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 3, 2021

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 3, 2021, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the year ended December 31, 2020. 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 3, 2021, the Company presented an updated Corporate Presentation during its financial results and corporate update 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 3, 2021.
99.2	OptiNose, Inc. Corporate Presentation, dated March 3, 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:March 3, 2021

Optinose Reports Fourth Quarter and Full Year 2020 Financial Results and Recent Operational Highlights

Company reports fourth quarter and full year 2020 XHANCE net revenue of $15.6 million and $48.4 million

Full year 2020 XHANCE prescriptions increased 70% compared to full year 2019

Company expects XHANCE net revenue for 2021 to be at least $80 million

Company expects top-line results from one of its clinical trials evaluating XHANCE as a potential treatment for Chronic Sinusitis by the end of 2021

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

YARDLEY, Pa., March 3, 2021 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, 2020, and provided recent operational highlights.

"I am proud of how the team at Optinose responded to the market disruptions created by the global pandemic, enabling us to deliver 70% year-over-year growth of prescriptions for XHANCE," stated CEO Peter Miller. "As a launch-stage product, new patient starts are a critical driver of future success. Following pandemic-related disruption in second quarter, we achieved consecutive all-time highs for new prescriptions of XHANCE in third and fourth quarter 2020. Looking ahead, we believe we expect sustained or increased XHANCE growth in 2021. Our expectations for first quarter 2021 include typical early-year effects on price and volume related to patient insurance that we believe are common for chronic treatments that derive a significant proportion of total prescriptions from refills, and for full year 2021 we expect XHANCE net revenue to be at least $80 million."

Fourth Quarter 2020 and Recent Highlights

Total and New XHANCE Prescriptions

The number of XHANCE® (fluticasone propionate) prescriptions increased by 36% from 54,300 in the fourth quarter 2019 to 73,900 in the fourth quarter 2020. In addition, XHANCE prescriptions increased by 70% from 153,700 for the full year of 2019 to 261,400 for the full year of 2020.

The number of new prescriptions for XHANCE increased by 16% from 21,200 in the fourth quarter of 2019 to 24,600 in the fourth quarter of 2020. In addition, new prescriptions for XHANCE increased by 31% from 67,400 for the full year of 2019 to 88,600 for the full year of 2020.

OPN-019

In June 2020, the Company announced the initiation of development of a new product candidate, OPN-019, which combines its proprietary intranasal Exhalation Delivery System (EDS) with an antiseptic.

Because components of the drug-device combination product candidate, including both the active drug and delivery device, are currently commercially available in the U.S., the Company anticipates a potential streamlined and accelerated development. Subsequent to a pre-Investigational New Drug (IND) submission the Company is engaged with FDA regarding an IND and clinical development pathway.

The Company has performed *in vitro* testing against SARS-CoV-2 with a candidate formulation in which a 4-log reduction (a 99.99% reduction) in virus count was produced. In addition, the Company performed tests against other pathogens. For most pathogens tested, 3-log to 6-log reductions (99.9% to 99.9999% reductions) in virus count were observed.

In April 2021, the Company expects to initiate a randomized, proof of concept study in subjects who have tested positive for SARS-CoV-2 infection, are recently infected, and who have mild or no symptoms. This pilot study being conducted in Mexico will evaluate both the magnitude and duration of viral load reduction after a single dose of OPN-019. The Company expects top-line results from this study in second quarter 2021.

The Company is focused on supporting the initial stages of development within our current operating expense guidance and intend to seek grants, partnerships, and/or other sources of capital to fund future development.

Fourth Quarter 2020 Financial Results

Revenue
The Company generated $15.6 million and $48.4 million of XHANCE net revenue during the three-month and twelve-month periods ended December 31, 2020, respectively. In addition, the Company generated $0.8 million of licensing revenue during the three and twelve-month periods ended December 31, 2020. Total revenues for the three and twelve-month periods ended December 31, 2020 were $16.4 million and $49.2 million.

Expenses and net loss
For the three-month and twelve-month periods ended December 31, 2020, research and development expenses were $6.4 million and $23.4 million, respectively. Selling, general and administrative expenses were $28.1 million and $105.4 million during the three-month and twelve-month periods ended December 31, 2020, respectively. The net loss for the three-month period ended December 31, 2020 was $23.9 million, or $0.46 per share (basic and diluted). The net loss for the twelve-month period ended December 31, 2020 was $99.8 million, or $2.07 per share (basic and diluted).

Cash
The Company had cash and cash equivalents of $144.2 million as of December 31, 2020. In December 2020, the Company received $20 million of cash following the issuance of the Third Delayed Draw Notes under its existing Note Purchase Agreement with Pharmakon. The $20 million of cash is included in the Company's cash balance of $144.2 million as of December 31, 2020.

