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2024 (unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 82,497	\$ 73,684
Accounts receivable, net	29,772	19,926
Inventory	11,301	8,052
Prepaid expenses and other current assets	4,645	3,671
Total current assets	128,215	105,333
Property and equipment, net	670	815
Other assets	2,135	1,581
Total assets	\$ 131,020	\$ 107,729
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 3,777	\$ 3,886
Accrued expenses and other current liabilities	32,668	42,411
Short term debt, net	125,985	130,227
Total current liabilities	162,430	176,524
Warrant liability	8,500	17,200
Other liabilities	1,187	611
Total liabilities	172,117	194,335
Stockholders' deficit		
Preferred stock, no par value; 5,000,000 shares authorized; no shares issued in 2024 or 2023	—	—
Common stock, \$0.001 par value; 350,000,000 shares authorized; 150,829,507 and 112,399,495 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively.	151	112
Additional paid-in capital	700,393	633,742
Accumulated deficit	(741,557)	(720,376)
Accumulated other comprehensive loss	(84)	(84)
Total stockholders' deficit	(41,097)	(86,606)
Total liabilities and stockholders' deficit	\$ 131,020	\$ 107,729

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
Net product revenues	\$ 20,437	\$ 19,823	\$ 55,807	\$ 51,122
Total revenues	20,437	19,823	55,807	51,122
Costs and expenses:				
Cost of product sales	2,065	2,225	5,277	6,502
Research and development	949	1,281	3,083	4,017
Selling, general and administrative	19,475	18,011	64,121	60,839
Total costs and expenses	22,489	21,517	72,481	71,359
Loss from operations	(2,052)	(1,694)	(16,674)	(20,236)
Other (income) expense:				
Unrealized (gain) loss on fair value of warrants	(6,900)	3,200	(8,700)	(7,190)
Interest income	(913)	(545)	(2,018)	(1,974)
Interest expense	5,294	4,940	15,212	14,436
Foreign currency loss	—	5	13	8
Net income (loss)	\$ 467	\$ (9,294)	\$ (21,181)	\$ (25,516)
Less: undistributed earnings to participating shareholders	(74)	—	—	—
Net income (loss) - basic	\$ 393	\$ (9,294)	\$ (21,181)	\$ (25,516)
Net income (loss) per share of common stock, basic	\$ —	\$ (0.08)	\$ (0.15)	\$ (0.23)
Weighted average common shares outstanding, basic	174,328,570	112,230,155	144,900,726	111,996,456
Net income (loss) - basic	\$ 393	\$ (9,294)	\$ (21,181)	\$ (25,516)
Add: Unrealized gain on fair value of warrants	—	—	(8,700)	—
Net income (loss) - diluted	\$ 393	\$ (9,294)	\$ (29,881)	\$ (25,516)
Net (loss) per share of common stock - diluted	\$ —	\$ (0.08)	\$ (0.20)	\$ (0.23)
Weighted average common shares outstanding - diluted	174,369,875	112,230,155	149,634,133	111,996,456

See accompanying notes to unaudited interim consolidated financial statements.

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2024</u>	<u>2023</u>	<u>2024</u>	<u>2023</u>
Net income (loss)	\$ 467	\$ (9,294)	\$ (21,181)	\$ (25,516)
Other comprehensive income (loss):				
Foreign currency translation adjustment	—	—	—	—
Comprehensive income (loss)	<u>\$ 467</u>	<u>\$ (9,294)</u>	<u>\$ (21,181)</u>	<u>\$ (25,516)</u>

See accompanying notes to unaudited interim consolidated financial statements.

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

Nine months ended September 30, 2024

	Stockholders' Equity (Deficit)					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	# of Shares	Par Amount \$				
Balance at December 31, 2023	112,399,495	\$ 112	\$ 633,742	\$ (720,376)	\$ (84)	\$ (86,606)
Stock compensation expense	—	—	1,456	—	—	1,456
Vesting of restricted stock units	478,520	1	—	—	—	1
Issuance of common stock under employee stock purchase plan	160,711	—	—	—	—	—
Net loss	—	—	—	(14,067)	—	(14,067)
Balance at March 31, 2024	113,038,726	\$ 113	\$ 635,198	\$ (734,443)	\$ (84)	\$ (99,215)
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	—	—	165
Net loss	—	—	—	(7,581)	—	(7,581)
Balance at June 30, 2024	149,678,410	\$ 150	\$ 699,105	\$ (742,024)	\$ (84)	\$ (42,853)
Stock compensation expense	—	\$ —	1,288	—	—	1,288
Vesting of restricted stock units	1,039,080	1	—	—	—	1
Issuance of common stock under employee stock purchase plan	112,017	—	—	—	—	—
Net income	—	—	—	467	—	467
Balance at September 30, 2024	150,829,507	\$ 151	\$ 700,393	\$ (741,557)	\$ (84)	\$ (41,097)

Nine Months Ended September 30, 2023

	Stockholders' Equity (Deficit)					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Par Amount \$				
Balance at December 31, 2022	111,492,761	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
Net loss	—	—	—	(18,847)	—	(18,847)
Balance at March 31, 2023	111,955,894	\$ 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	112,091,734	\$ 112	\$ 631,426	\$ (701,114)	\$ (84)	\$ (69,660)
Stock compensation expense	—	—	1,204	—	—	1,204
Vesting of restricted stock units	88,667	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	131,582	—	135	—	—	135
Net loss	—	—	—	(9,294)	—	(9,294)
Balance at September 30, 2023	112,311,983	\$ 112	\$ 632,765	\$ (710,408)	\$ (84)	\$ (77,615)

See accompanying notes to unaudited interim consolidated financial statements.

