

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 12, 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))

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 November 12, 2019, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 12, 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 November 12, 2019.
99.2	OptiNose, Inc. Corporate Presentation, dated November 12, 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: November 12, 2019



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

XHANCE net revenue grew 30% to \$8.7 million from second to third quarter 2019

XHANCE prescriptions increased 27% from second to third quarter 2019

Company expects XHANCE net revenues for 2019 to be in the range of \$30 - \$33 million

Conference call and webcast to be held today at 4:30 p.m. Eastern Time

YARDLEY, Pa., November 12, 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 September 30, 2019, and provided recent operational highlights.

"XHANCE continues to grow as the result of our successful commercial strategy and we believe there is a significant growth opportunity ahead," stated CEO Peter Miller. "We delivered strong growth for XHANCE in both the number of prescriptions and net revenue. Importantly, XHANCE average revenue per prescription increased to \$202 in the third quarter of 2019, which supports our objective to grow the business in way that can support future profitability." Mr. Miller also noted, "Overall, I am encouraged by the progress we are making with the XHANCE launch and towards other important corporate objectives including: activating sites and recruiting for the chronic sinusitis trials, conducting a DTC pilot in three U.S. cities, and completing a debt financing with Pharmakon that will enable us to focus on executing our plans to grow our business and create value for our investors."

Third Quarter 2019 and Recent Highlights

XHANCE Prescription Growth Rates

The number of XHANCE[®] (fluticasone propionate) prescriptions increased by 27% from second quarter to third quarter 2019 and by 18% from September to October 2019.

\$150 Million Debt Financing

In September, the Company entered into a note purchase agreement for up to \$150 million of senior secured notes with funds managed by Pharmakon Advisors, LP (Pharmakon), the investment manager of the BioPharma Credit funds.

Concurrent with entering into the agreement, Optinose issued \$80 million of senior secured notes, these initial proceeds were used to repay and retire the Company's previous indebtedness under its note purchase agreement with Athyrium Opportunities III Acquisition LP. An additional \$30 million of notes will be issued by Optinose by February 15, 2020 subject to the achievement of minimum XHANCE revenues and certain other conditions. Two additional tranches of notes of \$20 million each will be available to Optinose, at its option, in 2020 and 2021 subject to the achievement of minimum XHANCE revenues and certain other conditions. The notes will mature in September 2024.

Currax License Agreement

In September, the Company signed an agreement between its Norway-based subsidiary OptiNose AS and Currax Pharmaceuticals LLC (Currax) which grants Currax the exclusive rights to certain Optinose intellectual property for the purpose of marketing ONZETRA[®] XSAIL[®] (sumatriptan nasal powder) in the United States, Canada, and Mexico.

The Company received an \$4.48 million upfront payment, of which \$750,000 is being held in escrow for a limited period to cover indemnification obligations. Additionally, the Company is eligible to receive a one-time 10% royalty on ONZETRA net sales in excess of \$3 million solely for calendar year 2020, and an additional \$1 million milestone payment subject to the achievement of a specified regulatory milestone.

Third Quarter 2019 Financial Results

Revenue

The Company generated \$8.7 million and \$19.3 million of XHANCE net revenue during the three-month and nine-month periods ended September 30, 2019. In addition, the Company generated \$3.7 million and \$4.2 million of licensing revenue during the three-month and nine-month periods ended September 30, 2019. Total revenues for the three-month and nine-month periods ended September 30, 2019 were \$12.4 million and \$23.5 million.

Expenses and net loss

For the three-month and nine-month periods ended September 30, 2019, research and development expenses were \$5.5 million and \$15.4 million. Selling, general and administrative expenses were \$25.3 million and \$77.6 million during the three-month and nine-month periods ended September 30, 2019. The net loss for the three-month period ended September 30, 2019 was \$(28.8) million, or \$(0.69) per share (basic and diluted). The net loss for the nine-month period ended September 30, 2019 was \$(85.1) million, or \$(2.06) per share (basic and diluted).

