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 8, 2022

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 March 8, 2022, OptiNose, Inc. (the “Company”) issued a press release announcing its financial results for the year ended December 31, 2021. 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, 2022, OptiNose, Inc. (the Company) issued a press release announcing top-line results from ReOpen1. ReOpen 1 was a randomized double-blinded, placebo controlled Phase 3 clinical trial examining the safety and efficacy of XHANCE® versus a placebo Exhalation Delivery System™ in adults with chronic sinusitis with or without nasal polyps. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The Company will present top-line results from ReOpen1 during an investor call on March 7, 2022. 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 8, 2022.
99.2	OptiNose, Inc. Corporate Presentation, dated March 8, 2022.
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/ Keith A. Goldan
Keith A. Goldan
Chief Financial Officer

Date: March 7, 2022

Optinose Reports Fourth Quarter and Full Year 2021 Financial Results and Recent Operational Highlights

Company reports fourth quarter and full year 2021 XHANCE net revenue of $22.5 million *and* $73.7 million

Full year 2021 XHANCE prescriptions increased 28% compared to full year 2020

Company expects XHANCE net revenue for 2022 to be at least $90 million

Company expects top-line results from the second of two clinical trials evaluating XHANCE as a potential treatment for Chronic Sinusitis in second quarter 2022

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

YARDLEY, Pa., March 8, 2022 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, 2021, and provided recent operational highlights.

"For the full year of 2021 versus 2020, XHANCE net revenues increased 52%, while total prescriptions and new prescriptions increased by 28% and 27%, respectively," stated CEO Peter Miller. "I believe these are outstanding results particularly in the context of a pandemic environment which has constrained both patient visits to physician offices and the ability of our territory managers to broadly meet in-person with our targeted physicians. Looking forward, I expect 2022 to be exciting time for our company as we continue to produce strong revenue growth with our current business, and we expect to complete our second clinical trial evaluating XHANCE for the treatment of chronic sinusitis. If successful, XHANCE has the potential to be the first ever drug treatment approved by the FDA for this indication which could be a game changer for both the 30 million patients suffering from symptoms of chronic sinusitis and for our company."

Fourth Quarter 2021 and Recent Highlights

Total and New XHANCE Prescriptions

The number of XHANCE® (fluticasone propionate) prescriptions increased by 27% from 73,900 in the fourth quarter 2020 to 93,700 in the fourth quarter 2021. In addition, XHANCE prescriptions increased by *28%* from 261,400 for the full year of 2020 to 335,600 for the full year of 2021.

The number of new prescriptions for XHANCE increased by 21% from 24,600 in the fourth quarter of 2020 to 29,900 in the fourth quarter of 2021. In addition, new prescriptions for XHANCE increased by 27% from 88,600 for the full year of 2020 to 112,700 for the full year of 2021.

ReOpen1 Clinical Trial Top-line Results

In March 2022, the Company announced that the ReOpen1, a landmark clinical trial in chronic sinusitis, met both of its co-primary endpoints. A statistically significant improvement was demonstrated in patients with chronic sinusitis who were treated with the XHANCE Exhalation Delivery System™ in the ReOpen1 clinical trial compared to patients receiving an Exhalation Delivery System placebo as measured by both primary endpoints: first, a composite symptom score (comprising nasal congestion, facial pain or pressure, and nasal discharge) measured at week 4 and second, an objective measure of disease in the sinus cavities at week 24 (measured by average percent of the opacified volume on CT scan, summed across all of the ethmoid and maxillary sinuses).

The safety profile and tolerability of XHANCE in this trial were generally consistent with its currently labelled safety profile. Adverse events occurring at a rate of more than 3% with XHANCE and more common than the Exhalation Delivery System placebo were: epistaxis, nasopharyngitis, asthma, and cataract (nuclear and cortical).

Detailed results from this trial will be submitted for publication in a peer-reviewed journal and for presentation at future medical meetings

Fourth Quarter 2021 Financial Results

Revenue
The Company generated $22.5 million and $73.7 million of XHANCE net revenue during the three-month and twelve-month periods ended December 31, 2021, respectively. In addition, the Company generated $1.0 million of licensing revenue during the twelve-month period ended December 31, 2021. Total revenues for the three and twelve-month periods ended December 31, 2021 were $22.5 million and $74.7 million.