Corporate Guidance

XHANCE Net Revenue and Average Net Revenue per Prescription
The Company expects XHANCE net revenues for the full year of 2020 to be at least $80 million. This includes the Company's expectation that first quarter 2021 XHANCE net revenue will decrease compared to fourth quarter 2020. 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 2021 will be between $120 and $140, 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 improve substantially for the remainder of 2021. In addition, the Company expects full year 2021 XHANCE net revenue per prescription to increase compared to full year 2020 XHANCE net revenue per prescription of $185.

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 $137 - $142 million, of which the Company expects stock-based compensation to be approximately $11 million.

Chronic Sinusitis Clinical Trials
The Company expects top-line results from one of its clinical trials evaluating XHANCE as a potential treatment for Chronic Sinusitis by the end of 2021 and the other in the first half of 2022. Pauses in patient enrollment, due to the COVID-19 pandemic, at some clinical trial sites changed the Company's prior expectation of top-line results from both trials in the second half of 2021.

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 10, 2021 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID: 9833299.

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,	
	2020	2019	2020	2019
Revenues:				
Net product revenues	$ 15,597	$ 11,081	$ 48,367	$ 30,401
Licensing revenues	750	—	750	4,230
Total revenues	16,347	11,081	49,117	34,631
Costs and expenses:				
Cost of product sales	2,244	2,078	7,520	5,294
Research and development	6,448	5,379	23,378	20,783
Selling, general and administrative	28,107	26,545	105,438	104,155
Total costs and expenses	36,799	34,002	136,336	130,232
Loss from operations	(20,452)	(22,921)	(87,219)	(95,601)
Other expense	3,412	2,075	12,567	14,452
Net loss	$ (23,864)	$ (24,996)	$ (99,786)	$ (110,053)
Net loss per share of common stock, basic and diluted	$ (0.46)	$ (0.58)	$ (2.07)	$ (2.63)
Weighted average common shares outstanding, basic and diluted	52,327,655	43,467,985	48,275,230	41,877,527

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

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 144,156	$ 147,144
Other assets	44,657	25,506
Total assets	$ 188,813	$ 172,650
Total current liabilities	52,172	$ 36,139
Long-term debt, net	125,202	74,531
Other liabilities	4,651	397
Total stockholders' equity	6,788	61,583
Total liabilities and stockholders' equity	$ 188,813	$ 172,650

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 or increased XHANCE prescription and net revenue growth and potential growth drivers; early year effects on price and volume related to patient insurance; 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 one of its chronic sinusitis trials by the end of 2021 and the other in the first half of 2022; projected average net revenue per prescription for first quarter and full year 2021; projected XHANCE net revenue for first quarter and full year 2021; projected Company GAAP operating expenses and stock-based compensation for 2021; 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, 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; the Company’s ability to maintain adequate third-party reimbursement for XHANCE (market access); market opportunities for XHANCE may be smaller than expected; the Company’s ability to grow XHANCE prescriptions and net revenues; uncertainties and delays relating to the enrollment, completion, and results of clinical trials; unanticipated costs and expenses; our 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

Corporate Presentation

March 3, 2021

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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; early year effects on net revenue and prescriptions related to patient insurance; projected Company GAAP operating expenses and stock-based compensation for 2021; projected XHANCE net revenues for full year and first quarter 2021; projected XHANCE net revenue per prescription for the first quarter and 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; the expectation of top-line results from at least one chronic sinusitis trial by the end of 2021 and from the second trial in the first half 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 numbe 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 satisfy the conditions for an additional draw under the Pharmakon note purchase agreement and its ability to comply with the covenants and other terms o the 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.

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Full Year 2020 Highlights

+59%

XHANCE Net Revenue Growth FY 2020/FY 2019

+70%

XHANCE Prescriptions Growth FY 2020/FY 2019

+31%

XHANCE New Prescriptions Growth FY 2020/FY 2019

$129M

Full Year 2020 Operating Expenses (SG&A plus R&D)

