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): May 11, 2023

OPTINOSE, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-38241**	**42-1771610**
(State or Other Jurisdiction of Incorporation or Organization)	(Commission File No.)	(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)

☐ 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))

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

Item 2.02 Results of Operations and Financial Condition.

On May 11, 2023, OptiNose, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 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 May 11, 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 May 11, 2023.
99.2	OptiNose, Inc. Corporate Presentation, dated May 11, 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: May 11, 2023

Optinose Reports First Quarter 2023 Financial Results and Operational Updates

Strong progress towards strategic objectives including acceptance of sNDA for review and prioritization of potential launch of XHANCE as first drug approved to treat chronic rhinosinusitis

Company reports first quarter 2023 XHANCE net revenue of $11.8 million

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

YARDLEY, Pa., May 11, 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 March 31, 2023, and provided operational updates.

“We are pleased with the progress we made in the first quarter of 2023 towards our strategic objectives," stated CEO Ramy Mahmoud, MD, MPH. "Our effort to secure the first-ever drug approval for patients with chronic sinusitis took a major step forward last week when we announced that our supplemental new drug application was accepted for review with a target goal date of December 16, 2023. We are preparing our organization for a successful launch and operating more efficiently in our current business. These objectives are aimed at rapidly achieving uptake in the millions of chronic sinusitis patients in need of an effective therapy."

First Quarter 2023 and Recent 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) 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. Patents Covering XHANCE
The United States Patent and Trademark Office (USPTO) recently issued two additional patents covering XHANCE. These patents, U.S. Patents 11,554,229 and 11,602,603, have been listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) for XHANCE and have terms that expire in years 2036 and 2028, respectively. XHANCE is now covered by 15 Orange Book-listed patents.

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

First Quarter 2023 Financial Results

Total revenues
The Company reported $11.8 million in net revenue from sales of XHANCE during the three-month period ended March 31, 2023, a decrease of 20% compared to $14.8 million during the three-month period ended March 31, 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 and its guidance for first quarter 2023 net revenues to be approximately $10.0 million.

Costs and expenses and net loss
For the three-month period ended March 31, 2023, research and development expenses were $1.8 million and selling, general and administrative expenses were $22.7 million. The net loss for the period was $18.8 million, or $0.17 per share (basic and diluted).

Balance Sheet
The Company had cash and cash equivalents of $83.9 million as of March 31, 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 $62.0 to $68.0 million. In addition, the Company expects the full year 2023 XHANCE average net revenue per prescription to be approximately $200.

Operating Expenses
The Company expects 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.

Previously the Company expected total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2023 to be in the range of $90.0 to $95.0 million, of which the Company expected stock-based compensation to be approximately $8.0 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 March 31,	
	2023	**2022**
Revenues:		
Net product revenues	11,846	14,760
Total revenues	11,846	14,760
Costs and expenses:		
Cost of product sales	1,706	2,014
Research and development	1,785	4,802
Selling, general and administrative	22,723	29,339
Total costs and expenses	26,214	36,155
Loss from operations	(14,368)	(21,395)
Other expense	4,479	3,938
Net loss	$ (18,847)	$ (25,333)
Net loss per share of common stock, basic and diluted	$ (0.17)	$ (0.31)
Weighted average common shares outstanding, basic and diluted	111,774,425	82,447,861

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

	March 31 2023 (unaudited)	December 31, 2022
Cash and cash equivalents	$ 83,928	$ 94,244
Other assets	30,997	49,978
Total assets	$ 114,925	$ 144,222
Total current liabilities [1]	$ 166,303	$ 178,729
Other liabilities	22,407	22,116
Total stockholders' equity	(73,785)	(56,623)
Total liabilities and stockholders' equity	$ 114,925	$ 144,222

(1) – All outstanding principal and fees payable upon maturity have been classified as a current liability in accordance with Generally Accepted Accounting Principals ("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 months ended March 31, 2023 ("Q12023 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 Quarterly Report on Form 10-Q for the year ended March 31, 2023 (including the Q12023 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 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 forward-looking statements for this purpose and include, among others, statements relating to the potential benefits of XHANCE for the treatment of chronic sinusitis; the potential for XHANCE to be the first FDA-approved drug treatment for chronic sinusitis and the potential benefits thereof; patent protections; projected XHANCE net revenue and average net revenue per prescription for full year 2023; projected Company GAAP (selling, general and administrative expenses and research & development expenses) 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 XHANCE for its current and any potential future indication; the Company's ability to maintain adequate third-party reimbursement for 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 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 chronic rhinosinusitis; the potential that the FDA does not meet the PDUFA target goal date; the Company's ability to comply with the covenants and other terms of the Amended and Restated Pharmakon Note Purchase Agreement; the Company's ability to continue as a going concern; risks and uncertainties relating to intellectual property; and the risks, uncertainties and other factors discussed under the caption "Item 1A. Risk Factors" and elsewhere in the Company's most recent Form 10-K and Form 10-Q filings with the Securities and Exchange Commission - which are available at www.sec.gov. As a result, you are cautioned not to place undue reliance on any forward-looking statements. Any forward-looking statements made in this press release speak only as of the date of this press release, and the Company undertakes no obligation to update such forward-looking statements, whether as a result of new information, future developments or otherwise.