Expenses and net loss
For the three-month and twelve-month periods ended December 31, 2021, research and development expenses were $5.3 million and $25.3 million, respectively. Selling, general and administrative expenses were $26.3 million and $106.6 million during the three-month and twelve-month periods ended December 31, 2021, respectively. The net loss for the three-month period ended December 31, 2021 was $15.6 million, or $0.23 per share (basic and diluted). The net loss for the twelve-month period ended December 31, 2021 was $82.3 million, or $1.45 per share (basic and diluted).

Cash
The Company had cash and cash equivalents of $110.5 million as of December 31, 2021. In November 2021, The Company closed an underwritten public offering resulting in $42.8 million of net proceeds. The $42.8 million of cash is included in the Company's cash balance of $110.5 million as of December 31, 2021.

Corporate Guidance

XHANCE Net Revenue and Average Net Revenue per Prescription
The Company expects XHANCE net revenues for the full year of 2022 to be at least $90 million. This includes the Company's expectation that first quarter 2022 XHANCE net revenue will decrease compared to fourth quarter 2021. The primary driver of the sequential decrease to revenue is the Company's expectation that XHANCE average net revenue per prescription for the first quarter of 2022 will decrease, due to typical early-year effects on price and volume related to patient insurance that the Company believes are common for chronic treatments that derive a significant proportion of total prescriptions from refills. The Company expects XHANCE average net revenue per prescription to exceed $210 for full year 2022.

Operating Expenses
The Company expects total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2021 to be in the range of $135 to $140 million, of which the Company expects stock-based compensation to be approximately $10 million.

Chronic Sinusitis Clinical Trials
The Company expects top-line results from ReOpen2, the second its two clinical trials evaluating XHANCE as a potential treatment for chronic sinusitis, in the second quarter of 2022.

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.

To participate on the conference call, please dial (866) 916-4761 from the U.S. or +1 (409) 216-6496 from outside the U.S. In addition, following the completion of the call, a telephone replay will be accessible until March 15, 2022 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID: 8283756.

A simultaneous webcast of the call and presentation can be accessed by visiting the Investors section of Optinose's website at www.optinose.com. 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,	
	2021	2020	2021	2020
Revenues:				
Net product revenues	$ 22,509	$ 15,597	$ 73,652	$ 48,367
Licensing revenues	—	750	1,000	750
Total revenues	22,509	16,347	74,652	49,117
Costs and expenses:				
Cost of product sales	2,575	2,244	9,151	7,520
Research and development	5,260	6,448	25,318	23,378
Selling, general and administrative	26,342	28,107	106,633	105,438
Total costs and expenses	34,177	36,799	141,102	136,336
Loss from operations	(11,668)	(20,452)	(66,450)	(87,219)
Other expense	3,955	3,412	15,846	12,566
Net loss	$ (15,623)	$ (23,864)	$ (82,296)	$ (99,785)
Net loss per share of common stock, basic and diluted	$ (0.23)	$ (0.46)	$ (1.45)	$ (2.07)
Weighted average common shares outstanding, basic and diluted	67,831,835	43,467,985	56,851,921	48,275,230

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

	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 110,502	$ 144,156
Other assets	55,569	44,657
Total assets	$ 166,071	$ 188,813
Total current liabilities	59,235	$ 52,172
Long-term debt, net	126,418	125,202
Other liabilities	2,190	4,651
Total stockholders' equity	(21,772)	6,788
Total liabilities and stockholders' equity	$ 166,071	$ 188,813

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. Optinose has offices in the U.S. and Norway. To learn more, please visit www.optinose.com or follow us on Twitter and LinkedIn.