Cash

The Company had cash and cash equivalents of \$125.5 million as of September 30, 2019.

Corporate Guidance

XHANCE Net Revenue

The Company expects XHANCE net revenue for 2019 to be in the range of \$30.0 - \$33.0 million. Previously the Company expected XHANCE net revenue for 2019 to be in the range of \$29.0 - \$34.0 million.

XHANCE Average Net Revenue per Prescription

The Company expects XHANCE average net revenue per prescription for 2019, which is calculated by dividing XHANCE net revenue for 2019 by the estimated number of XHANCE prescriptions dispensed during 2019, to be in the range of \$195 - \$205. Previously the Company expected XHANCE average net revenue per prescription for 2019 to be in the range of \$185 - \$205.

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 \$126 - \$129 million, of which the Company expects stock-based compensation to be approximately \$10 million. Previously the Company expected total GAAP operating expenses for 2019 to be in the range of \$128 - \$133 million of which stock-based compensation was expected to be in the range of \$10 - \$11 million.

Chronic Sinusitis Clinical Trials

The Company expects top line results from the first of its two clinical trials evaluating XHANCE as a potential treatment for Chronic Sinusitis in the second half of 2021.

Company to Host Conference Call

Members of the Company's leadership team will host a conference call and presentation to discuss financial results and corporate updates beginning at 4:30 p.m. Eastern Time today.

To participate on the conference call, please dial (866) 916-4761 from the U.S. or +1 (409) 216-6496 from outside the U.S. In addition, following the completion of the call, a telephone replay will be accessible until November 19, 2019 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID: 6277826. 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)

	Nine Months Ended		Three Months Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Revenues:				
Net product revenues	\$ 19,320	\$ 4,042	\$ 8,667	\$ 1,902
Licensing revenues	4,230	—	3,730	—
Total revenues	<u>23,550</u>	<u>4,042</u>	<u>12,397</u>	<u>1,902</u>
Costs and expenses:				
Cost of product sales	3,216	870	1,389	319
Research and development	15,404	6,736	5,547	2,989
Selling, general and administrative	77,610	71,957	25,270	22,086
Total costs and expenses	<u>96,230</u>	<u>79,563</u>	<u>32,206</u>	<u>25,394</u>
Loss from operations	<u>(72,680)</u>	<u>(75,521)</u>	<u>(19,809)</u>	<u>(23,492)</u>
Other expense	12,378	4,755	8,999	1,631
Net loss	<u>\$ (85,058)</u>	<u>\$ (80,276)</u>	<u>\$ (28,808)</u>	<u>\$ (25,123)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (2.06)</u>	<u>\$ (2.04)</u>	<u>\$ (0.69)</u>	<u>\$ (0.61)</u>
Weighted average common shares outstanding, basic and diluted	<u>41,341,570</u>	<u>39,260,903</u>	<u>41,454,181</u>	<u>41,207,167</u>

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

	September 30,		December 31,	
	2019		2018	
	(unaudited)			
Cash and cash equivalents	\$ 125,490	\$ 200,990		
Other assets	23,887	15,999		
Total assets	<u>\$ 149,377</u>	<u>\$ 216,989</u>		
Total current liabilities	\$ 29,962	\$ 25,697		
Long-term debt, net	74,266	72,500		
Other liabilities	631	181		
Total stockholders' equity	44,518	118,611		
Total liabilities and stockholders' equity	<u>\$ 149,377</u>	<u>\$ 216,989</u>		

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, potential growth drivers and market opportunity; the Company's ability to grow the business to support future profitability; 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 the first of two chronic sinusitis trials in second half 2021; projected XHANCE net revenues for 2019; projected average net revenue per prescription for 2019; projected Company GAAP 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: 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.

