

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 5, 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))

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

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.

Item 2.02 Results of Operations and Financial Condition.

On March 5, 2020, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the year ended December 31, 2019. 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 5, 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 March 5, 2020.
99.2	OptiNose, Inc. Corporate Presentation, dated March 5, 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: March 5, 2020



**Optinose Reports Fourth Quarter and Full Year 2019 Financial Results
and Recent Operational Highlights**

Company reports fourth quarter and full year 2019 XHANCE net revenue of \$11.1 million and \$30.4 million

Fourth quarter 2019 XHANCE prescriptions increased 26% from third quarter 2019

Company expects full-year 2020 XHANCE net revenue to more than double

Company expects top-line results from both clinical trials evaluating XHANCE as a potential treatment for Chronic Sinusitis in the second half of 2021

Conference call and webcast to be held today at 7:30 a.m. Eastern Time

YARDLEY, Pa., March 5, 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 and year ended December 31, 2019, and provided recent operational highlights.

"We made significant progress in 2019 demonstrating that XHANCE can be the foundation on which to build a leading ENT and allergy focused company," stated CEO Peter Miller. "XHANCE continues to grow behind our successful commercial strategy and we delivered results for XHANCE net revenue, XHANCE average net revenue per prescription, and operating expenses that aligned with our full year 2019 guidance ranges. As we start 2020, we are encouraged by continued growth in new patients starting treatment with XHANCE. Our expectations for first quarter 2020 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. For full year 2020 we expect XHANCE net revenue to more than double compared to full year 2019. "

Fourth Quarter 2019 and Recent Highlights

XHANCE Prescription Growth

The number of XHANCE® (fluticasone propionate) prescriptions increased by 26% from third quarter to fourth quarter 2019 and by 285% from fourth quarter 2018 to fourth quarter 2019. Fourth quarter growth included increases in both new and refill prescriptions. Refill prescriptions increased from 5,300 in Q4 2018 to 33,000 in Q4 2019. As a proportion of total prescriptions refills increased from 37% in Q4 2018 to 61% in Q4 2019.

Pharmakon Agreement

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 \$30 million of cash is in addition to the Company's cash balance of \$147 million as of December 31, 2019.

Peer-Reviewed Scientific Journal Publications

In December 2019, the Company announced that results of EXHANCE-3, the fourth major registration trial from the development program supporting the initial FDA approval of XHANCE, were published in the peer-reviewed journal *Rhinology*¹, the official journal of the International Rhinologic Society.

In addition, in November 2019, results from a Phase 1 clinical trial to evaluate the pharmacokinetics and bioavailability of XHANCE were published in *Clinical Therapeutics*². This trial was also a part of the development program which supported the initial FDA approval of XHANCE.

Scientific Meeting Presentations

Data on XHANCE is expected to be presented on March 15, 2020 from 9:45 a.m. to 10:45 a.m. during the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual meeting scheduled March 13-16, 2020 in Philadelphia.

- Poster 478: *Efficient Topical Steroid Delivery to Grades 1 and 2 Nasal Polyps in the Osteomeatal Complex (OMC): Deposition Patterns With Exhalation Delivery System (EDS) and Conventional Intranasal Spray (INS) Visualized With Fluorescein in Silicone Cast.*

Abstracts are available on the AAAAI Annual Meeting website.

Fourth Quarter 2019 Financial Results

Revenue

The Company generated \$11.1 million and \$30.4 million of XHANCE net revenue during the three-month and twelve-month periods ended December 31, 2019, respectively. In addition, the Company generated \$4.2 million of licensing revenue during the twelve-month period ended December 31, 2019. No licensing revenue was generated during the three-month period ended December 31, 2019. Total revenues for the three-month and twelve-month periods ended December 31, 2019 were \$11.1 million and \$34.6 million.

Expenses and net loss

For the three-month and twelve-month periods ended December 31, 2019, research and development expenses were \$5.4 million and \$20.8 million, respectively. Selling, general and administrative expenses were \$26.5 million and \$104.2 million during the three-month and twelve-month periods ended December 31, 2019, respectively. The net loss for the three-month period ended December 31, 2019 was \$25.0 million, or \$0.58 per share (basic and diluted). The net loss for the twelve-month period ended December 31, 2019 was \$110.1 million, or \$2.63 per share (basic and diluted).

