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, 2023

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

For the transition period from _____ to _____.

Commission file number: 001-38241

OPTINOSE, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	OPTN	Nasdaq Global Select Market

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

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

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

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

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

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

The number of shares of the registrant's common stock outstanding at November 1, 2023 was 112,311,984 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

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

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;
- our planned activities in pursuit of a follow-on indication for chronic sinusitis;
- the potential for XHANCE to be the first product approved by the U.S. Food and Drug Administration (FDA) for the treatment of chronic sinusitis;
- the potential to expand 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 benefits of our patient affordability programs (including recent changes we made to the XHANCE co-pay assistance program) and their potential effect on XHANCE demand and financial results;
- our expectation for XHANCE prescriptions to be impacted by the seasonality observed in the INS market and the seasonal variation in patient visits with their doctor;
- our expectation for XHANCE prescriptions and average net revenue per prescription to be adversely impacted by the annual resetting of patient healthcare insurance plan deductibles and changes in individual patients' healthcare insurance coverage, both of which often occur in January;
- XHANCE prescription, net revenue, prescriber and other business trends;
- the potential for increasing rates of enforcement of payor utilization management criteria to negatively impact XHANCE prescription volumes;
- the rate and degree of market acceptance and market opportunity of XHANCE;
- the potential for us to decrease our reliance on sole-source suppliers and increase the third party manufacturing capacity that is available to us;
- our expectation that the research and development costs will significantly decrease in 2023 as compared to 2022;
- our expectation that our operating expenses (consisting of selling, general & administrative expenses and research & development expenses) in 2023 will be between $88.0 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 2023 will be between $66.0 million and $70.0 million;
- our expectation that the average net product revenue per prescription for XHANCE for the full year of 2023 will be approximately $200;
- our potential non-compliance with certain covenants of the A&R Note Purchase Agreement, and the consequences of failing to achieve compliance with such covenants or obtain a waiver or modification of such covenants;
- our belief that our existing cash and cash equivalents will be sufficient to fund our operations and debt service obligations for approximately the next 12 months if we are able to maintain compliance with the

financial and other covenants and terms of the A&R Note Purchase Agreement or obtain a waiver to or modification of such covenants;

- 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;
- our plans to liquidate and dissolve our wholly-owned subsidiaries, OptiNose AS and OptiNose UK, in 2023;

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, 2022, 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 data generated by independent third parties, by third parties on our behalf and by us concerning prescription data, inventory data, markets for XHANCE, XHANCE market access and the INS market. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual results, events or circumstances may differ materially from results, events and circumstances 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, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 66,845	$ 94,244
Accounts receivable, net	21,373	33,932
Inventory	8,043	9,443
Prepaid expenses and other current assets	2,359	2,865
Total current assets	98,620	140,484
Property and equipment, net	882	795
Other assets	1,905	2,943
Total assets	$ 101,407	$ 144,222
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 5,006	$ 5,291
Accrued expenses and other current liabilities	29,162	44,864
Short term debt, net	129,813	128,575
Total current liabilities	163,981	178,730
Warrant liability	14,300	21,490
Other liabilities	741	626
Total liabilities	179,022	200,846
Stockholders' deficit:		
Common stock, $0.001 par value; 350,000,000 shares authorized at September 30, 2023 and 200,000,000 shares authorized at December 31, 2022; 112,311,983 and 111,492,761 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	112	111
Additional paid-in capital	632,765	628,242
Accumulated deficit	(710,408)	(684,893)
Accumulated other comprehensive loss	(84)	(84)
Total stockholders' deficit	(77,615)	(56,624)
Total liabilities and stockholders' deficit	$ 101,407	$ 144,222

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Operations
For the Three and Nine Months Ended September 30, 2023 and 2022
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30, 2023	
	2023	2022	2023	2022
Revenues:				
Net product revenues	$ 19,823	$ 20,078	$ 51,122	$ 55,420
Total revenues	19,823	20,078	51,122	55,420
Costs and expenses:				
Cost of product sales	2,225	2,125	6,502	6,282
Research and development	1,281	3,267	4,017	12,339
Selling, general and administrative	18,011	25,486	60,839	84,339
Total operating expenses	21,517	30,878	71,358	102,960
Loss from operations	(1,694)	(10,800)	(20,236)	(47,540)
Other (income) expense:				
Unrealized (gain) loss on fair value of warrants	3,200	—	(7,190)	—
Interest income	(545)	(48)	(1,974)	(218)
Interest expense	4,940	4,207	14,436	12,365
Foreign currency (gains) loss	5	(5)	8	(3)
Net loss	$ (9,294)	$ (14,954)	$ (25,516)	$ (59,684)
Net loss per share of common stock, basic and diluted	$ (0.08)	$ (0.18)	$ (0.23)	$ (0.72)
Weighted average common shares outstanding, basic and diluted	112,230,155	83,320,704	111,996,456	82,846,868

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Comprehensive Income (Loss)
For the Three and Nine Months Ended September 30, 2023 and 2022
(in thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30, 2023	
	2023	2022	2023	2022
Net loss	$ (9,294)	$ (14,954)	$ (25,516)	$ (59,684)
Other comprehensive income (loss):				
Foreign currency translation adjustment	—	—	—	(3)
Comprehensive loss	$ (9,294)	$ (14,954)	$ (25,516)	$ (59,687)

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, 2023

	Stockholders' Equity (Deficit)					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2022	111,492,761	$ 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
Foreign currency translation adjustment	—	—	—	—	—	—
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	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	—	—
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
Foreign currency translation adjustment	—	—	—	—	—	—
Net loss	—	—	—	(9,294)	—	(9,294)
Balance at September 30, 2023	112,311,983	$ 112	$ 632,765	$ (710,408)	$ (84)	$ (77,615)