Optinose Investor Contact

Jonathan Neely
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267.521.0531

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Building a Leading ENT / Allergy Specialty Company

Corporate Presentation

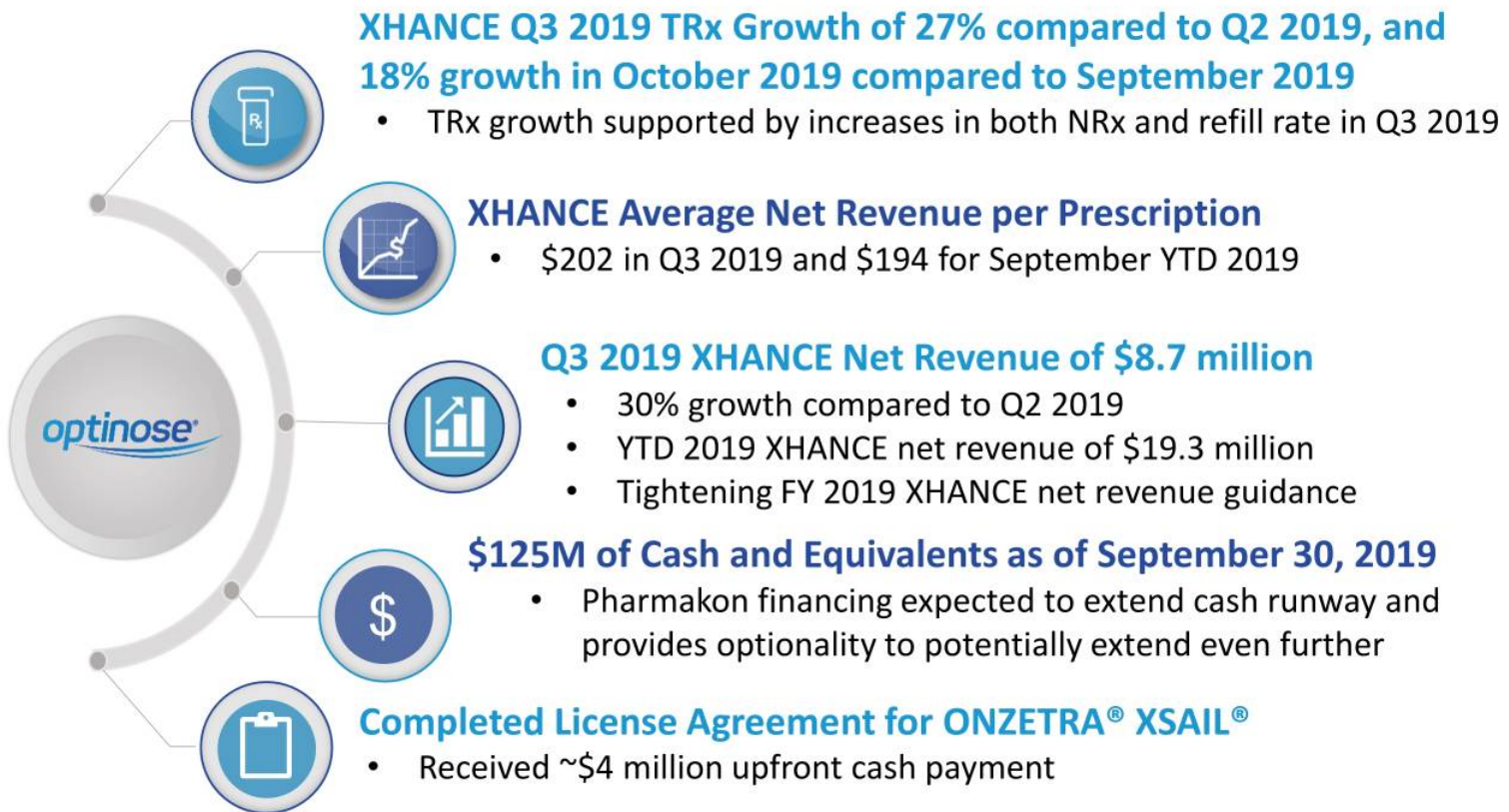
November 12, 2019

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 for continued XHANCE growth, potential growth drivers and market opportunity; potential effects of INS market seasonality on XHANCE prescriptions; the Company’s expectation that it will satisfy the conditions to issue an additional \$30 million of notes under the Pharmakon note purchase agreement and that the agreement will extend its cash runway; projected XHANCE net revenues for 2019; projected average net revenue per prescription for 2019; projected Company GAAP operating expenses and stock-based compensation for 2019; 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 the first of two chronic sinusitis trials in second half 2021; 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.