Cash

The Company had cash and cash equivalents of \$147.1 million as of December 31, 2019.

Corporate Guidance

XHANCE Net Revenue and Average Net Revenue per Prescription

The Company expects XHANCE net revenues for the full year of 2020 to more than double compared to the full year 2019. This includes the Company's expectation that first quarter 2020 XHANCE net revenue will decrease compared to fourth quarter 2019. 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 2020 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 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 \$148 - \$153 million, of which the Company expects 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 7:30 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 12, 2020 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID: 9566036. 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		Year Ended	
	December 31,		December 31,	
	2019	2018	2019	2018
Revenues:				
Net product revenues	\$ 11,081	\$ 3,023	\$ 30,401	\$ 7,065
Licensing revenues	—	—	4,230	—
Total revenues	<u>11,081</u>	<u>3,023</u>	<u>34,631</u>	<u>7,065</u>
Costs and expenses:				
Cost of product sales	2,078	718	5,294	1,588
Research and development	5,379	3,363	20,783	10,099
Selling, general and administrative	26,545	23,661	104,155	95,618
Total costs and expenses	<u>34,002</u>	<u>27,742</u>	<u>130,232</u>	<u>107,305</u>
Loss from operations	<u>(22,921)</u>	<u>(24,719)</u>	<u>(95,601)</u>	<u>(100,240)</u>
Other expense	2,075	1,662	14,452	6,417
Net loss	<u>\$ (24,996)</u>	<u>\$ (26,381)</u>	<u>\$ (110,053)</u>	<u>\$ (106,657)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.58)</u>	<u>\$ (0.64)</u>	<u>\$ (2.63)</u>	<u>\$ (2.68)</u>
Weighted average common shares outstanding, basic and diluted	<u>43,467,985</u>	<u>41,227,530</u>	<u>41,877,527</u>	<u>39,765,983</u>

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

	December 31, 2019	December 31, 2018
Cash and cash equivalents	\$ 147,144	\$ 200,990
Other assets	25,506	15,999
Total assets	\$ 172,650	\$ 216,989
Total current liabilities	36,139	\$ 25,697
Long-term debt, net	74,531	72,500
Other liabilities	397	181
Total stockholders' equity	61,583	118,611
Total liabilities and stockholders' equity	\$ 172,650	\$ 216,989

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 potential for continued XHANCE 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 both of its chronic sinusitis trials in second half 2021; projected average net revenue per prescription for first quarter and full year 2020; projected XHANCE net revenue for first quarter and full year 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: 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.

References

- 1 – Sher MR, Steven GC, Romett JL, Pien G, LeBenger K, Messina JC, Carothers JL, Mahmoud RA, Djupesland PG, EXHANCE-3: a cohort study of the exhalation delivery system with fluticasone for chronic sinusitis with or without nasal polyps, *Rhinology*, DOI: 10.4193/Rhin19.124.
- 2 - Messina JC, Offman E, Carothers JL, Mahmoud RA, A Randomized Comparison of the Pharmacokinetics and Bioavailability of Fluticasone Propionate Delivered via XHANCE® Exhalation Delivery System Versus FLONASE® Nasal Spray and FLOVENT® HFA Inhalational Aerosol, *Clinical Therapeutics*. 2019 November; 41(11):2343-2356 DOI: 10.1016/j.clinthera.2019.09.013.