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

	Nine Months Ended September 30,	
	2024	2023
Operating activities:		
Net loss	\$ (21,181)	\$ (25,516)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	218	282
Stock-based compensation	5,481	4,219
Change in fair value of warrant liability	(8,700)	(7,190)
Amortization of debt discount and issuance costs	1,531	1,242
Changes in operating assets and liabilities:		
Accounts receivable	(9,847)	12,559
Prepaid expenses and other assets	(128)	2,432
Inventory	(3,249)	1,348
Accounts payable	(109)	(346)
Accrued expenses and other liabilities	(10,568)	(16,471)
Cash used in operating activities	<u>(46,552)</u>	<u>(27,441)</u>
Investing activities:		
Purchases of property and equipment	(72)	(255)
Cash used in investing activities	<u>(72)</u>	<u>(255)</u>
Financing activities:		
Proceeds from sale of common stock and warrants	55,476	—
Proceeds from the exercise of stock options	—	1
Proceeds from issuance of common stock under employee stock purchase plan	166	299
Cash paid for financing costs	(206)	(4)
Cash provided by financing activities	<u>55,436</u>	<u>296</u>
Net increase (decrease) in cash and cash equivalents	8,812	(27,400)
Cash and cash equivalents at beginning of period	73,684	94,244
Cash and cash equivalents at end of period	<u>\$ 82,496</u>	<u>\$ 66,844</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 18,340	\$ 13,194
Supplemental disclosure of noncash activities:		
Recognition of right-of-use assets and lease liabilities	\$ 1,402	\$ 890

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 September 30, 2024, the Company had cash and cash equivalents of \$82,497 and a working capital deficit of \$34,215.

The Company is subject to a number of risks similar to other life sciences companies, including 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. The Company has incurred recurring net losses since its inception and has accumulated a deficit of \$741,557 as of September 30, 2024.

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 entered into a Note Purchase Agreement (the Note Purchase Agreement) on September 12, 2019 with funds managed by Pharmakon Advisors, LP (Pharmakon), the investment manager of the BioPharma Credit Funds (BioPharma) which was subsequently amended on August 13, 2020, March 2, 2021, November 16, 2021, August 10, 2022, and November 9, 2022.

On November 23, 2022, the Company amended and restated the Note Purchase Agreement (the A&R Note Purchase Agreement). Pursuant to the A&R Note Purchase Agreement, the financial covenants requiring the Company to achieve minimum trailing twelve-month consolidated XHANCE net product sales and royalties were modified. The Company entered into the first amendment to the A&R Note Purchase Agreement (the First Amendment) on March 5, 2024, which waived certain covenants. The Company entered into the second amendment to the A&R Note Purchase Agreement (the Second Amendment) on March 8, 2024, which further modified the financial covenants. On May 8, 2024, the Company entered into the third amendment to the A&R Note Purchase Agreement (the Third Amendment), which provided for a further waiver to the requirement that the Company's annual and quarterly consolidated financial statements not be subject to any statement as to "going concern" (the "going concern covenant") through the fiscal quarter ending September 30, 2025, and modified 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 (see [Note 8](#)). The principal balance outstanding under the A&R Note Purchase Agreement was \$130,000 at September 30, 2024.

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

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, including minimum trailing twelve-month consolidated XHANCE net sales and royalties the Company is required to achieve and its ability to generate sufficient cash flows from operations to meet its obligations and/or obtain additional capital through equity or debt financings, partnerships, collaborations, or other sources, as may be required. The A&R Note Purchase Agreement includes events of default, in certain cases subject to customary periods to cure, following which Pharmakon may accelerate all amounts outstanding pursuant to the Note Purchase Agreement. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business.

Additionally, commencing on September 30, 2025, the Company will be required to begin making principal repayments on its debt in eight quarterly installments of \$16.3 million each through maturity in June 2027. The Company believes that it is probable that, absent additional capital, it will not be able to maintain compliance with the minimum cash covenant under the A&R Note Purchase Agreement once it makes the second principal repayment, which is due on December 31, 2025.

The Company believes it is probable that it will not be able to maintain compliance with the trailing twelve-month minimum consolidated XHANCE net sales and royalties thresholds under the A&R Note Purchase Agreement for the entire one year period after the date these consolidated financial statements are issued, which will constitute a default under the A&R Note Purchase Agreement if the Company is unable to obtain a modification or waiver of such minimum consolidated XHANCE net sales and royalties thresholds.

In the event of the foregoing default, the holders of the Pharmakon Senior Secured Notes may declare an event of default under the A&R Note Purchase Agreement and may elect to accelerate the repayment of all unpaid principal, accrued interest and other amounts due, which may require the Company to delay or curtail its operations until additional funding is received. The terms of the A&R Note Purchase Agreement and the Pharmakon Senior Secured Notes, including applicable covenants, are described in [Note 8](#).

Management's plans to mitigate these risks include enhancing its commercial performance to accelerate growth in net revenues, seeking out partnership and collaboration opportunities to expand the market for XHANCE, and, if required, requesting a modification or waiver of the covenants under the A&R Note Purchase Agreement, or refinancing the debt. However, there can be no assurance that the Company will be successful in accelerating growth in net revenues, expanding the market for XHANCE through partnerships or collaborations, obtaining a modification or waiver of the covenants under the A&R Note Purchase Agreement, and/or refinancing the debt. If the Company is unable to accelerate growth in net revenues, expand the market for XHANCE through partnerships or collaborations, obtain a modification or waiver of the covenants under the A&R Note Purchase Agreement, or refinance the debt, the Company may need to delay or curtail its operations. As a result of these factors, management has concluded that substantial doubt exists about the Company's ability to continue as a going concern within one year after the date these consolidated financial statements are issued.

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 September 30, 2024 and its results of operations for the three and nine months ended September 30, 2024 and 2023 and cash flows for the nine months ended September 30, 2024 and 2023. Operating results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024. The

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

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 78% and 73% of the Company's accounts receivable at September 30, 2024 and 2023, respectively. Five customers represented approximately 74% and 50% of the Company's net product sales for the three months ended September 30, 2024 and 2023, respectively. Five customers represented approximately 73% and 40% of the Company's net product sales for the nine months ended September 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.