Nine Months Ended September 30, 2022

	Stockholders' Equity (Deficit)					
	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2021	82,238,900	$ 82	$ 588,288	$ (610,061)	$ (81)	$ (21,772)
Stock compensation expense	—	—	1,998	—	—	1,998
Vesting of restricted stock units	262,942	—	—	—	—	—
Issuance of common stock under employee stock purchase plan	179,206	1	249	—	—	250
Foreign currency translation adjustment	—	—	—	—	(1)	(1)
Net loss	—	—	—	(25,333)	—	(25,333)
Balance at March 31, 2022	82,681,048	$ 83	$ 590,535	$ (635,394)	$ (82)	$ (44,858)
Stock compensation expense	—	—	3,474	—	—	3,474
Vesting of restricted stock units and exercise of options	363,318	—	—	—	—	—
Foreign currency translation adjustment	—	—	—	—	(2)	(2)
Net loss	—	—	—	(19,397)	—	(19,397)
Balance at June 30, 2022	83,044,366	$ 83	$ 594,009	$ (654,791)	$ (84)	$ (60,783)
Stock compensation expense	—	—	1,917	—	—	1,917
Vesting of restricted stock units and exercise of options	267,967	—	98	—	—	98
Issuance of common stock under employee stock purchase plan	208,138	1	305	—	—	306
Foreign currency translation adjustment	—	—	—	—	—	—
Net loss	—	—	—	(14,954)	—	(14,954)
Balance at September 30, 2022	83,520,471	$ 84	$ 596,329	$ (669,745)	$ (84)	$ (73,416)

See accompanying notes to unaudited interim consolidated financial statements

OptiNose, Inc.
Consolidated Statements of Cash Flows
For the Nine Months Ended September 30, 2023 and 2022
(in thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2023	2022
Operating activities:		
Net loss	$ (25,516)	$ (59,684)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	282	400
Stock-based compensation	4,219	7,391
Change in fair value of warrant liability	(7,190)	—
Amortization of debt discount and issuance costs	1,242	1,689
Changes in operating assets and liabilities:		
Accounts receivable	12,559	8,833
Prepaid expenses and other assets	2,432	1,215
Inventory	1,348	1,524
Accounts payable	(346)	395
Accrued expenses and other liabilities	(16,471)	(11,734)
Cash used in operating activities	(27,441)	(49,971)
Investing activities:		
Purchases of property and equipment	(255)	(60)
Cash used in investing activities	(255)	(60)
Financing activities:		
Proceeds from the exercise of stock options	1	93
Proceeds from issuance of common stock under employee stock purchase plan	299	556
Cash paid for financing costs	(4)	—
Cash provided by financing activities	296	649
Effects of exchange rate changes on cash and cash equivalents	—	(12)
Net decrease in cash, cash equivalents and restricted cash	(27,400)	(49,394)
Cash, cash equivalents and restricted cash at beginning of period	94,244	110,515
Cash, cash equivalents and restricted cash at end of period	$ 66,845	$ 61,121
Supplemental disclosure of cash flow information:		
Cash paid for interest	13,194	10,637
Supplemental disclosure of noncash activities:		
Fixed asset purchases within accounts payable and accrued expenses	$ 61	$ 4
Recognition of right-of-use assets and lease liabilities	$ 890	$ 508

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. During 2022, the Company's board of directors approved the liquidation of OptiNose AS and OptiNose UK, which is expected to be completed in 2023, in order to simplify the corporate structure.

The Company is a specialty pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat (ENT) and allergy specialists. The Company's first commercial product, XHANCE® (fluticasone propionate) nasal spray, 93 microgram (mcg), is a therapeutic utilizing the Company's proprietary Exhalation Delivery System (EDS) that delivers a topically-acting corticosteroid for the treatment of chronic rhinosinusitis with nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps (commonly referred to as chronic sinusitis). 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. XHANCE was made widely available through commercial channels in April 2018. In January 2023, the indication statement for XHANCE was changed from “for the treatment of nasal polyps” to “for the treatment of chronic rhinosinusitis with nasal polyps” to reflect current FDA labeling terminology and not based on new XHANCE clinical trial data. In February 2023, the Company submitted a prior approval efficacy supplement (sNDA) to the FDA to support the approval of a new indication for XHANCE for the treatment of chronic rhinosinusitis.

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, 2023, the Company had cash and cash equivalents of $66,845 and a working capital deficiency of $65,361.

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 inception and has accumulated a deficit of $710,408 as of September 30, 2023.

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 (See Note 8). The principal balance outstanding under the A&R Note Purchase Agreement was $130,000 at September 30, 2023.

The Company's continuation as a going concern is dependent on its ability to maintain compliance with its 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 commencing with the trailing twelve months ending March 31, 2024 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 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 also requires the Company to maintain at all times a minimum of $30,000 of cash and cash equivalents. The Company believes that it is probable that its existing cash and cash equivalents will

not be adequate to fund its operations and maintain at least $30,000 of cash and cash equivalents as required under the A&R Note Purchase Agreement for at least twelve-months following the filing of this Form 10-Q, which will constitute a default of the liquidity financial covenant under the A&R Note Purchase Agreement if the Company is unable to obtain additional capital or obtain a waiver or modification to this liquidity covenant prior to falling below such $30,000 threshold.

The Company also believes it is probable that it will not achieve the trailing twelve-month minimum consolidated XHANCE net sales and royalties thresholds under the A&R Note Purchase Agreement for the initial period ending March 31, 2024, 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.

Further, the A&R Note Purchase Agreement includes a requirement that the report and opinion on the consolidated financial statements commencing with the year ending December 31, 2023, not be subject to any statement as to “going concern” (subject to certain exceptions). In addition, the consolidated financial statements commencing with the quarter ended March 31, 2024, shall also not be subject to any statement as to “going concern” (subject to certain exceptions). The Company has concluded that it is unlikely that it will be able comply with these provisions in 2024. Failure to comply with these provisions would also constitute an event of default under the A&R Note Purchase Agreement.

In the event of any of the foregoing defaults, the holders of the Pharmakon Senior Secured Notes 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 this risk may include reducing expenses, raising additional capital through equity or debt financings, partnerships, collaborations or other sources, and requesting a modification or waiver of the covenants under the A&R Note Purchase Agreement. However, there can be no assurance that the Company will be successful in reducing expenses, raising additional capital, or obtaining a modification or waiver of the covenants under the A&R Note Purchase Agreement. If the Company is unable to reduce expenses, raise additional capital or obtain a modification or waiver of the covenants under the A&R Note Purchase Agreement, 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, 2023 and its results of operations for the three and nine months ended September 30, 2023 and 2022 and cash flows for the nine months ended September 30, 2023 and 2022. Operating results for the three and nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023. The unaudited interim financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial statements. The accompanying unaudited interim financial statements should be read in conjunction with the annual audited financial statements and related notes as of and for the year ended December 31, 2022 contained in the Company’s annual report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 7, 2023.

