UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 10, 2023



OPTINOSE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

001-38241 (Commission File No.)

42-1771610 (I.R.S. Employer Identification No.)

1020 Stony Hill Road, Suite 300 Yardley, Pennsylvania 19067

(Address of principal executive offices and zip code)

(267) 364-3500 (Registrant's telephone number, including area code) (Former name or former address, if changed from last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

П Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-14(c)) П

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

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.

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

Title of each class Common stock, par value \$0.001 per share Trading symbol(s) OPTN

Name of each exchange on which registered Nasdag Global Select Market

Item 2.02 Results of Operations and Financial Condition.

On August 10, 2023, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2023. A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

* * *

The information included in Item 2.02 (including Exhibit 99.1) of this Form 8-K, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any Company filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On August 10, 2023, the Company will present an updated Corporate Presentation during its financial results and corporate updates call. A copy of the presentation is attached as Exhibit 99.2 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by OptiNose, Inc., dated August 10, 2023.
99.2	OptiNose, Inc. Corporate Presentation, dated August 10, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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, hereunto duly authorized.

OptiNose, Inc. By: /s/ Anthony Krick Anthony Krick Chief Accounting Officer

Date: August 10, 2023



Exhibit 99 1



Optinose Reports Second Quarter 2023 Financial Results and Operational Updates

Company reports second quarter 2023 XHANCE net revenue of \$19.5 million and increases full year 2023 XHANCE net revenue guidance

Strong improvement in operating efficiency in the first half of 2023 as SG&A and R&D expenses decreased by \$22M or 33% compared to first half 2022

Conference call and webcast to be held today at 8:00 a.m. Eastern Time

YARDLEY, Pa., August 10, 2023 Optinose (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, today reported financial results for the quarter ended June 30, 2023, and provided operational updates.

"We are pleased with the progress we made in the second quarter of 2023 towards our strategic objectives," stated CEO Ramy Mahmoud, MD, MPH. "That means we are outperforming our initial expectations for full year 2023 XHANCE net revenues while operating far more efficiently. It also means our effort to secure the first-ever drug approval for patients with chronic sinusitis is progressing towards the target goal date of December 16, 2023, and that we are effectively readying our organization for a successful launch. These objectives are preparing us, if our new indication is approved, to achieve rapid adoption for treatment of the tens of millions of chronic sinusitis patients in need of an effective medication."

Second Quarter 2023 Highlights

Chronic Rhinosinusitis Supplemental New Drug Application (sNDA)

In May the Company announced that the U.S. Food and Drug Administration (FDA) accepted its sNDA for XHANCE® (fluticasone propionate) in the Exhalation Delivery System[™] seeking a new indication for treatment of adults with chronic rhinosinusitis. The assigned Prescription Drug User Fee Act (PDUFA) target goal date is December 16, 2023.

Additional U.S. Patent Covering XHANCE

The United States Patent and Trademark Office (USPTO) recently issued an additional patent covering XHANCE. U.S. Patent 11,602,603, was listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) for XHANCE in April and has a term that expires in 2028. XHANCE is covered by 15 Orange Book-listed patents.

The full text of the patent is available on the USPTO website www.uspto.gov.

Second Quarter 2023 Financial Results

Total revenues

The Company reported \$19.5 million in net revenue from sales of XHANCE during the three-month period ended June 30, 2023 a decrease of 5% compared to \$20.6 million during the three-month period ended June 30, 2022. For the six-month period ended June 30, 2023 the Company reported \$31.3 million in net revenue from sales of XHANCE a decrease of 11% compared to \$35.3 million during the six-month period ended June 30, 2022. The year-over-year decrease in net revenue is consistent with the Company's previously communicated intent to prioritize its capital resources for a potential launch of XHANCE for the treatment of chronic rhinosinusitis.

Costs and expenses and net (loss) income

For the three-month and six-month periods ended June 30, 2023, research and development expenses were \$1.0 million and \$2.7 million, respectively. Selling, general and administrative expenses were \$20.1 million and \$42.8 million for the three-month and six-month periods ended June 30, 2023, respectively. In total, SG&A plus R&D expenses decreased by \$22.4 million, or 33%, to \$45.6 million for the six-month period ended June 30, 2022, total of \$67.9 million.