Key Takeaways and Q4 2020 Highlights

Largest Number of XHANCE New Prescriptions Since Launch

Full Year 2020 Performance Aligned with Company Guidance

Providing Initial Company Guidance for Q1 and Full Year 2021

Multiple factors support increased revenue growth in 2021

Topline data from one CS trial expected by the end of 2021

+41%

XHANCE Net Revenue Growth Q4 2020/Q4 2019

$144M

Cash and equivalents as of December 31, 2020

+36%

XHANCE TRx Growth Q4 2020/Q4 2019

$211

XHANCE Net Revenue per TRx in Q4 2020

+16

XHANCI NRx Grow Q4 2020/Q4

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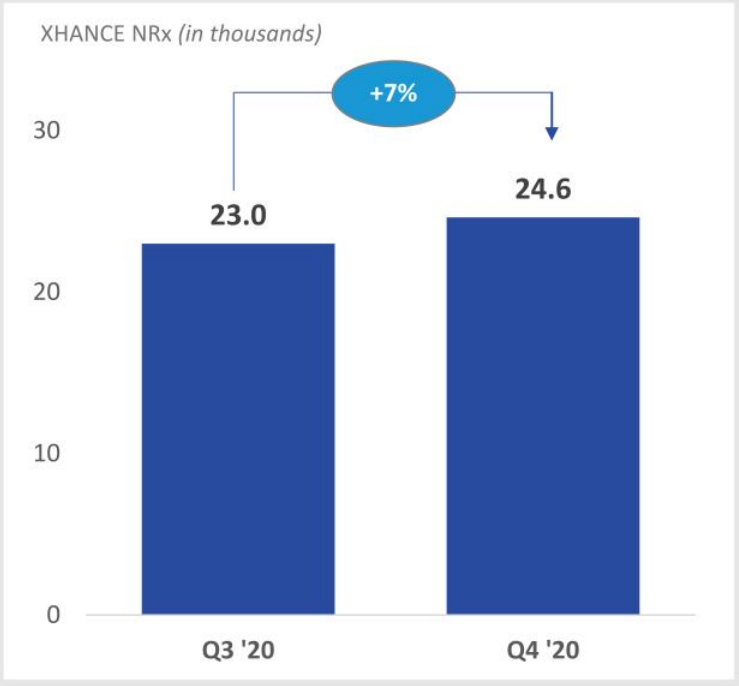
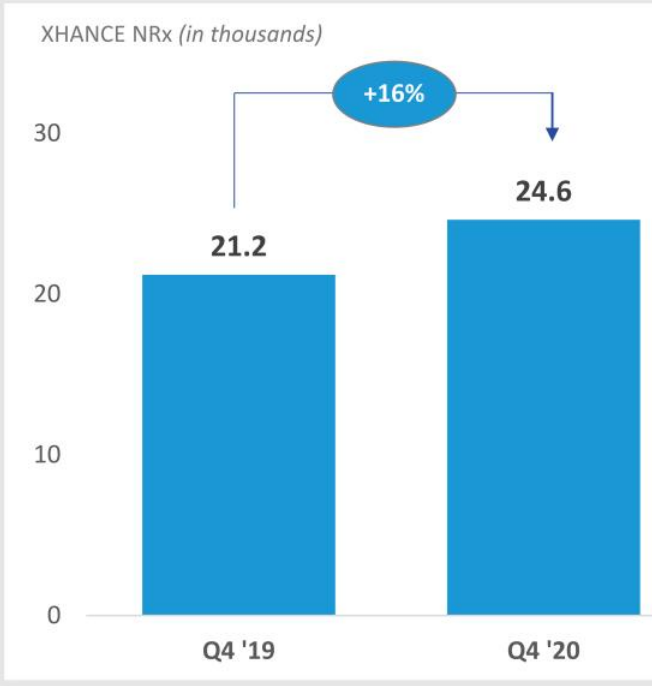
XHANCE Launch Update

Q4 2020 XHANCE New Prescriptions

New prescriptions of XHANCE increased 7% in Q4 2020 compared to Q3 2020 and increased 16% in Q4 2020 compared to Q4 2019



