

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 7, 2020



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 7, 2020, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 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 May 7, 2020, 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 May 7, 2020.
99.2	OptiNose, Inc. Corporate Presentation, dated May 7, 2020.

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: May 7, 2020



**Optinose Reports First Quarter 2020 Financial Results
and Operational Updates**

Company reports first quarter 2020 XHANCE net revenue of \$7.1 million

First quarter 2020 XHANCE prescriptions increased 149% from first quarter 2019

Conference call and webcast to be held today at 4:15 p.m. Eastern Time

YARDLEY, Pa., May 7, 2020 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, 2020, and provided operational updates.

"Since March we have been aggressively adapting to the COVID-19 environment," stated CEO Peter Miller. "Keeping the safety of patients, of physicians and other customers, and of our employees top of mind, we moved rapidly to enable virtualization of commercial activities. We also identified ways to reduce operating expenses while sustaining our ability to continue to drive growth. While large COVID-19 related reductions in patient flow through physician offices negatively influence the entire new prescription market, we are pleased with the comparative resilience of XHANCE during this period. During the pandemic, while not meeting our pre-crisis expectations, XHANCE has shown an increase in prescription volume. We have specific plans to accelerate growth as the crisis begins to ease. As we emerge into an uncertain 're-opening' period, we will leverage the comparative strength of XHANCE during the worst of the 'shelter at home' period and work closely with our physician audiences to meet needs that we expect to vary by geography and time to help optimize patient care with XHANCE."

Business Updates in Response to the COVID-19 Pandemic

In March 2020, Optinose transitioned to full-time, virtual work environment in which all employees (including sales representatives) were encouraged to work from their place of residence if their job functions allowed. The company's decision was based on actions taken by federal, state and local governments to contain the spread of severe acute respiratory coronavirus 2 (SARS-CoV-2) and the related Coronavirus Disease 2019 (COVID-19), as well as the impact of "social distancing" efforts and various mitigation actions implemented by healthcare practices across the United States.

Late in the first quarter the Company began to observe an impact of the COVID-19 pandemic on XHANCE prescription growth. XHANCE prescriptions increased by 8% for the six-week period ended April 24th compared to the prior six-week period ended March 13th. This six-week period coincides with its sales representatives transition to a virtual detailing model and the nationwide COVID-19 related environmental shifts. Although XHANCE prescriptions have grown during this initial COVID-19 period, the rate of growth was below the Company's pre-pandemic expectations.

Due to the adverse effect of the COVID-19 pandemic on the XHANCE prescription growth rate to date as well as the unknown effect in the future, the Company is withdrawing its previous XHANCE revenue guidance for 2020. If the effects of the COVID-19 pandemic on XHANCE net revenues become more certain, the Company will evaluate providing guidance for XHANCE net revenues.

The Company has taken actions to reduce 2020 operating expenses by approximately \$17 million while maintaining its ability to drive XHANCE growth and complete its ongoing chronic sinusitis trials. These expense reductions included a reprioritization of project spending, a reduction in payroll costs, and lower near-term clinical trial expenses as the result of temporarily paused patient enrollment at research sites in response to the acute COVID-19 environment.

Regarding the chronic sinusitis development program, previous guidance indicated that results from both studies would be available in the second half of 2021. Pauses in patient enrollment due to factors related to COVID-19 have

had, and may continue to have, varying effects in different countries and over time but have not yet led to a change in the Company's projected topline data availability. For those subjects currently ongoing in these studies, procedures to facilitate ongoing treatment and capture of data during the period of in-person care restrictions have been put in place.

First Quarter XHANCE Prescriptions

The number of XHANCE® (fluticasone propionate) prescriptions increased by 149% from first quarter 2019 to first quarter 2020.

First Quarter 2020 Financial Results

Net product revenues

The Company generated \$7.1 million in net product revenues from sales of XHANCE during the three-month period ended March 31, 2020.

Costs and expenses and net loss

For the three-month period ended March 31, 2020, research and development expenses were \$4.9 million and selling, general and administrative expenses were \$27.1 million. The net loss for the period was \$28.9 million, or \$0.63 per share (basic and diluted).

Cash

In February 2020, the Company received \$30 million of cash following the issuance of the First Delayed Draw Notes under its existing Note Purchase Agreement. The Company had cash and cash equivalents of \$148.5 million as of March 31, 2020.

Corporate Guidance

XHANCE Net Revenue per Prescription

The Company expects XHANCE average net revenue per prescription to improve substantially through the remainder of 2020.

