

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 6, 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.

Item 2.02 Results of Operations and Financial Condition.

On March 6, 2019, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the year ended December 31, 2018. 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 6, 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 March 6, 2019.
99.2	OptiNose, Inc. Corporate Presentation, dated March 6, 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: March 6, 2019



**Optinose Reports Fourth Quarter and Full Year 2018 Financial Results
and Recent Operational Highlights**

Company reports fourth quarter and full year 2018 net XHANCE revenue of \$3.0 million and \$7.1 million

XHANCE prescriptions increased 50 percent from Q3 to Q4 of 2018

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

YARDLEY, Pa., March 6, 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 year ended December 31, 2018, and provided recent operational highlights.

"We made great progress in 2018 building a business that can support long-term success," stated CEO Peter Miller. "Our focus on defining the appropriate target patient type for XHANCE, highlighting the strong data supporting the efficacy of XHANCE, and ensuring physician understanding and appreciation of our patient affordability program has bolstered physician perception of XHANCE. As a result of these efforts, I am happy to report that we accelerated XHANCE growth in the fourth quarter of 2018 and have continued to see strong growth in early 2019. The year ahead is an important one for Optinose and the launch of XHANCE. I am confident that we have the right team and plan to build a company that can serve the needs of ENT and allergy specialist physicians, and the patients they treat."

Fourth Quarter and Recent Highlights

Commercial Update

From third quarter to fourth quarter 2018 XHANCE® (fluticasone propionate) prescriptions increased by 50 percent. In addition, XHANCE prescriptions increased 38 percent from December 2018 to January 2019, and increased 39 percent from the four-week period ended January 25th to the four-week period ended February 22nd, which is the most recent four-week period available.

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

In April 2019, the Company plans to expand its sales force by 20 Territory Managers to call on an incremental 1,800 "XHANCE naive" physicians. The Company also intends to internalize its contract sales force in April 2019.

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.

Additional U.S. Patents Covering XHANCE

The United States Patent and Trademark Office (USPTO) recently issued four patents covering XHANCE. These patents, U.S. Patents 10,076,614, 10,076,615, 10,124,132, and 10,179,216, have been listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) for XHANCE and have terms that expire in years 2034, 2029, 2027, and 2033, respectively. XHANCE is now covered by 13 Orange Book-listed patents.

The full text of each patent is available on the USPTO website www.uspto.gov.

Inexia License Agreement

In February 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 their 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 and, for each product developed under the license agreement, is eligible to receive up to \$8 million of development milestone payments and up to \$37 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 will be responsible for all costs and activities related to the identification, development and commercialization of potential products under this license.

Scientific Meeting Presentations

Data on XHANCE was highlighted in four scientific posters presented during the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting which was held February 22-26, 2019:

- *Poster 190: Exhalation Delivery System (EDS) Intranasal Steroid vs Conventional Inhaled Nasal Steroids (INS): Patient Preference, Comfort and Ease of Use*
- *Poster 853: Lifetime Work Productivity Gains Among Patients with Chronic Rhinosinusitis with Nasal polyps (CRSwNP) Treated with EDS-FLU*
- *Poster 858: Evidence is Limited for the Efficacy and Safety of Corticosteroid Irrigation in Chronic Rhinosinusitis (CRS)*
- *Poster 859: Evidence for Twice-Daily Nasal Steroids Versus Once Daily for Treatment of Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)*

Abstracts are available on the AAAAI Annual Meeting website.

Fourth Quarter and Full Year 2018 Financial Results

Net product revenues

The Company generated \$3.0 million and \$7.1 million in net product revenue through the sales of XHANCE in the three- and twelve-month periods ended December 31, 2018, respectively.

Operating expenses and net loss

For the three-month period ended December 31, 2018, research and development expenses were \$3.4 million and selling, general and administrative expenses totaled \$23.7 million. Net loss for the period was \$26.4 million, or \$0.64 per share (basic and diluted).

For the year ended December 31, 2018, research and development expenses were \$10.1 million and selling, general and administrative expenses totaled \$95.6 million. Net loss for the period was \$106.7 million, or \$2.68 per share (basic and diluted).

Cash

The Company had cash and cash equivalents of \$201.0 million as of December 31, 2018.