Optinose Investor Contact

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267.521.0531

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Building a Leading ENT / Allergy Specialty Company

Corporate Presentation

March 5, 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: potential for continued XHANCE growth, potential growth drivers and market opportunity; 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 2020; projected XHANCE net revenues for full year and first quarter 2020; projected XHANCE net revenue per prescription for the first quarter and the remainder of 2020; expected XHANCE market share growth in 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: 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 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 Q4 2019 Highlights



Commercial Strategy Driving Strong XHANCE Growth

Substantial Growth Opportunity Remains for XHANCE

Strong Balance Sheet - Pharmakon Provides Access to Additional Cash

Full Year 2019 Performance Aligned with Company Guidance

Providing Initial Company Guidance for Q1 and Full Year 2020

+26%

XHANCE Net Revenue Growth Q4/Q3

\$204

XHANCE Net Revenue per TRx in Q4 2019

\$147M

Cash and equivalents as of December 31, 2019

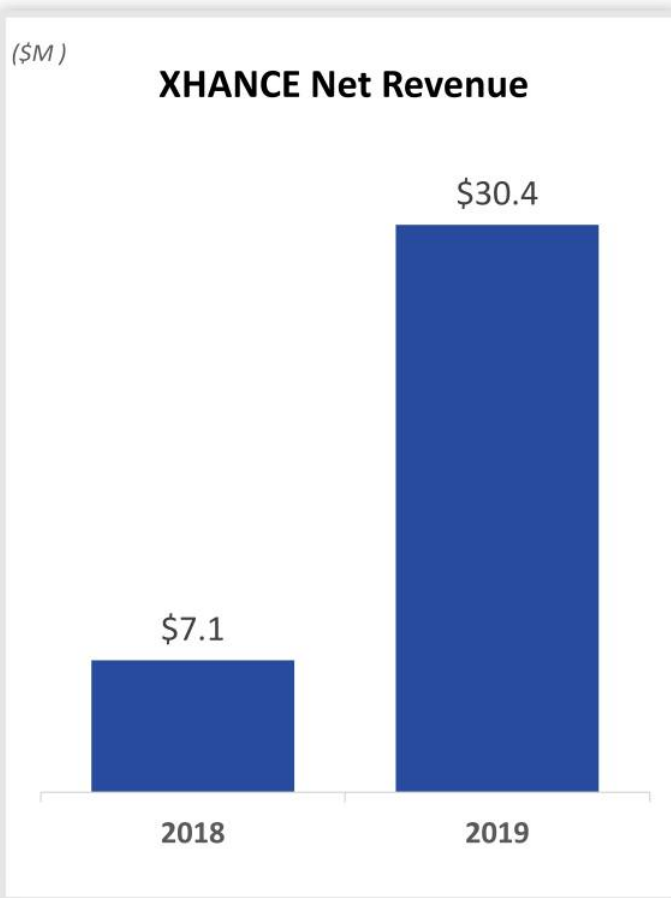
Up to
\$70M

Incremental cash available from Pharmakon through early 2021

+26%

XHANCE TRx Growth Q4/Q3

Full Year 2019 Highlights



+330%

XHANCE Net Revenue Growth
FY 2019/FY 2018

~154,000

XHANCE Prescriptions
in FY 2019

\$198

Full Year 2019 XHANCE
Net Revenue per TRx

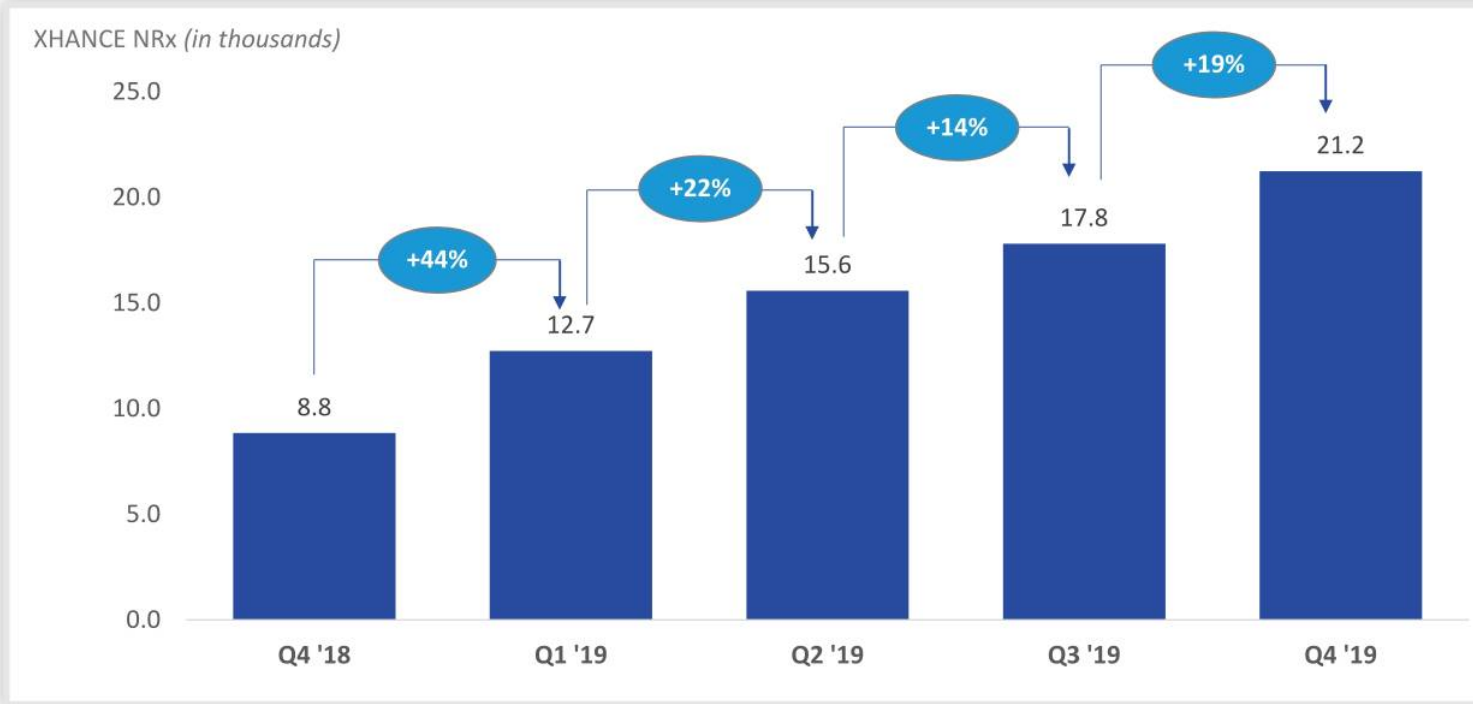
\$125M

Full Year 2019 Operating Expenses
(SG&A plus R&D)

