

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 5, 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 2.02 Results of Operations and Financial Condition.

On May 5, 2021, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 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 May 5, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by OptiNose, Inc., dated May 5, 2021.
99.2	OptiNose, Inc. Corporate Presentation, dated May 5, 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 5, 2020



**Optinose Reports First Quarter 2021 Financial Results
and Operational Updates**

Company reports first quarter total revenue of \$12.0 million

First quarter 2021 XHANCE net revenue of \$11.0 million increased 55% compared to first quarter 2020

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

YARDLEY, Pa., May 5, 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 ended March 31, 2021, and provided operational updates.

"XHANCE net revenues increased 55% in the first quarter of 2021 compared to first quarter 2020," stated CEO Peter Miller. "We believe this is strong growth, particularly in the context of the continuing impact of the COVID-19 pandemic on the number of patients visiting physician offices and pandemic-related restrictions that continue to limit in-person detailing of physician offices by our territory managers. Improvement to the business environment is just one factor that we believe will support XHANCE growth in the remainder of 2021. XHANCE growth and the completion of our clinical trials evaluating it for treatment of chronic sinusitis are the two most important objectives for our company right now and we are focused on achieving those as a team."

First Quarter 2021 and Recent Highlights

Total and New XHANCE Prescriptions

The number of XHANCE® (fluticasone propionate) prescriptions increased by 30% from 56,100 in the first quarter 2020 to 72,600 in the first quarter 2021.

The number of new prescriptions for XHANCE increased by 16% from 22,300 in the first quarter of 2020 to 25,900 in the first quarter of 2021.

First Quarter 2021 Financial Results

Total revenues

The Company generated \$11.0 million in net product revenues from sales of XHANCE during the three-month period ended March 31, 2021. In addition, the Company generated \$1.0 million of licensing revenue during the three-month period ended March 31, 2021. Total revenue for the three-month period ended March 31, 2021 was \$12.0 million.

Costs and expenses and net loss

For the three-month period ended March 31, 2021, research and development expenses were \$5.2 million and selling, general and administrative expenses were \$27.2 million. The net loss for the period was \$26.1 million, or \$0.49 per share (basic and diluted).

Cash

The Company had cash and cash equivalents of \$116.0 million as of March 31, 2021.

Corporate Guidance

XHANCE Net Revenue and Average Net Revenue per Prescription

The Company expects XHANCE net revenues for the full year of 2021 to be at least \$80 million. 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 \$10 million.

Chronic Sinusitis Clinical Trials

The Company now expects to complete enrollment in the first of its clinical trials evaluating XHANCE as a potential treatment for Chronic Sinusitis in third quarter 2021 with top line results in first quarter 2022. The Company expects top line results from the other trial in the first half of 2022.

OPN-019

In March 2021, the Company announced its plan to conduct 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 will evaluate both the magnitude and duration of viral load reduction after a single dose of OPN-019. Regulatory approval to initiate the pilot study is pending. The Company expects top-line results from this study in second quarter 2021.

The Company is focused on supporting the initial stages of OPN-019 development within its current operating expense guidance and intends to seek grants, partnerships, and/or other sources of capital to fund future development.

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 May 12, 2021 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID #5283136. 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	
	2021	2020
Revenues:		
Net product revenues	\$ 10,960	\$ 7,062
Licensing revenues	\$ 1,000	—
Total revenues	<u>11,960</u>	<u>7,062</u>
Costs and expenses:		
Cost of product sales	1,740	1,356
Research and development	5,225	4,932
Selling, general and administrative	27,184	27,060
Total costs and expenses	<u>34,149</u>	<u>33,348</u>
Loss from operations	<u>(22,189)</u>	<u>(26,286)</u>
Other expense	3,864	2,570
Net loss	<u>\$ (26,053)</u>	<u>\$ (28,856)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.49)</u>	<u>\$ (0.63)</u>
Weighted average common shares outstanding, basic and diluted	<u>52,997,730</u>	<u>45,906,162</u>