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 for continued XHANCE prescription and net revenue growth; early year effects on price and volume related to patient insurance; the potential benefits of XHANCE for the treatment of chronic sinusitis, the Company's plans to seek approval for a follow-on indication for XHANCE for the treatment of chronic sinusitis and the expectation of top-line results from the second of its two chronic sinusitis trials in the second quarter of 2022; the potential for XHANCE to be the first FDA-approved drug treatment for chronic sinusitis and, if approved for chronic sinusitis, the potential for such approval to be a game changer for both the 30 million patients suffering from chronic sinusitis and for the Company; projected average net revenue per prescription for first quarter and full year 2022; projected XHANCE net revenue for first quarter and full year 2022; projected Company GAAP operating expenses and stock-based compensation for 2022; and other statements regarding the Company's future operations, financial performance, financial position, prospects, 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 uncertainties caused by the COVID-19 pandemic; 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); the prevalence of chronic sinusitis and market opportunities for XHANCE may be smaller than expected; the Company's ability to grow XHANCE prescriptions and net revenues; unanticipated costs and expenses; potential for varying interpretation of the top-line results from ReOpen1; potential for the full data set from ReOpen1, when available, to contain results that conflict with or are inconsistent with the top-line results; risks and uncertainties relating to the completion and results of ReOpen2; uncertainties related to the clinical development program and regulatory approval of XHANCE for the treatment of chronic sinusitis; the Company's ability to comply with the covenants and other terms of the note purchase agreement entered into with funds managed by Pharmakon Advisors, LP; 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

optinose®

Building a Leading ENT / Allergy Specialty Company

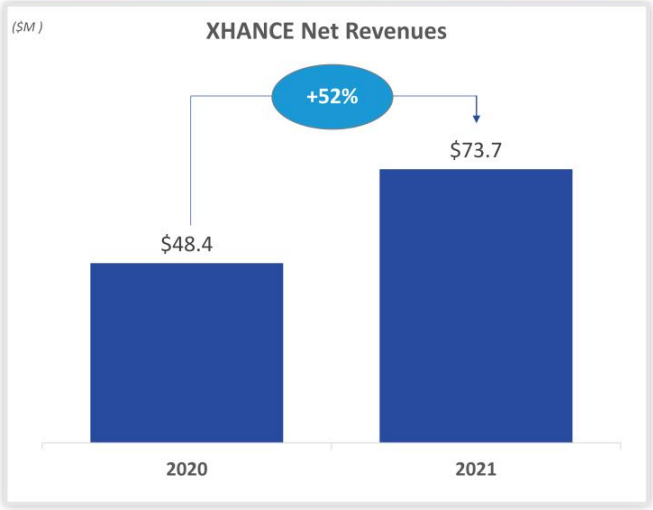
Corporate Presentation
March 8, 2022

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; potential early year effects on price and volume related to patient insurance; projected Company GAAP operating expenses and stock-based compensation for 2022; projected XHANCE net revenues for first quarter and full year 2022; projected XHANCE average net revenue per prescription for first quarter and full year 2022; the potential benefits of XHANCE for the treatment of chronic sinusitis; the expectation of having top-line results from ReOpen2 in the second quarter of 2022; the Company's plans to seek approval for a follow-on indication for 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 market expansion opportunities and other benefits of obtaining such indication; the Company's plan to secure a partnership to promote XHANCE in primary care and the prospects for, and potential benefits of, such potential partnership; 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 for its current and any potential future indication; 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; the prevalence of chronic sinusitis and market opportunities for XHANCE may be smaller than expected; unexpected costs and expenses; potential for varying interpretation of the top-line results from ReOpen1 and the potential for the full data set, when available, to contain results that conflict with or are inconsistent with the top-line results; risks and uncertainties relating to the completion and results of ReOpen2; uncertainties related to the clinical development program and regulatory approval of XHANCE for the treatment of chronic sinusitis; the Company's ability to comply with the covenants and other terms of the Pharmakon note purchase agreement; 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.

Full Year 2021 Highlights



+52%
XHANCE Net Revenue Growth
FY 2021/FY 2020

+28%
XHANCE Prescriptions
Growth FY 2021/FY 2020

+27%
XHANCE New Prescriptions
Growth FY 2021/FY 2020

$132M
Full Year 2021 Operating Expenses
(SG&A plus R&D)

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

Today

1 Million optinose

Up to approximately **1 Million** patients with nasal polyps (NP) are treated by specialty physicians who are the current focus of our sales deployment

With a CS Indication

10 Million

Up to approximately **10 Million** patients with NP or CS are treated by a physician annually

3 million optinose

Up to approximately **3 Million** patients with either NP or CS are treated by specialty physicians who are the current focus of our sales deployment

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

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Successful Development of XHANCE as a Treatment for Chronic Sinusitis Would Increase Opportunity and Address Certain Barriers to Broader Prescribing that Exist Today

