

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



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

XHANCE net revenue grew 68% to \$6.7 million from first to second quarter 2019

XHANCE prescriptions increased 51% from first to second quarter 2019

Company expects XHANCE net revenues for 2019 to be in the range of \$29 - \$34 million

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

YARDLEY, Pa., August 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 June 30, 2019, and provided recent operational highlights.

"We delivered 51% quarter-over-quarter growth in the number of XHANCE prescriptions during the second quarter of 2019, making this the third consecutive quarter of 50% or greater prescription growth," stated CEO Peter Miller. "Our revenue growth in the second quarter was comparably strong at 68% and our first half average revenue per prescription is within our full year guidance range." Mr. Miller also noted, "Our focus is on execution of our commercial strategy which is succeeding based on the launch performance of XHANCE. As one highlight, we are encouraged by the initial progress of the territory managers we hired in April to expand our physician reach by 25%. We expect these newly staffed territories to be one of several important drivers that can increase the number of patients starting treatment with XHANCE. Finally, what is more exciting than the growth we have experienced to date is the substantial market opportunity that is still available for XHANCE."

Second Quarter 2019 and Recent Highlights

XHANCE Commercial Update

The number of XHANCE[®] (fluticasone propionate) prescriptions increased by 51% from first quarter to second quarter 2019 and by 17% from June to July 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 April 2019, the Company expanded its number of sales territories from 80 to 100. The Company is now calling on an estimated 2,200 previously uncalled-on physicians in the new sales territories and is now targeting 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 treatment of nasal polyps, the Company plans to seek approval for a follow-on indication for treatment of chronic sinusitis in the U.S. in order to broaden its market opportunity. In May 2019, the Company initiated the second of two ongoing Phase 3b clinical trials for this condition.

Additional U.S. Patents Covering XHANCE

The United States Patent and Trademark Office (USPTO) recently issued two patents covering XHANCE. These patents, U.S. Patents 10,252,010 and 10,300,229, 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 2031 and 2035, respectively. XHANCE is now covered by 15 Orange Book-listed patents.

Second Quarter 2019 Financial Results

Revenue

The Company generated \$6.7 million and \$10.7 million of XHANCE net revenue during the three-month and six-month periods ended June 30, 2019. Total revenues for the six-month period ended June 30, 2019 was \$11.2 million.

Expenses and net loss

For the three-month period ended June 30, 2019, research and development expenses were \$5.3 million and selling, general and administrative expenses were \$26.0 million. The net loss for the period was \$(27.4) million, or \$(0.66) per share (basic and diluted).

Cash

The Company had cash and cash equivalents of \$144.0 million as of June 30, 2019.

Corporate Guidance

XHANCE Net Revenue

The Company expects XHANCE net revenue for 2019 to be in the range of \$29 - \$34 million.

XHANCE Average Net Revenue per Prescription

The Company continues to expect 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 \$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 \$128 - \$133 million, of which the Company expects stock-based compensation to be in the range of \$10 - \$11 million. Previously the Company expected total GAAP operating expenses for 2019 to be in the range of \$135 - \$142 million of which stock-based compensation was expected 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 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 August 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: 7548458. 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)

	Six Months Ended		Three Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
Revenues:				
Net product revenues	\$ 10,653	\$ 2,139	\$ 6,677	\$ 1,274
Licensing revenues	500	—	—	—
Total revenues	<u>11,153</u>	<u>2,139</u>	<u>6,677</u>	<u>1,274</u>
Costs and expenses:				
Cost of product sales	1,827	551	1,089	351
Research and development	9,857	3,747	5,295	2,046
Selling, general and administrative	52,340	49,871	26,000	21,860
Total costs and expenses	<u>64,024</u>	<u>54,169</u>	<u>32,384</u>	<u>24,257</u>
Loss from operations	<u>(52,871)</u>	<u>(52,030)</u>	<u>(25,707)</u>	<u>(22,983)</u>
Other expense	3,380	3,124	1,670	1,598
Net loss	<u>\$ (56,251)</u>	<u>\$ (55,154)</u>	<u>\$ (27,377)</u>	<u>\$ (24,581)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (1.36)</u>	<u>\$ (1.44)</u>	<u>\$ (0.66)</u>	<u>\$ (0.64)</u>
Weighted average common shares outstanding, basic and diluted	<u>41,283,478</u>	<u>38,271,101</u>	<u>41,310,608</u>	<u>38,688,366</u>

