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): April 17, 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)
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

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.

Item 7.01 Regulation FD Disclosure

On April 12, 2023, OptiNose, Inc. (the Company) issued a press release announcing that it will present a company overview and business update at the Needham Virtual Healthcare Conference on April 17, 2023 (the "Conference"). A copy of the presentation to be used at the Conference is furnished hereto as Exhibit 99.1 and is incorporated by reference herein.

* * *

The information included in Item 7.01 (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 9.01 Financial Statements and Exhibits.
(d) Exhibits

Exhibit No.	Description
99.1	Needham Virtual Healthcare Conference Presentation dated April 17, 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/ Michael F. Marino
Michael F. Marino
Chief Legal Officer

April 17, 2023

Exhibit 99.1

Building a Leading ENT / Allergy Specialty Company

Corporate Presentation
April 17, 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 and other business trends; impact of payor utilization management criteria; projected GAAP operating expenses and stock-based compensation for 2023; projected XHANCE net revenues for 2023; projected XHANCE average net revenue per prescription for 2023; the potential impact of cash preservation measures; the potential benefits of XHANCE for the treatment of chronic sinusitis; 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 partner to promote XHANCE in primary care and the prospects for, and potential benefits of, such 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 (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, regulatory actions and 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 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.

Key Takeaways

Chronic sinusitis is a 10-fold market opportunity for XHANCE

Submitted sNDA in February - acceptance decision by FDA anticipated by the start of May 2023

Potential for sNDA approval in December 2023

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

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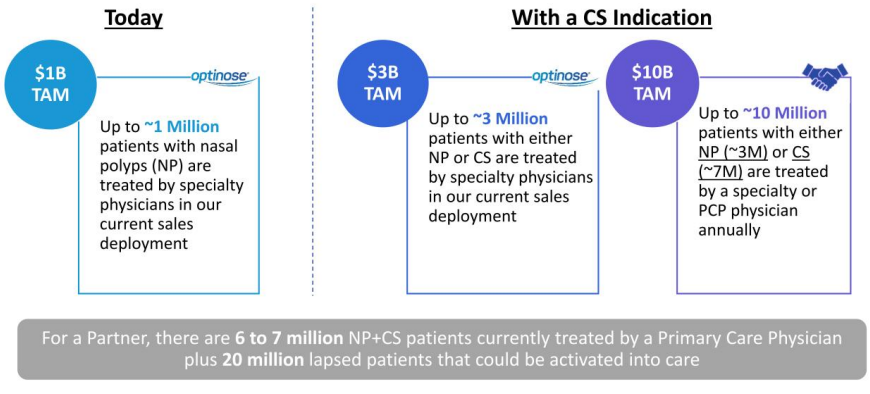
Successful Development of XHANCE as the First FDA-approved Drug Treatment for Chronic Sinusitis Creates Multiple New Opportunities for Growth



For a Partner, there are **6 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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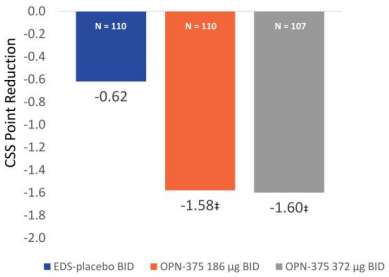
ReOpen Program

Combined Symptom Score (Co-Primary Endpoint)

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

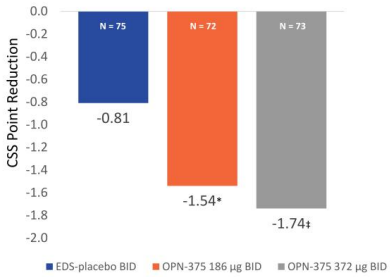
ReOpen-1 study

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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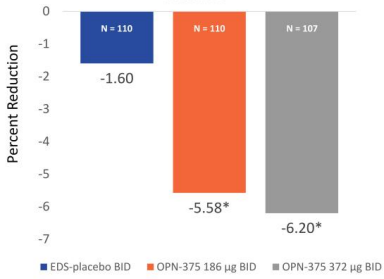
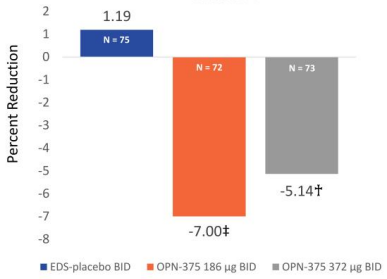
Average of Percentages of Opacified Volume (Ethmoid and Maxillary)

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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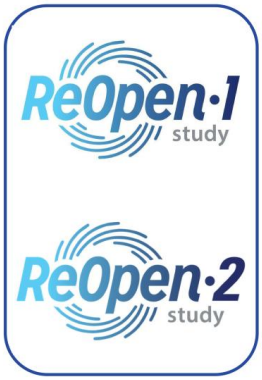
CS Supplemental NDA - Anticipated Next Steps



- 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

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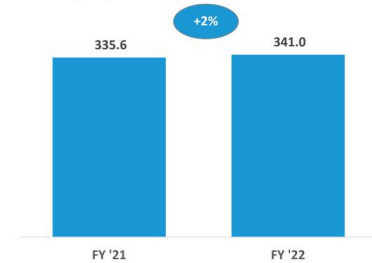
FY 2022 Performance

XHANCE New and Total Prescriptions

XHANCE New Prescriptions were flat and Total Prescriptions for Full Year 2022

XHANCE NRx *(in thousands)*

XHANCE Prescriptions *(in thousands)*



NRx for Intranasal Steroids Market increased 7% and TRx for Intranasal Steroids Market from Full Year 2021 to Full Year 2022

Estimated based on monthly prescription data from third parties and XHANCE preferred pharmacy network. The Market on this slide is defined as the sum of all intranasal steroid prescriptions based on monthly prescription data from third parties

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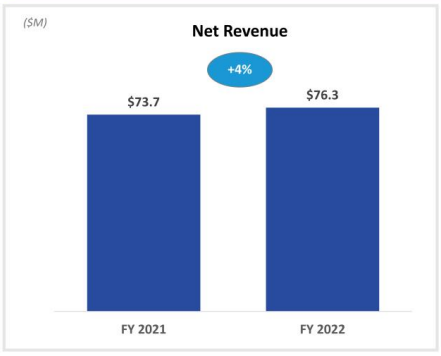
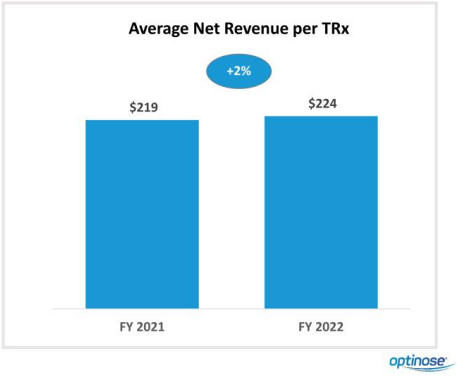
FY 2022 XHANCE Net Revenue and Net Revenue per Prescription

XHANCE Net Revenue increased 4% for Full Year 2022 and Average Net Revenue per TRx increased from $219 to $224 for Full Year 2022





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2023 Outlook

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
- **XHANCE Average Net Revenue per Prescription**
  - FY 2023 expected to be approximately $200

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Closing Remarks

Key Takeaways

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Investor Relations – NASDAQ: OPTN

As of December 31, 2022:

- **$94.2 million** in cash
- Debt: **$130 million**
- **111.5 million** common shares o/s
- **43.6 million** options, warrants & RSUs o/s

Optinose Investor Contact

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