Operating Expenses

The Company expects total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2020 to be in the range of \$131 - \$136 million, of which the Company expects stock-based compensation to be approximately \$11 million. Previously, the Company expected total GAAP operating expenses for 2020 to be in the range of \$148 - \$153 million, of which the Company expected stock-based compensation to be approximately \$12 million.

Chronic Sinusitis Clinical Trials

The Company expects top-line results from both of its clinical trials evaluating XHANCE as a potential treatment for Chronic Sinusitis 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 4:15 p.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 14, 2020 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID #1060697. 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	
	March 31,	
	2020	2019
Revenues:		
Net product revenues	\$ 7,062	\$ 3,976
Licensing revenues	—	500
Total revenues	7,062	4,476
Costs and expenses:		
Cost of product sales	1,356	738
Research and development	4,932	4,562
Selling, general and administrative	27,060	26,340
Total costs and expenses	33,348	31,640
Loss from operations	(26,286)	(27,164)
Other expense	2,570	1,710
Net loss	\$ (28,856)	\$ (28,874)
Net loss per share of common stock, basic and diluted	\$ (0.63)	\$ (0.70)
Weighted average common shares outstanding, basic and diluted	45,906,162	41,256,050

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

	March 31,	December 31,
	2020	2019
	<small>(unaudited)</small>	
Cash and cash equivalents	\$ 148,475	\$ 147,144
Other assets	25,695	25,506
Total assets	\$ 174,170	\$ 172,650
Total current liabilities	\$ 34,225	\$ 36,139
Long-term debt, net	104,656	74,531
Other liabilities	158	397
Total stockholders' equity	35,131	61,583
Total liabilities and stockholders' equity	\$ 174,170	\$ 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., the U.K. 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 impact of, our plans regarding and the uncertainty caused by the COVID-19 pandemic; the potential for continued XHANCE growth and potential growth drivers; plans to reduce operating expenses; plans to accelerate growth as the COVID-19 pandemic eases; the Company's intent to evaluate providing guidance for XHANCE net revenue as the effects of the COVID-19 pandemic on XHANCE net revenues become more certain; 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 both of its chronic sinusitis trials in second half 2021; expectation that XHANCE average net revenue per prescription will improve substantially through the remainder of 2020; projected Company GAAP operating expenses and stock-based compensation for 2020; 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: the extent and duration of the COVID-19 pandemic and its impact on the Company's business, results of operations and financial condition; 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 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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Building a Leading ENT / Allergy Specialty Company

Corporate Presentation

May 7, 2020

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: impact of, our plans regarding and the uncertainties caused by, the COVID-19 pandemic; potential for continued XHANCE growth, potential growth drivers and market opportunity; prescription, refill, prescribing frequency and market share trends; potential effects of INS market seasonality on XHANCE prescriptions; plans to reduce operating expenses and projected Company GAAP operating expenses and stock-based compensation for 2020; expectation that XHANCE net revenue per prescription will improve substantially for the remainder of 2020; 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 both chronic sinusitis trials in second half 2021; corporate guidance; 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: the extent and duration of the impact of the COVID-19 pandemic on the Company's business, results of operations and financial condition; 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, net revenues, and market share; 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 additional draws 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 2020 Highlights



Adapted Business to the COVID-19 Environment

Taking Action to Preserve Strength of Balance Sheet

Revising Financial Guidance for Full Year 2020

Commercial Strategy Driving Strong XHANCE Growth

Substantial Growth Opportunity Remains for XHANCE

+78%

XHANCE Net Revenue Growth Q1 2020/Q1 2019

+149%

XHANCE TRx Growth Q1 2020 / Q1 2019

\$126

XHANCE Net Revenue per TRx in Q1 2020

\$149M

Cash and equivalents as of March 31, 2020

Up to
\$40M

Incremental cash available from Pharmakon through early 2021

opti

COVID-19 Pandemic Response

Overview of COVID-19 Effects on our Business

Commercial

- Initiated a virtual sales model starting in mid-March and deployed new systems supporting 'virtualization' of most commercial efforts
- Launched the XHANCE ASSIST program to facilitate product adoption during crisis by physicians and patients suddenly facing a need for more 'virtual' care, delays in elective surgical procedures, and reluctance to visit pharmacies
 - ASSIST offers three months of XHANCE at \$0 out-of-pocket cost with home delivery to new commercially insured patients who start treatment by the end of May