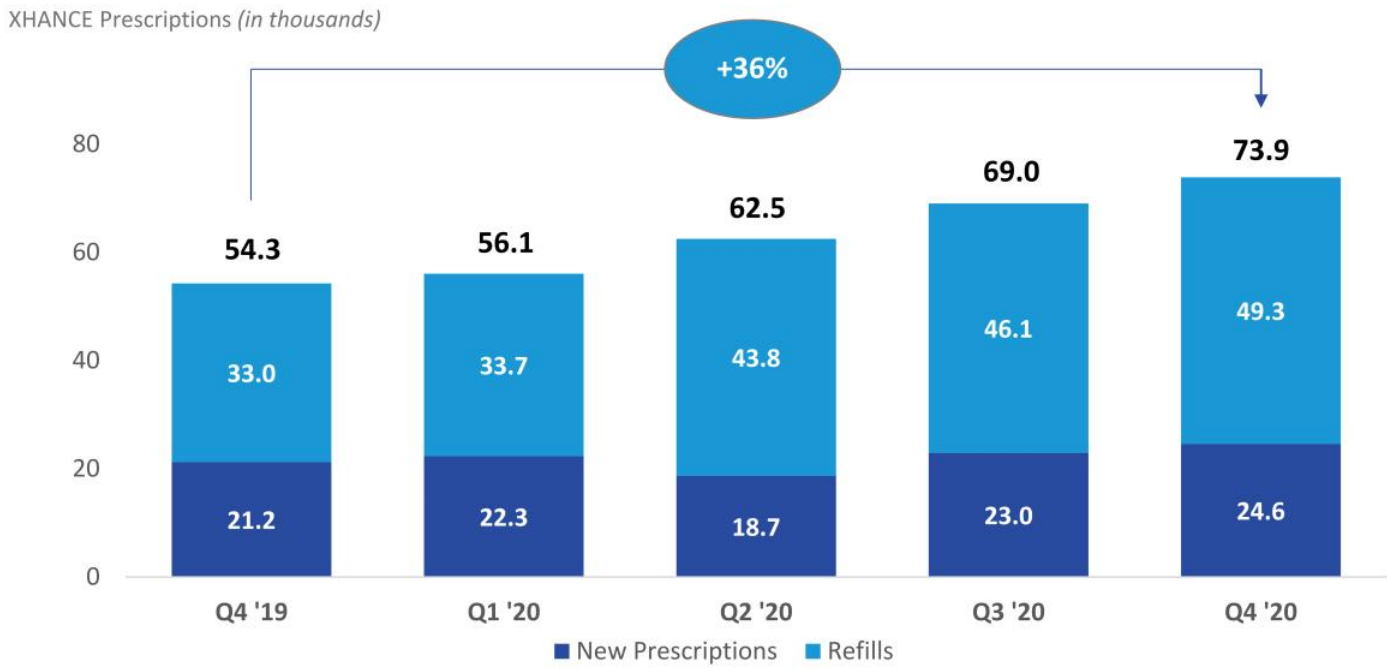


NRx for Intranasal Steroids Market increased 5% from Q3 2020 to Q4 2020, and decreased 21% from Q4 2019 to Q4 2020

Estimated based on monthly prescription data from public source and XHANCE preferred pharmacy network.

XHANCE Prescription Trends

Prescriptions of XHANCE increased 36% in Q4 2020 compared to Q4 2019

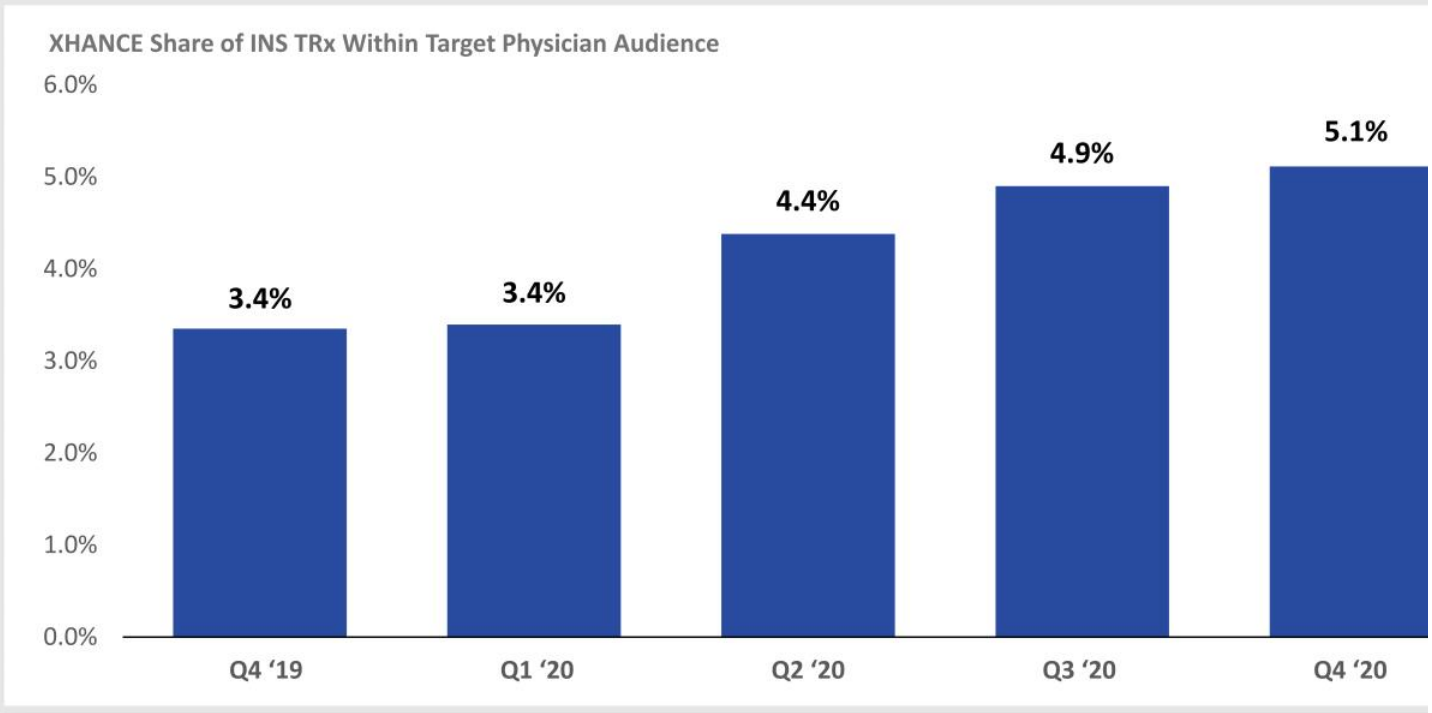


TRx for Intranasal Steroids Market increased 2% from Q3 2020 to Q4 2020, and decreased 13% from Q4 2019 to Q4 2020

Estimated based on monthly prescription data from public source and XHANCE preferred pharmacy network.