Other income of \$6.8 million for the three-month period ended June 30, 2023, includes a \$10.9 million unrealized gain on the fair value of warrants issued in November 2022.

Net income for the three-month period ended June 30, 2023, was \$2.6 million, or \$0.02 per share (basic and diluted). The net loss for the six-month period ended June 30, 2023, was \$16.2 million, or \$0.15 per share (basic and diluted).

Balance Sheet

The Company had cash and cash equivalents of \$71.3 million as of June 30, 2023.

Corporate Guidance

XHANCE Net Revenue and Average Net Revenue per Prescription The Company expects XHANCE net revenues for the full year of 2023 to be between \$64.0 to \$70.0 million. Previously, the Company expected XHANCE net revenues for the full year of 2023 to be between \$62.0 to \$68.0 million. In addition, the Company continues to expect the full year 2023 XHANCE average net revenue per prescription to be approximately \$200.

Operating Expenses The Company continues to expect total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2023 to be in the range of \$88.0 to \$93.0 million, of which the Company expects stock-based compensation to be approximately \$6.0 million.

Company to Host Conference Call

Members of the Company's leadership team will host a conference call and presentation to discuss financial results and corporate updates beginning at 8:00 a.m. Eastern Time today.

Participants may access the conference call live via webcast by visiting the Investors section of Optinose's website at http://ir.optinose.com/presentations. To participate via telephone, please register in advance at this link. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number and a personal PIN that can be used to access the call. In addition, a replay of the webcast will be available on the Company website for 60 days following the event.

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

	Three Months Ended June 30,				Six Months Ended June 30,			
		2023		2022	2023		2022	
Revenues:								
Net product revenues	\$	19,454	\$	20,582	\$ 	\$	35,342	
Total revenues		19,454		20,582	 31,299		36,342	
Costs and expenses:								
Cost of product sales	\$	2,571	\$	2,143	4,277		4,157	
Research and development	\$	951	\$	4,270	2,736		9,072	
Selling, general and administrative		20,104		29,514	 42,828		58,853	
Total costs and expenses		23,626		35,927	 49,841		72,082	
Loss from operations		(4,172)		(15,345)	 (18,542)		(35,740)	
Other (income) expense		(6,798)		4,052	(2,318)		7,990	
Net income (loss)	\$	2,626	\$	(19,397)	\$ (16,224)	\$	(43,730)	
Less: undistributed earnings to participating shareholders	\$	(53)	\$		\$ 	\$	_	
Net (loss) income - basic	\$	2,573	\$	(19,397)	\$ (16,224)	\$	(43,730)	
Net income (loss) per share of common stock - basic	\$	0.02	\$	(0.23)	\$ (0.15)	\$	(0.54)	
Weighted average common shares outstanding - basic		111,979,778		82,740,096	 111,877,669		82,594,786	
Net income (loss)	\$	2,626	\$	(19,397)	\$ (16,224)	\$	(43,730)	
Less: undistributed earnings to participating shareholders	\$	(53)	\$		\$ _	\$		
Net (loss) income - diluted	\$	2,573	\$	(19,397)	\$ (16,224)	\$	(43,730)	
Net income (loss) per share of common stock - diluted	\$	0.02	\$	(0.23)	\$ (0.15)	\$	(0.54)	
Weighted average common shares outstanding - diluted		112,042,097		82,740,096	 111,877,669		82,594,786	

OptiNose, Inc. Condensed Consolidated Balance Sheet Data (in thousands)

	 June 30 2023 maudited)	December 31, 2022				
Cash and cash equivalents	\$ 71,311	\$	94,244			
Other assets	 34,757		49,978			
Total assets	\$ 106,068	\$	144,222			
Total current liabilities ⁽¹⁾ Other liabilities Total stockholders' equity Total liabilities and stockholders' equity	\$ 164,299 11,429 (69,660) 106,068	\$	178,730 22,116 (56,624) 144,222			

(1) – All outstanding principal and fees payable upon maturity have been classified as a current liability in accordance with Generally Accepted Accounting Principles ("GAAP") because, as of the date hereof, the Company believes that it is probable that it will not maintain compliance with certain financial and liquidity covenants contained in its Amended and Restated Note Purchase Agreement for at least the next 12-months. As a result, the Company's unaudited financial statements for the three and six months ended June 30, 2022 (7Q2023 Financial Statements) will state that there is substantial doubt about the Company's ability to continue as a going concern (i.e., a 'going concern' paragraph). Please refer to the Company's Quaterly Report on Form 10-Q for the quarter ended June 30, 2023 (including the 202023 Financial Statements) which will be filed after the issuance of this press release for additional information.