XHANCE Launch Update

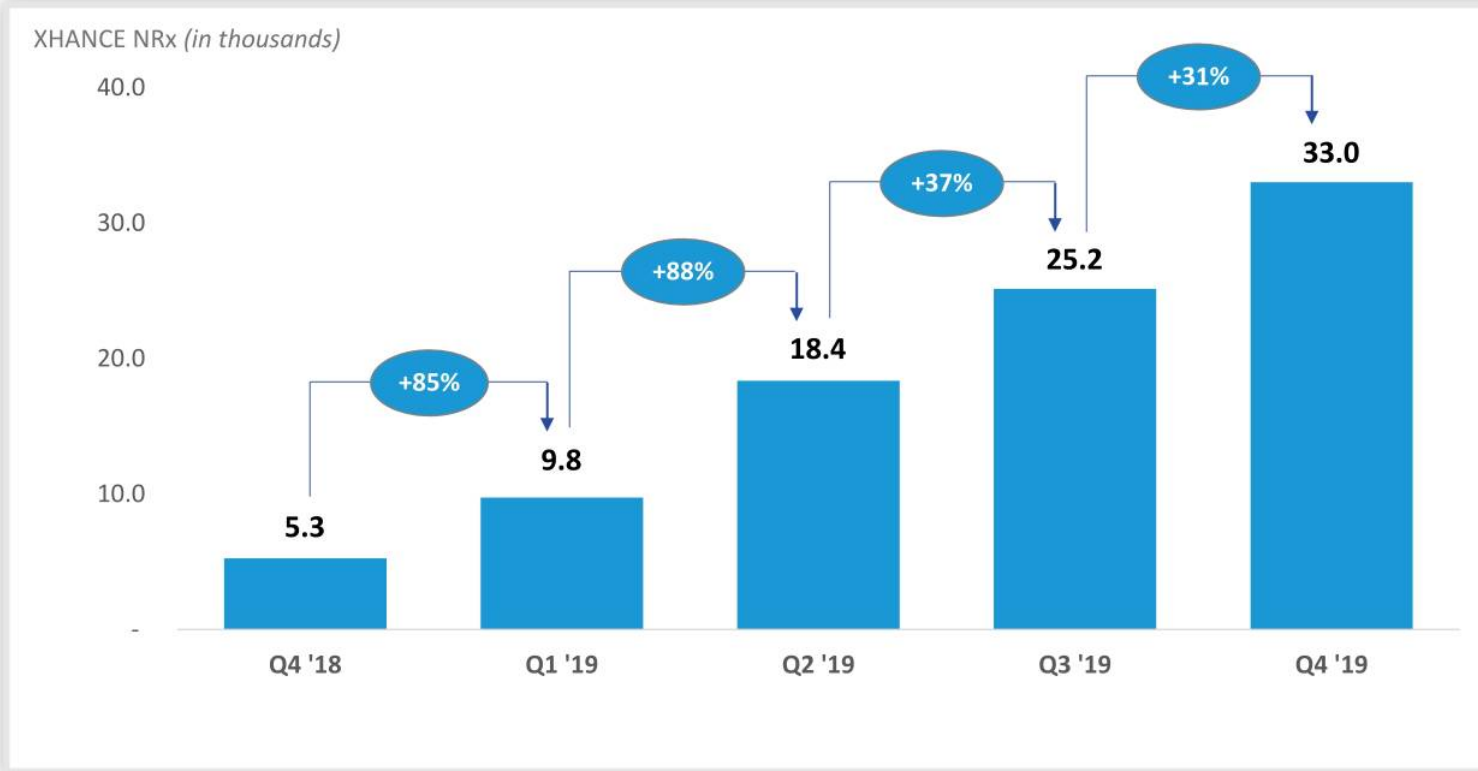
XHANCE New Prescription Trends

New prescriptions of XHANCE increased 19% in Q4 2019 compared to Q3 2019



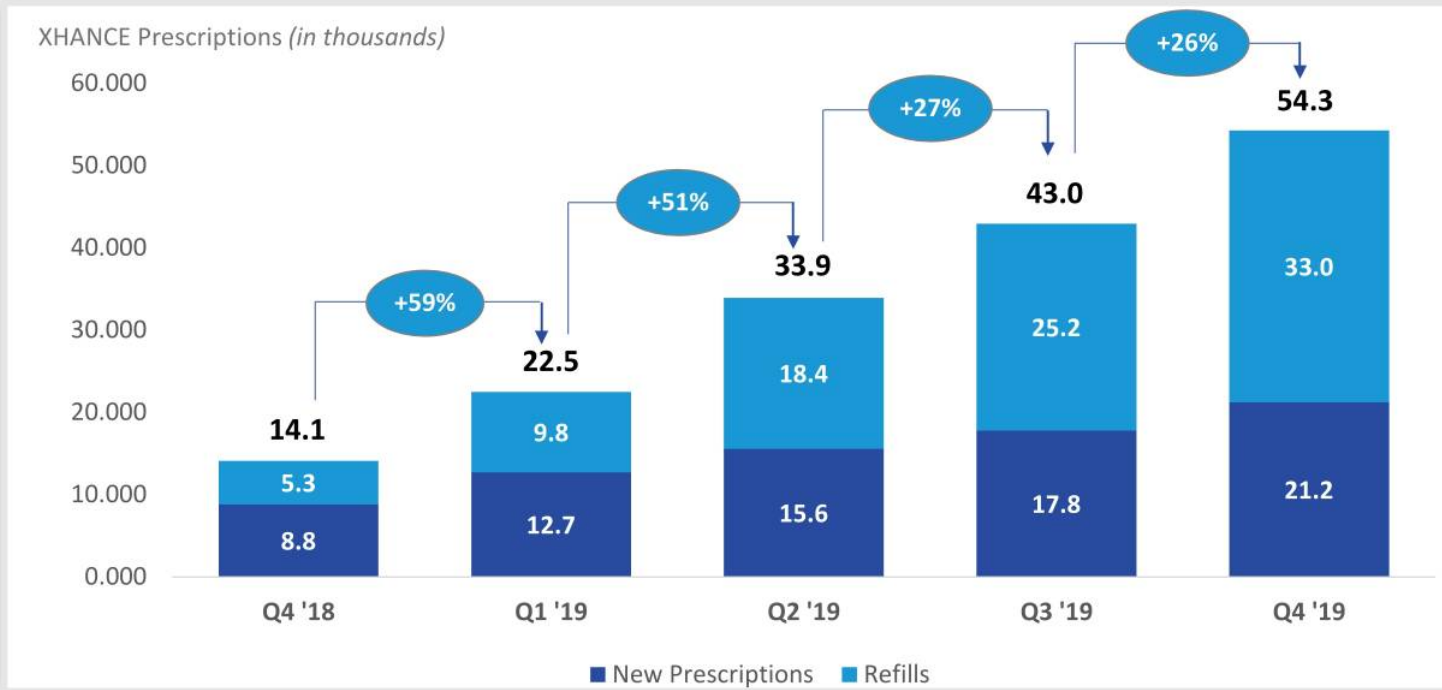
XHANCE Refill Prescriptions Trends

Refill Prescriptions of XHANCE increased 31% in Q4 2019 compared to Q3 2019



XHANCE Prescription Trends