Optinose Investor Contact
Jonathan Neely
jonathan.neely@optinose.com
267.521.0531

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Exhibit 99.2

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Building a Leading ENT / Allergy Specialty Company

Corporate Presentation
May 11, 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, prescriber 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 (selling, general and administrative expenses and research and development expenses) and stock-based compensation for 2023; projected XHANCE net revenues for 2023; projected XHANCE average net revenue per prescription for 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 for XHANCE to be the first FDA-approved drug treatment for chronic rhinosinusitis and 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 consequences thereof; 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 (market access) including any potential future indication; our ability to efficiently generate XHANCE prescriptions and net revenues; the prevalence of chronic sinusitis and market opportunities 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 rhinosinusitis; 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 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. Any forward-looking statements made in this presentation speak only as of the date of this presentation, and we undertake no obligation to update such forward-looking statements, whether as a result of new information, future developments or otherwise.

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Key Takeaways

Chronic sinusitis is a 10-fold market opportunity for XHANCE

sNDA accepted for review by FDA – 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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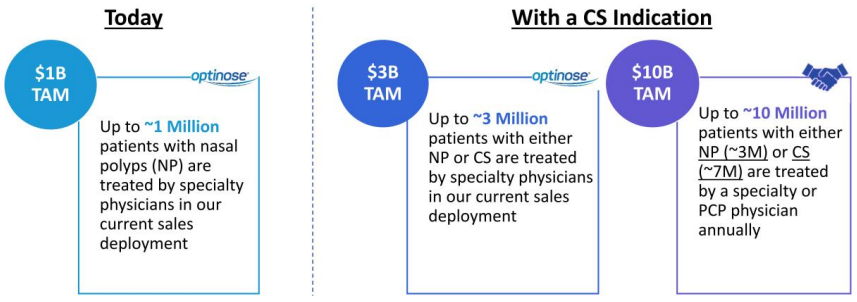
Successful Development of XHANCE as the First and Only FDA-approved Drug Treatment for Chronic Sinusitis Would Create Multiple New Growth Opportunities



For a Partner, there are **up to 7 million** NP+CS patients currently treated by a Primary Care Physician plus **20 million** lapsed patients that could be activated into care

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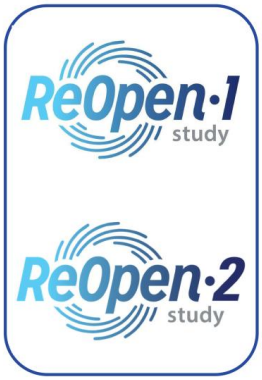
ReOpen Program Update

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 in December 2023
  - Standard review period was applied

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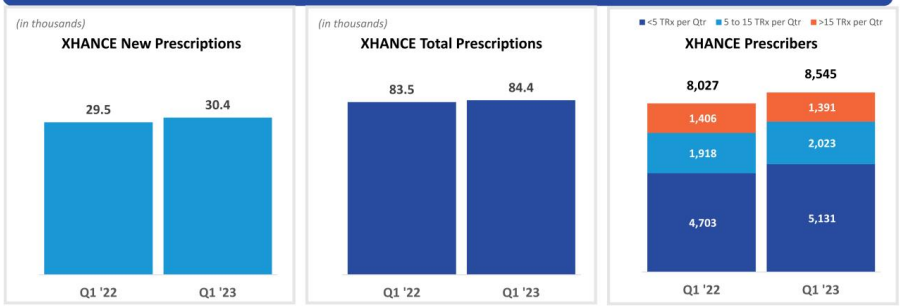
Q1 2023 Performance

XHANCE Prescriptions

XHANCE New Prescriptions increased 3% and Total Prescriptions increased 1% and HCPs who had more than 15 prescriptions filled by their patients decreased 1% from Q1 2022 to Q1 2023



NRx for Intranasal Steroids Market increased 8% from Q1 2022 to Q1 2023 and TRx for Intranasal Steroids Market increased 5% from Q1 2022 to Q1 2023

Estimated based on monthly prescription data from third parties and XHANCE preferred pharmacy network.
2022 data updated to reflect current prescription estimation methodology. Previously estimated 28,200 NRx and 81,000 TRx and XHANCE prescribers of <5, 5 to 15, and <15 of 4,286, 1,936, and 1,468, respectively. .