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

	March 31,	December 31,
	2021	2020
	(unaudited)	
Cash and cash equivalents	\$ 115,984	\$ 144,156
Other assets	41,962	44,657
Total assets	<u>\$ 157,946</u>	<u>\$ 188,813</u>
Total current liabilities	\$ 44,781	\$ 52,172
Long-term debt, net	125,584	125,202
Other liabilities	4,248	4,651
Total stockholders' equity	<u>(16,667)</u>	<u>6,788</u>
Total liabilities and stockholders' equity	<u>\$ 157,946</u>	<u>\$ 188,813</u>

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; 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 completing enrollment in the first of its chronic sinusitis trials in the third quarter of 2021 with top-line results in the first quarter of 2022 and top line results from the second trial in the first half of 2022; projected average net revenue per prescription for full year 2021; projected XHANCE net revenue for 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; 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 of the agreement; 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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Building a Leading ENT / Allergy Specialty Company

Corporate Presentation

May 5, 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; 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 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; the expectation of completing enrollment in one chronic sinusitis trial in third quarter 2021 with top-line results from that trial in first quarter 2022 and top line results 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 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 satisfy the conditions for an additional draw under the Pharmakon note purchase agreement and its ability to comply with the covenants and other terms of 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.

Key Takeaways and Q1 2021 Highlights



Q1 2021 Performance Aligned with Company Guidance

Largest Number of XHANCE New Prescriptions Since Launch

Multiple factors support continued revenue growth in 2021

Topline data from one CS trial expected in Q1 2022

+55%

XHANCE Net
Revenue Growth
Q1 2021/Q1 2020

\$116M

Cash and equivalents
as of March 31, 2021

+30%

XHANCE
TRx Growth
Q1 2021/Q1 2020

\$151

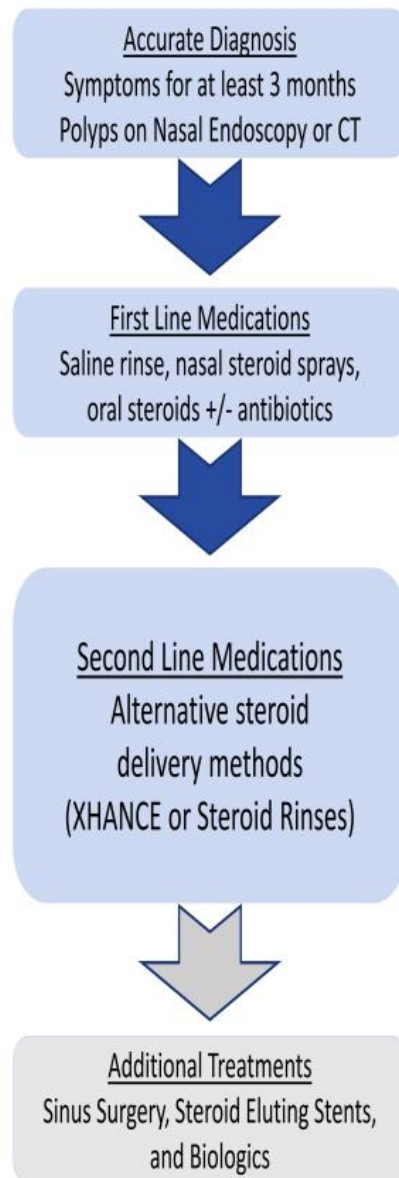
XHANCE Net Revenue
per TRx
in Q1 2021

+16%

XHANCE
NRx Growth
Q1 2021/Q1 2020

Emerging Consensus Identifies Treatment with XHANCE as Unique Step in Care for Patients with Nasal Polyps

- Recognition of XHANCE by physician experts as a step in between initial care with standard nasal steroid sprays and before escalation of care with surgery or biologic medicines has increased in recent months
- AAACI Shared Decision Tool and the American Rhinology Society's sinushealth.com