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- Level 3 — Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

At September 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 September 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 September 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

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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, September 30, 2023, and the nine month periods ended September 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 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 nine month periods ended

September 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 shares outstanding for the periods presented:

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Basic net income (loss) per common share calculation:				
Net income (loss)	\$ 467	(9,294)	\$ (21,181)	\$ (25,516)
Less: undistributed earnings to participating shareholders	(74)	—	—	—
Net income (loss) – basic	393	(9,294)	(21,181)	(25,516)
Weighted-average shares of common stock outstanding – basic	174,328,570	112,230,155	144,900,726	111,996,456
Net income (loss) per share of common stock - basic	\$ —	\$ (0.08)	\$ (0.15)	\$ (0.23)
Net income (loss) – basic	\$ 393	\$ (9,294)	\$ (21,181)	\$ (25,516)
Add: Unrealized gain on fair value of warrants	—	—	(8,700)	—
Net income (loss) - diluted	\$ 393	\$ (9,294)	\$ (29,881)	\$ (25,516)
Weighted average shares of common stock outstanding - diluted	174,369,875	112,230,155	149,634,133	111,996,456
Net income (loss) per share of common stock - diluted	\$ —	\$ (0.08)	\$ (0.20)	\$ (0.23)
Computation of basic and diluted shares:				
Weighted average shares of common stock outstanding - basic	174,328,570	112,230,155	144,900,726	111,996,456
<u>Potential common shares:</u>				
Restricted stock units	41,305	—	—	—
Dilutive warrants	—	—	4,733,407	—
Weighted average shares of common stock outstanding - diluted	174,369,875	112,230,155	149,634,133	111,996,456

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.

	September 30,	
	2024	2023
Stock options	9,108,884	10,153,661
Restricted stock units	3,518,338	2,012,552
Common stock warrants	28,034,593	32,768,000
Employee stock purchase plan	115,834	190,186
Total	40,777,649	45,124,399

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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 nine months ended September 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 September 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.

In November 2024, the FASB issued ASU No. 2024-03, *Disaggregation of Income Statement Expenses*. ASU No. 2024-03 requires new financial statement disclosures that disaggregate information, in a tabular format, about prescribed categories of relevant income statement captions. ASU No. 2024-03 is effective for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating ASU No. 2024-03 and its impact on the Company's related disclosures.

4. Fair Value Measurements***Assets and Liabilities Measured at Fair Value on a Recurring Basis***

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

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

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

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

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

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level 1, 2 and 3 during the three months ended September 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 September 30, 2024 categorized by the level of inputs used in the valuation of each liability.

	September 30, 2024			
	Total	Level 1	Level 2	Level 3
Liabilities				
Warrant Liability	\$ 8,500	\$ —	\$ —	\$ 8,500
Total Liabilities	<u>\$ 8,500</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 8,500</u>
	December 31, 2023			
Liabilities				
Warrant Liability	\$ 17,200	\$ —	\$ —	\$ 17,200
Total Liabilities	<u>\$ 17,200</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 17,200</u>

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):

	<u>Warrant Liability</u>
Balance, December 31, 2023	\$ 17,200
Warrants issued	—
Change in fair value of liability	(8,700)
Balance, September 30, 2024	<u>\$ 8,500</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

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effect of the Warrants shall be reduced to the price of the shares of common stock issued or sold or deemed to be issued or sold in the dilutive issuance in the manner set forth in the Warrant.

A holder of Warrants will not have the right to exercise any portion of a Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or on election of such holder, prior to the issuance of any Warrants, 9.99%) of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants; provided, however, such holder may increase or decrease such percentage to any other percentage not in excess of 19.99%, 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:

	September 30, 2024	December 31, 2023
Stock price	\$ 0.67	\$ 1.29
Strike price	\$ 1.00	\$ 2.57
Expected volatility	65.0 %	60.0 %
Risk-free interest rate	3.5 %	3.9 %
Expected dividend yield	— %	— %
Expected life (years)	3.1	3.9
Fair value per warrant	\$ 0.28	\$ 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:

	September 30, 2024	December 31, 2023
Raw materials	\$ 2,272	\$ 2,400
Work-in-process	6,211	3,281
Finished goods	2,818	2,371
Total inventory	\$ 11,301	\$ 8,052

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:

	September 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	655	609
Construction in process	115	115
	<u>5,751</u>	<u>5,679</u>
Less: accumulated depreciation	(5,081)	(4,864)
	<u>\$ 670</u>	<u>\$ 815</u>

Depreciation expense was \$65 and \$102 for the three months ended September 30, 2024 and 2023, respectively. Depreciation expense was \$217 and \$281 for the nine months ended September 30, 2024 and 2023, respectively.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of:

	September 30, 2024	December 31, 2023
Accrued expenses:		
Product revenue allowances	\$ 19,911	\$ 20,145
Selling, general and administrative expenses	4,976	6,229
Research and development expenses	262	644
Payroll expenses	5,481	6,801
Accrued interest	—	4,666
Other	1,034	3,015
Total accrued expenses	<u>\$ 31,664</u>	<u>\$ 41,500</u>
Other current liabilities:		
Lease liability	\$ 1,004	\$ 911
Total other current liabilities	<u>1,004</u>	<u>911</u>
Total accrued expenses and other current liabilities	<u>\$ 32,668</u>	<u>\$ 42,411</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 September 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

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

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

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

The Pharmakon Senior Secured Notes are secured by a pledge of substantially all of the assets of the Company and the Guarantors and the A&R Note Purchase Agreement contains affirmative and negative covenants customary for financings of this type, including limitations on the Company's and its subsidiaries' ability, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, repay junior indebtedness, incur a material adverse change and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the A&R Note Purchase Agreement contains financial covenants requiring the Company to maintain certain minimum trailing twelve-month consolidated XHANCE net sales and royalties, tested on a quarterly basis, and to maintain compliance with the Liquidity Covenant. As of September 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 believes that it is probable that it will not maintain compliance with the required trailing twelve-month minimum consolidated XHANCE net sales and royalties thresholds for the entire one year period after the date these consolidated financial statements are issued. As a result, in accordance with FASB Accounting Standards Codification 470, the Company has classified all outstanding principal and the payment of additional fees upon maturity as a current liability in the accompanying consolidated balance sheet as of September 30, 2024. 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.