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 73% and 40% of the Company's accounts receivable at September 30, 2023 and 2022, respectively. Five customers represented approximately 50% and 31% of the Company's net product sales for the three months ended September 30, 2023 and 2022, respectively. Five customers represented approximately 40% and 29% of the Company's net product sales for the nine months ended September 30, 2023 and 2022, 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. The Company has initiated the process of qualifying an alternate third-party supplier for select components of XHANCE. Alternate third party suppliers of XHANCE components are subject to qualification and approval from the FDA.

Fair value of financial instruments

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

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

At September 30, 2023 and 2022, 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, 2023, 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, 2023, there were no financial assets or liabilities measured at fair value on a recurring basis other than the liability classified warrants.

In November 2022, the Company issued warrants in connection with a public offering. Pursuant to the terms of the warrant agreement, the Company could be required to settle the warrants in cash in the event of an acquisition of the Company and, as a result, the warrants are required to be measured at fair value and reported as liability in the consolidated balance sheet. The Company recorded the fair value of the warrants upon issuance using a Monte Carlo simulation and is required to revalue the warrants at each reporting date with any changes in fair value recorded on our statement of operations. The valuation of the warrants is considered under Level 3 of the fair value hierarchy due to the need to use assumptions in the valuation that are both significant to the fair value measurement and unobservable. The change in the fair value of the Level 3 warrants liabilities is reflected in the statement of operations for the three and nine months ended September 30, 2023.

Net product revenues

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

Provider Chargebacks and Discounts. Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These components of variable consideration are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable.

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

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

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

(in thousands, except share and per share data)

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

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

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

Net income (loss) per common share

Basic net income (loss) per common share is determined by dividing net income (loss) applicable to common stockholders by the weighted average common shares outstanding during the period. For the three and nine months ended September 30, 2023 and 2022, the outstanding Common Stock options, Restricted Stock units, Common Stock warrants and shares to be issued under the Company's 2017 Employee Stock Purchase Plan have been excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, the weighted average shares used to calculate both basic and diluted net loss per share are the same.

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

	September 30,	
	2023	2022
Stock options	10,153,661	9,581,947
Restricted stock units	2,012,552	1,871,021
Common stock warrants	32,768,000	2,500,000
Employee stock purchase plan	190,186	74,935
Total	45,124,399	14,027,903

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, 2023 and 2022, the Company recorded no tax expense or benefit due to the expected current year loss and its historical losses. As of September 30, 2023 and December 31, 2022, 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.

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

Level 2: Quoted prices in markets that are not active or inputs which are observable, either directly or indirectly, for substantially the full te1m of the asset or liability; and

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

Determining which category an asset or liability falls within the hierarchy requires significant judgment. The Company evaluates its hierarchy disclosures each reporting period. There were no transfers between Level I, 2 and 3 during the three months ended September 30, 2023.

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, 2023 categorized by the level of inputs used in the valuation of each liability.

	September 30, 2023			
	Total	Level 1	Level 2	Level 3
Liabilities				
Warrant Liability	$ 14,300	$ —	$ —	$ 14,300
Total Liabilities	$ 14,300	$ —	$ —	$ 14,300

	December 31, 2022			
Liabilities				
Warrant Liability	$ 21,490	$ —	$ —	$ 21,490
Total Liabilities	$ 21,490	$ —	$ —	$ 21,490

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

Warrant Liability

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

	Warrant Liability
Balance, December 31, 2022	$ 21,490
Warrants issued	—
Change in fair value of liability	(7,190)
Balance, September 30, 2023	$ 14,300

(in thousands, except share and per share data)

Assumptions Used in Determining Fair Value of Liability-Classified Warrants

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

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

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

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

	September 30, 2023	December 31, 2022
Stock price	$ 1.23	$ 1.85
Strike price	$ 2.57	$ 2.57
Expected volatility	57.5 %	45.0 %
Risk-free interest rate	4.6 %	3.8 %
Expected dividend yield	— %	— %
Expected life (years)	4.10	4.90
Fair value per warrant	$ 0.47	$ 0.71

5. Inventory

Inventory consisted of the following:

	September 30, 2023	December 31, 2022
Raw materials	$ 2,114	$ 1,691
Work-in-process	3,345	5,010
Finished goods	2,584	2,742
Total inventory	$ 8,043	$ 9,443

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

(in thousands, except share and per share data)

6. Property and Equipment

Property and equipment, net, consisted of the following:

	September 30, 2023	December 31, 2022
Computer equipment and software	$ 1,425	$ 1,203
Furniture and fixtures	366	366
Machinery and equipment	3,144	3,067
Leasehold improvements	609	609
Construction in process	115	115
	5,659	5,360
Less: accumulated depreciation	(4,777)	(4,565)
	$ 882	$ 795

Depreciation expense was $102 and $144 for the three months ended September 30, 2023 and 2022, respectively. Depreciation expense was $281 and $399 for the nine months ended September 30, 2023 and 2022, respectively. In addition, depreciation expense of $608 was charged to inventory as of September 30, 2023, which represents depreciation expense related to equipment involved in the manufacturing process.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of:

	September 30, 2023	December 31, 2022
Accrued expenses:		
Selling, general and administrative expenses	$ 3,914	$ 3,799
Research and development expenses	619	1,298
Payroll expenses	5,798	7,888
Product revenue allowances	15,556	27,993
Other	2,144	1,915
Total accrued expenses	28,031	42,893
Other current liabilities:		
Lease liability	1,131	1,971
Total other current liabilities	1,131	1,971
Total accrued expenses and other current liabilities	$ 29,162	$ 44,864

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 after achieving the $9,000 consolidated XHANCE net sales and royalties threshold for the quarter ended December 31, 2019 and $20,000 was issued on December 1, 2020 after achieving the $14,500 consolidated XHANCE net sales and royalties threshold for the quarter ended September 30, 2020.

On November 23, 2022, the Company amended and restated the Note Purchase Agreement, initially entered into on September 12, 2019 and amended through November 9, 2022, among the Company, its subsidiaries, OptiNose US, Inc., OptiNose AS and OptiNose UK, Ltd. and BioPharma Credit PLC, as collateral agent, and the purchasers party thereto from time to time (the A&R Note Purchase Agreement). Pursuant to the A&R Note Purchase Agreement, certain modifications to the affirmative and negative covenants, events of default and other provisions were made, including, without limitation, (i) the requirement for the Company to deliver quarterly and annual financial statements that, commencing with the Company's consolidated financial statements for the year ending December 31, 2023 and subject to certain exceptions, are not subject to a “going concern” statement (the Going

Concern Covenant) and (ii) the removal of certain exceptions to the negative covenants which previously permitted the Company to enter into certain transactions without the consent of the holders of the Pharmakon Senior Secured Notes, including permitted acquisitions, swap contracts, convertible bonds and revolving credit facilities. The financial covenants requiring the Company to achieve minimum trailing twelve-month consolidated XHANCE net product sales and royalties were amended to be pushed back to March 31, 2024.