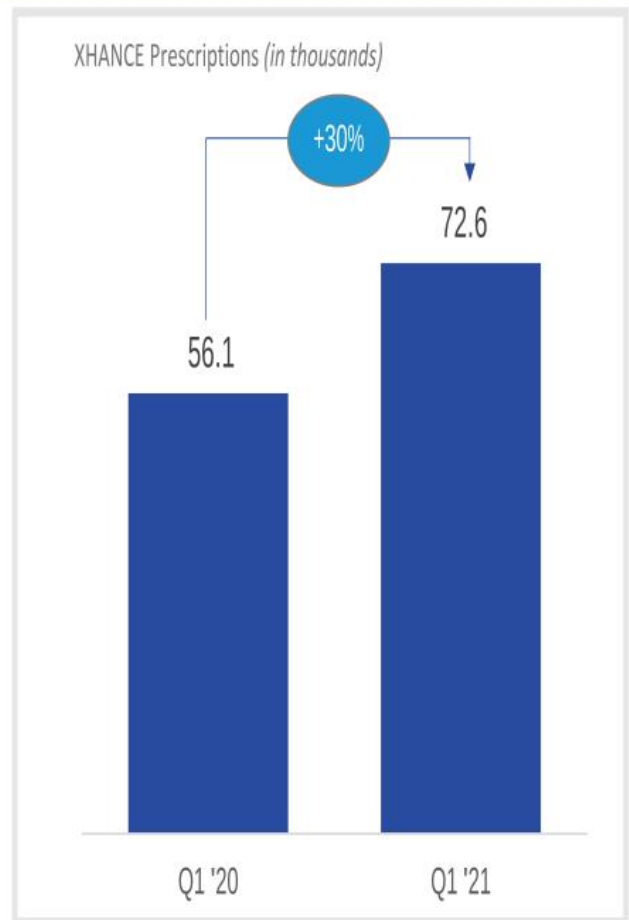
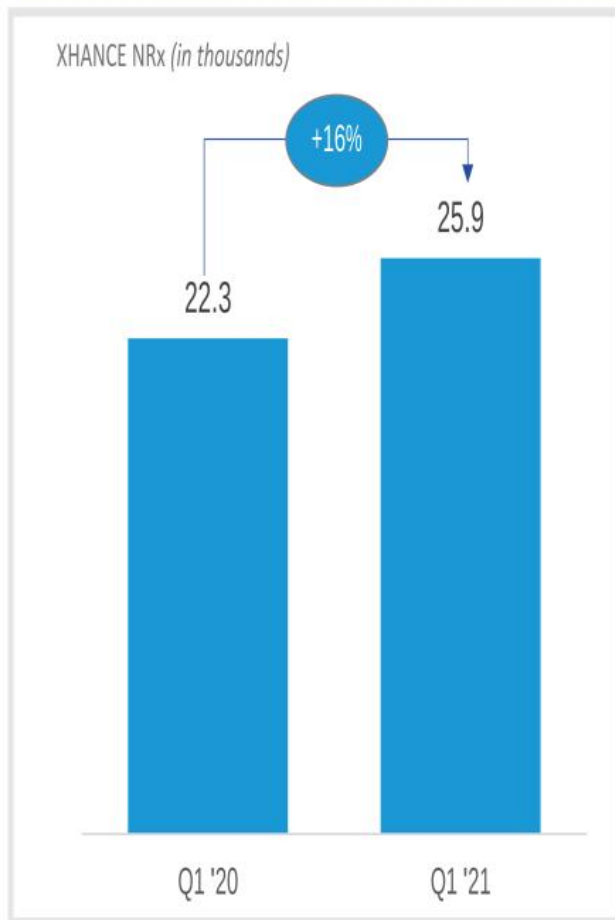


Flowchart based on information from: <https://sinushealth.com/conditions/treatment-of-nasal-polyyps/>