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

	June 30,	December 31,
	2019	2018
	(unaudited)	
Cash and cash equivalents	\$ 143,963	\$ 200,990
Other assets	22,609	15,999
Total assets	<u>\$ 166,572</u>	<u>\$ 216,989</u>
Total current liabilities	\$ 24,367	\$ 25,697
Long-term debt, net	72,869	72,500
Other liabilities	864	181
Total stockholders' equity	<u>68,472</u>	<u>118,611</u>
Total liabilities and stockholders' equity	<u>\$ 166,572</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 plans to seek approval for a follow-on indication for XHANCE for the treatment of chronic sinusitis and the potential benefits of such indication; projected XHANCE net revenues for 2019; projected average 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; uncertainties and delays relating to the enrollment, completion, and results of clinical trials; unanticipated costs and expenses; 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
jonathan.neely@optinose.com
267.521.0531

###

Building a Leading ENT / Allergy Specialty Company

Corporate Presentation

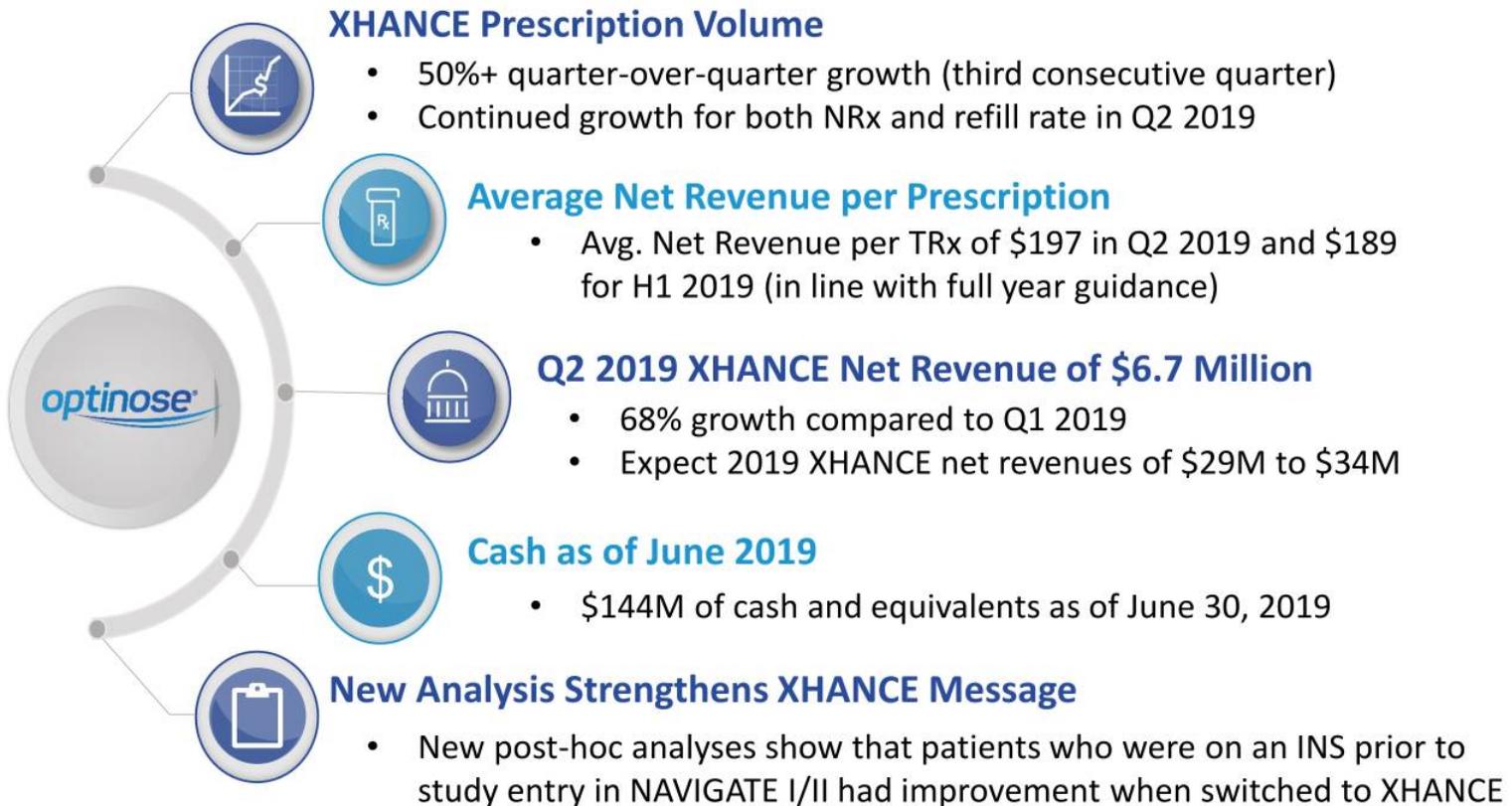
August 12, 2019

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 benefits of XHANCE® and our EDS technology; potential drivers of XHANCE growth; potential benefits of XHANCE sales force expansion, the availability of 7-day samples and the initiation of a DTC pilot; market access objectives; potential benefits of patient affordability programs; potential effects of INS market seasonality on XHANCE prescriptions; the initiation and timing of clinical trials for chronic sinusitis; projected 2019 XHANCE net revenues; projected 2019 operating expenses and stock-based compensation; projected 2019 average XHANCE revenue per prescription; 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; 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.

