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): March 7, 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 March 7, 2023, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2022. 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 March 7, 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 March 7, 2023
99.2	OptiNose, Inc. Corporate Presentation, dated March 7, 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: March 7, 2023



Optinose Reports Fourth Quarter and Full Year 2022 Financial Results and Recent Operational Highlights

Company reports fourth quarter and full year 2022 XHANCE net revenue of \$20.9 million and \$76.3 million

Company submitted sNDA for XHANCE label expansion in February 2023

Physicians diagnose chronic sinusitis 10 times more frequently than XHANCE's current nasal polyps indication and there is no FDA-approved medication for these patients

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

YARDLEY, Pa., March 7, 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 and year ended December 31, 2022, and provided recent operational highlights.

"Our strategic focus for 2023 is on working to secure the first-ever drug approval for patients with chronic sinusitis," stated CEO Ramy Mahmoud, MD, MPH. "This year, we are also preparing our organization for that future opportunity by taking actions to increase the efficiency of our current business and to prepare for a successful launch aimed at rapidly making the product available to millions of patients in need."

Fourth Quarter 2022 and Recent Highlights

Chronic Sinusitis Supplemental New Drug Application (sNDA) On February 16th, the Company submitted a supplemental New Drug Application for XHANCE[®] (fluticasone propionate) Exhalation Delivery System[™] seeking a new indication for treatment of adults with chronic rhinosinusitis to the U.S. Food and Drug Administration (FDA). The company anticipates a submission acceptance decision by FDA by the start of May 2023. Assuming acceptance and a standard review period the Company expects the FDA's PDUFA action date to be in December 2023.

Scientific Meeting Presentations

Data from the landmark ReOpen program evaluating the efficacy and safety of XHANCE in adult patients with chronic sinusitis was presented at IDWeek 2022 on October 21, 2022 and at the American College of Asthma, Allergy and Immunology (ACAAI) 2022 Annual Scientific Meeting on November 12, 2022.

Fourth Quarter and Full Year 2022 Financial Results

Revenue

The Company reported \$20.9 million in net revenue from sales of XHANCE during the three-month period ended December 31, 2022, a decrease of 7% compared to \$22.5 million during the three-month period ended December 31, 2021. This decrease was primarily driven by a decrease in prescription volumes. For the twelve-month period ended December 31, 2022, the Company reported \$76.3 million in net revenue from sales of XHANCE, an increase of 4% compared to \$73.7 million during the twelve-month period ended December 31, 2021.

Expenses and net loss

For the three-month and twelve-month periods ended December 31, 2022, research and development expenses were \$2.9 million and \$15.3 million, respectively. Selling, general and administrative expenses were \$23.3 million and \$107.6 million during the three-month and twelve-month periods ended December 31, 2022, respectively. The net loss for the three-month period ended December 31, 2022 was \$15.1 million, or \$0.17 per share (basic and diluted). The net loss for the twelve-month period ended December 31, 2022 was \$74.8 million, or \$0.87 per share (basic and diluted).

The Company had cash and cash equivalents of \$94.2 million as of December 31, 2022.

Corporate Guidance

Operating Expenses

The Company has prioritized the potential launch of XHANCE as a treatment for chronic sinusitis and will reduce total GAAP operating expenses for full year 2023 compared to full year 2022 by approximately \$30.0 million or 25%. Approximately half of the \$30.0 million reduction is attributable to sales and marketing and the remainder is attributable to reduced research and development, and general and administrative expenses. As part of actions intended to reduce total operating expenses for full year 2023 the Company reduced its number of territory managers by approximately 15% at the end of 2022. As a result of these actions, the Company expects total GAAP operating expenses for 2023 to be in the range of \$90.0 to \$95.0 million, of which the Company expects stock-based compensation to be approximately \$8.0 million.

XHANCE Net Revenue and Average Net Revenue per Prescription The Company expects XHANCE net revenues for the full year of 2023 to be between \$62.0 to \$68.0 million. XHANCE net revenues attributable to a launch as a treatment for patients with chronic sinusitis are not assumed in the full year 2023 guidance range. In addition, the Company's expectation for full year 2023 XHANCE net revenues includes its expectation that first quarter 2023 XHANCE net revenues will be approximately \$10.0 million. The Company expects XHANCE average net revenue per prescription to be approximately \$200 for full year 2023.