The A&R Note Purchase Agreement extended the maturity date of the Pharmakon Senior Secured Notes from September 12, 2024 to June 30, 2027 (New Maturity Date), extended the interest-only period from September 2023 to September 2025, after which principal repayments will commence starting on September 30, 2025 and will be made in eight equal quarterly installments of principal and interest through the New Maturity Date. As part of the A&R Note Purchase Agreement the Pharmakon Senior Secured Notes now bear an amended interest rate through the New Maturity Date equal to the 3-month Secured Overnight Financing Rate (subject to a 2.50% floor), determined as of the date that is two business days prior to the commencement of each quarter, plus 8.50% per annum, which interest rate shall be increased by an additional 3.00% per annum upon the occurrence and during the continuation of any event of default. The Effective Interest Rate as of September 30, 2023 is 13.62%.

In conjunction with the A&R Note Purchase Agreement, a modification was made to the “make-whole” premium payment due in connection with any principal prepayments (whether mandatory or voluntary) made prior to the 3-year anniversary of the date of the A&R Note Purchase Agreement. On any such prepayment date, the Company will be required to pay a make-whole premium in the amount of (i) for any prepayment date occurring up until and including the 18-month anniversary of the date of the A&R Note Purchase Agreement, the foregone interest from such prepayment date through the 18-month anniversary of such prepayment date; and (ii) for any prepayment after the 18-month anniversary of the date of the A&R Note Purchase Agreement, the foregone interest from such prepayment date through the 3-year anniversary of the date of the A&R Note Purchase Agreement; provided, however, that in no event shall the amount of all make-whole premium payments exceed $24,000 in the aggregate.

As an inducement for the holders of the Pharmakon Senior Secured Notes to enter into the A&R Note Purchase Agreement, the Company is required to pay the holders of the Pharmakon Senior Secured Notes an amendment fee of $3,900 (representing 3.00% of the 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 (i) reduced to $1,300 in the event that the Company repays the Pharmakon Senior Secured Notes in full prior to the one-year anniversary of the date of the A&R Note Purchase Agreement and (ii) 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.

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 have at least $30,000 of cash and cash equivalents at all times. 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 BioPharma may accelerate all amounts outstanding under the Pharmakon Senior Secured Notes.

The Company believes that it is probable that it will not achieve the trailing twelve-month minimum consolidated XHANCE net sales and royalties thresholds that it is required to achieve commencing with the period ending March 31, 2024. Additionally, without additional capital, the Company believes that it is probable that it will not be able to maintain at least $30,000 of cash and cash equivalents for at least twelve-months following the filing of this Form 10-Q. In addition, the Company believes that it is unlikely that it will be able to maintain compliance with the Going Concern Covenant in 2024. As a result, in accordance with FASB Accounting Standards Codification 470, the

(in thousands, except share and per share data)

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 March 31, 2023.

The Company recorded interest expense of $4,940 and $4,207 during the three months ended September 30, 2023 and 2022, respectively. The Company recorded interest expense of $14,436 and $12,365 during the nine months ended September 30, 2023 and 2022, 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, 2023	December 31, 2022
Face amount	$ 130,000	$ 130,000
Front end fees	(555)	(666)
Debt issuance costs	(5,612)	(6,739)
Back end fees	5,980	5,980
Debt, net	$ 129,813	$ 128,575

9. Employee Benefit Plans

For US employees, the Company maintains a defined contribution 401(k) retirement plan. As of September 30, 2023, $100 was recorded in accrued liabilities related to the Company match. The Company's contributions are made in cash.

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

10. Stockholders' Equity

As of September 30, 2023, the Company had the following warrants outstanding to purchase shares of Common Stock:

Number of Shares	Classification	Exercise Price Per Share	Expiration Date
2,500,000	Equity	$1.60	November 15, 2024
30,268,000	Liability	$2.565	November 23, 2027

(in thousands, except share and per share data)

11. Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options and shares issued under the Company's 2010 Stock Incentive Plan and 2017 Employee Stock Purchase Plan (2017 Plan) in the following expense categories of its accompanying consolidated statements of operations for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cost of product sales	$ 9	$ 10	$ 27	$ 30
Research and development	129	219	410	648
General and administrative	1,067	1,721	3,793	6,716
	$ 1,205	$ 1,950	$ 4,230	$ 7,394

In addition, stock-based compensation expense of $87 was capitalized to inventory as of September 30, 2023, which represents the stock-based compensation expense incurred related to employees involved in the manufacturing process of finished goods and samples.

Stock Options

The Company issues stock-based awards pursuant to its 2010 Stock Incentive Plan. Effective as of October 12, 2017, the Company's 2010 Stock Incentive Plan was amended and restated (A&R Plan). The Company has issued service-based, performance-based, and market-based stock options that generally have a contractual life of up to 10 years and may be exercisable in cash or as otherwise determined by the Company's board of directors or committee thereof. Vesting generally occurs over a period of not greater than four years. Performance-based options may vest upon the achievement of certain milestones. As of September 30, 2023, all of the performance conditions related to performance-based stock options issued by the Company had been achieved. Market-based options may vest upon the achievement of certain market-based objectives relating to the trading price of the Company's Common Stock.

The following table summarizes the activity related to stock option grants to employees and non-employees for the nine months ended September 30, 2023:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual life
Outstanding at December 31, 2022	9,364,070	$ 6.88	6.05
Granted	2,287,677	1.65	
Exercised	—	—	
Expired	(755,801)	7.76	
Forfeited	(742,285)	2.53	
Outstanding at September 30, 2023	10,153,661	$ 5.96	5.68
Exercisable at September 30, 2023	5,868,254	$ 8.93	3.58

During the nine months ended September 30, 2023, stock options to purchase 2,287,677 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 $1.14. 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.