Strong growth in both new prescriptions and refills drove XHANCE quarterly prescription growth of 26% in Q4 2019

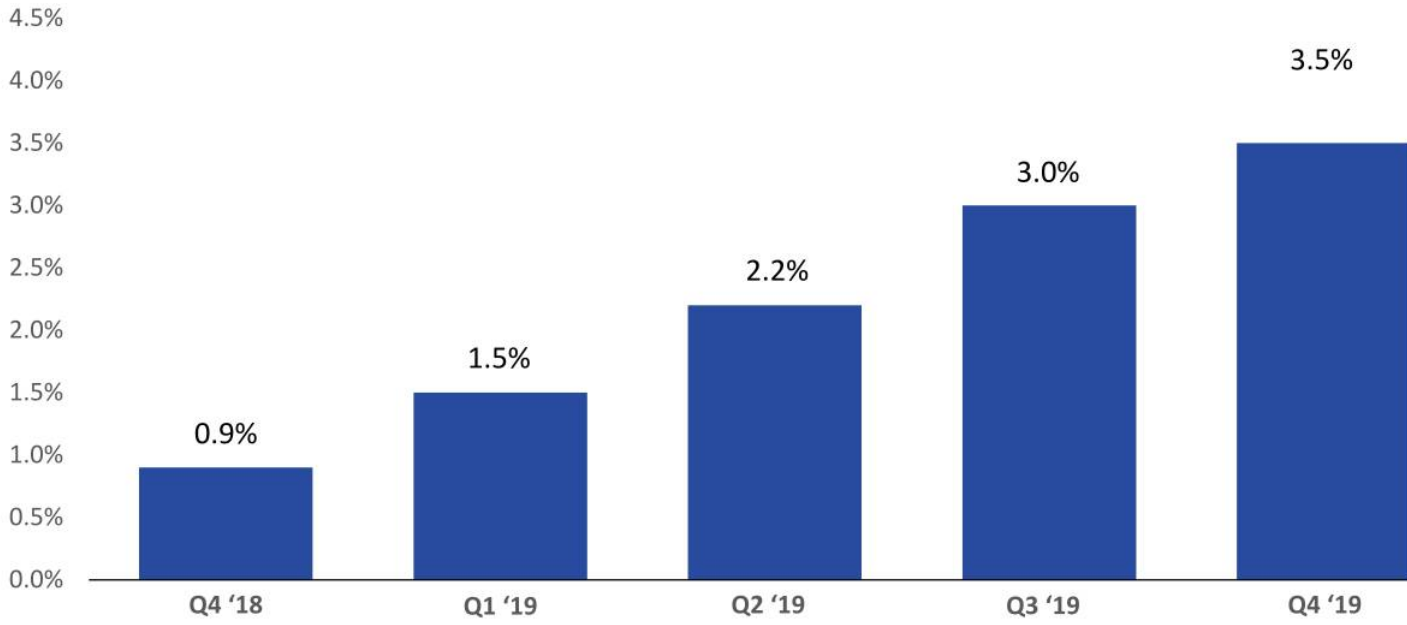


TRx for Intranasal Steroids Market increased 3% from Q4 2018 to Q1 2019, increased 1% from Q1 to Q2 2019, decreased 11% from Q2 to Q3 2019, and increased 9% from Q3 to Q4 2019