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 December 31,				Year Ended December 31,		
		2022	2021		2022	2021	
Revenues:							
Net product revenues	\$	20,856	\$ 2	,509	\$ 76,276	\$ 73,652	
Licensing revenues		_		_	-	1,000	
Total revenues		20,856	2	,509	76,276	74,652	
Costs and expenses:							
Cost of product sales		2,981		,575	9,263	9,151	
Research and development		2,921		,260	15,260	25,318	
Selling, general and administrative		23,310	2	,340	107,649	106,633	
Total costs and expenses		29,212	3	,175	132,172	141,102	
Loss from operations		(8,356)	(1	,666)	(55,896)	(66,450)	
Other expense		6,793		,958	18,937	15,846	
Net loss	\$	(15,149)	\$ (1	,624)	\$ (74,833)	\$ (82,296)	
Net loss per share of common stock, basic and diluted	\$	(0.17)	\$	0.23)	\$ (0.87)	\$ (1.45)	
Weighted average common shares outstanding, basic and diluted		94,960.91	67,83	,835	85,900,139	56,851,921	

OptiNose, Inc. Condensed Consolidated Balance Sheet Data

(in thousands)	
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	December 31, 2022	December 31, 2021
Cash and cash equivalents	\$ 94,244	\$ 110,502
Other assets	49,978	55,569
Total assets	\$ 144,222	\$ 166,071
Total current liabilities ⁽¹⁾ Long-term debt, net Other liabilities Total stockholders' equity Total liabilities and stockholders' equity	178,729 	\$ 59,235 126,418 2,190 (21,772) \$ 166,071

(1) - The principal balance of our loan payable has been classified as a current liability in accordance with Generally Accepted Accounting Principals ("GAAP") because the Company believes that it is probable that it will not be able to maintain compliance with certain financial and liquidity covenants contained in the Note Purchase Agreement for at least the next 12-months. As a result, the Company's audited financial statements for the year ended December 31, 2022 ("D222 Audited Financial Statements") will state that there is substantial doubt about the Company's ability to continue as a going concern" paragraph). Please refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2022 (including the 2022 Audited Financial Statements") which will be filed after the fissuance 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 LinkedIn.

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; the Company's expectation for a submission acceptance decision by the FDA by the start of May 2023 and expectation that the FDA's PDUFA action date to be in December 2023; the potential for XHANCE to be the first FDA-approved drug treatment for chronic sinusitis and the potential benefits thereof; projected average net revenue per prescription for full year 2023; projected XHANCE net revenue for first quarter and full year 2023; projected average net revenue per prescription for full year 2023; projected XHANCE be the first FDA-approved drug treatment for operating 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 Chronic sinusitis and market opportunities for XHANCE may be smaller than expected; the Company's ability to efficiently generate XHANCE (market access) including any future indication; the prevalence of chronic sinusitis and market opportunities for XHANCE may be smaller than expected; the Company's ability to efficiently generate XHANCE (market access) including any future indicati

Optinose Investor Contact Jonathan Neely

jonathan.neely@optinose.com 267.521.0531

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EXHIBIT 99.2





Corporate Presentation March 7, 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, refill, market share and other business trends; potential effects of INS market seasonality on XHANCE prescriptions; potential early year effects on price and volume related to patient insurance; impact of payor utilization management criteria; commercial strategies; projected GAAP operating expenses and stock-based compensation for 2023; projected XHANCE average net revenue prescription for full year 2023; the potential for an SNDA submission acceptance decision from the FDA by the start of May 2023 and the potential for an SNDA submission acceptance decision from the FDA by the start of May 2023 and the potential for an FDA approval decision on the sNDA in December 2023; the potential for XHANCE to be the first FDA-approved drug treatment for chronic sinusitis and the potential market expansion opportunities and other benefits of obtaining such indication; our plan to seek a partnership to promote XHANCE in primary care and the potential consequences thereof; and other statements regarding to our future operation, financial performance, prospects, intentions, strategies, objective and the potential consequences thereof; and other statements are the Agreement and the potential consequences thereof; and other statements are of chronic sinusitis to our future operation, 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 maintain adequate third party reimbursement for XHANCE may be smaller than expected; unexpected costs and expenses; our ability to achieve 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 sinusitis; our ability to comply 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 eraliting 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, and the reliance on otherwise.