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The Company recorded interest expense of \$5,294 and \$4,940 during the three months ended September 30, 2024 and 2023, respectively. The Company recorded interest expense of \$15,212 and \$14,436 during the nine months ended September 30, 2024 and 2023, respectively. Interest expense included total coupon interest and the amortization of debt issuance costs.

The Pharmakon debt balance is comprised of the following:

	September 30, 2024	December 31, 2023
Face amount	\$ 130,000	\$ 130,000
Front end fees	(477)	(518)
Debt issuance costs	(4,838)	(5,235)
Back end fees	1,300	5,980
Debt, net	<u>\$ 125,985</u>	<u>\$ 130,227</u>

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 \$1.2 million in purchases during the nine months ended September 30, 2024 under the Supply Agreement.

10. Employee Benefit Plans

The Company maintains a defined contribution 401(k) retirement plan. For the nine months ended September 30, 2024 and 2023, \$872 and \$677 respectively, were recorded in expense for the Company match. For the three months ended September 30, 2024 and 2023, the match expense was \$223 and \$201, respectively. 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 September 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.

OptiNose, Inc.
Notes to Unaudited Interim Consolidated Financial Statements
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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 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cost of product sales	\$ 15	\$ 9	\$ 66	\$ 27
Research and development	10	129	42	410
General and administrative	1,265	1,067	5,373	3,793
	<u>\$ 1,290</u>	<u>\$ 1,205</u>	<u>\$ 5,481</u>	<u>\$ 4,230</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 September 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.

OptiNose, Inc.
Notes to Unaudited Interim Consolidated Financial Statements
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The following table summarizes the activity related to stock option grants to employees and non-employees for the nine months ended September 30, 2024:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Outstanding at December 31, 2023	8,527,626	\$ 5.03	6.55
Granted	1,703,101	1.56	
Exercised	—	—	
Expired	(853,327)	9.68	
Forfeited	(268,516)	1.66	
Outstanding at September 30, 2024	<u>9,108,884</u>	\$ 4.04	6.7
Exercisable at September 30, 2024	<u>5,194,658</u>	\$ 5.79	5.5

During the nine months ended September 30, 2024, service-based stock options to purchase 1,703,101 shares of common stock were granted to employees and generally vest over four years. The stock options had an estimated weighted average grant date fair value of \$1.56. 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 September 30, 2024 was \$0 and \$0, respectively. At September 30, 2024, the unrecognized compensation cost related to unvested stock options, other than market-based stock options, expected to vest was \$3,513. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.4 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 nine months ended September 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 674,167 inducement 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:

	<u>Nine Months Ended September 30,</u> <u>2024</u>
Risk free interest rate	4.26 %
Expected term (in years)	5.9
Expected volatility	75.03 %
Annual dividend yield	0.00 %

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

Restricted Stock Units

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

The following table summarizes the activity related to RSUs granted to employees for the nine months ended September 30, 2024:

	Shares
Balance at December 31, 2023	1,897,421
Granted	3,574,200
Vested and settled	(1,677,284)
Expired/forfeited/canceled	(275,999)
Balance at September 30, 2024	<u>3,518,338</u>
Expected to vest at September 30, 2024	<u>3,518,338</u>

During the nine months ended September 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 nine months ended September 30, 2024. As of December 31, 2023, the milestone associated with the previously granted performance based-RSUs was achieved. At September 30, 2024, the unrecognized compensation cost related to unvested service-based RSUs expected to vest was \$5,569, to be recognized over an estimated weighted-average amortization period of 3.23 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 nine months ended September 30, 2024, the Company issued 272,728 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:

	<u>Nine Months Ended September 30,</u> <u>2024</u>
Risk free interest rate	0.05 %
Expected term (in years)	0.5
Expected volatility	67.93 %

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 \$320 in the third quarter of 2024 which represents a 36% increase when compared to the \$236 average XHANCE net product revenues per prescription in the third quarter of 2023. The increase in average net product revenues per prescription is partly 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, part of the increase was the result of an increase in channel inventory associated in part with the addition of new pharmacies within the Hub network. 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. In the first quarter of 2024 we further reduced the amount of co-pay assistance available to patients that do not have coverage for XHANCE or have high out of pocket costs, which changes were designed to further 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 third quarter of 2024 was 63,900, which represents a 24% decrease for total prescriptions when compared to estimated third quarter 2023 prescriptions of 84,100. We believe the third 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.

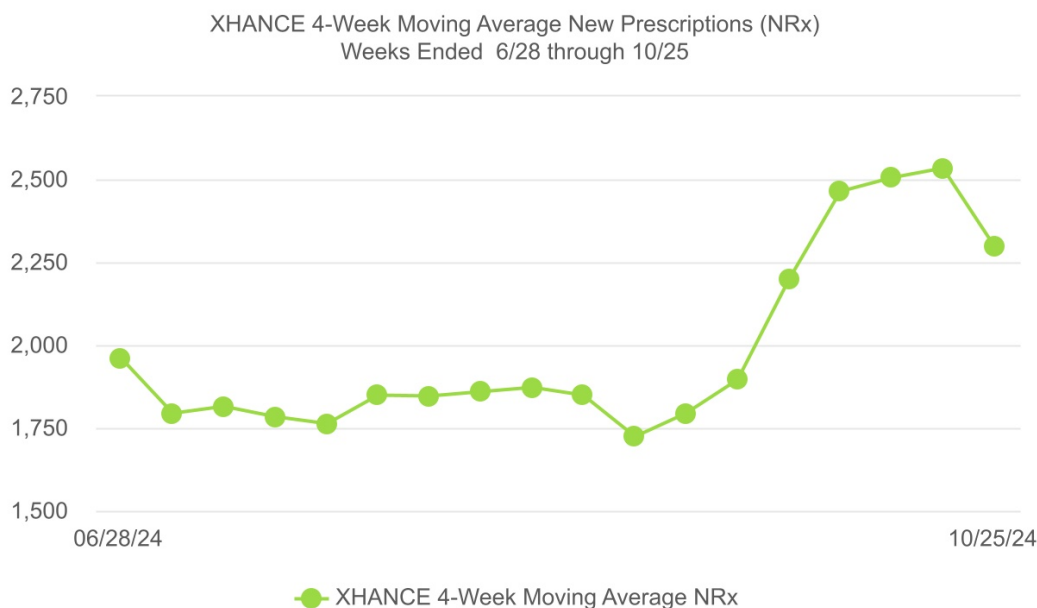
A seasonal effect has historically been observed in both the INS and XHANCE prescription markets in which market volume generally peaks near the middle of the second quarter and declines into the early part of the third quarter of each calendar year.