Chronic Sinusitis Trials

- Temporary pauses in recruitment of new patients at global sites due to COVID-19
- For already enrolled subjects, procedures to facilitate ongoing treatment and capture of data during the period of in-person care restrictions have been implemented

Operating Expenses

- Taking actions to reduce FY 2020 Operating Expenses by ~\$17 million while maintaining the ability to execute our growth strategy for XHANCE

XHANCE Resilience

Prescriptions of XHANCE increased 8% from the 6-weeks ended March 13, 2020 to the 6-weeks ended April 24, 2020



- During initial crisis period (6-weeks ended April 24), sales representatives were required to 'shelter at home' and adopt 'virtual' activity, many target physician offices restricted access, patient flow through ENT and Allergy physician office was substantially reduced, and most elective surgery was constrained
- XHANCE prescription volume grew, showing initial resilience during this period
- XHANCE treats a chronic disease, and regular activity buoyed overall performance

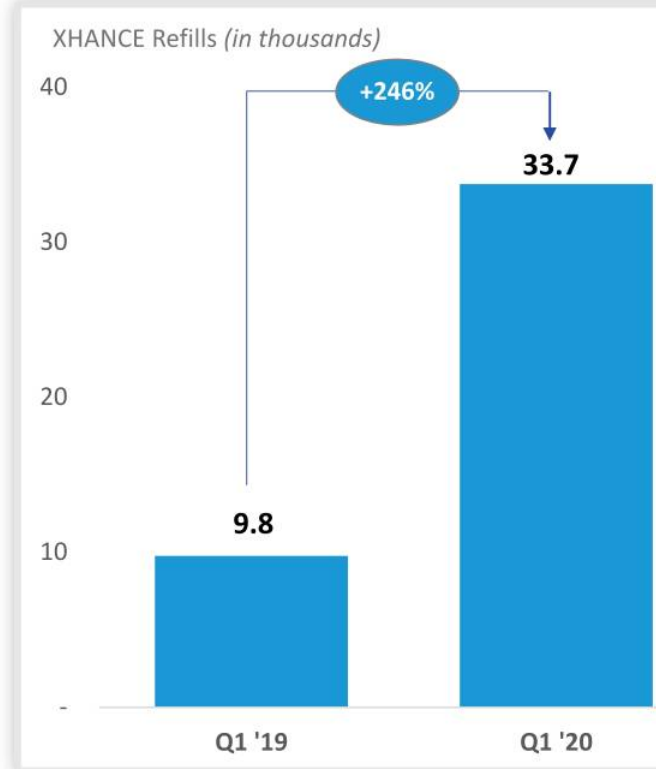
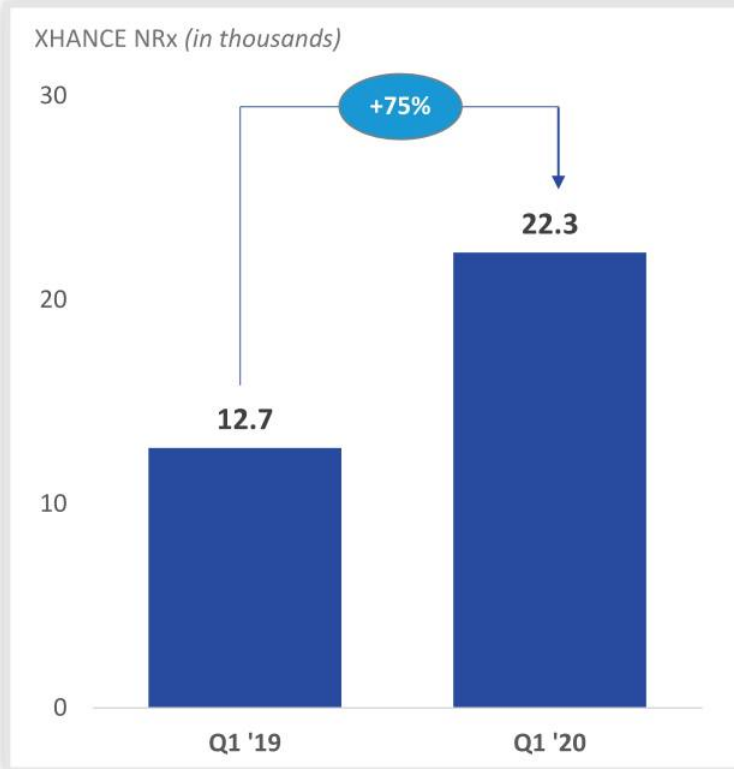
TRx for Intranasal Steroids Market decreased 2% from the 6-weeks ended March 13th to the 6-weeks ended April 24th