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 increased consistently in 2019 and we believe share will continue to increase in 2020

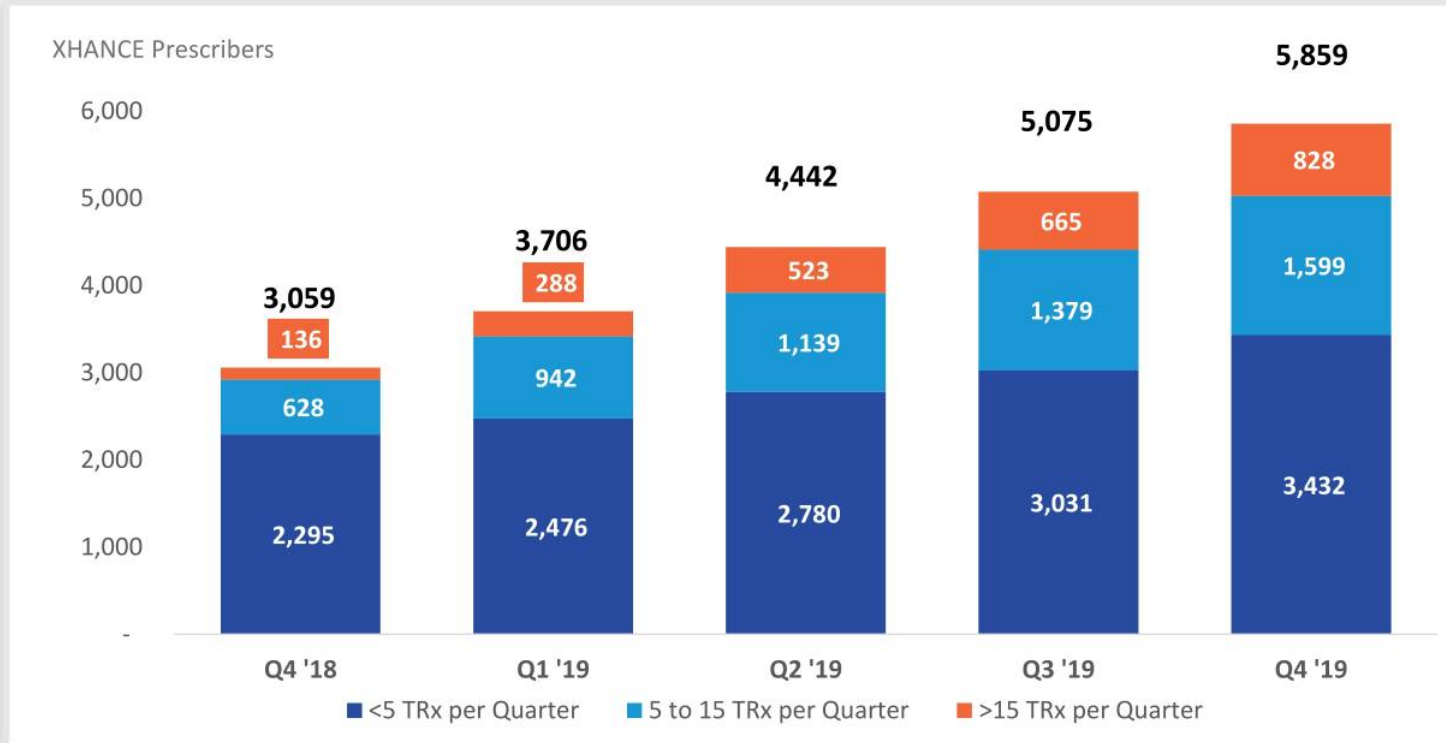
XHANCE Share of INS TRx Within Target Physician Audience



