

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): November 13, 2018



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 November 13, 2018, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 13, 2018, 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 November 13, 2018.
99.2	OptiNose, Inc. Corporate Presentation, dated November 13, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

OptiNose, Inc.

By: /s/ Keith A. Goldan

Keith A. Goldan

Chief Financial Officer

Date: November 13, 2018



**Optinose Reports Third Quarter 2018 Financial Results
and Recent Operational Highlights**

Company reports third quarter net XHANCE revenue of \$1.9 million

Company reports 42% monthly XHANCE prescription growth from August to October

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

YARDLEY, Pa., Nov. 13, 2018 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 September 30, 2018, and provided recent operational highlights.

"We are encouraged by the strong prescription growth driven by our revised commercial efforts, launched in mid-August," commented CEO Peter Miller. "We are also pleased by a growing volume of patient feedback about the benefits of XHANCE and we believe that positive clinical experience, coupled with our current patient affordability program, is encouraging broader trial of XHANCE. As we look ahead to the final weeks of 2018, we are focused on continuing to initiate new patients and prescribers, which we believe will result in continued growth in 2019. Before the end of this year we also expect to start the first of two planned clinical trials in pursuit of a new indication for the treatment for chronic sinusitis. We believe successful development of XHANCE for this first-in-class indication will increase our long-term growth potential."

Third Quarter and Recent Highlights

Commercial Update

From August to October monthly XHANCE® prescriptions increased by 42%. Through November 2, 2018 more than 3,800 unique physicians have prescribed XHANCE.

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.

Scientific Meeting Presentations

In October 2018, Optinose presented data regarding its product XHANCE at the American Rhinologic Society (ARS) 64th Annual Meeting and the American Academy Of Otolaryngology-Head And Neck Surgery Annual Meeting (AAO-HNSF).

Data on XHANCE was highlighted in three podium presentations and one scientific poster presented during the ARS Annual Meeting and in one podium presentation during the AAO-HNSF Annual Meeting.

Abstracts are available on the ARS Annual Meeting and AAO-HNSF Annual Meeting websites.

XHANCE Development Update

In addition to XHANCE's existing indication for nasal polyps, we plan to initiate a clinical program to seek approval for a follow-on indication for the treatment of chronic sinusitis in the U.S. in order to broaden our market opportunity, and the Company expects to initiate the clinical program in the fourth quarter of 2018.

Third Quarter 2018 Financial Results

Revenue

The Company generated \$1.9 million in net revenue through the sales of XHANCE in the three-month period ended September 30, 2018.

Operating expenses and net loss

For the three-month period ended September 30, 2018, research and development expenses were \$3.0 million and selling, general and administrative expenses totaled \$22.1 million. Net loss for the period was \$25.1 million, or \$0.61 per share (basic and diluted).

Cash

The Company had cash and cash equivalents of \$221.5 million as of September 30, 2018.

Corporate Guidance**Research and development**

The Company expects to initiate a clinical program in pursuit of a new indication for XHANCE for the treatment of chronic sinusitis in the fourth quarter of 2018.

Operating Expenses

The Company estimates total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2018 to be in the range of \$112 - \$115 million (previous estimate of \$117 - \$121 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 November 20, 2018 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID #6156615. 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.