Corporate Guidance

Research and development

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

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 March 13, 2019 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID #3567768. 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)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2018	2017	2018	2017
	(unaudited)			
Net product revenues	\$ 3,023	\$ —	\$ 7,065	\$ —
Cost of product sales	718	—	1,588	—
Gross margin	2,305	—	5,477	—
Operating expenses:				
Research and development	3,363	1,212	10,099	16,832
Selling, general and administrative	23,661	18,484	95,618	31,698
Total operating expenses	27,024	19,696	105,717	48,530
Loss from operations	(24,719)	(19,696)	(100,240)	(48,530)
Other (income) expense:	1,662	(145)	6,418	372
Net loss	\$ (26,381)	\$ (19,551)	\$ (106,658)	\$ (48,902)
Deemed dividend	—	714	—	11,969
Accretion to redemption value	—	3	—	1,096
Net loss attributable to common stockholders	\$ (26,381)	\$ (20,268)	\$ (106,658)	\$ (61,967)
Net loss per share of common stock, basic and diluted	\$ (0.64)	\$ (0.64)	\$ (2.68)	\$ (5.63)
Weighted average common shares outstanding, basic and diluted	41,227,530	31,567,310	39,765,983	10,999,121

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

	December 31, 2018	December 31, 2017
Cash and cash equivalents	\$ 200,990	\$ 234,854
Other assets	15,999	6,282
Total assets	<u>\$ 216,989</u>	<u>\$ 241,136</u>
Total current liabilities	\$ 25,697	\$ 14,777
Long-term debt, net	72,500	71,863
Other liabilities	181	—
Total stockholders' equity	<u>118,611</u>	<u>154,496</u>
Total liabilities and stockholders' equity	<u>\$ 216,989</u>	<u>\$ 241,136</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 benefits of XHANCE and the Company's patient affordability programs; potential for continued XHANCE growth; sales force expansion; the initiation, timing and benefits of a clinical program of XHANCE for chronic sinusitis; the scope and duration of patent protection afforded by the referenced patents; projected Company operating expenses and stock-based compensation for 2019; 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 Company's ability to successfully commercialize XHANCE; 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; uncertainties and delays relating to the initiation, enrollment and completion of clinical trials; unanticipated costs; the Company's ability to grow XHANCE prescriptions and become profitable; risks and uncertainties relating to intellectual property; 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

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267.521.0531

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**Building a Leading ENT / Allergy
Specialty Company**

Corporate Presentation

March 6, 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 timing of XHANCE sales force expansion, the availability of 7-day samples and the initiation of a DTC pilot; market access objectives; 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

