

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): November 16, 2021



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)
- 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-4(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 8.01 Other Events.

On November 16, 2021, the Company will be presenting an updated Corporate Presentation during its financial results and corporate update call. A copy of the presentation is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	OptiNose, Inc. Corporate Presentation, dated November 16, 2021.

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/ Keith A. Goldan

Keith A. Goldan

Chief Financial Officer

Date: November 16, 2021



Corporate Presentation
November 16, 2021

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: potential for continued XHANCE prescription and net revenue growth and factors supporting such growth; prescription, refill and market share trends; potential effects of INS market seasonality on XHANCE prescriptions; projected Company GAAP operating expenses and stock-based compensation for 2021; projected XHANCE net revenues for full year 2021; projected XHANCE net revenue per prescription for the remainder of 2021; the Company’s plans to seek approval for a follow-on indication for XHANCE for the treatment of chronic sinusitis and the potential benefits of such indication; prospects for potential partnerships to promote XHANCE in primary care; the expectation of having top-line results from one chronic sinusitis trial in the first quarter of 2022 and results from the second trial in the second quarter of 2022; our development, timing of data, and funding plans for OPN-019 and the potential benefits of OPN-019; and other statements regarding the Company’s future operations, financial performance, prospects, intentions, 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, the COVID-19 pandemic; physician and patient acceptance of XHANCE; the Company’s ability to maintain adequate third party reimbursement for XHANCE (market access); the Company’s ability to grow XHANCE prescriptions and net revenues; market opportunities for XHANCE may be smaller than expected; uncertainties and delays relating to the initiation, enrollment, completion and results of clinical trials; unexpected costs and expenses; the Company’s ability to comply with the covenants and other terms of the Pharmakon note purchase agreement; the Company’s ability to continue as a going concern; risks relating to the closing of the announced common stock offering; 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.



**XHANCE[®] Continues to Have Significant
Growth Potential**

Opportunity for Substantial Continuing Growth with the Nasal Polyps Indication in the Current Target Audience



Our commercial team promotes XHANCE to a universe of largely ENT and Allergy specialists, with direct sales by representatives deployed against 100 territories augmented by targeted non-personal promotion to expand reach



Approximately **1 Million** patients with diagnosed nasal polyps (NP) are treated by specialty physicians who are the current focus of our sales call plans



In that audience, despite ongoing challenges created by the pandemic environment, XHANCE is expected to produce \$71 to \$75 million in net revenue for FY 2021 with Y/Y growth of 47% to 55%



optinose

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



optinose®

Chronic sinusitis (CS) indication has potential to **triple** the number patients for whom Optinose can promote XHANCE as an appropriate treatment

3x

- **Today:** up to approximately **1 Million** patients with nasal polyps (NP) are treated by specialty physicians who are the current focus of our sales deployment
 - Optinose has achieved a leading physician preference share for XHANCE for treating NP patients
 - Some payers require a diagnosis of NP
- **With CS:** approximately **3 Million** patients with either NP or CS are treated by specialty physicians who are the current focus of our sales deployment
 - CS approval could enable Optinose to extend established physician preference share, and prescribing, to a much larger set of patients

Source: Palmer J et al. A cross-sectional population-based survey of the prevalence, disease burden, and characteristics of the US adult population with symptoms of chronic rhinosinusitis (CRS). Poster session presented at: 62nd Annual Meeting of the American Rhinologic Society, September 16-17, 2016, San Diego, CA. Optinose Market Research. Data on file.

There are Potential Partners with Current “High Audience Crossmatch” Primary Care Deployments that Could Enable Promotion for up to 30 Million Patients



For a Partner, there are **6-7 million** NP+CS patients currently treated by a Primary Care Physician and **20 million** lapsed patients that could be activated

- Approximately **10 Million** patients with NP or CS are treated by a physician annually
 - CS indication could enable significant physician audience expansion for a primary care partner, allowing access to a greatly-expanded pool of patients beyond reach of Optinose deployment
- Approximately **30 Million** patients have NP or CS, of which approximately 20 million are believed to know they suffer CS symptoms but have stopped seeking regular care from a physician for nasal symptoms
 - CS indication and promotional messaging could enable ‘lapsed patient’ activation by a partner (e.g., by DTC promotion)

Source: Palmer J et al. A cross-sectional population-based survey of the prevalence, disease burden, and characteristics of the US adult population with symptoms of chronic rhinosinusitis (CRS). Poster session presented at: 62nd Annual Meeting of the American Rhinologic Society, September 16-17, 2016, San Diego, CA. Optinose Market Research. Data on file.