Investor Conferences

Chief Executive Officer Peter Miller will present at the Jefferies 2018 London Healthcare Conference on November 15, 2018, at 3:00 a.m. ET. Additionally, Mr. Miller will present at the 30th Annual Piper Jaffray Healthcare Conference on November 27, 2018, at 1:30 p.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		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Net product revenues	\$ 1,902	\$ —	\$ 4,042	\$ —
Cost of product sales	319	—	870	—
Gross margin	1,583	—	3,172	—
Operating expenses:				
Research and development	2,989	6,641	6,736	15,620
Selling, general and administrative	22,086	6,553	71,957	13,214
Total operating expenses	25,075	13,194	78,693	28,834
Loss from operations	(23,492)	(13,194)	(75,521)	(28,834)
Other (income) expense:	1,631	(126)	4,756	517
Net loss	\$ (25,123)	\$ (13,068)	\$ (80,277)	\$ (29,351)
Deemed dividend	—	4,105	—	11,255
Accretion to redemption value	—	19	—	1,093
Net loss attributable to common stockholders	\$ (25,123)	\$ (17,192)	\$ (80,277)	\$ (41,699)
Net loss per share of common stock				
basic	\$ (0.61)	\$ (4.23)	\$ (2.04)	\$ (10.25)
diluted	\$ (0.61)	\$ (4.23)	\$ (2.04)	\$ (10.25)
Weighted average common shares outstanding				
basic	41,207,167	4,067,717	39,260,903	4,067,717
diluted	41,207,167	4,067,717	39,260,903	4,067,717

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

	September 30,	December 31,
	2018	2017
	(Unaudited)	
Cash and cash equivalents	\$ 221,491	\$ 234,854
Other assets	16,131	6,282
Total assets	\$ 237,622	\$ 241,136
Total current liabilities	\$ 22,362	\$ 14,777
Long-term debt, net	72,318	71,863
Other liabilities	212	—
Total stockholders' equity	142,730	154,496
Total liabilities and stockholders' equity	\$ 237,622	\$ 241,136

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 initiation, timing and benefits of a clinical program of XHANCE for chronic sinusitis; projected Company operating expenses for 2018; the potential benefits of the Company's patient affordability programs; 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 obtain 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; 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

November 13, 2018



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 future growth; potential benefits of our patient affordability programs; market access objectives; potential effects of INS market seasonality on XHANCE prescriptions; market opportunities; commercial strategies; initiation of DTC pilot; the initiation and timing of clinical trials for chronic sinusitis; projected 2018 operating expenses; expectations regarding average revenue per prescription in fourth quarter of 2018; 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.

This presentation and our accompanying remarks also contain estimates, projections, market research and other data generated by independent third parties and by us concerning our industry, XHANCE, brand awareness, market access, the estimated size of markets, the prevalence of certain medical conditions and the perceptions and preferences of patients and physicians. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual events and circumstances may differ materially from events and circumstances reflected in this information. You are cautioned not to give undue weight to such information.

Optinose Key Priorities



Accelerate XHANCE® prescription growth



Advance our clinical program for XHANCE for a follow-on indication for the treatment of chronic sinusitis

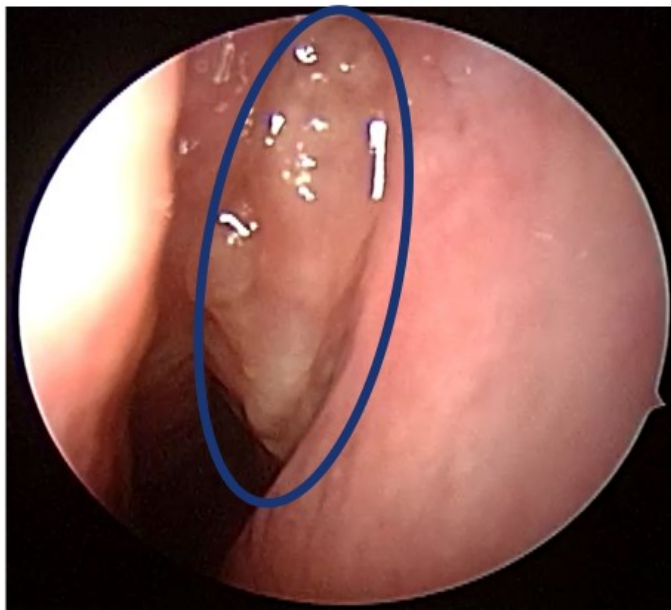


Support our commercial and development objectives through efficient use of capital

- ~\$220 Million of cash as of September 30, 2018

XHANCE Launch Update

Examples of Positive XHANCE Physician Feedback *



"The polyps were significantly reduced and patient symptoms improved. The results were dramatic." - ENT

*Testimonials and images reflect real life experience of those who have reported using XHANCE. However, they are individual results and results do vary. We do not claim that they are typical results that users will generally achieve.