XHANCE Launch Update

Q1 2020 XHANCE New and Refill Prescriptions

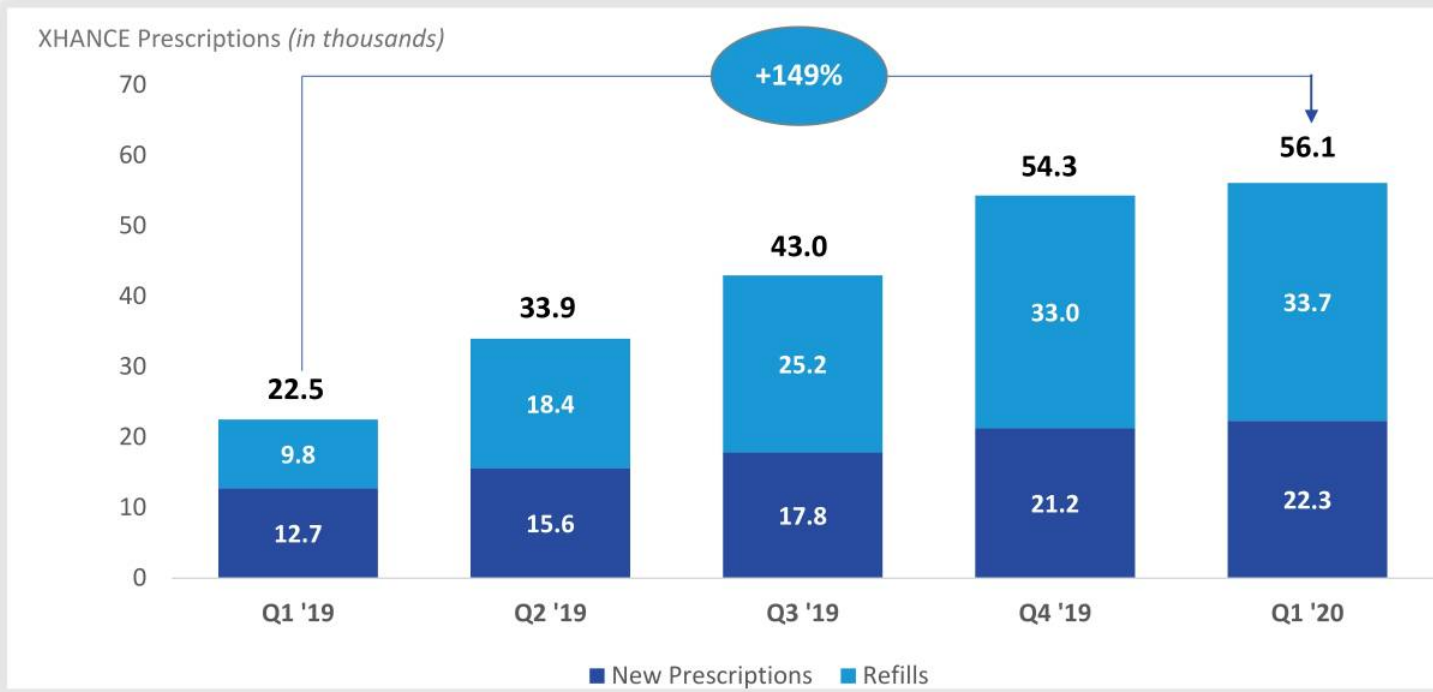
New prescriptions of XHANCE increased 75% in Q1 2020 compared to Q1 2019