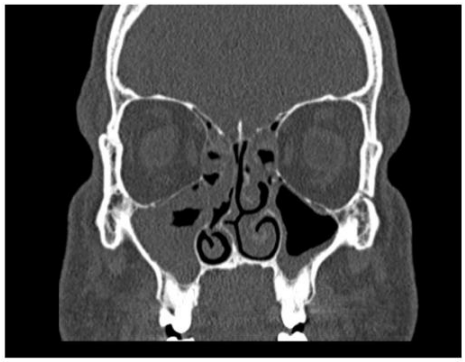
Insurance

- Today, **~80%** of commercial lives are in plans that cover XHANCE, but **~half** require physicians to attest that they are prescribing for the approved indication
- This is important because chronic sinusitis (CS) is diagnosed much more frequently than nasal polyps (NP)
- **~10 million** patients diagnosed with CS/NP are actively treated by physicians compared to **~1 million** with NP

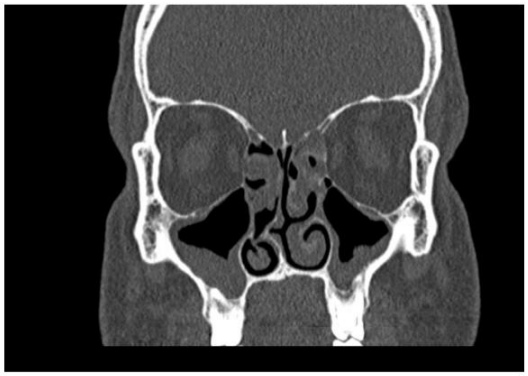
Objective evidence from large RCT of effect on inflammation deep inside the sinuses would be available for XHANCE for the first time

Representative APOV Improvement in ReOpen1 in Patient Treated with XHANCE 186 µg BID

Baseline



Week 24



6.4% Improvement

Images reflect individual results and results and may not be representative of results generally.

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Key Takeaways and Q4 2021 Highlights

Consistent Commercial Execution Driving Q4 2021 Growth

FY 2022 Revenue Guidance Implies Y/Y Growth of at least 22%

Positive Top-Line Results from ReOpen1 Reported in 1Q2022

Top-Line Data from ReOpen2 Expected in Q2 2022

+44%
XHANCE Net Revenue Growth Q4 2021/Q4 2020

$111M
Cash and equivalents as of December 31, 2021

+27%
XHANCE TRx Growth Q4 2021/Q4 2020

$240
XHANCE Net Revenue per TRx in Q4 2021

+21%
XHANCE NRx Growth Q4 2021/Q4 2020

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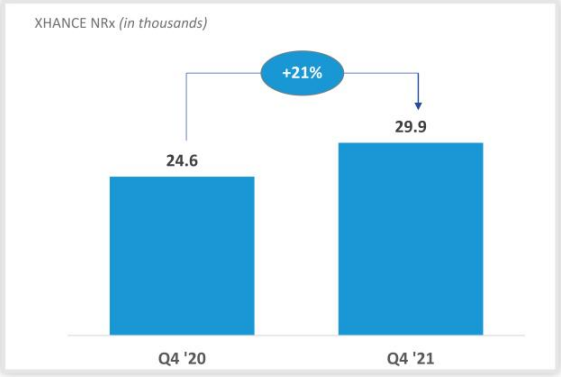
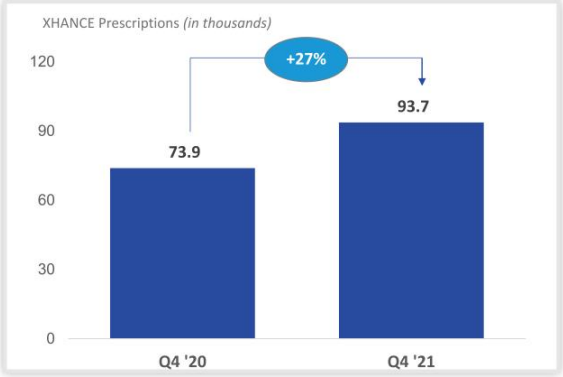
XHANCE New and Total Prescriptions

XHANCE New Prescriptions increased 21% and Total Prescriptions increased 27% from Q4 2020 to Q4 2021





NRx for Intranasal Steroids Market increased 14% from Q4 2020 to Q4 2021 and TRx for Intranasal Steroids Market increased 6% from Q4 2020 to Q4 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

