

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 9, 2019



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 9, 2019, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 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 May 9, 2019, 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 9, 2019.
99.2	OptiNose, Inc. Corporate Presentation, dated May 9, 2019.

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 9, 2019



**Optinose Reports First Quarter 2019 Financial Results
and Recent Operational Highlights**

Company reports first quarter 2019 total revenues of \$4.5 million.

XHANCE first quarter net product revenues grew to \$4.0 million

XHANCE prescriptions increased 59% from fourth quarter 2018 to first quarter 2019

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

YARDLEY, Pa., May 9, 2019 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, 2019, and provided recent operational highlights.

"We delivered 59% quarter-over-quarter growth in the number of XHANCE prescriptions during the first quarter of 2019. These strong first quarter results sustain the growth trend we reported in the previous quarter", stated CEO Peter Miller. "Our focus continues to be executing our strategy which includes multiple new growth drivers that we believe will help sustain an excellent rate of growth for XHANCE. These include the internalization of our sales force, completed in April, with a 25% expansion in our sales territories and availability, starting this week, of a new 7-day sample that we believe will encourage trial and adoption of XHANCE."

First Quarter and Recent Highlights

XHANCE Commercial Update

The number of XHANCE[®] (fluticasone propionate) prescriptions increased by 59% from fourth quarter 2018 to first quarter 2019.

Based on currently available third-party data and our internal analyses, the Company estimates that more than 75% of commercially insured lives are in a plan in which XHANCE is covered in a Tier 3 formulary position.

In April 2019, the Company expanded its number of sales territories from 80 to 100. The Company plans to call on an estimated 2,200 previously uncalled-on physicians in the new sales territories, and to now target over 10,000 total physicians. At the same time, the Company completed its transition from a contract sales force model to an internal sales force model.

XHANCE Development Update

In addition to XHANCE's existing indication for nasal polyps, the Company plans to seek approval for a follow-on indication for the treatment of chronic sinusitis in the U.S. in order to broaden its market opportunity. In December 2018, the Company initiated the first of two anticipated Phase 3b clinical trials.

Inexia License Agreement

In January 2019, the Company entered into a license agreement with Inexia Limited (Inexia) whereby Inexia has obtained rights that will enable the use of Optinose's Exhalation Delivery Systems and other intellectual property in Inexia's effort to discover and develop novel therapies based on positive modulators of Orexin OX1 and OX2 for neurological diseases.

In exchange for this license, the Company received an upfront payment of \$0.5 million and, for each product developed under the license agreement, is eligible to receive up to \$8.0 million of development milestone payments and up to \$37.0 million of sales milestone payments. The Company is also eligible to receive tiered, low-to-mid single digit royalties based on net sales of any products successfully developed and commercialized under the license agreement.

Inexia is responsible for all costs and activities related to the identification, development and commercialization of potential products under this license.

First Quarter 2019 Financial Results

Net product and licensing revenues

The Company generated \$4.5 million of total revenues including \$4.0 million in net product revenues from sales of XHANCE and \$0.5 million in licensing revenues during the three-month period ended March 31, 2019.

Costs and expenses and net loss

For the three-month period ended March 31, 2019, research and development expenses were \$4.6 million and selling, general and administrative expenses were \$26.3 million. The net loss for the period was \$28.9 million, or \$0.70 per share (basic and diluted).

Cash

The Company had cash and cash equivalents of \$171.3 million as of March 31, 2019.

Corporate Guidance

Research and development

The Company expects to initiate a second Phase 3b clinical trial in Q2 2019 to support the pursuit of a new indication for XHANCE for the treatment of chronic sinusitis.

Operating expenses

The Company expects total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2019 to be in the range of \$135 - \$142 million, of which the Company expects stock-based compensation to be in the range of \$10 - \$12 million.

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 16, 2019 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID #1233839. 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.

Upcoming Investor Conferences

Chief Executive Officer Peter Miller is scheduled to present at the RBC Capital Markets Global Healthcare Conference on May 22, 2019, at 9:00 a.m. ET and at the Jefferies 2019 Global Healthcare Conference on June 4, 2019 at 11:00 a.m. ET.

A live webcast will be available for each conference in the Investors section of the Optinose website. A replay will be available for 30 days following the conclusion of each event.