(in thousands, except share and per share data)

The aggregate intrinsic value of stock options outstanding and stock options exercisable, other than market-based stock options, as of September 30, 2023 was $27 and $0, respectively. At September 30, 2023, the unrecognized compensation cost related to unvested stock options, other than market-based stock options, expected to vest was $4,030. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.69 years.

Included in the table above are 959,215 market-based options granted. 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, 2023, 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 905,500 options granted outside the A&R Plan. The grants were made pursuant to the Nasdaq inducement grant exception in accordance with Nasdaq Listing Rule 5635(c)(4).

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, 2023:

	Shares
Balance at December 31, 2022	1,477,660
Granted	1,627,174
Vested and settled	(567,915)
Expired/forfeited/canceled	(524,367)
Balance at September 30, 2023	2,012,552
Expected to vest at September 30, 2023	2,012,552

During the nine months ended September 30, 2023, the Company granted 1,627,174 RSUs at a weighted-average grant date fair value of $1.86, all of which were service-based RSUs. No performance-based RSUs were granted in the nine months ended September 30, 2023. As of September 30, 2023, the milestone associated with the previously granted performance based-RSUs was achieved. At September 30, 2023, the recognized compensation cost related to vested performance-based RSUs was $1,820. At September 30, 2023, the unrecognized compensation cost related to unvested service-based RSUs expected to vest was $3,570, to be recognized over an estimated weighted-average amortization period of 2.83 years. The unrecognized compensation cost related to unvested performance-based RSUs was $241, which will be recognized over the remaining service period.

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

2017 Employee Stock Purchase Plan

Under the 2017 Plan, shares of Common Stock may be purchased by eligible employees who elect to participate in the 2017 Plan at 85% of the lower of the fair market value of Common Stock on the first or last day of designated offering periods. The Company recognized stock-based compensation expense related to the 2017 Plan of $48 and $53 during the three months ended September 30, 2023 and 2022, respectively. The Company recognized stock-based compensation expense related to the 2017 Plan of $125 and $215 during the nine months ended September 30, 2023 and 2022, respectively.

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

The Company calculated the fair value of each option grant and the shares issued under the 2017 Plan on the respective dates of grant using the following weighted average assumptions:

	Nine Months Ended September 30,	
	2023	**2022**
Risk free interest rate	0.05 %	0.17 %
Expected term (in years)	0.5	0.5
Expected volatility	68.13 %	88.13 %
Annual dividend yield	0.00 %	0.00 %

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, 2022, filed with the Securities and Exchange Commission (SEC) on March 7, 2023. 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 "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 nasal polyps and, if approved, chronic rhinosinusitis without nasal polyps (commonly referred to as chronic sinusitis). 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.

In September 2017, the U.S. Food and Drug Administration (FDA) approved XHANCE for the treatment of nasal polyps in patients 18 years of age or older. XHANCE was made widely available through commercial channels in April 2018. In January 2023, the indication statement for XHANCE was changed from "for the treatment of nasal polyps" to "for the treatment of chronic rhinosinusitis with nasal polyps". This modification was the result of a change in FDA labeling terminology and was not based on new XHANCE clinical trial data.

In March and June 2022, we announced positive top line results from our two Phase 3b clinical trials (ReOpen1 and ReOpen2) of XHANCE for a follow-on indication for the treatment of chronic sinusitis. The results of ReOpen1 and ReOpen2 are summarized in our Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 7, 2023. In February 2023, we submitted a prior approval efficacy supplement (sNDA) to support the approval of a new indication for XHANCE for the treatment of chronic rhinosinusitis in patients 18 years of age or older. The FDA accepted the sNDA for review and assigned a Prescription Drug User Fee Act (PDUFA) goal date of December 16, 2023. If the sNDA is approved, XHANCE has the potential to be the first drug therapy approved by the FDA for the treatment of chronic sinusitis.

As a result of the FDA's evolving view on the terminology to be applied to what was historically labeled "chronic sinusitis" and "nasal polyps", it is uncertain whether the ReOpen1 and ReOpen2 clinical trials that we conducted for XHANCE will, if approved, result in an additional indication using the language "for the treatment of chronic sinusitis", "for the treatment of chronic rhinosinusitis", "for the treatment of chronic rhinosinusitis without nasal polyps", or other similar language. It is our view that these variations in terminology are synonymous from a promotional perspective and that all are distinct from XHANCE's current indication. In this Quarterly Report on Form 10-Q, we 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 Prescriptions and Market Share. Based on third-party inventory and prescription data as well as data from PPN partners, the total estimated number of XHANCE prescriptions in the third quarter of 2023 was 84,100, which represents a 6% decrease for prescriptions when compared to estimated third quarter 2022 prescriptions of 89,900. In first quarter and second quarter 2023 we updated the methodology used to estimate XHANCE prescriptions. For reference, under the methodology used in 2022 we estimated prescriptions of 86,600 in the third quarter of 2022. The INS prescription market decreased 1% from third quarter 2022 to third quarter 2023 based on third-party prescription data.

A seasonal effect has historically been observed in the INS prescription market 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. Based on third-party prescription data, INS market prescriptions were flat from the fourth quarter of 2021 to the first quarter of 2022, increased 7% from the first quarter of 2022 to the second quarter of 2022, decreased 7% from the second quarter of 2022 to the third quarter of 2022, increased 4% from the third quarter of 2022 to the fourth quarter of 2022, increased 1% from the fourth quarter of 2022 to the first quarter of 2023, increased 3% from the first quarter of 2023 to the second quarter of 2023, and decreased 9% from the second quarter of 2023 to the third quarter of 2023.

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.

Previously we tracked the market share of XHANCE within our current target audience because market share normalizes XHANCE prescriptions for market effects including the INS market seasonality, seasonal variation in patient visits with their doctor, annual deductible resets and annual changes in individual patient's healthcare insurance coverage referenced above. We calculated market share as the proportion of XHANCE prescriptions to the number of prescriptions written for other INS within our current target physician audience. However, most of the INS prescriptions written within our target physician audience are for chronic sinusitis, allergic rhinitis and other conditions outside of our nasal polyp indication. Due to the limitations of this denominator, which also does not include prescriptions for the several biologic products that are indicated to treat chronic rhinosinusitis with nasal polyps, and the fact that we now have five years of historical XHANCE prescription data, we have stopped tracking market share but will continue to track year-over-year prescription growth.