Chronic Sinusitis Phase 3b Clinical Trial Data is a Near-Term Event



Recruitment
Completed
July 2021

Top-line results
expected in Q1 2022



Recruitment
Completed
October 2021

Top-line results
expected in Q2 2022



Q3 2021 Performance

Key Takeaways and Q3 2021 Highlights



Consistent Commercial Execution Driving Q3 2021 Growth

Multiple Factors Support Continued Revenue Growth

FY 2021 Revenue Guidance Implies Y/Y Growth of 47% to 55%

Both CS Trials Enrolled – Top Line Data Expected Q1 and Q2 2022

+41%

XHANCE Net
Revenue Growth
Q3 2021/Q3 2020

\$84M

Cash and equivalents
as of
September 30, 2021

+25%

XHANCE
TRx Growth
Q3 2021/Q3 2020

\$253

XHANCE Net
Revenue per TRx
in Q3 2021

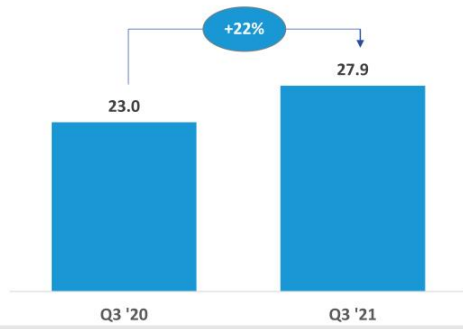
+22%

XHANCE
NRx Growth
Q3 2021/Q3 2020

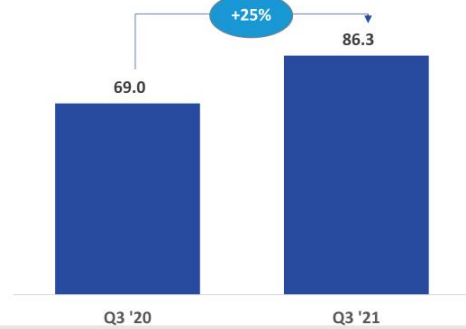
XHANCE New and Total Prescriptions

XHANCE New Prescriptions increased 22% and Total Prescriptions increased 25% from Q3 2020 to Q3 2021

XHANCE NRx (in thousands)



XHANCE Prescriptions (in thousands)



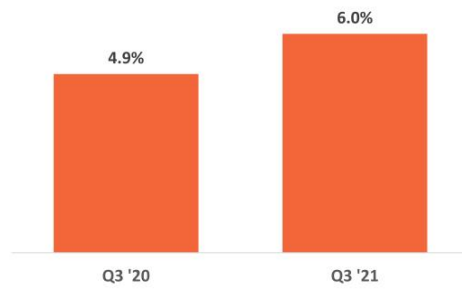
NRx for Intranasal Steroids Market increased 9% from Q3 2020 to Q3 2021 and TRx for Intranasal Steroids Market increased 4% from Q3 2020 to Q3 2021

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.

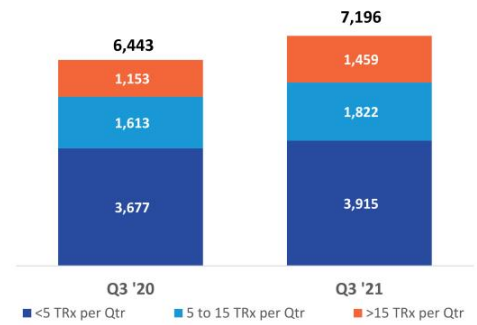
XHANCE Market Share & Prescribers by Prescribing Frequency

XHANCE market share increased from 4.9% to 6.0% and HCPs who had more than 15 XHANCE prescriptions filled by their patients in a quarter increased by 27% (1,459 versus 1,153) from Q3 2020 to Q3 2021

XHANCE Share of INS TRx Within Target Physician Audience



XHANCE Prescribers



The Market on this slide is defined as the sum of all intranasal steroid prescriptions written by physicians in the XHANCE target physician audience of approximately 18,000 physicians. Estimated based on monthly prescription data from third parties and XHANCE preferred pharmacy network.



Q3 2021 Financial Update

Financial Review – XHANCE Net Revenue

XHANCE Net Revenue Increased 41% from Q3 2020 to Q3 2021 and 56% on a Year-to-Date Basis

(\$M)

Net Revenue



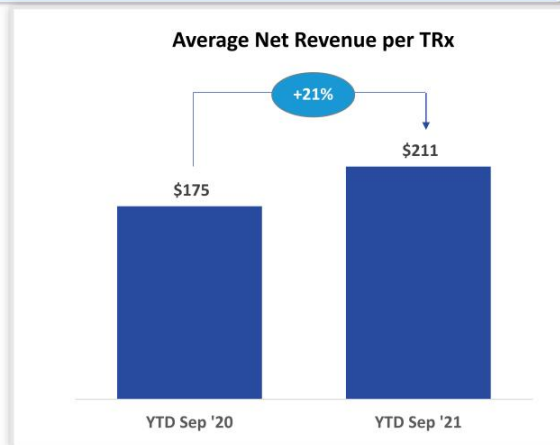
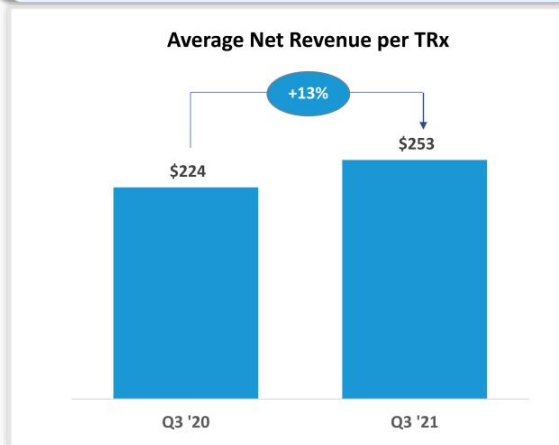
(\$M)