OptiNose, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended	
	March 31,	
	2019	2018
Revenues:		
Net product revenues	\$ 3,976	\$ 865
Licensing revenues	500	—
Total revenues	<u>4,476</u>	<u>865</u>
Costs and expenses:		
Cost of product sales	738	200
Research and development	4,562	1,701
Selling, general and administrative	26,340	28,011
Total costs and expenses	<u>31,640</u>	<u>29,912</u>
Loss from operations	<u>(27,164)</u>	<u>(29,047)</u>
Other expense	1,710	1,525
Net loss	<u>\$ (28,874)</u>	<u>\$ (30,572)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.70)</u>	<u>\$ (0.81)</u>
Weighted average common shares outstanding, basic and diluted	<u>41,256,050</u>	<u>37,849,199</u>

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

	March 31,	December 31,
	2019	2018
	(unaudited)	
Cash and cash equivalents	\$ 171,316	\$ 200,990
Other assets	21,676	15,999
Total assets	<u>\$ 192,992</u>	<u>\$ 216,989</u>
Total current liabilities	\$ 26,868	\$ 25,697
Long-term debt, net	72,680	72,500
Other liabilities	1,091	181
Total stockholders' equity	<u>92,353</u>	<u>118,611</u>
Total liabilities and stockholders' equity	<u>\$ 192,992</u>	<u>\$ 216,989</u>

About Optinose

Optinose is a global 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; the Company's plans to call on an estimated 2,200 previously uncalled-on physicians in new sales territories as a result of the sales force expansion; the Company's plans to seek approval for a follow-on indication for XHANCE for the treatment of chronic sinusitis, the potential benefits of such indication and the initiation of a second Phase 3b clinical trial in second quarter 2019 in pursuit of such indication; projected Company GAAP operating expenses and stock-based compensation for 2019; the Company's plans to participate in upcoming investor conferences; 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 become profitable; uncertainties and delays relating to the initiation, enrollment, completion, and results of clinical trials; unanticipated costs and expenses; risks and uncertainties relating to drug discovery, development and commercialization and the receipt of payments under the Inexia license agreement; 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

###

Building a Leading ENT / Allergy Specialty Company

Corporate Presentation

May 9, 2019

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 benefits of XHANCE® and our EDS technology; potential drivers of XHANCE growth; the XHANCE sales force expansion, the availability of 7-day samples and the initiation of a DTC pilot; market access objectives and patient affordability programs; potential effects of INS market seasonality on XHANCE prescriptions; the initiation and timing of clinical trials for chronic sinusitis; projected 2019 operating expenses and stock-based compensation; expectations regarding average revenue per prescription in 2019; and other statements regarding our 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; our ability to obtain, maintain and increase insurance coverage for XHANCE (market access); our ability to grow XHANCE prescriptions and become profitable; uncertainties and delays relating to the initiation, enrollment, completion and results of clinical trials; market opportunities for XHANCE may be smaller than we believe; unexpected costs and expenses; 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.

Optinose Key Priorities



Continue to drive XHANCE® prescription growth



Advance our XHANCE clinical program for a follow-on indication for the treatment of Chronic Sinusitis



Support our commercial and development objectives through efficient use of capital

- \$171 Million of cash as of March 31, 2019

XHANCE Launch Update

Key Levers to Continue to Drive XHANCE Growth

Continued Execution of Strategy

(Defined Appropriate Patient Type, Enhanced Efficacy Message & Affordability Program)