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 third 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 our hub and PPN

partners, the total estimated number of XHANCE new prescriptions in the third quarter of 2024 was 25,600, which represents a 7% decrease for new prescriptions when compared to estimated third quarter 2023 new prescriptions of 27,400. We believe an inflection in new prescriptions occurred in September and continued through the week ended October 25 (which is the most recent week for which a full prescription data set was available prior to the filing of this Form 10-Q). The four-week moving average of weekly new prescriptions ranged between approximately 1,760 to 1,960 for the weeks ended June 28, 2024, through September 6, 2024. Following the inflection first observed in September, the moving average increased to approximately 2,300 to 2,500 NRx per week in October (through the week ended October 25) an increase of approximately 20% to 40% compared to the prior range.



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 third quarter of 2024 was 38,200, which represents a 32% decrease for refill prescriptions when compared to estimated third quarter 2023 refill prescriptions of 56,600.

- 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 third quarter of 2024 was 8,548, which represents a 1% increase when compared to the estimated 8,427 physicians who had at least one patient fill a prescription for XHANCE in the third quarter of 2023. In addition, the total estimated number of physicians who had at least one patient fill a prescription for XHANCE was 8,478 in the fourth quarter of 2023, 8,451 in the first quarter of 2024, and 8,561 in the second 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 inventory and 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 third quarter of 2024 was 1,056, which represents a 22% decrease when compared to the estimated 1,346 physicians who had more than 15 XHANCE prescriptions filled by their patients in the third 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, 1,023 in the first quarter of 2024, and 1,056 in the second quarter of 2024.

- **Market Access.** We believe that as of September 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 commercial covered lives as of September 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 \$20.4 million and \$19.8 million in net product revenues for the three months ended September 30, 2024 and 2023, respectively, and \$55.8 million and \$51.1 million for the nine months ended September 30, 2024 and 2023, respectively. In accordance with GAAP, we determine net product revenues for XHANCE, with specific assumptions for variable consideration components including but not limited to trade discounts and allowances, co-pay assistance programs and payor rebates.

Based on available XHANCE prescription data purchased from third parties and data from our hub and PPN partners, our average XHANCE net product revenues per prescription were \$320 in the third quarter of 2024 which represents a 36% increase when compared to the \$236 average XHANCE net product revenues per prescription in the third quarter of 2023. We believe the increase in average net product revenues per prescription is partly 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, part of the increase was the result of an increase in channel inventory associated in part with the addition of new pharmacies within the Hub network.

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 lowering of the guidance range for full year 2024 XHANCE net revenues is the result of a slower than anticipated return to demand growth. As a result, we expect full year 2024 net product revenues will be between \$75.0 to \$79.0 million. Previously, we expected full year 2024 net product revenues to be between \$85.0 to \$90.0 million. 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 nine months of 2024, in addition, third quarter of 2024 benefited from additional channel inventory that included the stocking of new pharmacies within our Hub network. As a result, we believe average net product revenues per prescription will be approximately \$270 for the full year of 2024. Previously, we believed that average net revenues per prescription would exceed \$250. We expect full year 2024 operating expenses (consisting of selling, general & administrative expenses and research & development expenses) will be between \$90.0 to \$93.0 million, of which we expect non-cash stock-based compensation expense will be approximately \$6.0 million. Previously, we expected full year 2024 operating expenses to be between \$95.0 to \$101.0 million, of which we expected non-cash stock-based compensation expense would be approximately \$6.0 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.

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 nine months ended September 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 September 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 September 30,	
	2024	2023
Revenues:		
Net product revenues	\$ 20,437	\$ 19,823
Total revenues	20,437	19,823
Costs and expenses:		
Cost of product sales	2,065	2,225
Research and development	949	1,281
Selling, general and administrative	19,475	18,011
Total operating expenses	22,489	21,517
Loss from operations	(2,052)	(1,694)
Other (income) expense:		
Interest expense, net	4,381	4,395
Other income	(6,900)	3,205
Total other expense (income)	(2,519)	7,600
Net income (loss)	\$ 467	\$ (9,294)

Net product revenues

Net product revenues related to sales of XHANCE were \$20.4 million and \$19.8 million for the three months ended September 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 increase average net revenue per prescription.

Cost of product sales

Cost of product sales related to XHANCE were \$2.1 million and \$2.2 million for the three months ended September 30, 2024 and 2023, respectively.

Research and development expense

Research and development expense was \$0.9 million and \$1.3 million for the three months ended September 30, 2024 and 2023, respectively. The \$0.3 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 \$19.5 million and \$18.0 million for the three months ended September 30, 2024 and 2023, respectively. The \$1.5 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.

Interest (income) expense, net

Interest (income) expense, net, was \$4.4 million and \$4.4 million for the three months ended September 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 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 September 30, 2024.

Other income includes primarily \$6.9 million and \$3.2 million for the three months ended September 30, 2024 and 2023, respectively of unrealized gains on the fair value of warrants.