XHANCE Share of INS Prescriptions Within the Target Physician Audience Increased in Q4 2020 and a Large Opportunity Remains

New for 2021 - we increased the size of our target physician audience from ~10,000 to ~18,0 to include all ENT and Allergy physicians who prescribe INS and to reflect expanded in-perso reach following the launch of the kaléo co-promotion

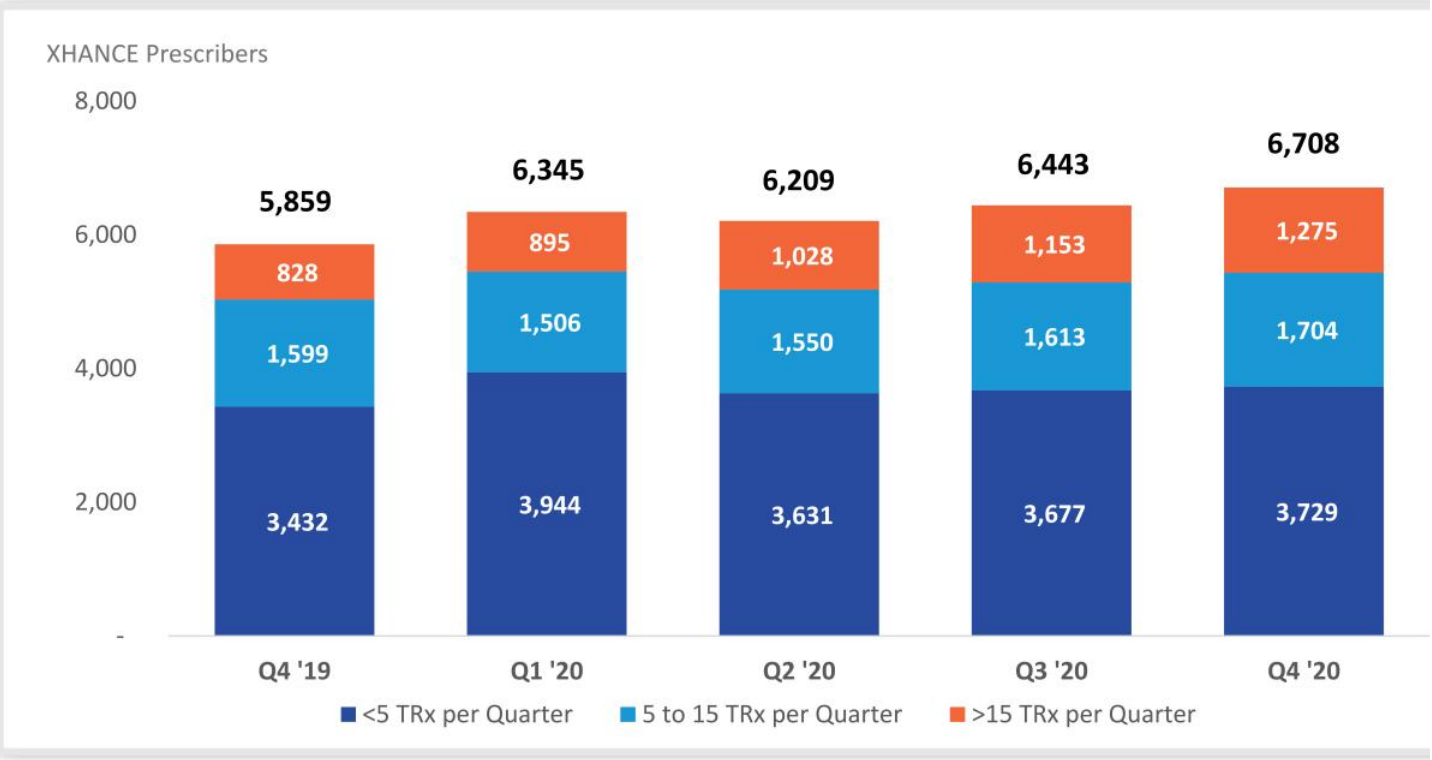


The Market on this slide is defined as the sum of all intranasal steroid prescriptions written by physicians in the XHANCE target physician audience of approximately 18,000 physicians.

Estimated based on monthly prescription data from third parties and XHANCE preferred pharmacy network.