XHANCE Launch Update

XHANCE New and Total Prescriptions

XHANCE New Prescriptions increased 16% and Total Prescriptions increased 30% from Q1 2020 to Q1 2021



NRx for Intranasal Steroids Market decreased 30% from Q1 2020 to Q1 2021 and
TRx for Intranasal Steroids Market decreased 23% from Q1 2020 to Q1 2021

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

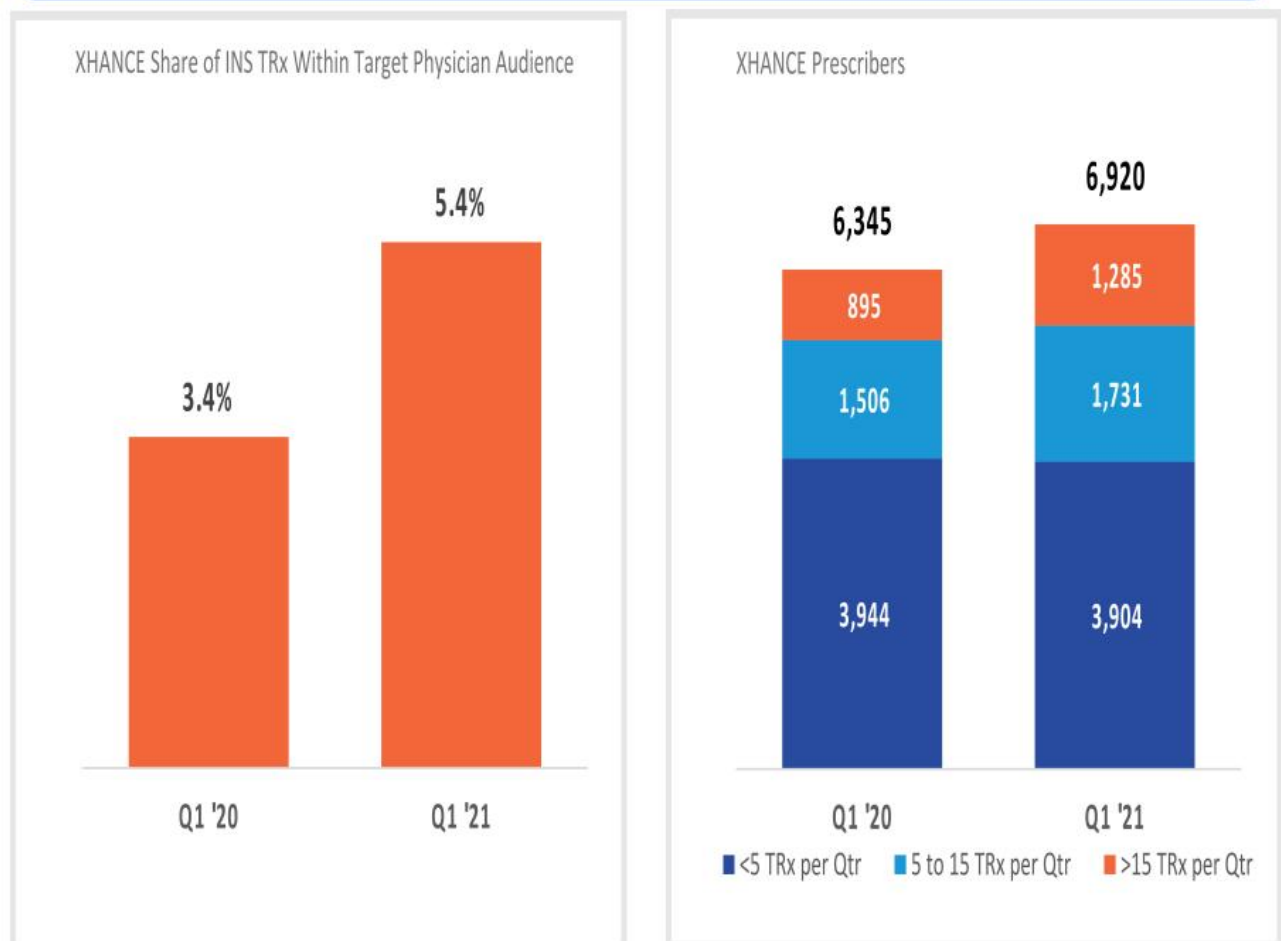
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The Market on this slide is defined as the sum of all intranasal steroid prescriptions based on monthly prescription data from third parties