- XHANCE New Prescriptions 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. Based on third-party inventory and prescription data as well as data from PPN partners, the total estimated number of XHANCE new prescriptions in the third quarter of 2023 was 27,400, which represents a 4% decrease for new prescriptions when compared to estimated third quarter 2022 new prescriptions of 28,600. In first quarter 2023 we updated the methodology used to estimate XHANCE new prescriptions. For reference, under the prior methodology we estimated new prescriptions of 28,000 in the third quarter of 2022. Based on third-party prescription data, the INS market for new prescriptions increased 1% from the third quarter of 2022 to the third quarter of 2023 and decreased 11% from the second quarter of 2023 to the third quarter of 2023.

  We track refill prescriptions and provide patient co-pay assistance to support refill programs that are administered by our PPN partners. Based on third-party inventory and prescription data as well as data from PPN partners, the total estimated number of XHANCE refill prescriptions in the third quarter of 2023 was 56,600, which represents a 8% decrease for refill prescriptions when compared to estimated third quarter 2022 refill prescriptions of 61,300. In first quarter and second quarter 2023 we updated the methodology used to estimate XHANCE refill prescriptions. For reference, under the prior methodology we estimated refill prescriptions of 58,600 in the third quarter of 2022.

- Prescribing Breadth and Depth. We track the number of physicians who prescribe XHANCE in a time period to evaluate the breadth of prescribing. Based on third-party inventory and prescription data as well as data from PPN partners, the total estimated number of physicians who had at least one patient fill a prescription for XHANCE in the third quarter of 2023 was 8,427, which represents a 5% increase when compared to the estimated 8,056 physicians who had at least one patient fill a prescription for XHANCE in the third quarter of 2022. In addition, the total estimated number of physicians who had at least one patient fill a prescription for XHANCE was 8,313 in the fourth quarter of 2022, 8,545 in the first quarter of 2023, and 8,624 in the second quarter of 2023. In first quarter 2023 we updated the methodology used to estimate XHANCE prescriptions and as a consequence updated our estimate for the number of physicians who had at least one patient fill a prescription for XHANCE. For reference, under the prior methodology we estimated the number of physicians who had at least one patient fill a prescription for XHANCE was 7,892 in the third quarter of 2022.

We also track the number of prescriptions filled by a prescribing physician's patients in a time period to evaluate depth of prescribing. Based on third-party prescription data as well as data from PPN partners, the total estimated number of physicians who had more than 15 XHANCE prescriptions filled by their patients in the third quarter of 2023 was 1,346, which represents a 9% decrease when compared to the estimated 1,485 physicians who had more than 15 XHANCE prescriptions filled by their patients in the third quarter of 2022. In addition, the total estimated number of physicians who had more than 15 XHANCE prescriptions filled by their patients was 1,509 in the fourth quarter of 2022, 1,391 in the first quarter of 2023, and 1,428 in the second quarter of 2023. In first quarter 2023 we updated the methodology used to estimate XHANCE prescriptions and as a consequence updated our estimate for the number of physicians who had more than 15 XHANCE prescriptions filled by their patients. For reference, under the prior methodology we estimated the number of physicians who had more than 15 XHANCE prescriptions filled by their patients was 1,491 in the third quarter of 2022.

- 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 $236 in the third quarter of 2023 which represents a 6% increase when compared to the $223 average XHANCE net product revenues per prescription in the third quarter of 2022. The increase in average net product revenues per prescription is primarily the result of increased shipments and an increase in the price paid for individual units of XHANCE. In first quarter and second quarter 2023 we updated the methodology used to estimate XHANCE prescriptions. For reference under the prior methodology we estimated net product revenues per prescription of $232 for the third quarter of 2022.

  During the second half of 2023 we modified 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 profitability to us due to their high reliance on our co-pay assistance program. In the future we may make additional changes to our co-pay assistance program designed to increase average net revenue per prescription.

- Market Access. We believe that as of September 30, 2023 approximately 80% of commercially insured lives were in plans that covered XHANCE. 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. Further, we believe that approximately half of the commercially covered lives as of September 30, 2023 are in a plan that requires a prior authorization and most of those prior authorizations request information regarding prior use of INS and patient diagnosis for an FDA-approved indication. In some cases, patients do not meet the payors' utilization management criteria, or providers 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 will not gain access to XHANCE treatment. We believe increasing rates of enforcement of the utilization management criteria had a negative effect on XHANCE prescription volume growth in 2022 and could have a negative effect on prescription volume in the future. These requirements include physician attestation to a diagnosis of nasal polyps which can be a hurdle for some physicians in our target audience because it is not a diagnosis they make commonly.

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 $19.8 million and $20.1 million in net product revenues for the three months ended September 30, 2023 and 2022, respectively, and $51.1 million and $55.4 million for the nine months ended September 30, 2023 and 2022. 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 PPN partners, who collectively dispensed more than 80% of our total prescriptions (TRxs) in the period, our average XHANCE net product revenues per prescription were $236 in the third quarter of 2023 which represents a 6% increase compared to the $223 average XHANCE net product revenues per prescription in the third quarter of 2022. The increase in average net product revenues per prescription is primarily the result of increased shipments and an increase in the price paid for individual units of XHANCE.

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 and PPN partners, patient utilization rates of our co-pay assistance and other affordability programs and the proportion of patients acquiring XHANCE through an insurance benefit. There is also the potential for variability that results from changes in estimation methodology by us and the third parties that we rely upon to provide certain prescription and inventory data which may lead to revisions of historical estimates of prescription volumes and our calculated average net product revenues per prescription.

We expect full year 2023 net product revenues will be between $66.0 to $70.0 million. Previously, we expected full year 2023 net product revenues will be between $64.0 to $70.0 million. In December 2022, we reduced our number of territory managers from approximately 90 to approximately 77 as part of actions intended to reduce total operating expenses for full year 2023 by approximately $30.0 million compared to 2022, of which approximately half is related to sales and marketing. In addition, our expectation of full year 2023 net product revenues between $66.0 and $70.0 million does not assume net product revenues attributable to a potential launch of XHANCE as a treatment for patients with chronic sinusitis. The year-over-year decrease to net product revenues is attributable to an expected increase in gross-to-net deductions and an expected decrease in units shipped. The expected increase in gross-to-net deductions includes increased rebates, co-pay assistance and changes in business mix. For the full year 2023, we believe average net product revenues per prescription will be approximately $200. The expected year-over-year decrease in net product revenues is also a byproduct of our previously communicated intent to prioritize our capital resources for a potential launch of XHANCE for the treatment of chronic sinusitis.