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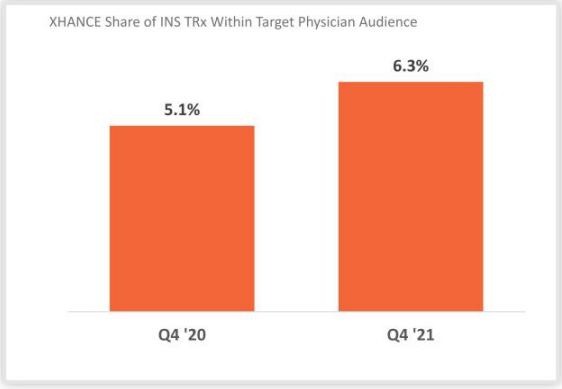
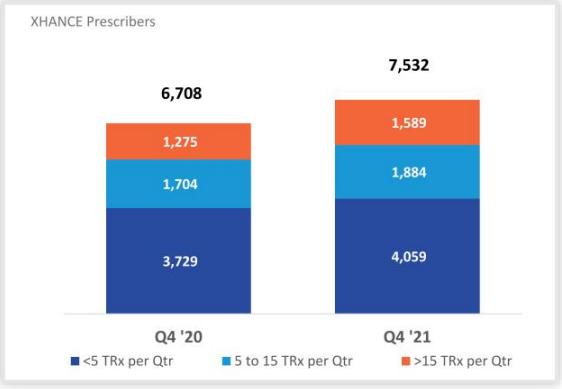
XHANCE Market Share & Prescribers by Prescribing Frequency

XHANCE market share increased from 5.1% to 6.3% and HCPs who had more than 15 XHANCE prescriptions filled by their patients in a quarter increased by 25% (1,589 versus 1,275) from Q4 2020 to Q4 2021





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.

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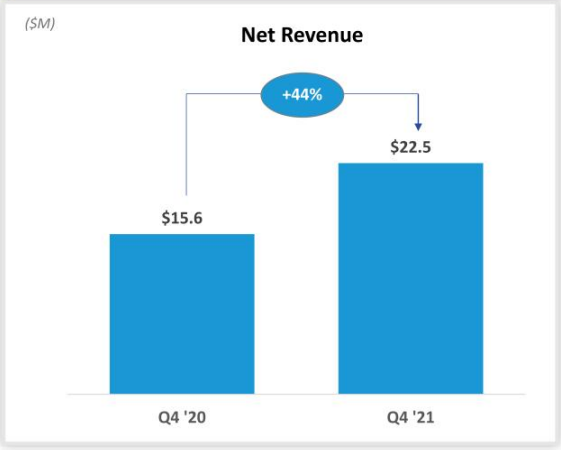
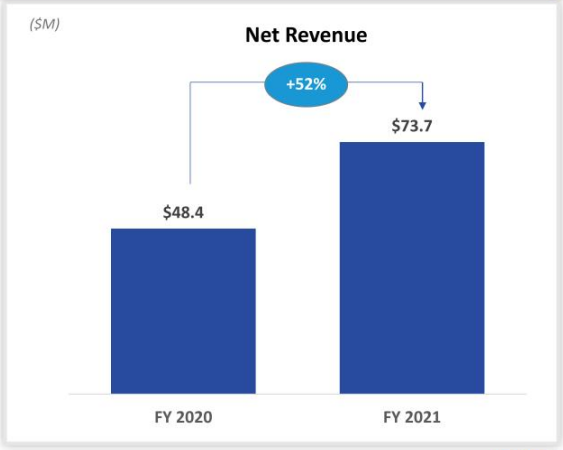
Q4 and Full Year 2021 Financial Update

Financial Review – XHANCE Net Revenue

XHANCE Net Revenue Increased 44% from Q4 2020 to Q4 2021 and 52% for Full Year 2021