Q3 2019 Key Highlights

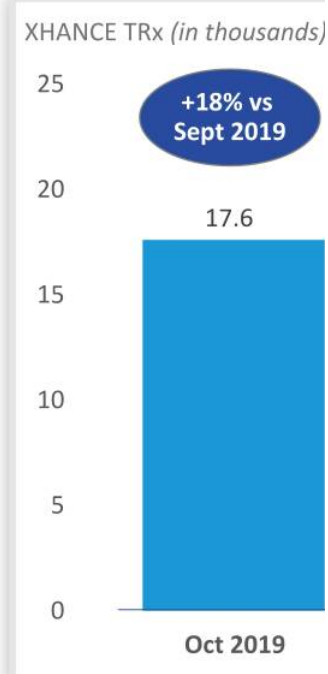
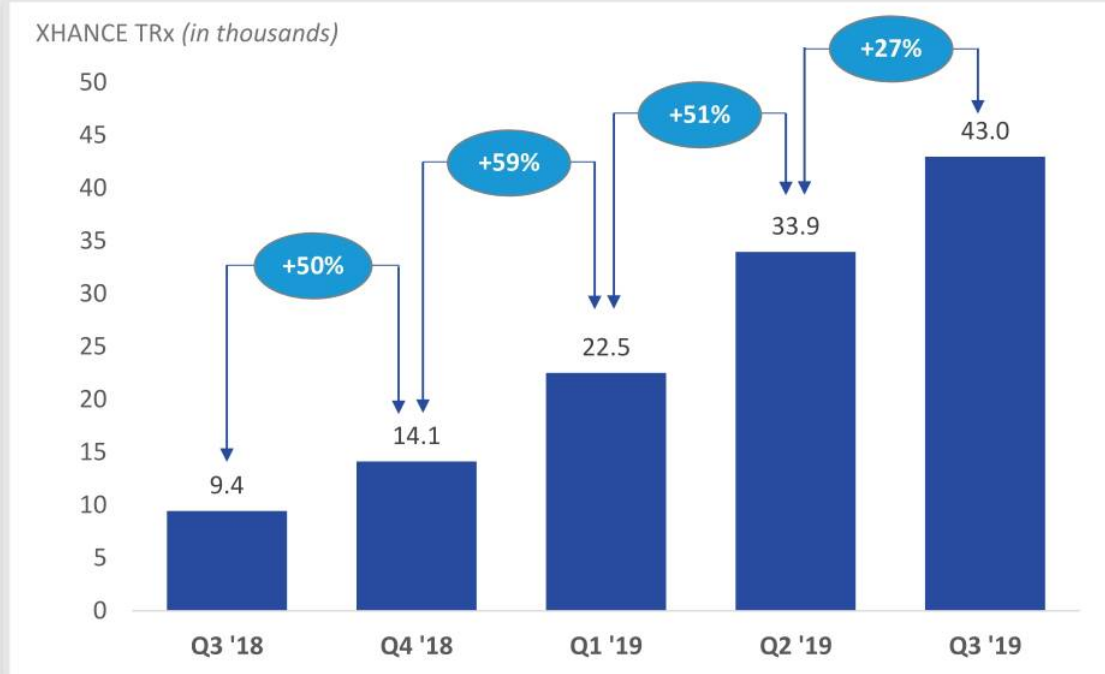


A blue-tinted image featuring a silhouette of a person's head and hand holding a lightbulb. Several other lightbulbs are scattered in the background against a gradient blue sky.