- \$201 Million of cash as of December 31, 2018



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

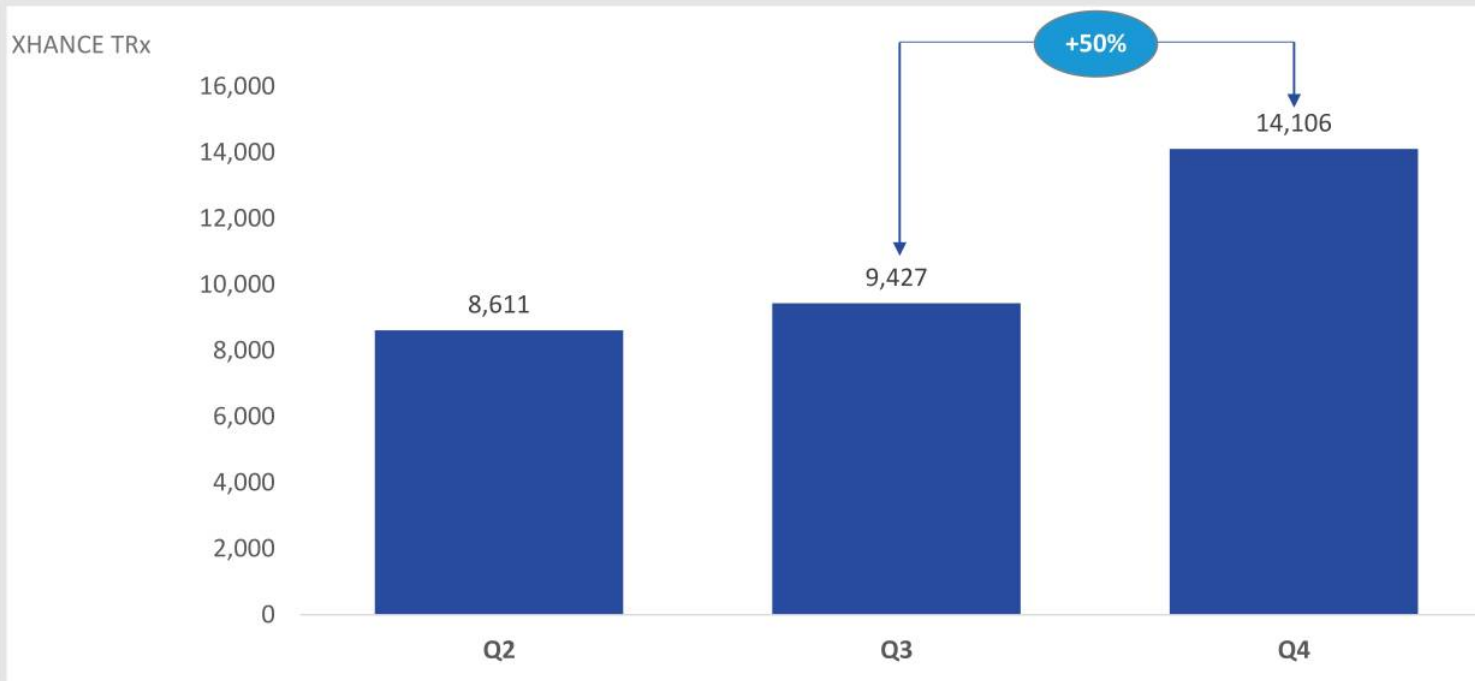
Increase Payer Coverage

Direct to Consumer Pilot



XHANCE Prescription Volume Grew 50% in Q4 2018 Versus Q3 2018

Accelerated growth in fourth quarter 2018 driven by promotional materials and patient affordability program rolled out in August/September 2018

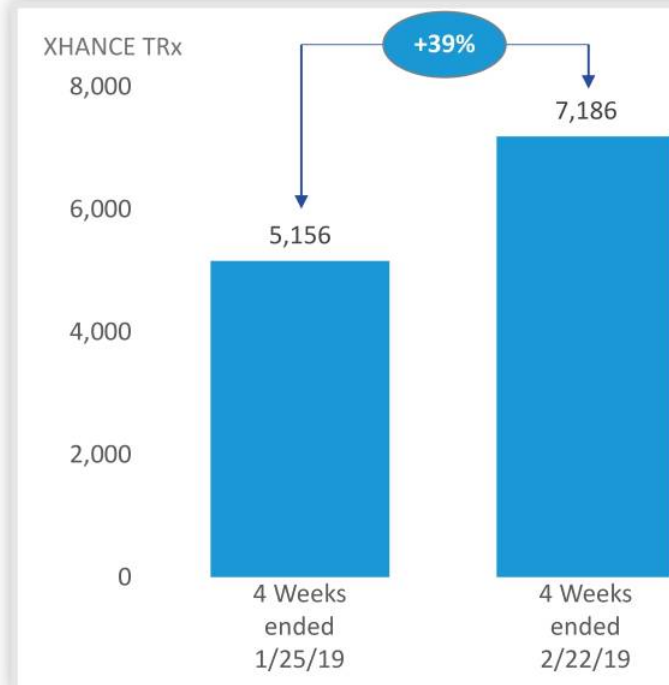
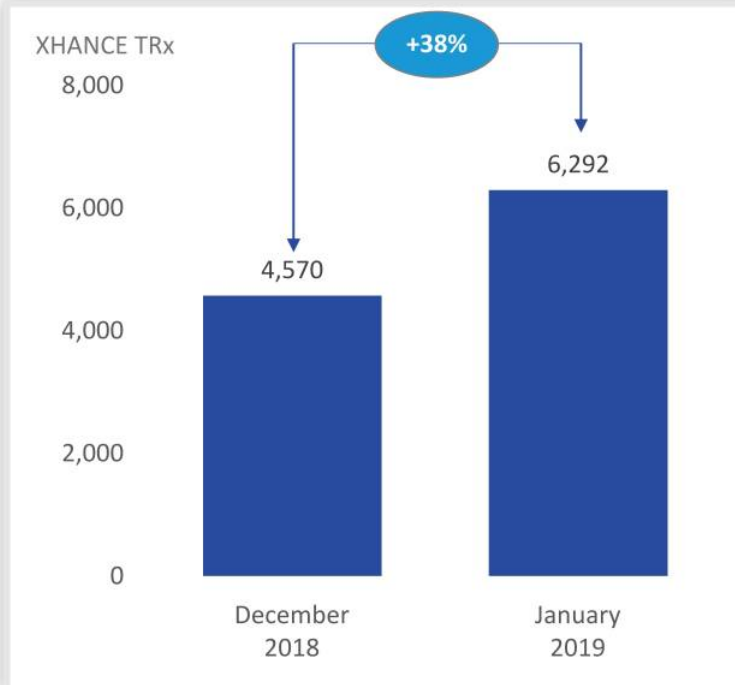