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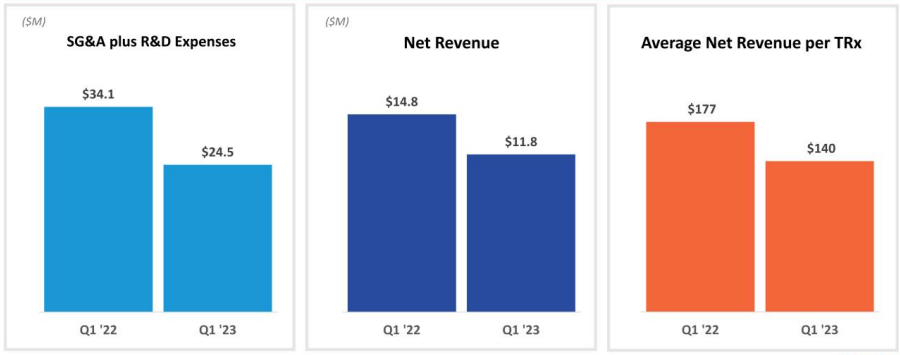
Q1 2023 Financial Update

Financial Review – First Quarter 2023

SG&A plus R&D expenses decreased by ~$10M from Q1 2022 to Q1 2023 while Q1 2023 XHANCE Net Revenues exceeded previous guidance of approximately $10 million



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2023 Outlook

Full Year 2023 Financial Guidance

- **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
  - Previously expected to be between $90 to $95 million; approximately $8 million of which represented 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
- **XHANCE Average Net Revenue per Prescription**
  - FY 2023 expected to be approximately $200

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Closing Remarks

Key Takeaways

Chronic sinusitis is a 10-fold market opportunity for XHANCE

sNDA accepted for review by FDA – 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

Analyst Coverage [1]
Cantor Fitzgerald: Brandon Folkes
Jefferies: Glen Santangelo
Piper Sandler: David Amsellem

As of March 31, 2023:

- **$83.9 million** in cash
- Debt: **$130 million**
- **112 million** common shares o/s
- **46 million** options, warrants & RSUs o/s

Optinose Investor Contact

Jonathan Neely,
VP, Investor Relations and
Business Development
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1 - Optinose is followed by the analysts listed above. Please note that any opinions, estimates or forecasts regarding the Company's performance made by these analysts are theirs alone and do not represent opinions, forecasts or predictions of Optinose or its management. Optinose does not by its reference above or distribution imply its endorsement of or concurrence with such information, conclusions or recommendations.

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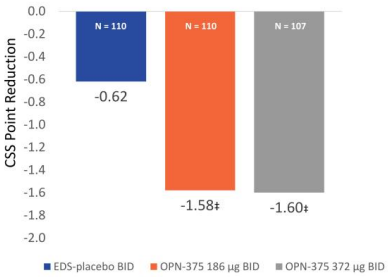
Appendix - ReOpen Program
Co-Primary Endpoints

Combined Symptom Score (Co-Primary Endpoint)

Improvement in combined symptoms with XHANCE; Consistent with NAVIGATE I and II

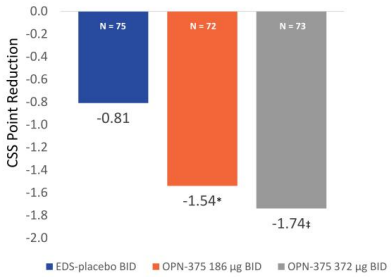
ReOpen-1 study

LS Mean Change in CSS from Baseline to Week 4



ReOpen-2 study

LS Mean Change in CSS from Baseline to Week 4



OPN-375 is XHANCE; BID, twice daily; CSNS, composite symptom nasal score.

*$P \leq .05$ vs EDS placebo.

‡$P \leq .001$ vs EDS-placebo.

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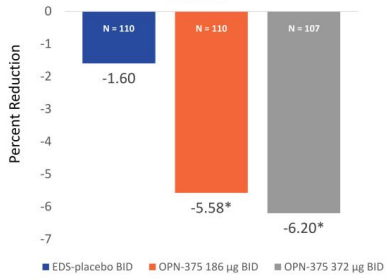
Average of Percentages of Opacified Volume (Ethmoid and Maxillary)

Objective Evidence of Effect in Sinus Cavities by CT Scan; Co-Primary Endpoint

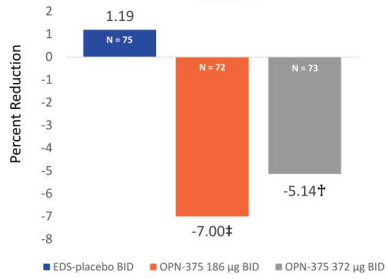
ReOpen-1 study

LS Mean Change in APOV of the Ethmoid and Maxillary Sinuses from Baseline to Week 24



ReOpen-2 study

LS Mean Change in APOV of the Ethmoid and Maxillary Sinuses from Baseline to Week 24



OPN-375 is XHANCE; BID, twice daily; CSNS, composite symptom nasal score.

*$P \leq .05$ vs EDS placebo.

†$P \leq .01$ vs EDS-placebo.

‡$P \leq .001$ vs EDS-placebo.

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Building a Leading ENT / Allergy Specialty Company

Corporate Presentation
May 11, 2023