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

Number of XHANCE Prescribers by Prescribing Frequency

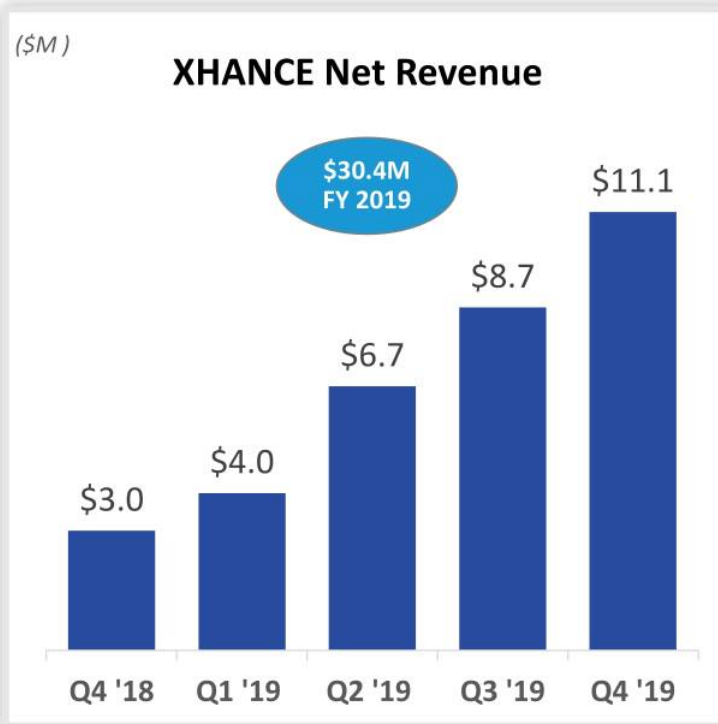
Physicians who had more than 15 XHANCE prescriptions filled by their patients in a quarter, a group that averaged ~40 prescriptions per physician in Q4 2019, increased more than 500% from Q4 2018 to Q4 2019 (828 versus 136).



Q4 2019 Financial Update

Financial Review – Fourth Quarter 2019

Q4 2019 XHANCE Net Revenue Increased 26% to \$11.1 Million



Average Net Revenue per TRx

- Average XHANCE net revenue of \$204 per TRx in Q4 2019
 - Increased from \$202 in Q3 2019
- Average XHANCE net revenue of \$198 per TRx for Full Year 2019

First Quarter and Full Year 2020 Financial Guidance

- **XHANCE Net Revenue and Average Net Revenue per TRx**
 - **FY 2020** expected to more than double compared to FY 2019
 - **Q1 2020** expected to decrease compared to Q4 2019 as a result of:
 - **Q1 2020** XHANCE Net Revenue per Prescription that is expected to be between \$120 - \$140
 - XHANCE Net Revenue per Prescription expected to improve substantially for the remainder of 2020
- **Operating Expense (GAAP) expected to be between \$148 – \$153 million**
 - Approximately \$12 million of which represents stock-based compensation

Pipeline Update

XHANCE Chronic Sinusitis Indication (sNDA)

The Chronic Sinusitis clinical research program includes two Phase 3b clinical trials {24-week randomized, double-blind, placebo-controlled, parallel-group, multicenter studies}

Study -3205

- Top line results expected in second half 2021
- Estimated enrollment: 378 patients
- ClinicalTrials.gov Identifier: NCT03781804

Study -3206

- Top line results expected in second half 2021
- Estimated enrollment: 399 patients
- ClinicalTrials.gov Identifier: NCT03960580

Co-primary endpoints for each trial include an objective measure of inflammation and a subjective measure of symptom relief

Closing Remarks

Key Takeaways and Q4 2019 Highlights



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+26%

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XHANCE Net Revenue per TRx in Q4 2019

Up to
\$70M

Incremental cash available from Pharmakon through early 2021

+26%

XHANCE TRx Growth Q4/Q3

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 2019:

- \$147 million in cash
- Long-term debt: \$80 million
- 45.9 million common shares o/s
- 10.1 million options & warrants 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 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

March 5, 2020