Our Updated Patient Assistance Program Addresses Physician Perceptions Regarding Affordability and Access



XHANCE™

XTENDED Patient Support

- \$0 co-pay for initial Rx for all commercial patients
- Maximum out of pocket of \$30 for refills for covered commercial patients
- Maximum out of pocket of \$50 for non-covered commercial patients
- Program design driven by patient willingness to pay research and physician willingness to prescribe research

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*
- Recently signed first Part D contract and expanding Medicaid coverage



Writers

- More than 3,800 physicians have written a prescription through November 2nd
- Number of weekly prescribers growing week over week

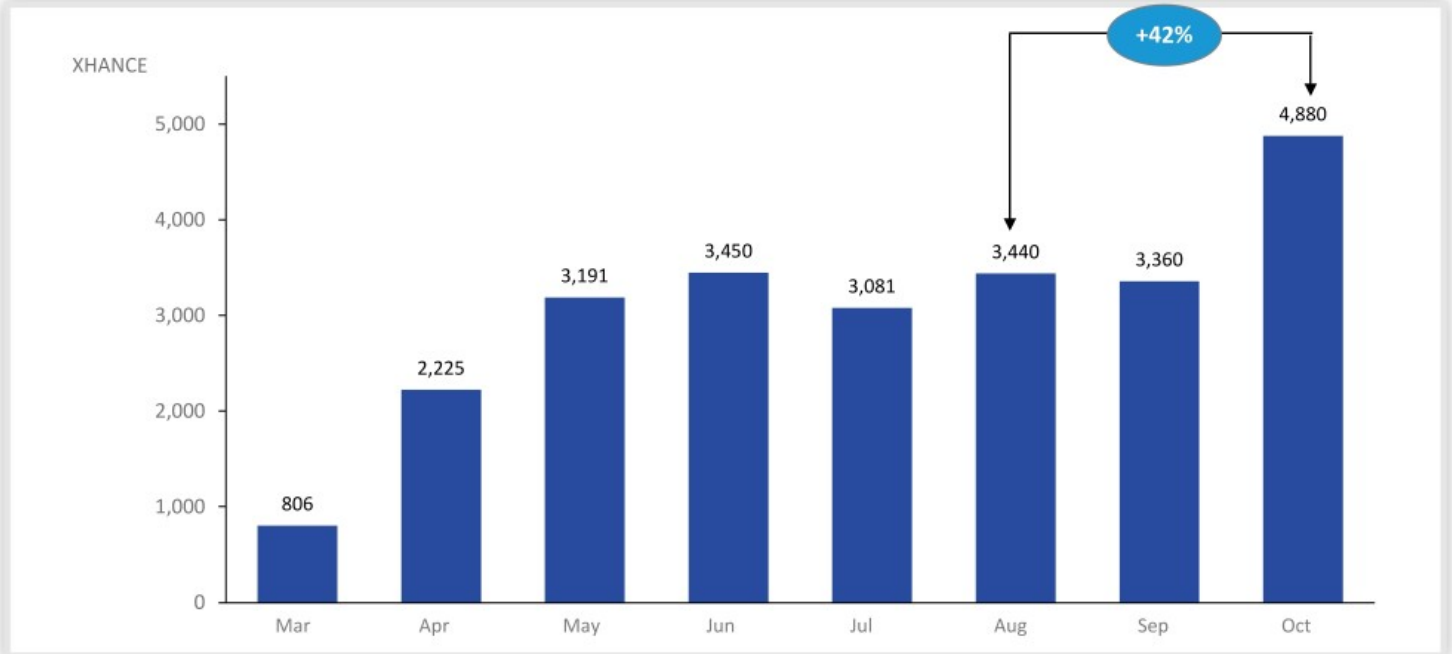


Direct to Consumer

- Initiating pilot program in Q4 using digital-only approach for DTC

XHANCE Monthly Prescription Volumes

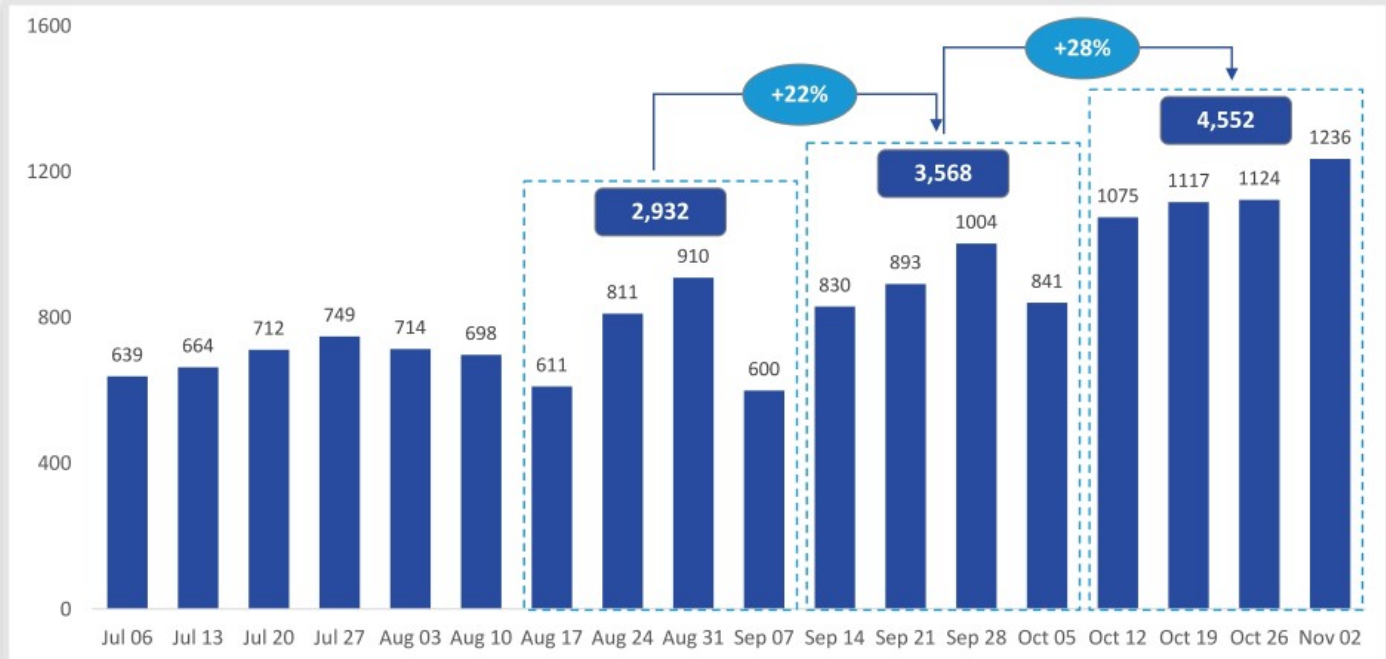
New promotional materials and patient affordability program rolled out week of August 17



Market TRx for Intranasal Steroids increased 10% from August 2018 to October 2018

XHANCE Weekly Prescription Volumes

New promotional materials and patient affordability program rolled out week of August 17