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, ongoing research efforts of new products and device improvements. We expense research and development costs as incurred. These expenses include:

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

- expenses for regulatory activities, including filing fees paid to regulatory agencies and costs incurred to compile and respond to filings with the FDA prior to regulatory approval of products for commercial sale; 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.

Assuming we do not need to conduct additional studies to support an FDA approval of XHANCE for the treatment of chronic sinusitis and we do not undertake new development programs, we expect significantly lower research and development expenses in 2023.

Selling, general and administrative expense

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

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

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 A&R Note Purchase Agreement.

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, 2023 and 2022

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

	Three Months Ended September 30,	
	2023	2022
Revenues:		
Net product revenues	$ 19,823	$ 20,078
Total revenues	19,823	20,078
Costs and expenses:		
Cost of product sales	2,225	2,125
Research and development	1,281	3,267
Selling, general and administrative	18,011	25,486
Total operating expenses	21,517	30,878
Loss from operations	(1,694)	(10,800)
Other (income) expense:		
Interest expense	4,395	4,159
Other (income) expense	3,205	(5)
Total other (income) expense	7,600	4,154
Net loss	$ (9,294)	$ (14,954)

Net product revenues

Net product revenues related to sales of XHANCE were $19.8 million and $20.1 million for the three months ended September 30, 2023 and 2022, respectively. Revenue decrease is attributable primarily to a a decrease in units sold to customers during the three months ended September 30, 2023. The year-over-year decrease in net product revenues is consistent with our previously communicated intent to prioritize our capital resources for a potential launch of XHANCE for the treatment of chronic sinusitis.

Cost of product sales

Cost of product sales related to XHANCE were $2.2 million and $2.1 million for the three months ended September 30, 2023 and 2022, respectively. The increase of $0.1 million can be attributed to an increase in the cost to produce XHANCE in 2023.

Research and development expense

Research and development expense was $1.3 million and $3.3 million for the three months ended September 30, 2023 and 2022, respectively. The $2.0 million decrease is attributable to a decrease in costs related to the conduct of our clinical trials of XHANCE for the treatment of chronic sinusitis, both trials had top-line data readouts in 2022.

Selling, general and administrative expense

Selling, general and administrative expense was $18.0 million and $25.5 million for the three months ended September 30, 2023 and 2022, respectively. The $7.5 million decrease was due primarily to a $4.7 million decrease in sales, marketing and administrative costs as well as a $2.8 million decrease in payroll and related costs.

Interest (income) expense, net

Interest (income) expense, net, was $4.4 million and $4.2 million for the three months ended September 30, 2023 and 2022, respectively, which was primarily comprised of interest expense on the Pharmakon Senior Secured Notes during both periods.

Other (income) expense, net

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, 2023.

Other (income) expense was $3.2 million for the three months ended September 30, 2023 and represents the unrealized gain on the fair value of warrants.

Comparison of nine months ended September 30, 2023 and 2022

	Nine Months Ended September 30,	
	2023	**2022**
Revenues:		
Net product revenues	$ 51,122	$ 55,420
Total revenues	51,122	55,420
Costs and expenses:		
Cost of product sales	6,502	6,282
Research and development	4,017	12,339
Selling, general and administrative	60,839	84,339
Total operating expenses	71,358	102,960
Loss from operations	(20,236)	(47,540)
Other (income) expense:		
Interest expense	12,462	12,147
Other income	(7,182)	(3)
Total other (income) expense	5,280	12,144
Net loss	$ (25,516)	$ (59,684)

Net product revenues

Net product revenues related to sales of XHANCE were $51.1 million and $55.4 million for the nine months ended September 30, 2023 and 2022, respectively. Revenue decrease is attributable primarily to a decrease in units sold to customers as well as a decrease in our average net revenue per prescription during the nine months ended September 30, 2023. The year-over-year decrease in net product revenues is consistent with our previously communicated intent to prioritize our capital resources for a potential launch of XHANCE for the treatment of chronic sinusitis.

Cost of product sales

Cost of product sales related to XHANCE were $6.5 million and $6.3 million for the nine months ended September 30, 2023 and 2022, respectively. The increase of $0.2 million can be attributed to an increase in the cost to produce XHANCE in 2023.

Research and development expense

Research and development expense was $4.0 million and $12.3 million for the nine months ended September 30, 2023 and 2022, respectively. The $8.3 million decrease is attributable to a decrease in costs related to the conduct of our clinical trials of XHANCE for the treatment of chronic sinusitis, both trials had top-line data readouts in 2022.

Selling, general and administrative expense

Selling, general and administrative expense was $60.8 million and $84.3 million for the nine months ended September 30, 2023 and 2022, respectively. The $23.5 million decrease was due primarily to a $12.2 million decrease in sales, marketing and other administrative costs and an $11.3 million decrease in payroll and related costs.

Interest (income) expense, net

Interest (income) expense, net, was $12.5 million and $12.1 million for the nine months ended September 30, 2023 and 2022, respectively, which was primarily comprised of interest expense on the Pharmakon Senior Secured Notes during both periods.

Other (income) expense, net

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, 2023.

Other income was $7.2 million for the nine months ended September 30, 2023 and represents the unrealized gain 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 $25.5 million and $59.7 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $710.4 million. We have funded our operations primarily through the sale and issuance of stock and debt, as well as through sales of XHANCE and licensing revenues. As of September 30, 2023, we had $66.8 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,	
	2023	2022
Net cash used in operating activities	$ (27,440)	$ (49,971)
Net cash used in investing activities	(255)	(60)
Net cash provided by financing activities	296	649
Effects of exchange rates on cash and cash equivalents	—	(12)
Net decrease in cash, cash equivalents and restricted cash	$ (27,399)	$ (49,394)

Operating activities

Cash used in operating activities decreased by $22.6 million, from $50.0 million for the nine months ended September 30, 2022 to $27.4 million for the nine months ended September 30, 2023. The decrease in cash used in operating activities was attributable to a decrease in net loss and a decrease in accounts receivable due to increased collections, partially offset by a decrease in accrued expenses for the nine months ended September 30, 2023.

Investing activities

Cash used in investing activities increased from the nine months ended September 30, 2022 to the nine months ended September 30, 2023 due to an increase in equipment and software purchases during the nine months ended September 30, 2023.

Financing activities

Cash provided by financing activities decreased from the nine months ended September 30, 2022 to the nine months ended September 30, 2023 due to a decrease in proceeds from the issuance of common stock under our employee stock purchase plan.