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Key Takeaways

Chronic sinusitis is a 10-fold market opportunity for XHANCE

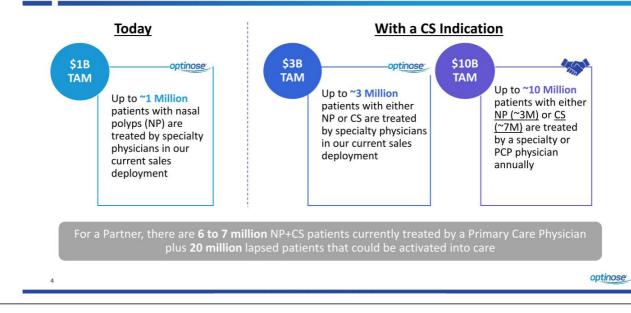
Submitted sNDA to FDA in February which creates potential for approval by December 2023

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



optinose

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







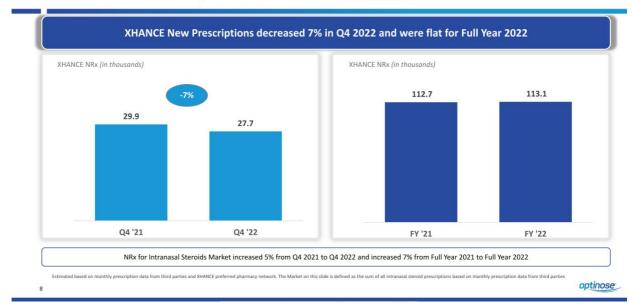
CS Supplemental NDA - Anticipated Next Steps



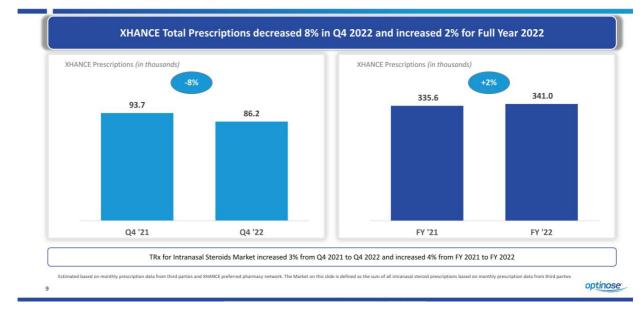
- As planned, we submitted our supplemental new drug application (sNDA) in pursuit of a new indication in February 2023
 - Submission acceptance decision by FDA anticipated by the start of May 2023
 - Assuming acceptance and a standard review period FDA's PDUFA action date should be in December 2023