TRx for Intranasal Steroids Market increased 11% from Q3 2018 to Q4 2018

XHANCE Prescription Volume Grew 38% in Jan 2019 vs Dec 2018 and 40% for the Most Recent 4 week Period Ending Feb 22, 2019

January 2019 TRx increased 38% versus December 2018 TRx

XHANCE TRx increased 39% in the most recent 4-Week over 4-Week period



Market TRx for Intranasal Steroids increased 5% from December 2018 to January 2019 and decrease 1% from the 4-week period ended 1/25/19 to the 4-week period ended 2/22/19

Additional Commercial Updates



Market Access

- Nationally, we believe more than **75% of commercial lives** are in a plan where XHANCE is covered in a Tier 3 formulary position*



Sales Force Expansion

- Expect to deploy Territory Managers in new territories in April
- Increase of ~25% in deployed territories



Direct to Consumer

- Expect to initiate DTC pilot in 2019
- Will include broadcast in three cities



7-Day Sample

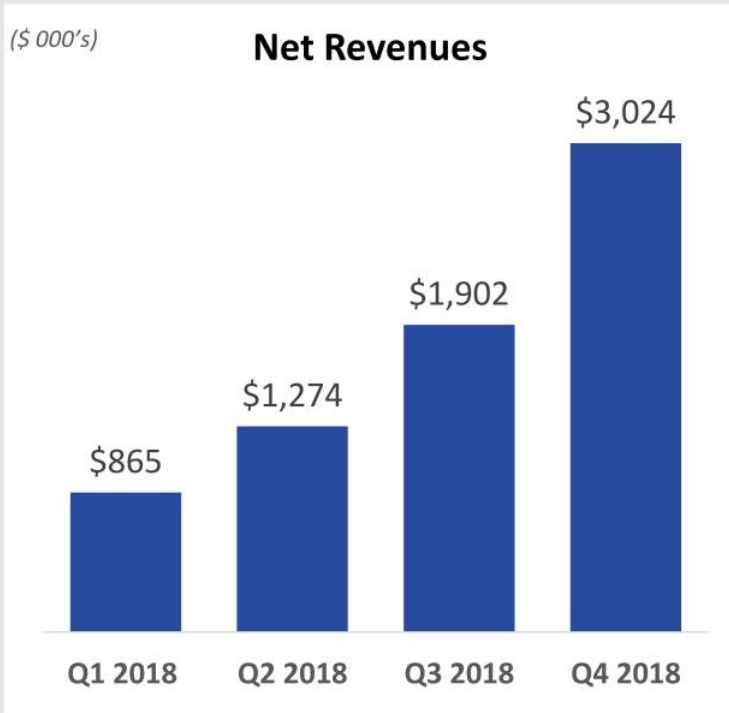
- Expected availability of 7-Day XHANCE sample in 2Q 2019

A horizontal banner image with a blue background. On the left, a black silhouette of a person's head and shoulder is shown in profile, looking upwards. A hand is visible holding a lightbulb. Several other lightbulbs are scattered across the blue background, some appearing to float or be suspended. The text "Q4 2018 Financial Update" is centered in white.