XHANCE Launch Update

XHANCE Prescription Volume Grew 27% in Q3 versus Q2 2019 and 18% in October versus September 2019

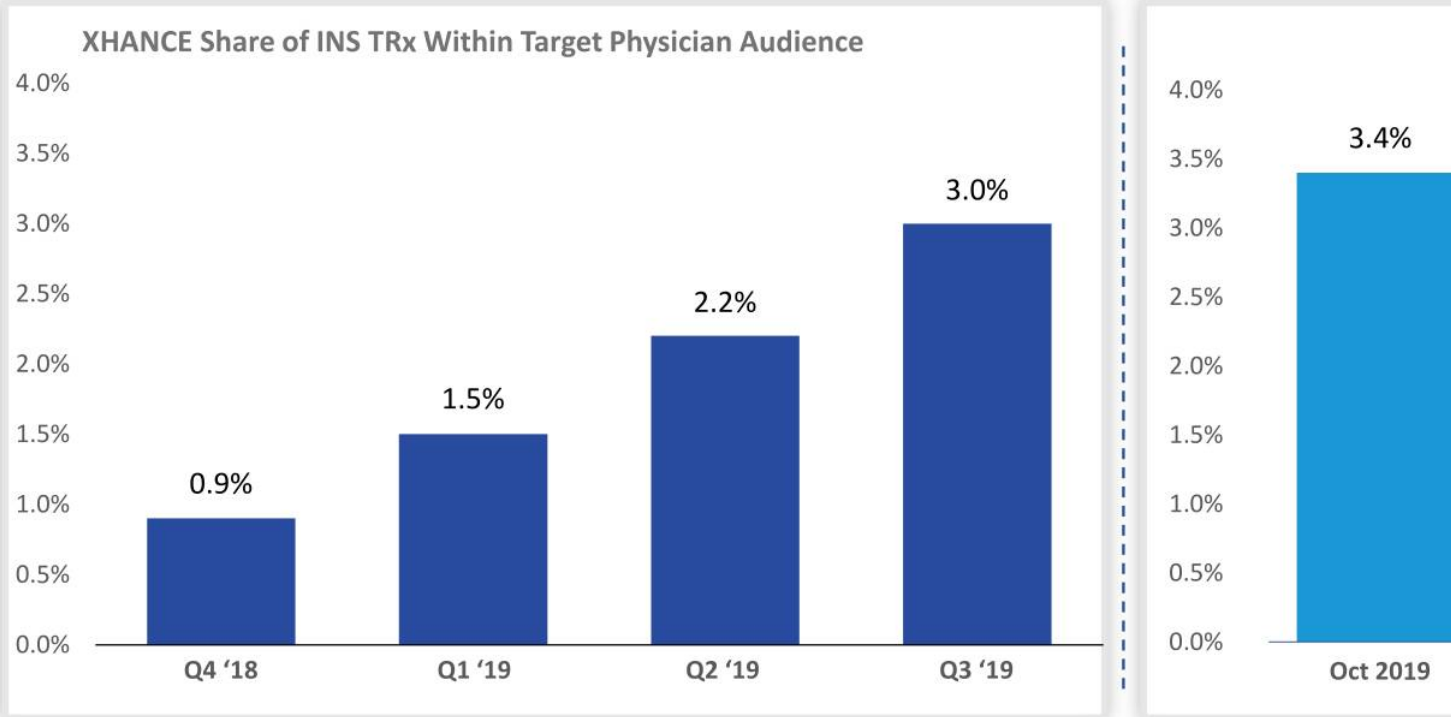
Strong growth in both new prescriptions and refills drove XHANCE quarterly prescription growth of 27% in Q3 2019



TRx for Intranasal Steroids Market increased 11% from Q3 to Q4 2018, increased 3% from Q4 2018 to Q1 2019, increased 1% from Q1 to Q2 2019, decreased 11% from Q2 to Q3 2019 and increased 10% from September to October 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 has increased consistently in 2019 and that trend continues in early Q4 2019



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 (IQVIA) and XHANCE preferred pharmacy network.