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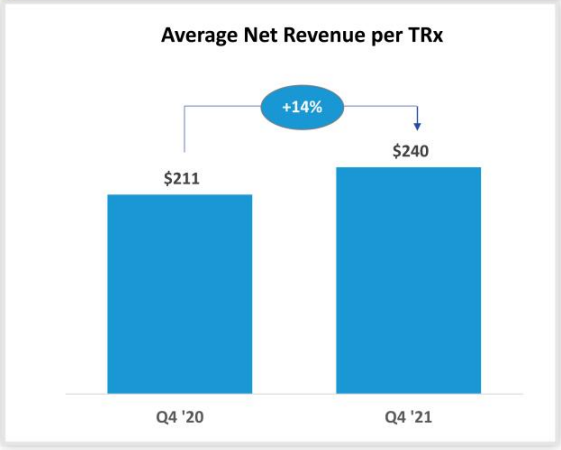
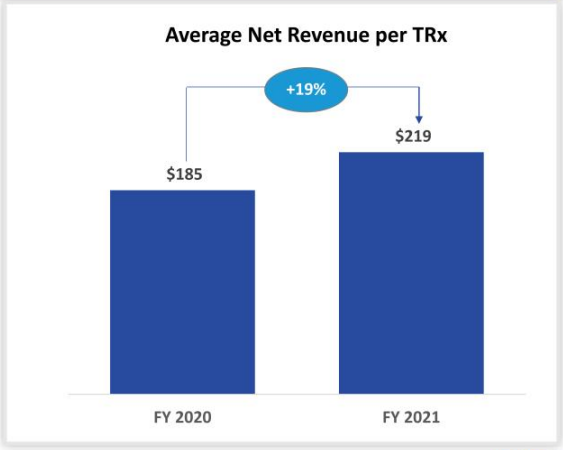
Financial Review – XHANCE Average Net Revenue per Prescription

XHANCE Average Net Revenue per TRx Increased from $211 to $240 from Q4 2020 to Q4 2021 and from $185 to $219 for Full Year 2021





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Full Year 2022 Financial Guidance

- **XHANCE Net Revenue**
  - Expected to be at least $90 million
- **XHANCE Average Net Revenue per Prescription**
  - FY 2022 expected to exceed $210
  - Q1 2022 expected
- **Operating Expense (GAAP)**
  - Expected to be between $135 – $140 million; approximately $10 million of which represents stock-based compensation

Additional Phase 3b Clinical Trial Data Expected in Q2 2022

Recruitment Completed July 2021

Top-line results expected in Q1 2022

Recruitment Completed October 2021

Top-line results expected in Q2 2022

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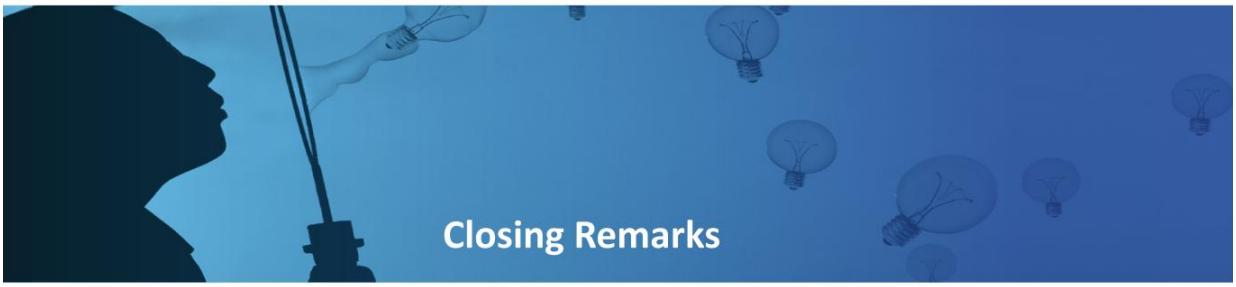

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$240
XHANCE Net Revenue per TRx in Q4 2021

+21%
XHANCE NRx Growth Q4 2021/Q4 2020

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Investor Relations – NASDAQ: OPTN

Analyst Coverage [1]
BMO: Gary Nachman
Cantor Fitzgerald: Brandon Folkes
Cowen: Ken Cacciatore
Jefferies: David Steinberg
Piper Sandler: David Amsellem

At 31 December 2021:

- **$111 million** in cash
- Long-term debt: **$130 million**
- **82.2 million** common shares o/s
- **12.4 million** options, warrants & RSUs o/s

Optinose Investor Contact

Jonathan Neely,
VP, Investor Relations and Business Development
267-521-0531
Investors@optinose.com

 investors@optinose.com  www.optinose.com  @optinose

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.

optinose®

Building a Leading ENT / Allergy Specialty Company

Corporate Presentation

March 8, 2022