Sales Force Expansion

7-Day Samples

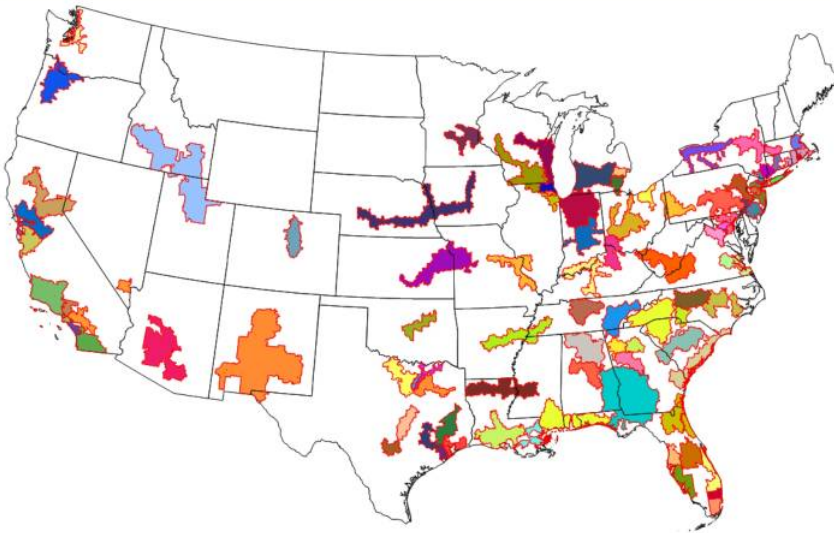
Increase Payer Coverage

Direct to Consumer Pilot



Deployed Territory Managers to New Territories in April and no Promote XHANCE in 100 Territories Total

XHANCE® Sales Territories

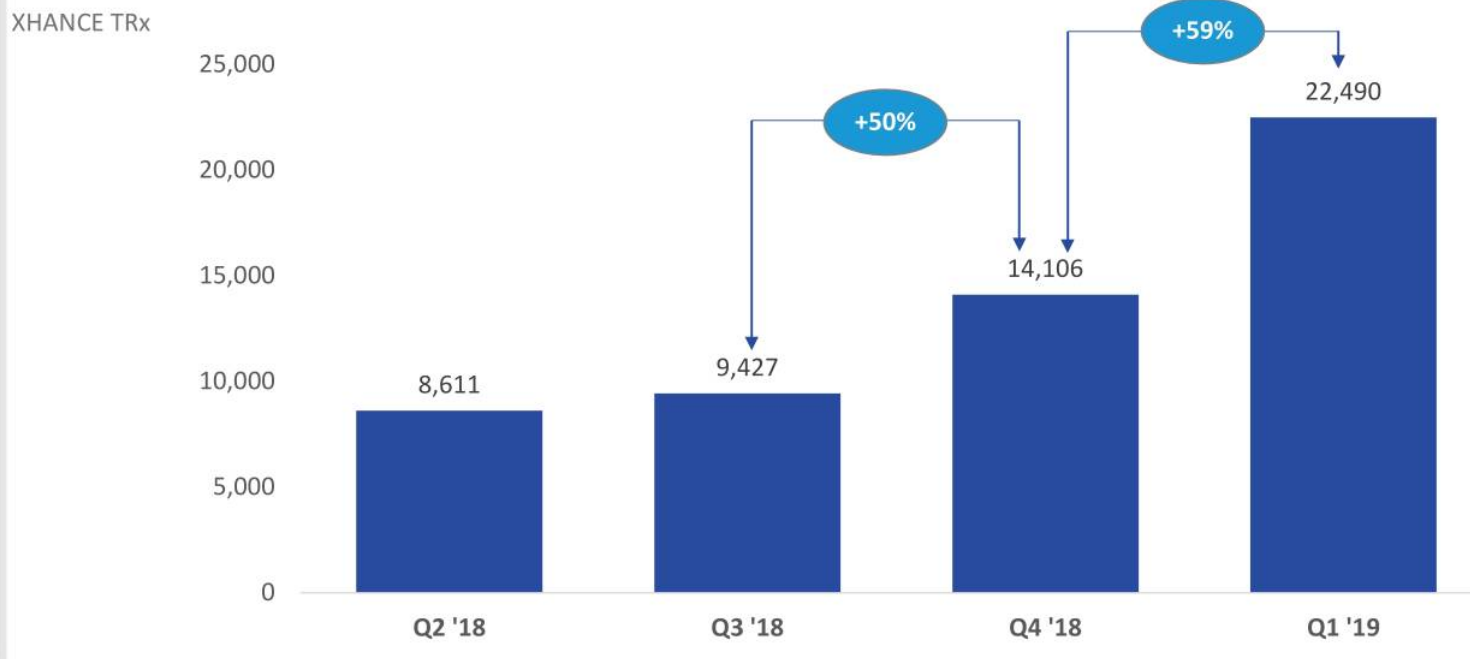


- Albany, NY
- Albuquerque, NM
- Baltimore, MD
- Boston, MA
- Charleston, SC
- Columbia, SC
- Detroit (South), MI
- Dothan, AL
- Fort Wayne, IN
- Grand Rapids, MI
- Greenville, SC
- Huntington, WV
- Jackson, MS
- Knoxville, TN
- Memphis, TN
- Nashville, TN
- Pittsburgh, PA
- Portland, OR
- Providence, RI
- Stamford, CT
- Suffolk County, NY