About Optinose

Optinose is a specialty pharmaceutical company focused on serving the needs of patients cared for by ear, nose and throat (ENT) and allergy specialists. To learn more, please visit www.optinose.com or follow us on Twitter and LinkedIr

About XHANCE

About XHANCE XHANCE is a drug-device combination product that uses the Exhalation Delivery System (also referred to as the EDS) designed to deliver a topical anti-inflammatory to the high and deep regions of the nasal cavity where sinuses ventilate and drain. XHANCE is approved by the U.S. Food and Drug Administration for the treatment of chronic rhinosinusitis with nasal polyps in patients 18 years of age or older and has been studied for treatment of chronic sinusitis (notably including patients without polyps in the nasal cavity) in two phase 3 trials. ReOpen1 and ReOpen2. Top-line results from these trials are the first ever that we are aware of that show improvement in both symptoms and inflammation inside the sinuses, and reduction in acute exacerbations of disease, with a nasal therapy for chronic sinusitis patients, including patients with or without nasal polyps. If approved, XHANCE may be the first drug ever FDA-approved for treatment of chronic rhinosinusitis either with or without nasal polyps.

Important Safety Information

CONTRAINDICATIONS: Hypersensitivity to any ingredient in XHANCE.

WARNINGS AND PRECAUTIONS:

- Local Nasal Adverse Reactions: epistaxis, erosion, ulceration, septal perforation, Candida albicans infection, and impaired wound healing. Monitor patients periodically for signs of possible changes on the nasal mucosa. Avoid use in patients with recent nasal ulcerations, nasal surgery, or nasal trauma until healing has occurred.
- Close monitoring for glaucoma and cataracts is warranted. Hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, contact dermatitis, rash, hypotension, and bronchospasm) have been reported after administration of fluticasone propionate. Discontinue XHANCE if such reactions occur.
- Immunosuppression and Risk of Infection: potential increased susceptibility to or worsening of infections

(e.g., existing tuberculosis; fungal, bacterial, viral, or parasitic infection; ocular herpes simplex). Use with caution in patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients.

Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue XHANCE slowly
Patients with major risk factors for decreased bone mineral content should be monitored and treated with established standards of care.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥ 3%) are epistaxis, nasal septal ulceration, nasopharyngitis, nasal mucosal erythema, nasal mucosal ulcerations, nasal congestion, acute sinusitis, nasal septal erythema, headache, and pharyngitis.

DRUG INTERACTIONS: Strong cytochrome P450 3A4 inhibitors (e.g., ritonavir, ketoconazole): Use not recommended. May increase risk of systemic corticosteroid effects.

USE IN SPECIFIC POPULATIONS: Hepatic impairment. Monitor patients for signs of increased drug exposure

Please see full Prescribing Information, including Instructions for Use

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. All statements that are not historical facts are hereby identified as forwardlooking statements for this purpose and include, among others, statements relating to the potential benefits of XHANCE for the treatment of chronic sinusitis without nasal polyps (commonly referred to as, chronic sinusitis); the potential for XHANCE to be the first FDA-approved drug treatment for chronic sinusitis and the potential benefits thereof; objectives and preparations to launch XHANCE, if approved, for the treatment of chronic sinusitis; patent protections; projected XHANCE net revenue and average net revenue per prescription for full year 2023; projected Company GAAP operating expenses (selling, general and administrative expenses and research & development expenses) and stock-based compensation for 2023; potential non-compliance with certain covenants under the Amended and Restated Pharmakon Note Purchase Agreement and the consequences thereof; and other statements regarding the Company's future operations, financial performance, financial position, prospects, objectives, strategies and other future events. Forward-looking statements are based upon management's current expectations and assumptions and are subject to a number of risks, uncertainties and other factors that could cause actual results and events to differ materially and adversely from those indicated by such forward-looking statements including, among others: physician and patient acceptance of XHANCE for its current and any potential future indication; the Company's ability to efficiently generate XHANCE prescriptions and net revenues; unanticipated costs and expenses; the Company's ability to achieve its financial guidance; potential for varying interpretation of the results from the ReOpen program; uncertainties related to the clinical development program and regulatory approval of XHANCE for the treatment of chroni