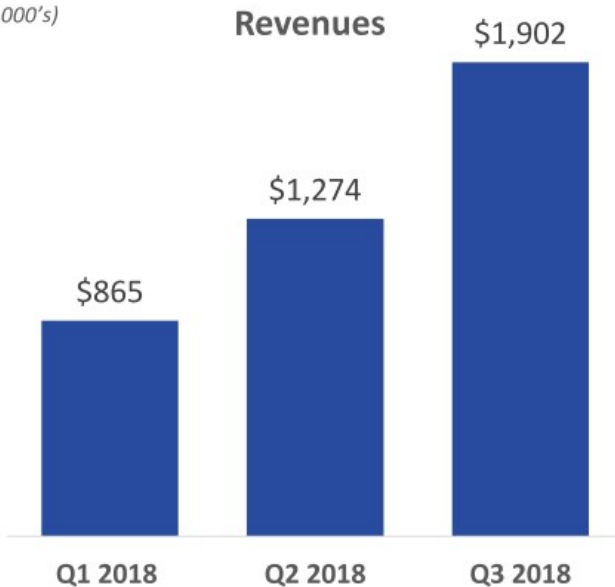
Market TRx for Intranasal Steroids increased 9% and decreased 2% in the four week periods ended Oct. 5 and Nov. 2 respectively

Q3 2018 Financial Update

Financial Review – Third Quarter 2018

Q3 2018 Revenues and Average Revenue per Prescription

(\$ 000's)



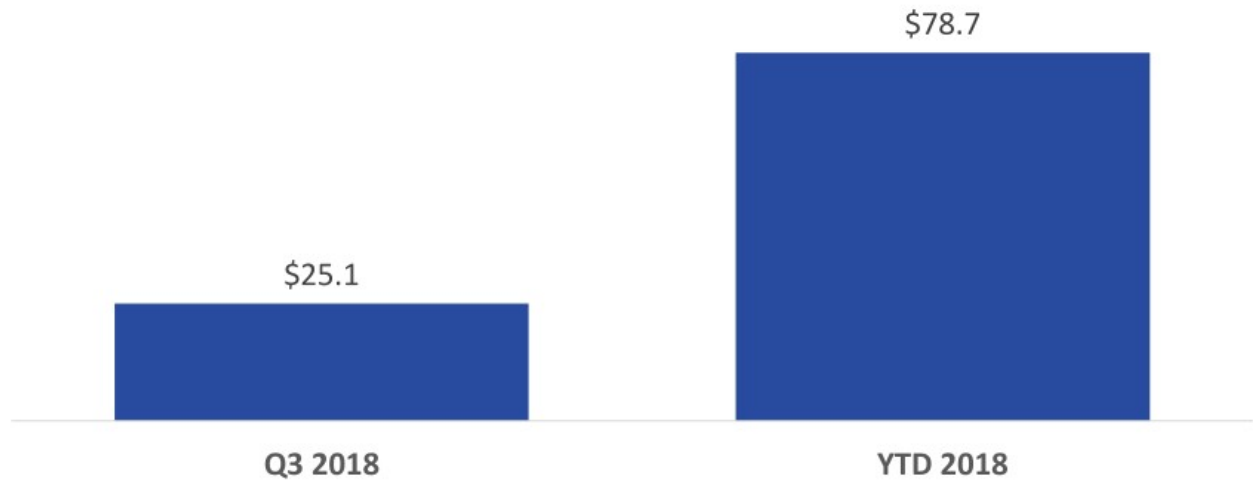
- Average revenue of ~\$191 per TRx in Q3 increased 33% compared to average revenue of ~\$144 per TRx in Q2
- Increase is primarily attributable to lower rates of utilization of our patient affordability program in Q3 versus Q2
- We expect average revenue per TRx to be lower in Q4 versus Q3 due largely to higher utilization of our patient affordability program

Financial Review – Fourth Quarter and Full Year 2018

Full year 2018 Operating Expenses expected to be in the range of \$112M to \$115M - prior range was \$117M to \$121M

(\$M)

Operating Expenses



Pipeline Update and Closing Remarks

XHANCE: “Chronic Sinusitis” Follow-on Indication (sNDA)