NEW

XHANCE Prescription Volume Grew 59% in Q1 2019 versus Q4 2018

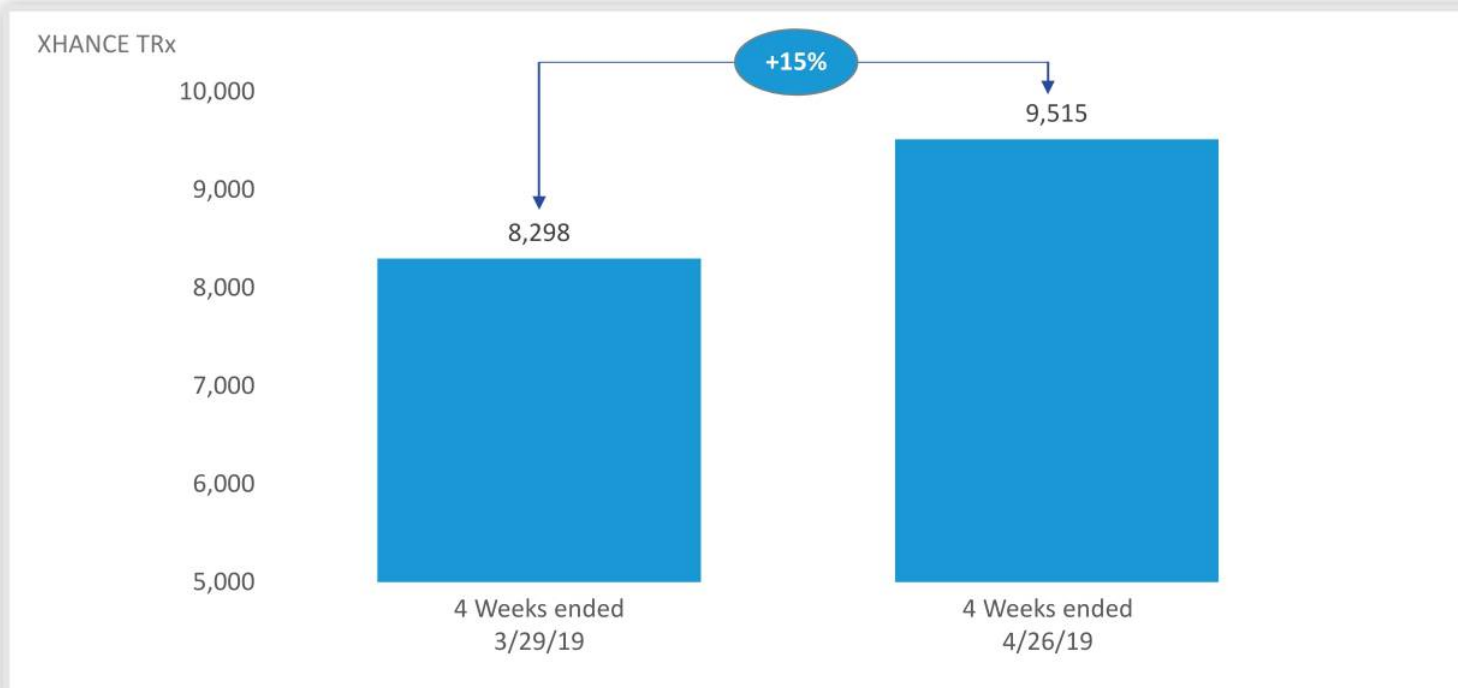
Continued growth in Q1 2019 driven by promotional materials and patient affordability program rolled out in August/September 2018



TRx for Intranasal Steroids Market increased 3% from Q4 2018 to Q1 2019

XHANCE Prescription Volume Grew 15% for the most recent 4 Week Period Ended April 26, 2019