* October market share estimated as of October 25, 2019

Additional Commercial Updates



DTC Test Market Pilot nearing completion

- Full analysis at the end of the pilot is expected to drive decisions regarding a potential DTC program in 2020



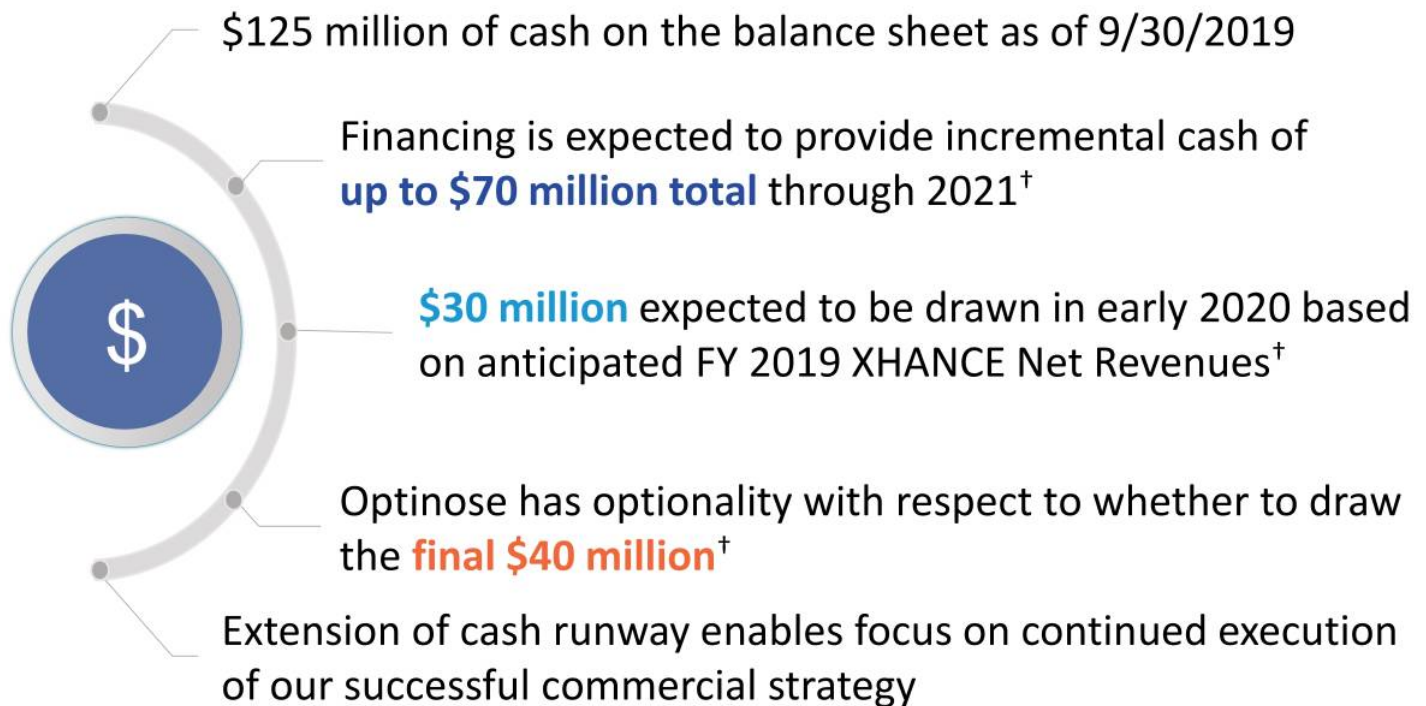
XHANCE Target Physician Perception Survey

- We are encouraged by the continued progress we see in our market research
- “Good results seen in their patients” has become one of the leading reasons given by surveyed physicians for prescribing XHANCE, along with “it is different and provides better medication deposition”

A blue-tinted image featuring a silhouette of a person's head and shoulders on the left, holding a string of light bulbs. Several light bulbs are shown in various positions, some appearing to float or be held. The background is a solid blue color.