Number of XHANCE Prescribers by Prescribing Frequency

Physicians who had more than 15 XHANCE prescriptions filled by their patients in a quarter increased by 54% from Q4 2019 to Q4 2020 (1,275 versus 828)



Estimated based on monthly prescription data from third parties and XHANCE preferred pharmacy network.

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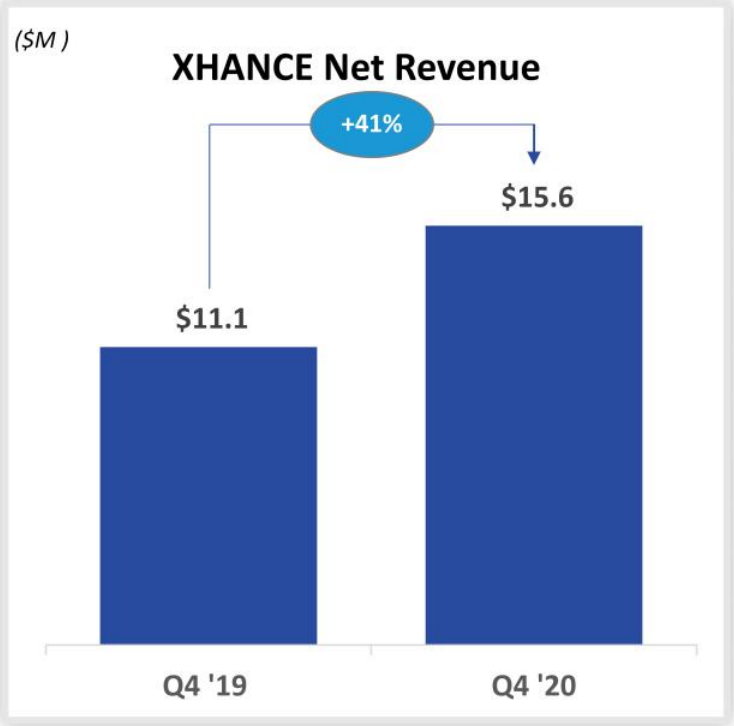
Financial Review – Fourth Quarter 2020

Q4 2020 XHANCE Net Revenue Increased 41% Compared to Q4 2020

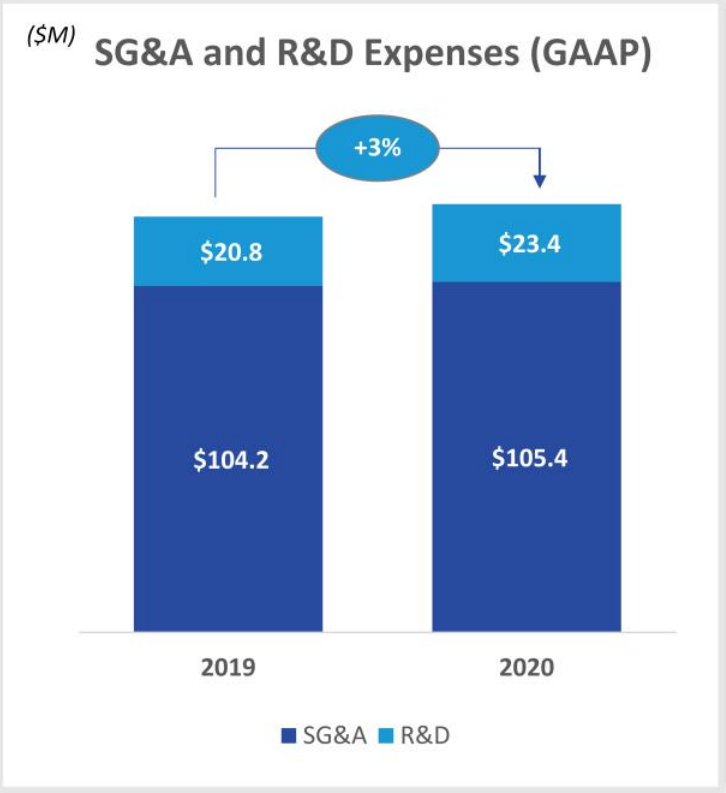


XHANCE Average Net Revenue per TRx

- $211 in Q4 2020
  - $204 in Q4 2019
- $185 for full year 2020
  - $198 for full year 2019