Optinose Investor Contact Jonathan Neely

jonathan.neely@optinose.com 267.521.0531

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Exhibit 99.2





Corporate Presentation August 10, 2023

Forward-Looking Statements

This presentation and our accompanying remarks contain "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. All statements that are not historical facts are hereby identified as forward-looking statements for this purpose and include, among others, statements relating to: the generation of XHANCE prescriptions and net revenues and factors impacting the generation of future prescriptions and net revenues; prescription, net revenue, prescription and ther twest seasonality on XHANCE prescriptions; potential effects of INS market seasonality on XHANCE prescriptions; potential effects on price and volume related to patient insurance; impact of payor utilization management criteria; commercial strategies; projected GAAP operating expenses (selling, general & administrative expenses and research & development expenses) and stock-based compensation for 2023; projected XHANCE hor the sNDA in December 2023; the potential benefits of XHANCE for the treatment of chronic sinusitis; the potential for an FDA action on the sNDA in December 2023; the potential market expansion opportunities and other benefits of obtaining such indication; our plan to seek a partner to promote XHANCE in primary care and the prospects for, and potential benefits of, such potential partnership; potential non-compliance with certain covenants under the A&R Pharmakon Note Purchase Agreement and the potential covenants under the A&R Pharmakon Note Purchase Agreement and the potential covenants under the A&R Pharmakon Note Purchase Agreement and the potential partnership; and other statements regarding to our future operations, financial performance, prospects, intentions, strategies, objectives and other future events.

Forward-looking statements are based upon management's current expectations and assumptions and are subject to a number of risks, uncertainties and other factors that could cause actual results and events to differ materially and adversely from those indicated by such forward-looking statements including, among others: impact of, and the uncertainties caused by, physician and patient acceptance of XHANCE for its current and any potential future indication; our ability to maintain adequate third party reimbursement for XHANCE for its current and any potential future indication; our ability to maintain adequate third party reimbursement for XHANCE for its current and any potential future indication; our ability to adverse our financial guidance; potential for varying interpretation of the results from the ReOpen Program; uncertainties related to the clinical development program and regulatory approval of XHANCE for the treatment of chronic rhinosinusitis; our ability to combly with the covenants and other terms of the A&R Pharmakon Note Purchase Agreement; our ability to continue as a going concern; risks and uncertainties relating to intellectual property; and the risks, uncertainties and other factors discussed in the "Risk Factors" section and elsewhere in our most recent Form 10-K and Form 10-Q filings with the Securities and Exchange Commission – which are available at http://www.sec.gov. As a result, you are cautioned not to place undue reliance on any forward-looking statements, may forward-looking statements, dury abort to other as a result of new information, future developments or otherwise.

2

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Key Takeaways

Chronic sinusitis is a 10-fold market opportunity for XHANCE

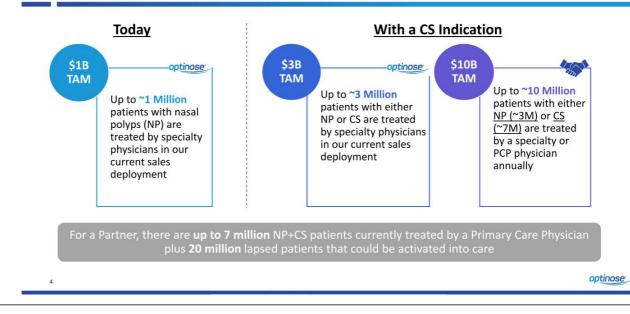
sNDA target action date in December 2023

Executing our strategy to prioritize the potential launch of XHANCE as the first-ever FDA approved drug treatment for CS



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Successful Development of XHANCE as the <u>First and Only</u> FDA-approved Drug Treatment for Chronic Sinusitis Would Create Multiple New Growth Opportunities