Comparison of nine months ended September 30, 2024 and 2023

	Nine Months Ended September 30,	
	2024	2023
Revenues:		
Net product revenues	\$ 55,807	\$ 51,122
Total revenues	55,807	51,122
Costs and expenses:		
Cost of product sales	5,277	6,502
Research and development	3,083	4,017
Selling, general and administrative	64,121	60,839
Total operating expenses	72,481	71,358
Loss from operations	(16,674)	(20,236)
Other (income) expense:		
Interest (income) expense, net	13,194	12,461
Other income	(8,687)	(7,181)
Total other expense	4,507	5,280
Net loss	\$ (21,181)	\$ (25,516)

Net product revenues

Net product revenues related to sales of XHANCE were \$55.8 million and \$51.1 million for the nine months ended September 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 increase average net revenue per prescription.

Cost of product sales

Cost of product sales related to XHANCE were \$5.3 million and \$6.5 million for the nine months ended September 30, 2024 and 2023, respectively. The decrease of \$1.2 million can be primarily attributed to an a lower number of units sold in 2024.

Research and development expense

Research and development expense was \$3.1 million and \$4.0 million for the nine months ended September 30, 2024 and 2023, respectively. The \$0.9 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 \$64.1 million and \$60.8 million for the nine months ended September 30, 2024 and 2023, respectively. The \$3.3 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 \$13.2 million and \$12.5 million for the nine months ended September 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.

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 September 30, 2024.

Other income includes primarily \$8.7 million and \$7.2 million for the nine months ended September 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 \$21.2 million and \$25.5 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of \$741.6 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 September 30, 2024, we had \$82.5 million in cash and cash equivalents.

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

	Nine Months Ended September 30,	
	2024	2023
Net cash used in operating activities	\$ (46,552)	\$ (27,441)
Net cash used in investing activities	(72)	(255)
Net cash provided by financing activities	55,436	296
Net decrease in cash and cash equivalents	<u>\$ 8,812</u>	<u>\$ (27,400)</u>

Operating activities

Cash used in operating activities increased by \$19.1 million, from \$27.4 million for the nine months ended September 30, 2023 to \$46.6 million for the nine months ended September 30, 2024. The increase in cash used in operating activities was attributable to an increase in accounts receivable and inventory, as well as a decrease in

accounts payable and accrued expenses, partially offset by a smaller loss from operations for the nine months ended September 30, 2024.

Investing activities

Cash used in investing activities decreased from the nine months ended September 30, 2023 to the nine months ended September 30, 2024 due to an decrease in equipment and software purchases during the nine months ended September 30, 2024.

Financing activities

Cash provided by financing activities increased from the nine months ended September 30, 2023 to the nine months ended September 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 \$90 million and \$93 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 \$84 million and \$87 million. The \$84 million to \$87 million range is approximately a \$4 million to \$7 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

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 September 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.

As of September 30, 2024 we had \$82.5 million in cash and cash equivalents. In the event we are able to maintain compliance with the financial covenants and terms of the A&R Pharmakon Note Purchase Agreement or obtain a waiver to or modification of such covenants, we believe our existing cash and cash equivalents would be sufficient to fund our operations and debt service obligations for at least the next 12 months. However, as discussed below and elsewhere in this Form 10-Q, there is substantial doubt about our ability to maintain compliance with such financial covenants and terms of the A&R Note Purchase Agreement and our ability to continue as a going concern.

We will likely require additional capital in the future secured through equity or debt financings, partnerships, collaborations, or other sources in order to maintain compliance with the financial covenants of the A&R Note Purchase Agreement as discussed below, to meet our debt service obligations, including repayment of the Pharmakon Senior Secured Notes, and to carry out our planned development and commercial activities. If additional capital is not obtained when required, we may need to delay or curtail our operations until additional funding is received.

Our continuation as a going concern is dependent on 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, the requirement for us to maintain at least \$30.0 million of cash and cash equivalents at all times (reduced to \$20.0 million following the date of the first quarterly payment of principal due on September 30, 2025), referred to as "the liquidity covenant", and the requirement that our annual and quarterly financial statements not be subject to any qualification or statement as to "going concern" commencing with our financial statements for the fiscal year ending December 31, 2025), and the other provisions under the A&R Note Purchase Agreement, and our ability to generate sufficient cash flows from operations to meet our debt service obligations and to fund our operations and/or obtain additional capital through equity or debt financings, partnerships, collaborations, or other sources. The A&R Note Purchase Agreement includes events of default, in certain cases subject to customary periods to cure, following which Pharmakon may accelerate all amounts outstanding pursuant to the A&R Note Purchase Agreement. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business.

The A&R Note Purchase Agreement includes a requirement that we achieve certain minimum trailing twelve-month consolidated XHANCE net sales and royalties thresholds. We believe it is probable that we will not maintain compliance with the trailing twelve-month minimum consolidated XHANCE net sales and royalties thresholds for the entire one year period after the date these consolidated financial statements are issued. If we fail to achieve a

minimum consolidated XHANCE net sales and royalties threshold, it will constitute a default under the A&R Note Purchase Agreement if we are unable to obtain a modification or waiver of such minimum consolidated XHANCE net sales and royalties threshold.

In the event of the foregoing default, the holders of the Pharmakon Senior Secured Notes may declare an event of default under the A&R Note Purchase Agreement and may elect to accelerate the repayment of all unpaid principal, accrued interest and other amounts due (which would also require us to pay an interest make-whole premium as specified in the A&R Note Purchase Agreement if the repayment of the debt is accelerated prior to May 21, 2026).

Additionally, 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. We believe it is probable that, absent additional capital, we will not be able to maintain compliance with the minimum cash covenant under the A&R Note Purchase Agreement once we make the second principal repayment, which is due on December 31, 2025.