FY 2020 Operating Expenses

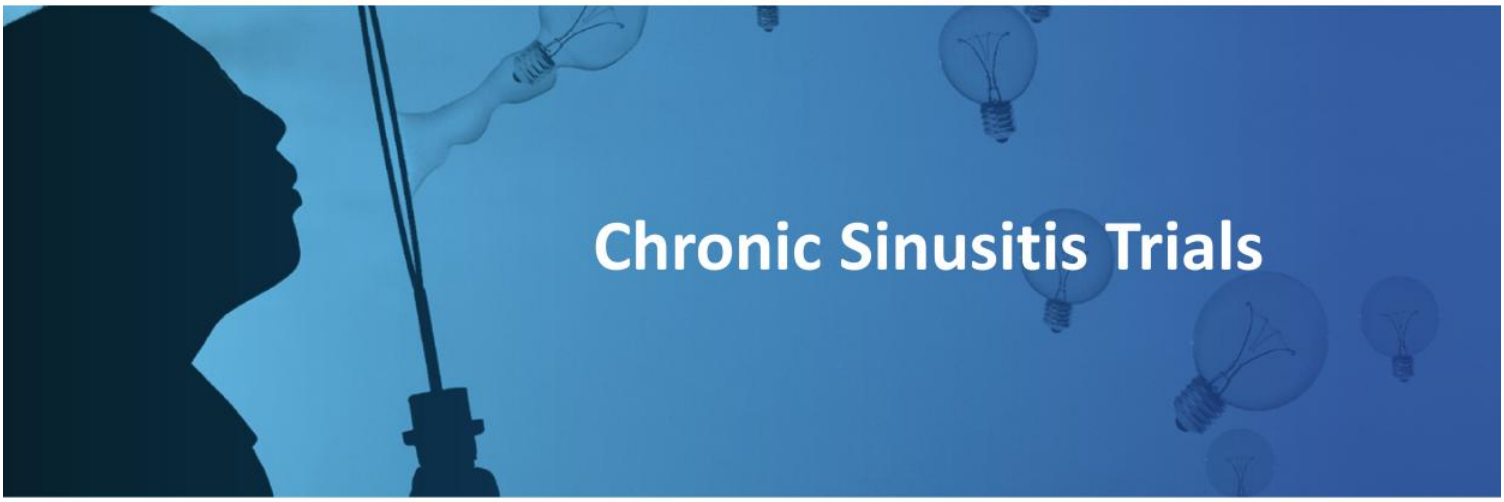
FY 2020 Operating Expenses (SG&A plus R&D) increased 3% compared to FY 201



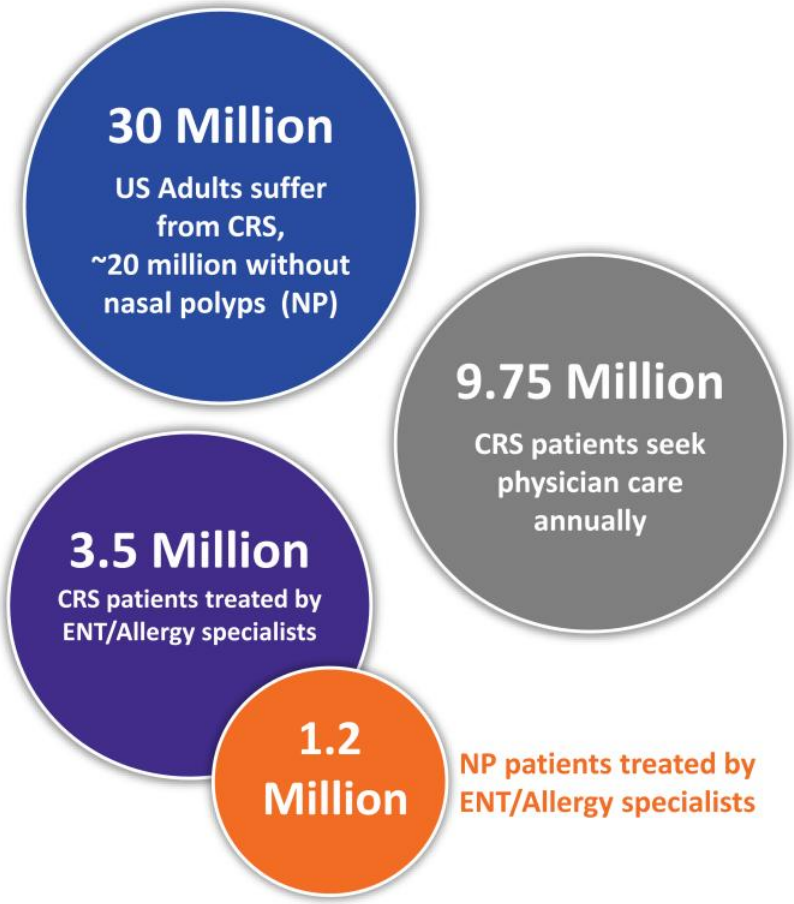
- **FY 2020 R&D increased 12% compared to FY 2019**
  - Driven by the conduct of ou CS clinical trials
- **FY 2020 SG&A increased 1% compared to FY 2019**
  - Increased volume related expenses offset by expense reductions in response to th COVID-19 pandemic