Projected 2023 operating expenses

We expect that our total GAAP operating expenses, consisting of selling, general & administrative expenses and research & development expenses, for 2023 will be between $88.0 million and $93.0 million of which approximately $6.0 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 $82.0 million and $87.0 million. The $88.0 million to $93.0 million range is approximately a $30.0 million reduction compared to 2022, of which approximately half is related to reductions in sales and marketing. The decrease in selling, general, & administrative expenses from 2022 to 2023 is anticipated as the result of actions taken to reduce near-term employee-related and third party expenses while preserving necessary capabilities to launch XHANCE, if approved, as a treatment for patients with chronic sinusitis. In addition, the completion in 2022 of our clinical trial program in pursuit of a follow-on indication for XHANCE for the treatment of chronic sinusitis is the primary driver of an expected decrease in research & development expenses.

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, and activities in pursuit of a follow-on indication for the treatment of chronic sinusitis;
- 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, if approved, 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 for its current indication and any future indication;
- the outcome, timing and cost of the FDA regulatory approval process of XHANCE for chronic sinusitis, including the potential for the FDA to require that we perform additional studies and clinical trials;
- 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;
- our clinical development plans for XHANCE, including the outcome, timing and cost of studies mandated under the Pediatric Research Equity Act, and activities in pursuit of a follow-on indication for the treatment of chronic sinusitis;
- 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 $30.0 million of cash and cash equivalents at all times), and the other provisions under the A&R Note Purchase Agreement, and, if needed and available from the holders of the Pharmakon Senior Secured Notes, the costs and conditions associated with obtaining a waiver or modification of such covenants or other provisions.

As of September 30, 2023, we had $66.8 million in cash and cash equivalents. We will likely require additional capital in the near term in order to maintain compliance with the financial covenants and other terms under the A&R Note Purchase Agreement and to meet the debt service obligations under our outstanding Pharmakon Senior Secured Notes, and to continue to fund our operations.

Our continuation as a going concern is dependent on our ability to maintain compliance with our covenants under the A&R Note Purchase Agreement, including minimum trailing twelve-month consolidated XHANCE net sales and royalties we are required to achieve commencing with the trailing twelve months ending March 31, 2024, and our ability to generate sufficient cash flows from operations to meet our 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 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.

We believe it is probable that we will not achieve the trailing twelve-month minimum consolidated XHANCE net sales and royalties thresholds under the A&R Note Purchase Agreement for the initial period ending March 31, 2024, which 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. We believe that it is probable that our existing cash and cash equivalents will not be adequate to fund our operations and maintain at least $30.0 million of cash and cash equivalents as required under the A&R Note Purchase Agreement for at least twelve-months following the filing of this Form 10-Q, which will also constitute a default of the liquidity financial covenant under the A&R Note Purchase Agreement if we are unable to obtain additional capital or obtain a waiver or modification to this liquidity covenant prior to falling below such $30.0 million threshold.

Further, the A&R Note Purchase Agreement includes a requirement that commencing with the report and opinion on the consolidated financial statements commencing with the year ending December 31, 2023 and that all of our subsequent quarterly and annual financial statements, not be subject to any statement as to “going concern” (subject to certain exceptions). We have concluded that it is unlikely that we will be able comply with these provisions in 2024. Failure to comply with these provisions would also constitute an event of default under the A&R Note Purchase Agreement.

In the event of any of the foregoing defaults, the holders of the Pharmakon Senior Secured Notes may elect to accelerate the repayment of all unpaid principal, accrued interest and other amounts due, which may require us to delay or curtail our operations until additional funding is received. These factors raise substantial doubt about our ability to continue as a going concern. The terms of the A&R Note Purchase Agreement and the Pharmakon Senior Secured Notes, including applicable covenants, are described in Note 8. In the event we are able to maintain compliance with the financial and other covenants and terms of the A&R Note Purchase Agreement or obtain a waiver to or modification of such covenants, we believe our existing cash and cash equivalents will be sufficient to fund our operations and debt service obligations for approximately the next 12 months.

We will likely require additional capital in the future secured through equity or debt financings, partnerships, collaborations, or other sources in order to meet our debt service obligations, including repayment, under 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.

Additionally, we may never become profitable, or if we do, may not be able to sustain profitability on a recurring basis.

Critical accounting policies

The Critical Accounting Policies and Significant Judgments and Estimates included in our annual report on Form 10-K for the year ended December 31, 2022, as filed with the SEC on March 7, 2023, have not materially changed.

Recent accounting pronouncements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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

Our Chief Executive Officer and our Principal Financial Officer evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of the end of the period covered by this report. Based on this evaluation, our Chief Executive Officer and Principal Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2023.

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, 2023 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

ITEM 6. EXHIBITS

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

INDEX TO EXHIBITS

Exhibit Number	Exhibit Description
3.1	Fourth Amended and Restated Certificate of Incorporation of OptiNose, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with the SEC on October 18, 2017).
3.2	Amended and Restated Bylaws of OptiNose, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K (File No. 001-38241), as filed with the SEC on October 18, 2017).
3.3	Certificate of Amendment of Fourth Amended and Restated Certificate of Incorporation of OptiNose, Inc. (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 10-Q (File No. 001-38241), as filed with the SEC on August 10, 2023).
31.1 *	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.
31.2 *	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15a-14(a) under the Exchange Act.
32.1 **	Certification Pursuant to 18 U.S.C. Section 1350 of principal executive officer.
32.2 **	Certification Pursuant to 18 U.S.C. Section 1350 of principal financial officer.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

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 9, 2023

OPTINOSE, INC.

By: /s/ ANTHONY J. KRICK

Name: Anthony J. Krick

Title: *Vice President, Finance & Chief Accounting 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 9, 2023

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

CERTIFICATION UNDER SECTION 302 OF THE

SARBANES-OXLEY ACT OF 2002

I, Anthony Krick, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of OptiNose, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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

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

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

Date: November 9, 2023

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

CERTIFICATION UNDER SECTION 906 OF THE

SARBANES-OXLEY ACT OF 2002

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

1. the Quarterly Report on Form 10-Q of the Company for the period ending September 30, 2023 (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 9, 2023

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

CERTIFICATION UNDER SECTION 906 OF THE

SARBANES-OXLEY ACT OF 2002

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

1. the Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2023 (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 9, 2023

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