Our plans to seek to mitigate these default risks include enhancing our commercial performance to accelerate growth in net revenues, seeking out partnership and collaboration opportunities to expand the market for XHANCE, and, if required, requesting a modification or waiver of the covenants under the A&R Note Purchase Agreement, or refinancing the debt. However, there can be no assurance that we will be successful in accelerating growth in net revenue, expanding the market for XHANCE, obtaining a modification or waiver of the covenants under the A&R Note Purchase Agreement, or refinancing the debt. If we are unable to accelerate growth in net revenue, expand the market for XHANCE, obtain a modification or waiver of the covenants under the A&R Note Purchase Agreement, and/or refinance the debt, we may need to delay or curtail its operations until we obtain additional capital which may not be available on a timely basis, on favorable terms, or at all, and such capital, if obtained, may not be sufficient to meet our payment obligations or enable us to continue to implement our long-term business strategy. In such an event, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. These factors raise substantial doubt about our ability to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the fair value for such assets or less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. Additionally, if we seek additional financing to fund our debt service obligations and business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide funding to us on commercially reasonable terms, if at all.

Critical accounting policies

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

Recent accounting pronouncements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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

Our Chief Executive Officer and our Chief 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 Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 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 September 30, 2024 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

ITEM 1A. RISK FACTORS

Except as set forth below, there have been no material changes to the risk factors previously disclosed in Part I, "Item 1A, Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the SEC on March 7, 2024.

We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern.

As of September 30, 2024, we had cash and cash equivalents of \$82.5 million and have \$130.0 million of outstanding Pharmakon Senior Secured Notes under the A&R Note Purchase Agreement. Our accumulated deficit as of September 30, 2024 was \$741.6 million. We have incurred significant net losses since inception and also expect to incur substantial losses in future periods.

Our continuation as a going concern is dependent on 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, the requirement for us to maintain at least \$30.0 million of cash and cash equivalents at all times (reduced to \$20.0 million following the date of the first quarterly payment of principal due on September 30, 2025) and the requirement that commencing with our financial statements for the fiscal year ending December 31, 2025 that our annual and quarterly financial statements not be subject to any qualification or statement as to "going concern"), and the other provisions under the A&R Note Purchase Agreement, and our ability to generate sufficient cash flows from operations to meet our debt service obligations and to fund our operations and/or obtain additional capital through equity or debt financings, partnerships, collaborations, or other sources.

The A&R Note Purchase Agreement includes a requirement that we achieve certain minimum trailing twelve-month consolidated XHANCE net sales and royalties thresholds through maturity. We believe it is probable that we will not maintain compliance with the trailing twelve-month minimum consolidated XHANCE net sales and royalties thresholds for the entire one year period after the filing of this Form 10-Q. If we fail to achieve a minimum consolidated XHANCE net sales and royalties threshold, it will constitute a default under the A&R Note Purchase Agreement if we are unable to obtain a modification or waiver of such minimum consolidated XHANCE net sales and royalties threshold.

The A&R Note Purchase Agreement also requires us to maintain at all times a minimum of \$30.0 million of cash and cash equivalents, which will be reduced to \$20.0 million following the date of the first quarterly payment of principal due on September 30, 2025 (referred to as, the "liquidity covenant"). If we are unable to secure additional capital through equity or debt financings, partnerships, collaborations, or other sources, we believe that it is probable that we will not be able to maintain compliance with the liquidity covenant under the A&R Note Purchase Agreement once we make the second principal repayment, which is due on December 31, 2025, which will also constitute a default under the A&R Note Purchase Agreement if we are unable to obtain a waiver or modification of such liquidity covenant.

Further, the A&R Note Purchase Agreement includes a requirement that commencing with the report and opinion on our consolidated financial statements commencing with our financial statements for the fiscal year ending December 31, 2025 that all of our quarterly and annual financial statements, not be subject to any statement or qualification as to "going concern" (referred to as, the "going concern covenant"). As a general matter, financial statements are subject to a "going concern" uncertainty disclosure if it is probable that the company's available capital is not sufficient to fund its operations and obligations for at least twelve months following the issuance of such financial statements including obligations that could become due during such twelve month period as a result of some future event (for instance, the potential that the Pharmakon Senior Secured Notes could become due if it is deemed probable that we will not maintain compliance with the covenants and other terms under the A&R Note Purchase Agreement during such twelve month period). If we are unable to secure additional capital through equity or debt financings, partnerships, collaborations, or other sources, we believe it is unlikely that we will be able comply with the going concern covenant commencing with our financial statements for the fiscal year ending December 31, 2025, which will constitute a default under the A&R Note Purchase Agreement if we are unable to obtain a modification or waiver of such going concern covenant.

In the event of any of the foregoing defaults, the holders of the Pharmakon Senior Secured Notes may declare an event of default under the A&R Note Purchase Agreement and may elect to accelerate the repayment of all unpaid principal, accrued interest and other amounts due (which would also require us to pay an interest make-whole premium as specified in the A&R Note Purchase Agreement if the repayment of the debt is accelerated prior to May 21, 2026), which may require us to delay or curtail our operations until we obtain additional capital which may not be available on a timely basis, on favorable terms, or at all, and such capital, if obtained, may not be sufficient to meet our payment obligations or enable us to continue to implement our long-term business strategy. In such an event, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. These factors raise substantial doubt about our ability to continue as a going concern. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the fair value for such assets or less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. Additionally, if we seek additional financing to fund our debt service obligations and business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide funding to us on commercially reasonable terms, if at all.

Our failure to comply with the covenants or other terms of the A&R Note Purchase Agreement, including as a result of events beyond our control, could result in a default under the A&R Note Purchase Agreement that could materially and adversely affect the ongoing viability of our business.

Each holder of the Pharmakon Senior Secured Notes may elect to accelerate the repayment of all unpaid principal and accrued interest under such holders' Pharmakon Senior Secured Notes upon consummation of a specified change of control transaction or occurrence of certain events of default (as specified in the A&R Note Purchase Agreement), including, among other things:

- our default in a payment obligation under the Pharmakon Senior Secured Notes;
- our breach of the financial covenants, affirmative covenants, restrictive covenants or other terms of the A&R Note Purchase Agreement, including (i) the trailing twelve-month minimum consolidated XHANCE net sales and royalties covenant, (ii) the requirement to maintain at least \$30.0 million of cash and cash equivalents (reduced to \$20.0 million following the date of the first quarterly payment of principal due on September 30, 2025) and (iii) the requirement to deliver quarterly and annual financial statements that, commencing with the fiscal period ending December 31, 2025, are not subject to a "going concern" statement or qualification;
- our breach of reporting obligations;
- our failure to properly maintain the collateral;
- any circumstance that could reasonably be expected to have a material adverse effect (as defined in the A&R Note Purchase Agreement) on us;
- certain regulatory and/or commercial actions that cause an ongoing delay in commercialization of XHANCE; and
- certain specified insolvency and bankruptcy-related events.