Early Q2 2019 Prescription Trends Aligned with Q4 2018 and Q1 2019 Growth Rates

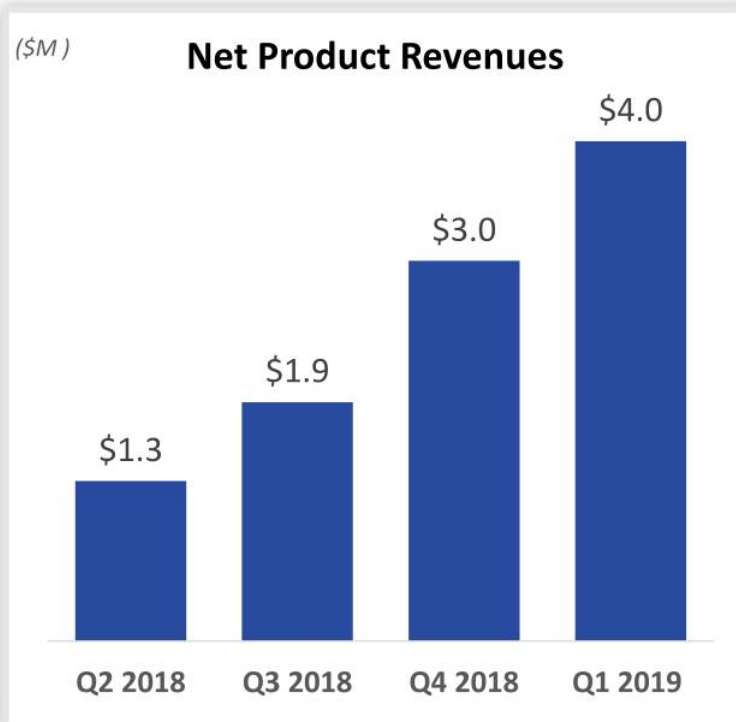


Market TRx for Intranasal Steroids increased 3% from the 4-week period ended 3/29/19 to the 4-week period ended 4/26/19

Q1 2019 Financial Update

Financial Review – First Quarter 2019

Q1 2019 Net Product Revenues and Average Net Product Revenues per TRx



- Net product revenues increased 32% in Q1 2019 versus Q4 2018
- Average net product revenues of \$177 per TRx Q1 2019
 - Slightly higher than expected range of \$155 to \$175

Financial Review – 2019 Financial Guidance

- Full Year 2019 Operating Expenses (GAAP) expected to be in the range of \$135 - \$142 million
 - \$10 - \$12 million of which represents stock-based compensation
 - First Quarter 2019 Operating Expenses of \$30.9 million
- Full Year 2019 average net revenue per prescription of XHANC expected to be in the range of \$185 - \$205

Pipeline Update

XHANCE Chronic Sinusitis Indication (sNDA)

Study 3205 - ClinicalTrials.gov Identifier: NCT03781804

- 24-week randomized, double-blind, placebo-controlled, parallel-group, multicenter study
- First patient enrolled in Q4 2018
- Estimated enrollment: 378 patients
- Focused on successful execution of site initiation plan in Q1 2019


Second Chronic Sinusitis Study

- Expected to start in Q2 2019

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

Closing Remarks


Building a leading ENT/Allergy Specialty Company



XHANCE[®] represents a significant opportunity in the ENT/Allergy market with the current indication




Potential for CS indication provides pipeline value



Future business development expected to focus on leveraging ENT/Allergy infrastructure and expertise



Recent license of EDS technology demonstrates ability to add value from applications outside ENT/Allergy



\$171 million of cash as of March 31, 2019

Investor Relations – NASDAQ: OPTN

Analyst Coverage¹

BMO: Gary Nachman

Jefferies: David Steinberg

Cantor Fitzgerald: Brandon Folkes

Piper Jaffray: David Amsellem

RBC: Randall Stanicky

At 31 March 2019:

- **\$171 million** in cash
- **Long-term debt: \$75 million**
- **41.3 million** common shares o/s
- **9.6 million** options & warrants o/s

Optinose Investor Contact

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



investors@optinose.com



www.optinose.com



[@optinose](https://twitter.com/optinose)

1 - Optinose is followed by the analysts listed above. Please note that any opinions, estimates or forecasts regarding the Company's performance made by these 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 9, 2019