Refill prescriptions of XHANCE increased 246% in Q1 2020 compared to Q1 2019



XHANCE Prescription Trends

Prescriptions of XHANCE increased 149% in Q1 2020 compared to Q1 2019

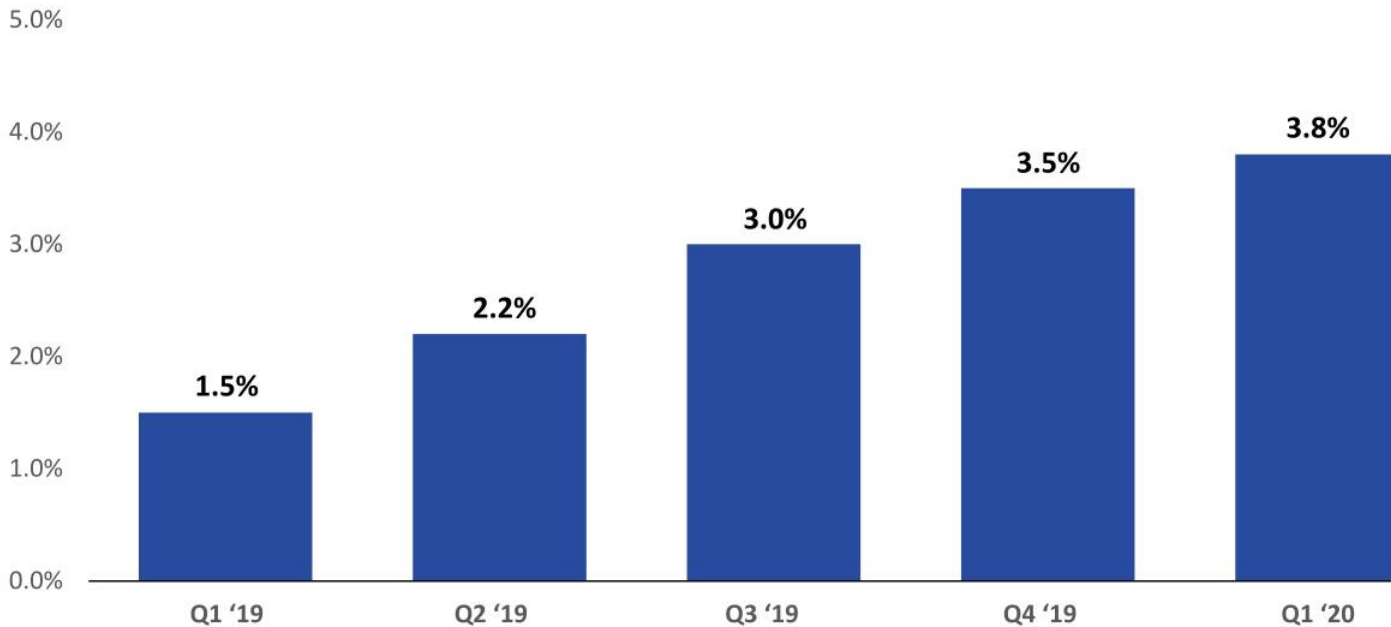


TRx for Intranasal Steroids Market increased 6% from Q1 2019 to Q1 2020.

XHANCE Share of INS Prescriptions Within the Target Physician Audience is Growing and the Remaining Opportunity is Large

Market share within the XHANCE target physician audience of 3.8% in Q1 2020 an increase of 2.5 times compared to Q1 2019 share of 1.5%

XHANCE Share of INS TRx Within Target Physician Audience



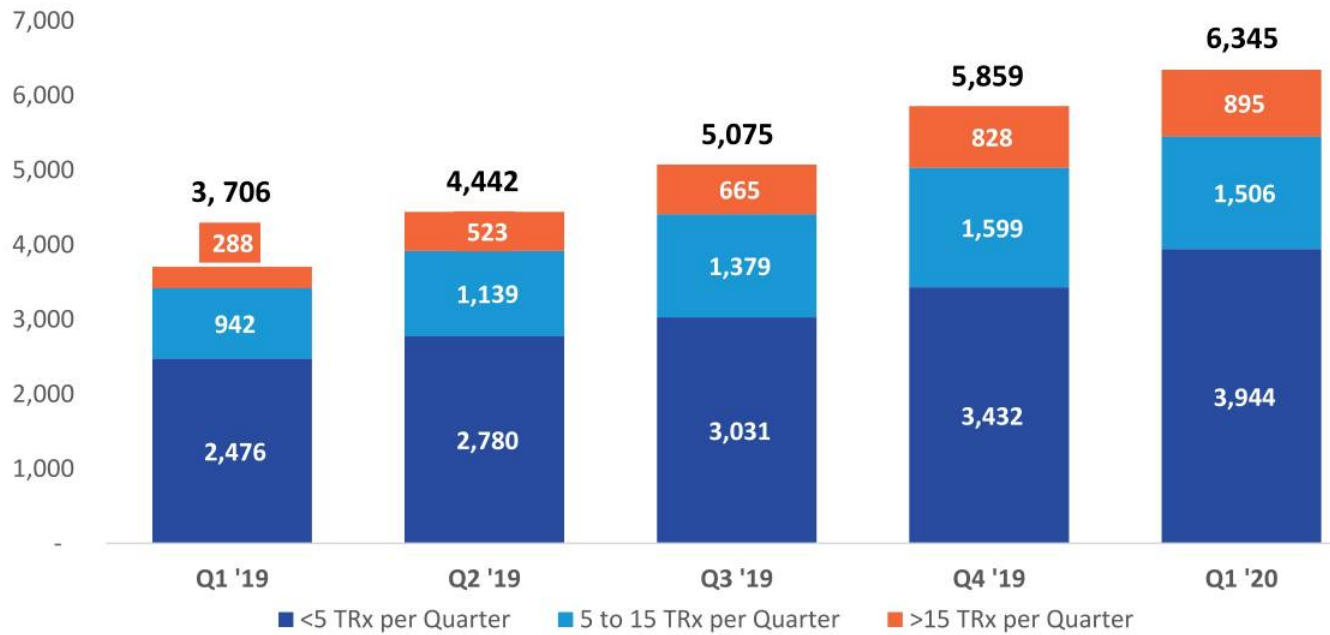
The Market on this slide is defined as the sum of all intranasal steroid prescriptions written by physicians in the XHANCE target physician audience of approximately 10,000 physicians.