XHANCE Market Share and Prescribers by Prescribing Frequency

XHANCE market share increased from 3.4% to 5.2% from Q1 2020 to Q1 2021 and Physicians who had more than 15 XHANCE prescriptions filled by their patients in a quarter increased by 44% from Q1 2020 to Q1 2021 (1,285 versus 895)

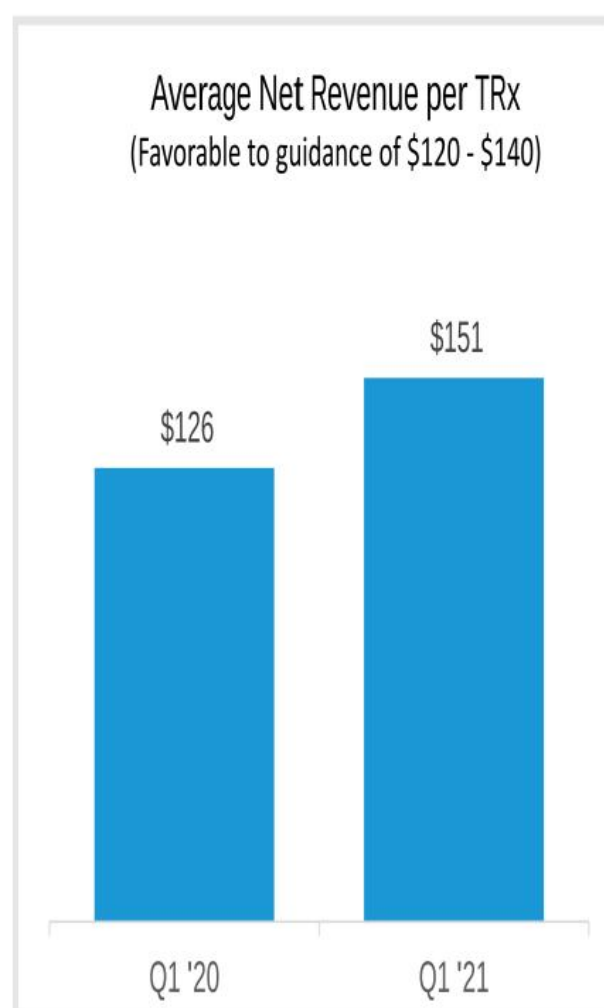


The Market on this slide is defined as the sum of all intranasal steroid prescriptions written by physicians in the XHANCE target physician audience of approximately 18,000 physicians. Estimated based on monthly prescription data from third parties and XHANCE preferred pharmacy network.