Q4 2018 Financial Update

Financial Review – Fourth Quarter and Full Year 2018

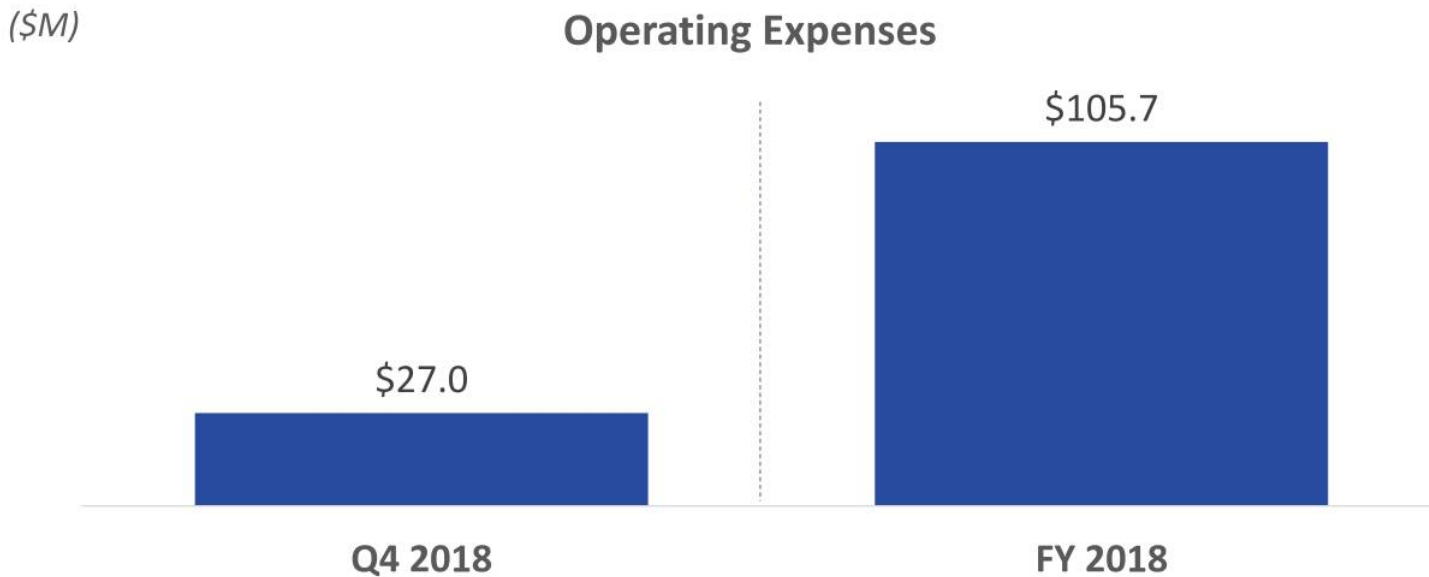
Q4 2018 Net Revenues and Average Net Revenue per Prescription



- Net revenue increased 59% in Q4 versus Q3 2018
- Average net revenue of ~\$214 per TRx in Q4 increased ~6% compared to average revenue of ~\$202 per TRx in Q3
- Increase is primarily attributable to lower rates of utilization of our patient affordability program in Q4 versus Q3
- Average net revenue per TRx of \$193 for the nine month period ended December 31, 2018

Financial Review – Fourth Quarter and Full Year 2018

Full year 2018 Operating Expenses were \$105.7M, favorable versus expected range of \$112M to \$115M



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
- Q1 2019 average net revenue per prescription of XHANCE expected to be in the range of \$155 - \$175
- Full Year 2019 average net revenue per prescription of XHANCE 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
- Key actions in Q1 2019 include the initiation of additional trial sites

Second Chronic Sinusitis Study


- Expected to start in 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



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



Recent license with Inexia demonstrates ability to add value from technology applications outside ENT/Allergy



\$201 million of cash as of December 31, 2018

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 December 2018:

- **\$201 million** in cash
- **Long-term debt: \$75 million**
- **41.3 million** common shares o
- **8.1 million** options & warrants

Optinose Investor Contact

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Relations and 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 6, 2019