First Quarter and Full Year 2021 Financial Guidance

- **XHANCE Net Revenue**
  - **FY 2021** expected to be at least $80 million
  - **1Q 2021** expected to decrease compared to Q4 2020 similar to the pattern of calendar effect on XHANCE net revenue reported last year
    - **Q1 2021** XHANCE net revenue per prescription is expected to be between $120 - $140
  - XHANCE net revenue per prescription expected to improve substantially for the remainder of 2021
    - **Full year 2021** XHANCE Net Revenue per Prescription expected to increase compared to full year 2020
- **Operating Expense (GAAP) expected to be between $137 – $142 million**
  - Approximately $11 million of which represents stock-based compensation


Chronic Sinusitis Trials

Chronic Sinusitis (CS) is a Large Market for XHANCE that Includ Opportunities for Potential Partners

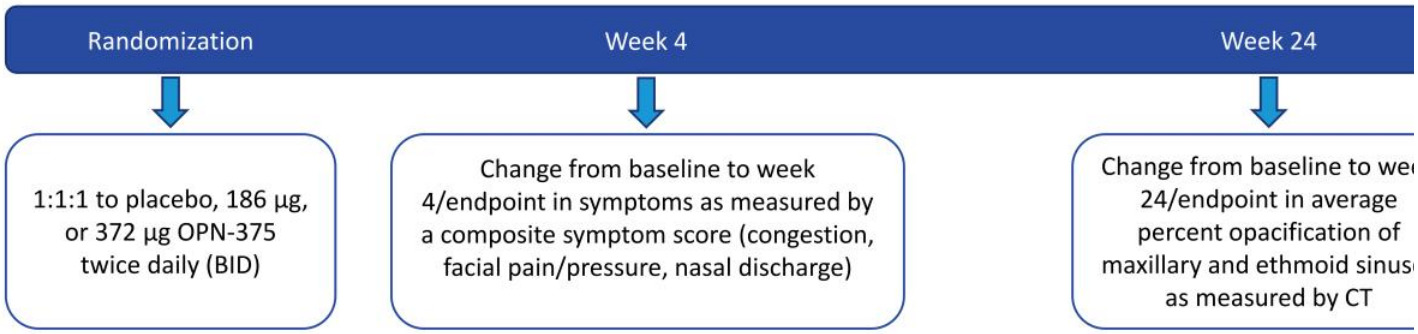


- Our commercialization of XHANCE is currently focused ENT and Allergy specialists w treat ~3.5 million CRS patient which includes ~1.2 million patients who have nasal poly
- Successful development of XHANCE as the first FDA approved treatment for chro sinusitis could support our commercial efforts and also create opportunities outside ENT and Allergy to more fully address the needs of ~30 mil US adults who have CRS

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.

XHANCE Chronic Sinusitis Indication (sNDA)

- The Chronic Sinusitis clinical research program includes two Phase 3b clinical trials
- Both trials are 24-week randomized, double-blind, placebo-controlled, parallel-group, multicenter studies
- Both trials have co-primary endpoints: 1) a measure of patient-reported symptom relief and 2) a measure of effect inside the sinus cavities



Top-line results are expected from one trial by the end of 2021

OPN-019 Pilot Study

- Human *in vivo* data will supplement *in vitro* data
  - Prior *in vitro* testing against SARS-CoV-2 with a candidate formulatic produced a 4-log reduction in virus count
- Randomized, adaptive proof of concept single-dose study to evaluate change in viral load after OPN-019 in adults with COVID-19
- Assessments will include reduction in viral load by qRT-PCR and in number of infectious viral particles by culture
- Up to three cohorts of 10 patients are planned
- Top line results expected within second quarter 2021

- We intend to support initial stages of development for OPN-019 within current operating expense guidance
- Grants, partnerships, and/or other sources of capital will be necessary to fund future development


Closing Remarks

Key Takeaways and Q4 2020 Highlights

Largest Number of XHANCE New Prescriptions Since Launch

Full Year 2020 Performance Aligned with Company Guidance

Providing Initial Company Guidance for Q1 and Full Year 2021

Multiple factors support increased revenue growth in 2021

Topline data from one CS trial expected by the end of 2021

+41%
XHANCE Net Revenue Growth Q4 2020/Q4 2019

$144M
Cash and equivalents as of December 31, 2020

+36%
XHANCE TRx Growth Q4 2020/Q4 2019

$211
XHANCE Net Revenue per TRx in Q4 2020

+16
XHANCI NRx Grow Q4 2020/Q4

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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
RBC: Randall Stanicky

At 31 December 2020:

- **$144 million** in cash
- Long-term debt: **$130 million**
- **52.9 million** common shares o/s
- **9.2 million** options, warrants & RSUs o/

Optinose Investor Contact

Jonathan Neely, VP, Investor Relations and Business Operations
267-521-0531


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 the
are theirs alone and do not represent opinions, forecasts or predictions of Optinose or its management. Optinose does not by its reference above or distri
imply its endorsement of or concurrence with such information, conclusions or recommendations.

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Corporate Presentation

March 3, 2021

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