Met with FDA
regarding CS
study design

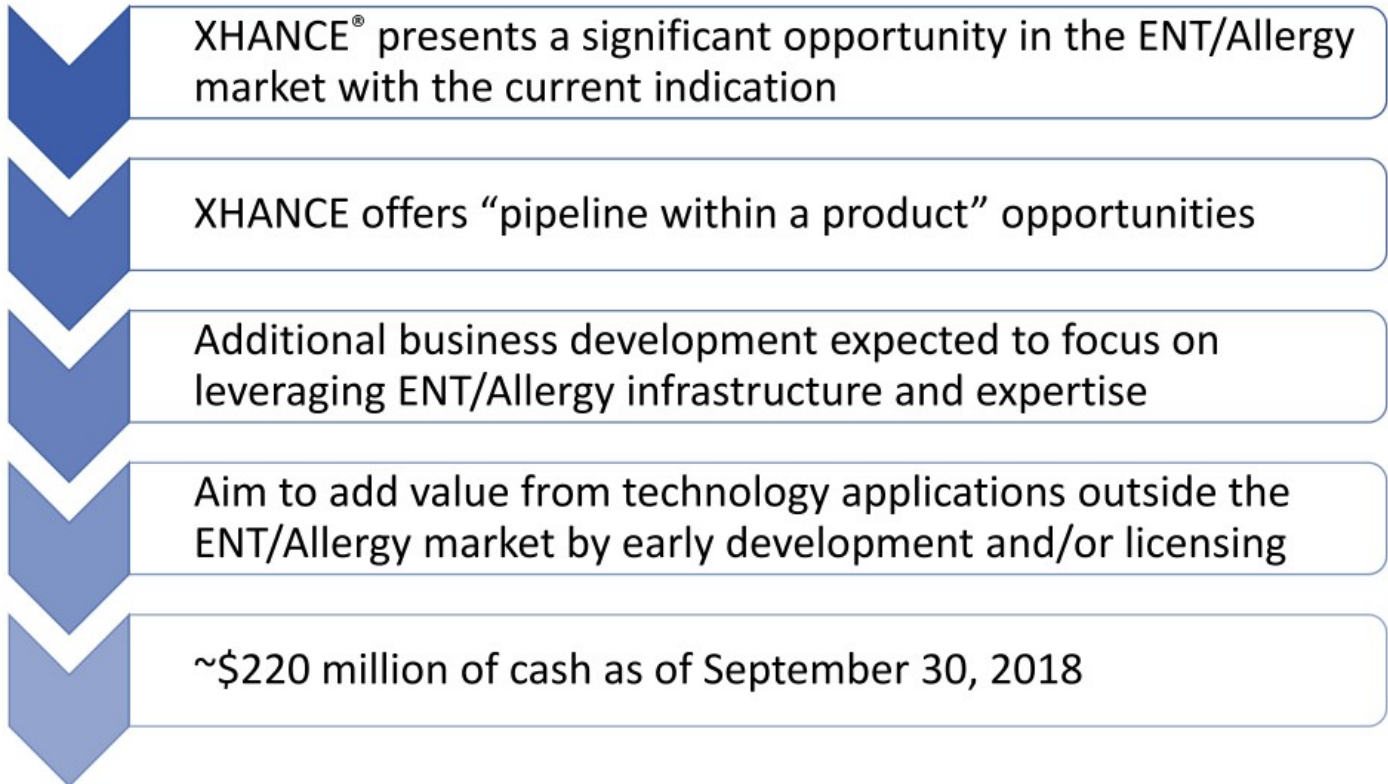
Selection of CRO
and study
locations

First patient
expected to enroll
in 4Q 2018

Chronic Sinusitis trial design expected to include co-primary endpoints: both an objective measure of inflammation and a subjective measure of symptom relief

Emerging Growth Company with Approved Products

BUILDING A LEADING ENT / ALLERGY SPECIALTY COMPANY



Investor Relations – NASDAQ: OPTN

Analyst Coverage¹

BMO: Gary Nachman

Jefferies: David Steinberg

Cantor Fitzgerald: William Tanner

Piper Jaffray: David Amsellem

RBC: Randall Stanicky

At 30 September 2018:

- ~\$220 million in cash
- Long-term debt: \$75 million
- 41.2 million common shares o/s
- 8.0 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 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

November 13, 2018

optinose