Estimated based on monthly prescription data from public source 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 211% from Q1 2019 to Q1 2020 (895 versus 288)

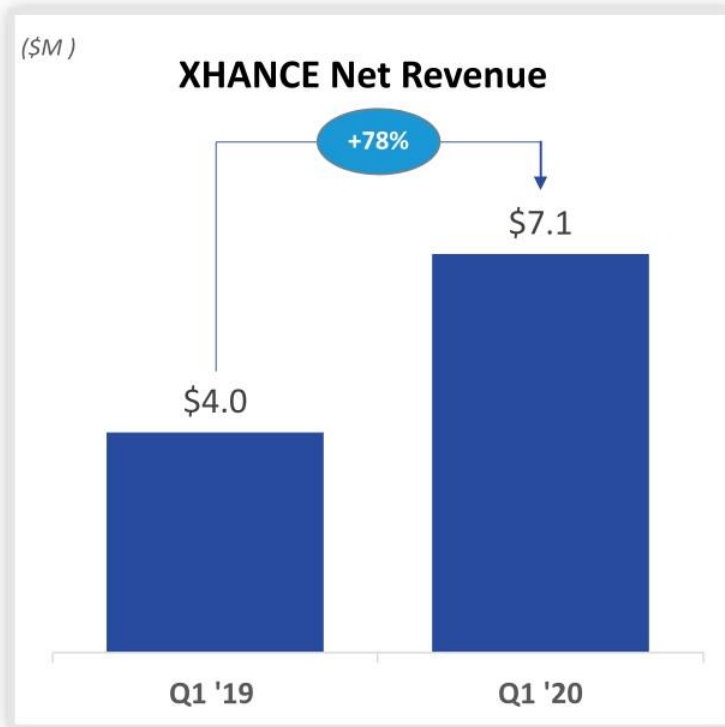
XHANCE Prescribers



Q4 2019 Financial Update

Financial Review – First Quarter 2020

Q1 2020 XHANCE Net Revenue Increased 78% Compared to Q1 2019



XHANCE Average Net Revenue per TRx

- XHANCE average net revenue of \$126 per TRx in Q1 2020
 - Expectation was \$120 – \$1 for Q1 2020

Corporate Guidance Update

- **XHANCE Net Revenue and Average Net Revenue per TRx**
 - Withdrawing FY 2020 revenue guidance given uncertainties related to the COVID-19 pandemic
 - XHANCE Average Net Revenue per Prescription expected to improve substantially for the remainder of 2020
- **Operating Expense (GAAP) expected to be between \$131 – \$136 million**
 - Approximately \$11 million of which represents stock-based compensation
 - Prior guidance range of \$148 – \$153 million, \$12 million of which was stock based compensation
- **Chronic Sinusitis Clinical Trials**
 - Expect top-line results from both trials evaluating XHANCE as a potential treatment for Chronic Sinusitis in the second half of 2021

Closing Remarks

Key Takeaways and Q1 2020 Highlights



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Cash and equivalents as of March 31, 2020

Up to
\$40M

Incremental cash available from Pharmakon through early 2021

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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 March 2020:

- \$149 million in cash
- Long-term debt: \$110 million
- 45.9 million common shares o/s
- 11.1 million options & warrants o/s

Optinose Investor Contact

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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 the 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 7, 2020