Net Revenue



Financial Review – XHANCE Average Net Revenue per Prescription

XHANCE Average Net Revenue per TRx Increased from \$224 to \$253 from Q3 2020 to Q3 2021 and from \$175 to \$211 on a Year-to-Date Basis



Full Year 2021 Financial Guidance

- **XHANCE Net Revenue**
 - Expected to be between \$71 – \$75 million
 - Previously expected to exceed \$80 million
- **XHANCE Average Net Revenue per Prescription**
 - Expected to exceed \$210
 - Previously expected to exceed \$200
- **Operating Expense (GAAP)**
 - Expected to be between \$132 – \$137 million; approximately \$10 million of which represents stock-based compensation
 - Prior guidance range of \$137 – \$142 million; approximately \$10 million of which represented stock-based compensation

Revised Debt Terms¹

TTM Revenue Covenants (\$ 000's)	
Q4 2021	\$68,000
Q1 2022	\$70,000
Q2 2022	\$75,000
Q3 2022	\$80,000
Q4 2022	\$90,000
Q1 2023	\$98,750
Q2 2023	\$102,500
Q3 2023	\$106,250
Q4 2023	\$110,000
Q1 2024	\$113,750
Q2 2024	\$117,500

Revised XHANCE Net Revenue Covenants

- On average ~\$15.5M less than prior covenants for periods from Q4 2021 to Q4 2023
- On average ~\$22.1M less than prior covenants for periods from Q1 2022 to Q3 2022

Loan Amortization Delayed by 9 Months

- First principal payments due in September 2023 compared to December 2022 previously

Fee for Revised Terms

- Cancellation of all existing outstanding warrants, to be replaced with 2.5 million newly-issued 3-year warrants with a strike price equal to the Offering Price.
- Make-whole provision for the entire principal balance of \$130M is reset to 30 months effective as of the closing of the Offering, with a cap (limit) equal to a make-whole equivalent of 15 months.

¹ - The revised debt terms are contingent upon closing of the Offering

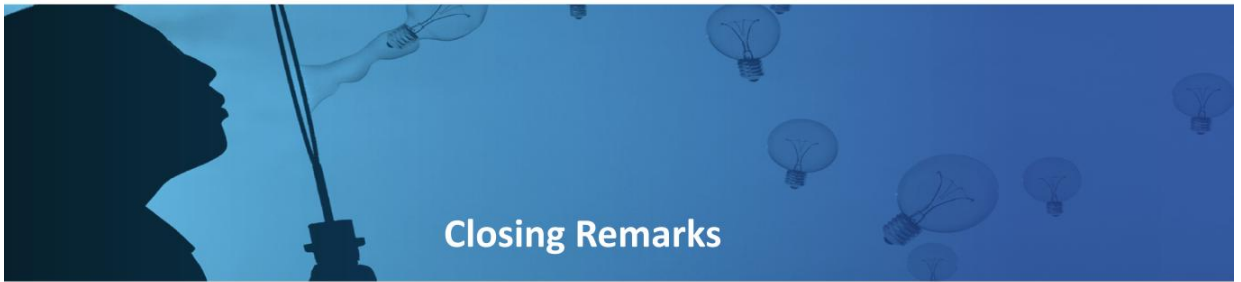


Chronic Sinusitis Clinical Trials Update

XHANCE Chronic Sinusitis Program

- Announced that recruitment for trial -3206 (ReOpen2) completed in October
 - Recruitment for -3205 (ReOpen1) was previously completed
- In Q3 we conducted a pre-planned, blinded, interim analysis (IA) to assess variance for the symptom and CT-scan co-primary endpoints in trial -3206 (ReOpen2)
 - The observed variance in the IA was less than the variance assumed for the purpose of sample size estimation during initial design of the study
 - Given this result, we reduced sample size while maintaining estimated statistical power for the final analysis
 - Final enrollment of ~210 compared to original target enrollment of 399

Top-line results expected from ReOpen1 in Q1 2022 and from ReOpen2 in Q2 2022



Closing Remarks

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Investor Relations – NASDAQ: OPTN

At 30 September 2021:

- \$84 million in cash
- Long-term debt: \$130 million
- 53.4 million common shares o/s
- 10.8 million options, warrants & RSUs o/s

Optinose Investor Contact

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Corporate Presentation
November 16, 2021