Subject to any applicable cure period set forth in the Pharmakon Senior Secured Notes, all amounts outstanding with respect to the Pharmakon Senior Secured Notes (principal and accrued interest), as well as any applicable interest "make-whole" payments, would become due and payable immediately upon an event of default and shall be subject to a default interest rate of an additional 3%. Our assets or cash flow may not be sufficient to fully repay our obligations under the Pharmakon Senior Secured Notes if the obligations thereunder are accelerated upon any events of default. Further, if we are unable to repay, refinance or restructure our obligations under the Pharmakon Senior Secured Notes, or obtain a waiver or modification to the financial covenants or any other terms under the A&R Note Purchase Agreement as may be required in the future, the holders of such Pharmakon Senior Secured Notes could proceed to protect and enforce their rights under the Pharmakon Senior Secured Notes by exercising such remedies (including foreclosure on the assets securing our obligations under the Pharmakon Senior Secured Notes and the A&R Note Purchase Agreement) as are available to the holders thereunder and in respect thereof under applicable law, either by suit in equity or by action at law, or both, whether for specific performance of any covenant or other agreement contained in the Pharmakon Senior Secured Notes or in aid of the exercise of any power granted in the Pharmakon Senior Secured Notes. Any such action would materially and adversely affect the ongoing viability of our business.

In the event that we maintain compliance with the trailing twelve-month minimum consolidated XHANCE net sales and royalties that we are required to meet each quarter, maintain at least \$30.0 million of cash and cash equivalents (reduced to \$20.0 million following the date of the first quarterly payment of principal due on September 30, 2025) and deliver quarterly and annual financial statements that, commencing with the fiscal period ending December 31, 2025, are not subject to a "going concern" statement or qualification, and maintain compliance with all other terms of the A&R Note Purchase Agreement, in each case, to avoid an acceleration of payments due under the Pharmakon Senior Secured Notes, then we will be required to repay the notes in eight equal quarterly payments of \$16.25 million starting on September 30, 2025. The Pharmakon Senior Secured Notes are guaranteed by us and certain of our subsidiaries and are secured by a pledge of substantially all of our and their assets.

We are required to achieve the following minimum trailing twelve-month XHANCE net sales and royalties under the A&R Note Purchase Agreement (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

We could be delisted from Nasdaq, which would harm the liquidity of our stock and our ability to raise capital, and may cause the market price of our stock to decline.

Nasdaq requires listing issuers to comply with certain standards in order to remain listed on its exchange. On October 16, 2024, we were notified (the "Notice") by Nasdaq Stock Market, LLC ("Nasdaq") that on October 16, 2024, the average closing price of our common stock over the prior 30 consecutive trading days had fallen below \$1.00 per share, which is the minimum average closing price required to maintain listing on Nasdaq under Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Requirement"). Nasdaq's notice had no immediate effect on the listing or trading of our common stock. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we are provided an initial compliance period of 180 calendar days to regain compliance with the Minimum Bid Requirement. To regain compliance, the closing bid price of our common stock must meet or exceed \$1.00 per share for a minimum of 10 consecutive business days prior to the deadline. If we do not achieve compliance with the Minimum Bid Requirement within 180 calendar days, we may be eligible for an additional 180 calendar days to regain compliance. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other Nasdaq initial listing standards, with the exception of the Minimum Bid Requirement, and provide written notice of our intention to cure the minimum bid price deficiency during the second compliance period.

If the Nasdaq staff determines that we will not be able to cure the deficiency, or if we are otherwise not eligible for such additional compliance period, Nasdaq will provide notice that our common stock will be subject to delisting. In the event we receive notice that our common stock is being delisted, Nasdaq rules permit us to appeal any delisting determination by the Nasdaq staff. There can be no assurance that the Company will be able to regain compliance with the Minimum Bid Requirement or maintain compliance with the other listing requirements.

If, for any reason, Nasdaq were to delist our securities from trading on its exchange and we are unable to obtain listing on another reputable national securities exchange, a reduction in some or all of the following may occur, each of which could materially adversely affect our stockholders:

- liquidity and marketability of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock

In addition, if we cease to be eligible to trade on Nasdaq, we may have to pursue trading on a less recognized or accepted market, such as the over the counter markets, our stock may be traded as a “penny stock” which would make transactions in our stock more difficult and cumbersome, and we may be unable to access capital on favorable terms or at all, as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock. This may also cause the market price of our common stock to further decline.

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	<u>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).</u>
3.2	<u>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).</u>
3.3	<u>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).</u>
10.1	<u>Employment Agreement, dated October 4, 2024 between OptiNose US, Inc. and P. Terrence Kohler, Jr. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with SEC on October 7, 2024.</u>
31.1 *	<u>Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.</u>
31.2 *	<u>Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act</u>
32.1 **	<u>Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer.</u>
32.2 **	<u>Certification Pursuant to 18 U.S.C. Section 1350 of principal financial officer.</u>
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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 12, 2024

OPTINOSE, INC.

By: /s/ TERRY KOHLER

Name: Terry Kohler

Title: *Chief Financial Officer*

(Principal Financial and Accounting Officer)

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: November 12, 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, Terry Kohler, 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: November 12, 2024

/s/ Terry Kohler
Terry Kohler
Chief Financial 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 September 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: November 12, 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, Terry Kohler, Chief Financial 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 September 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: November 12, 2024

/s/ Terry Kohler
Terry Kohler
Chief Financial Officer
(Principal Financial and Accounting Officer)