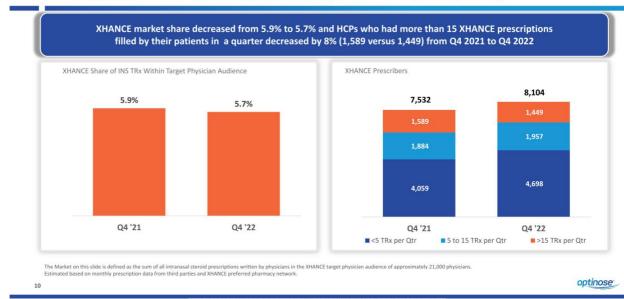




XHANCE New Prescriptions



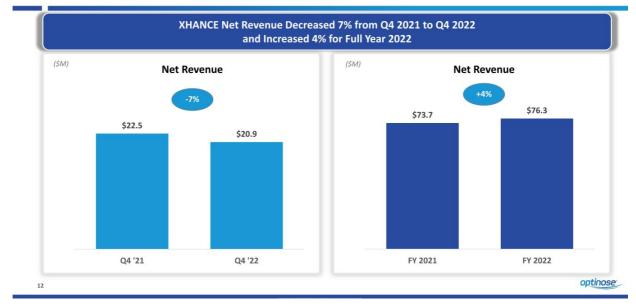
XHANCE Total Prescriptions



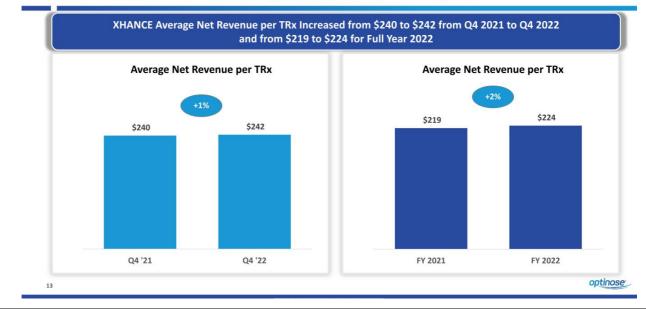
XHANCE Market Share & Prescribers by Prescribing Frequency







Financial Review – XHANCE Net Revenue



Financial Review – XHANCE Average Net Revenue per Prescription





Full Year and Q1 2023 Financial Guidance

- Operating Expense (GAAP)
 - Actions taken to reduce FY 2023 operating expenses by ~\$30 million compared to FY 2022 actual of \$123 million
 - Expected to be between \$90 to \$95 million; approximately \$8 million of which represents stock-based compensation
- XHANCE Net Revenue
 - FY 2023 expected to be between \$62 to \$68 million
 - FY 2023 expectation does not include net revenues from a CS launch
 - Q1 2023 expected to be approximately \$10 million
- XHANCE Average Net Revenue per Prescription
 - FY 2023 expected to be approximately \$200

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Key Takeaways

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Chronic sinusitis is a 10-fold market opportunity for XHANCE

Submitted sNDA to FDA in February which creates potential for approval by December 2023

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



Investor Relations – NASDAQ: OPTN

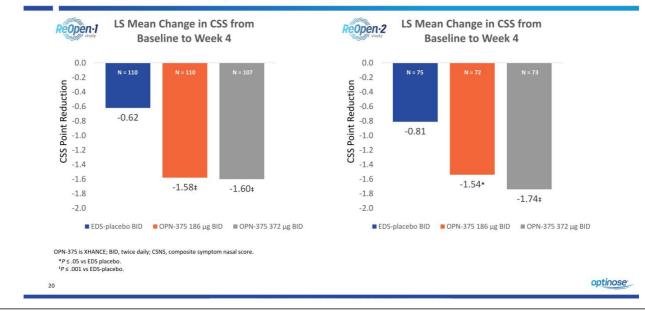
Analyst Coverage ¹	As of December 31, 2022: – \$94.2 million in cash				
BMO: Gary Nachman	 Debt: \$130 million 111.5 million common shares o/s 				
Cantor Fitzgerald: Brandon Folkes	 43.6 million options, warrants & RSUs o/s Optinose Investor Contact 				
Jefferies: Glen Santangelo	Jonathan Neely, VP, Investor Relations and				
Piper Sandler: David Amsellem	Business Development 267-521-0531 Investors@optinose.com				
investors@optinose.com www.d · Optinose is followed by the analysts listed above. Please note that any opinions, esti are theirs alone and do not represent opinions, forecasts or predictions of Optinose imply its endorsement of or concurrence with such information, conclusions or reco	e or its management. Optinose does not by its reference above or distribution				
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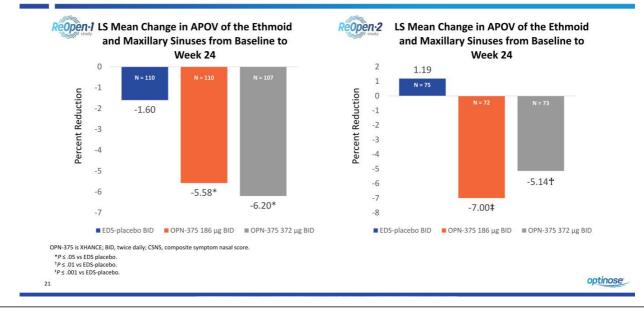




Combined Symptom Score (Co-Primary Endpoint) Improvement in combined symptoms with XHANCE; Consistent with NAVIGATE I and II



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







Corporate Presentation March 7, 2023