Q1 2021 Financial Update

Financial Review – First Quarter 2021

Q1 2021 XHANCE Net Revenue Increased 55% Compared to Q1 2020



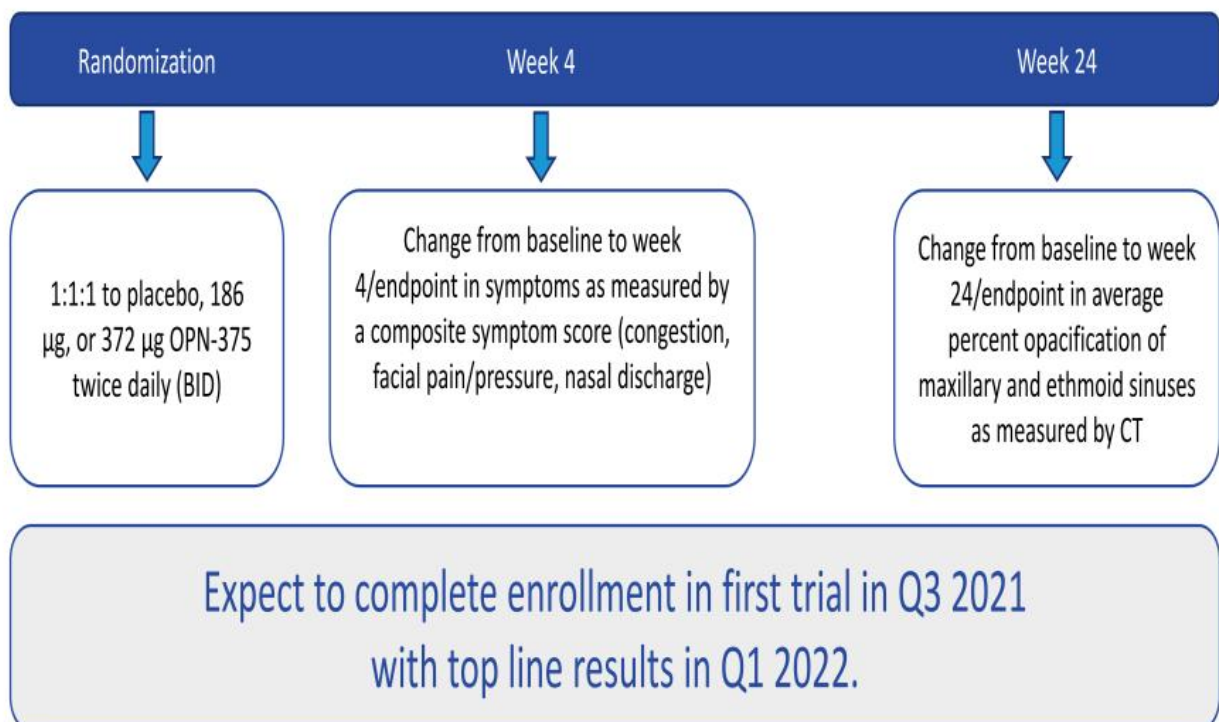
Full Year 2021 Financial Guidance

- **XHANCE Net Revenue and Average Net Revenue per Prescription**
 - **FY 2021** expected to be at least \$80 million
 - Average net revenue per prescription expected to improve substantially for the remainder of 2021 compared to \$151 in Q1 2021
 - **FY 2021** average net revenue per prescription expected to increase compared to full year 2020 of \$185
- **Operating Expense (GAAP) expected to be between \$137 – \$142 million**
 - Approximately \$10 million of which represents stock-based compensation

Pipeline Updates

XHANCE Chronic Sinusitis Indication (sNDA)

- In April 2021 we completed a blinded interim analysis (IA) to assess the variance in the symptom co-primary endpoint in trial -3205
 - The observed variance in the IA is lower than the variance assumed when sample size/power were estimated during the design of the study
 - Data on approximately half the projected enrollment for -3205 included in IA
 - Therefore, we do not plan to change sample size on the basis of this analysis
- We may elect to conduct a future IA of the CT scan co-primary endpoint



OPN-019 Pilot Study

- In March we announced a plan to conduct a 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
 - Regulatory approval to initiate the study is pending
- 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 Q1 2021 Highlights



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per TRx
in Q1 2021

+16%

XHANCE
NRx Growth
Q1 2021/Q1 2020

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: Daniel Busby

At 31 March 2021:

- \$116 million in cash
- Long-term debt: \$130 million
- 53.1 million common shares o/s
- 11.4 million options, warrants & RSUs o/s

Optinose Investor Contact

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Business Operations
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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.

Building a Leading ENT / Allergy Specialty Company

Corporate Presentation

May 5, 2021