Q3 2019 Financial Update

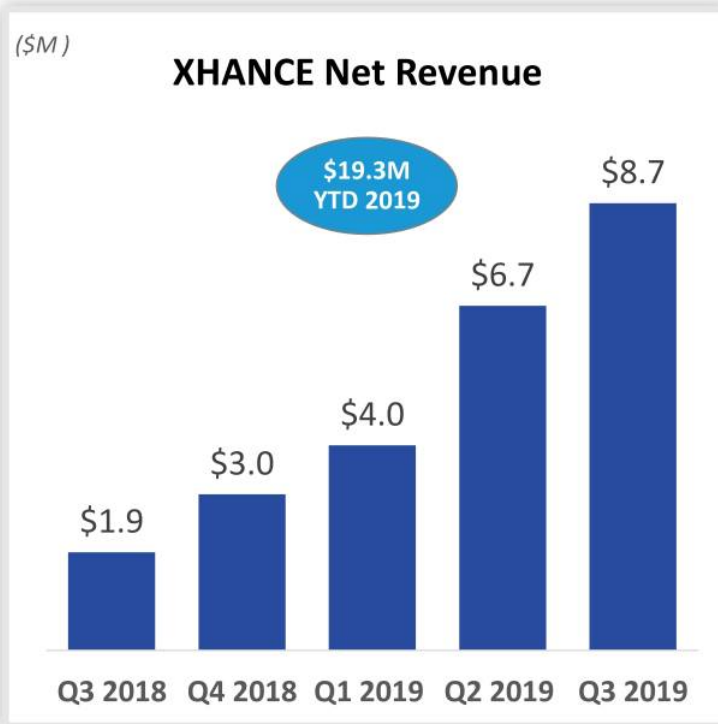
Pharmakon Debt Financing Expected to Extend Cash Runway



[†] Availability is subject to the achievement of XHANCE net revenue thresholds and certain other conditions

Financial Review – Third Quarter 2019

Q3 2019 XHANCE Net Revenue Increased 30% to \$8.7 Million



Average Net Revenue per TRx

- Average XHANCE net revenue of \$202 per TRx in Q3 2019
 - Increased from \$197 in Q2 2019
- Average XHANCE net revenue of \$194 per TRx YTD September 2019

Updated 2019 Financial Guidance

- **2019 XHANCE Net Revenue** expected to be \$30 - \$33 million
 - Prior guidance range was \$29 - \$34 million
- **2019 XHANCE Average Net Revenue per Prescription** expected to be \$195 - \$205
 - Prior guidance range was \$185 to \$205
- **2019 Operating Expenses (GAAP)** expected to be \$126 – \$129 million; Approximately \$10 million of which represents stock-based compensation
 - Prior guidance range of \$128 - \$133 million; \$10 - \$11 million of which was stock based compensation



Pipeline Update

XHANCE Chronic Sinusitis Indication (sNDA)

The Chronic Sinusitis development program includes two Phase 3b clinical trials that are 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

- First patient enrolled in Q2 2019
- 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



Commercial Strategy Driving Strong XHANCE Growth

Substantial Growth Opportunity Remains for XHANCE

Maintaining/Improving on all Financial Guidance Measures

Strong Balance Sheet - Pharmakon Provides Access to Additional Cash

Successfully completing other important corporate objectives

+30%

XHANCE Net Revenue Growth Q3/Q2

\$125M

Cash and equivalents as of September 30, 2019

\$202

XHANCE Net Revenue per TRx in Q3 2019

Up to
\$70M

Incremental cash available from recent financing

+27%

XHANCE TRx Growth Q3/Q2

Investor Relations – NASDAQ: OPTN

Analyst Coverage ¹

BMO: Gary Nachman

Jefferies: David Steinberg

Cantor Fitzgerald: Brandon Folkes

Piper Jaffray: David Amsellem

RBC: Randall Stanicky

At 30 September 2019:

- \$125 million in cash
- Long-term debt: \$80 million
- 41.5 million common shares o/s
- 10.4 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

November 12, 2019