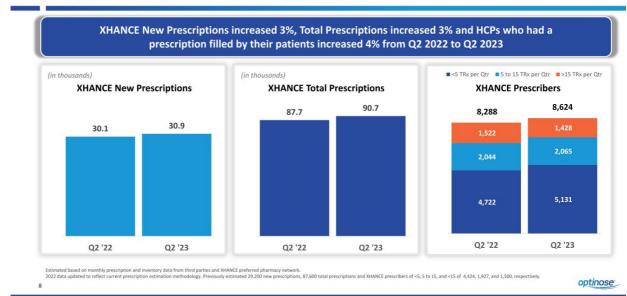
CS Supplemental NDA - Anticipated Next Steps



- FDA accepted for review our supplemental new drug application (sNDA) in pursuit of a new indication
- PDUFA target action date is December 16, 2023
 - Standard review period was applied



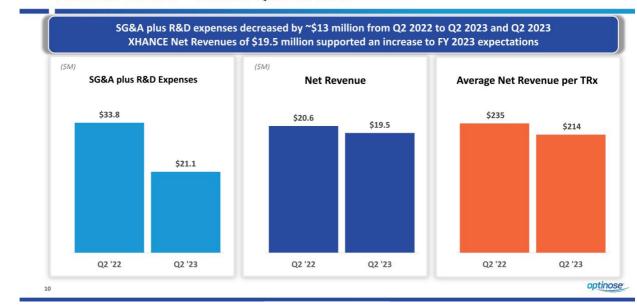




XHANCE Prescriptions – Second Quarter 2023







Financial Review – Second Quarter 2023





Full Year 2023 Financial Guidance

XHANCE Net Revenue

- FY 2023 expected to be between \$64 to \$70 million
- Previously expected to be between \$62 to \$68 million
- FY 2023 expectation does not include net revenues from a CS launch
- XHANCE Average Net Revenue per Prescription
 - FY 2023 expected to be approximately \$200
- GAAP Operating Expenses (SG&A and R&D Expenses)
 - Expected to be between \$88 to \$93 million; approximately \$6 million of which represents stock-based compensation

12





Key Takeaways

14

Chronic sinusitis is a 10-fold market opportunity for XHANCE

sNDA target action date in December 2023

Executing our strategy to prioritize the potential launch of XHANCE as the first-ever FDA approved drug treatment for CS



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Investor Relations – NASDAQ: OPTN

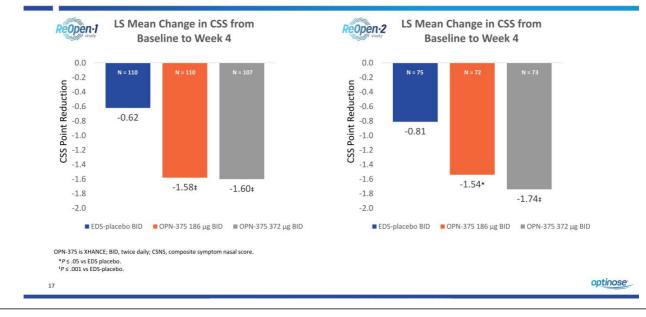




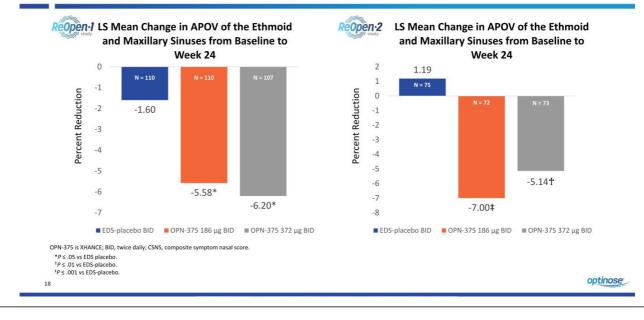




Combined Symptom Score (Co-Primary Endpoint) Improvement in combined symptoms with XHANCE; Consistent with NAVIGATE I and II



Average of Percentages of Opacified Volume (Ethmoid and Maxillary) Objective Evidence of Effect in Sinus Cavities by CT Scan; Co-Primary Endpoint







Corporate Presentation August 10, 2023