Q2 2019 Key Highlights



XHANCE Launch Update

Commercial Strategy is Successfully Growing XHANCE

And Additional Accelerators Support this Strategy

Differentiate XHANCE on Efficacy

- Newly available post-hoc subgroup analysis on previous INS patients* who switched to XHANCE
- Video evidence illustrating the efficacy of XHANCE

Drive New Patient Starts

- 25% Increase in Sales Territories
- New 7-Day Sample
- Initiated Direct to Consumer (DTC) Pilot in Charlotte, Cleveland and Hartford in August 2019

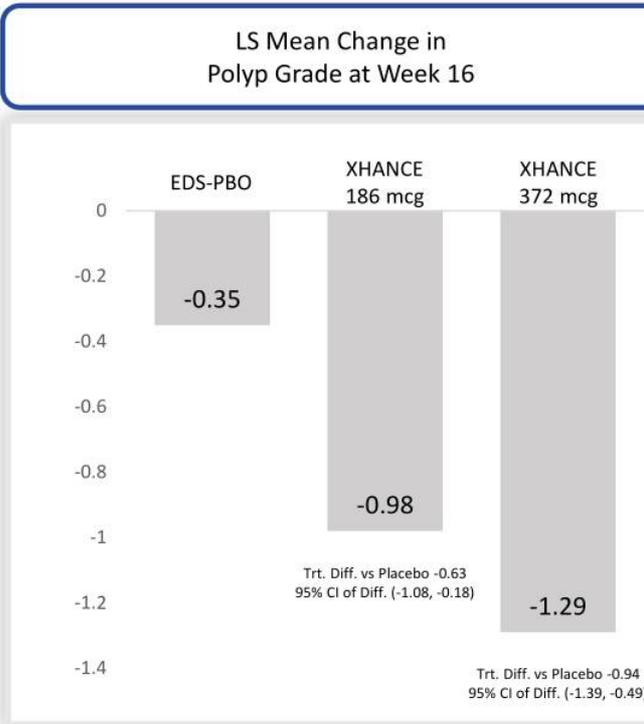
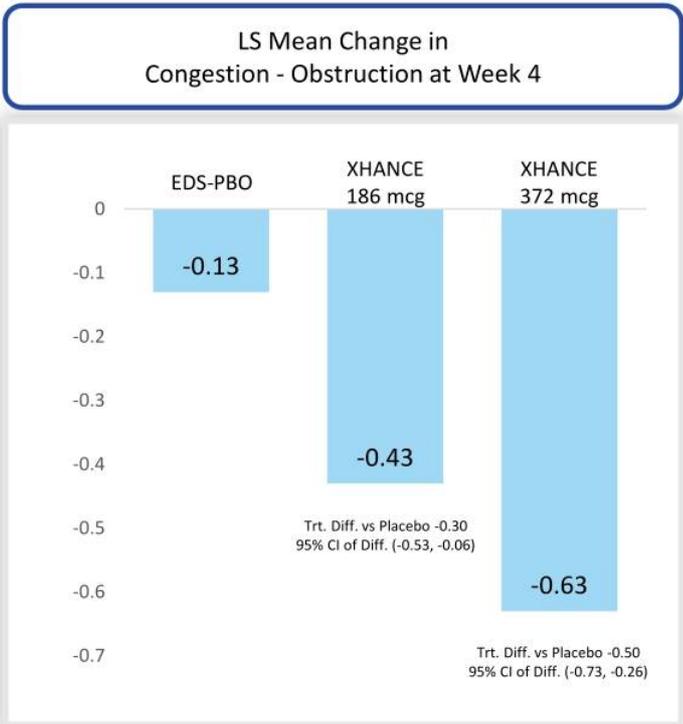
Access and Affordability

- New payer contract including access to previously closed large healthcare system
- Continued expansion of preferred pharmacy network

*patients that reported being on an INS for a minimum of 30 days prior to study entry in Navigate I & II

Patients with moderate-to-severe symptoms despite using conventional nasal steroids[†] improved significantly when switched to XHANCE

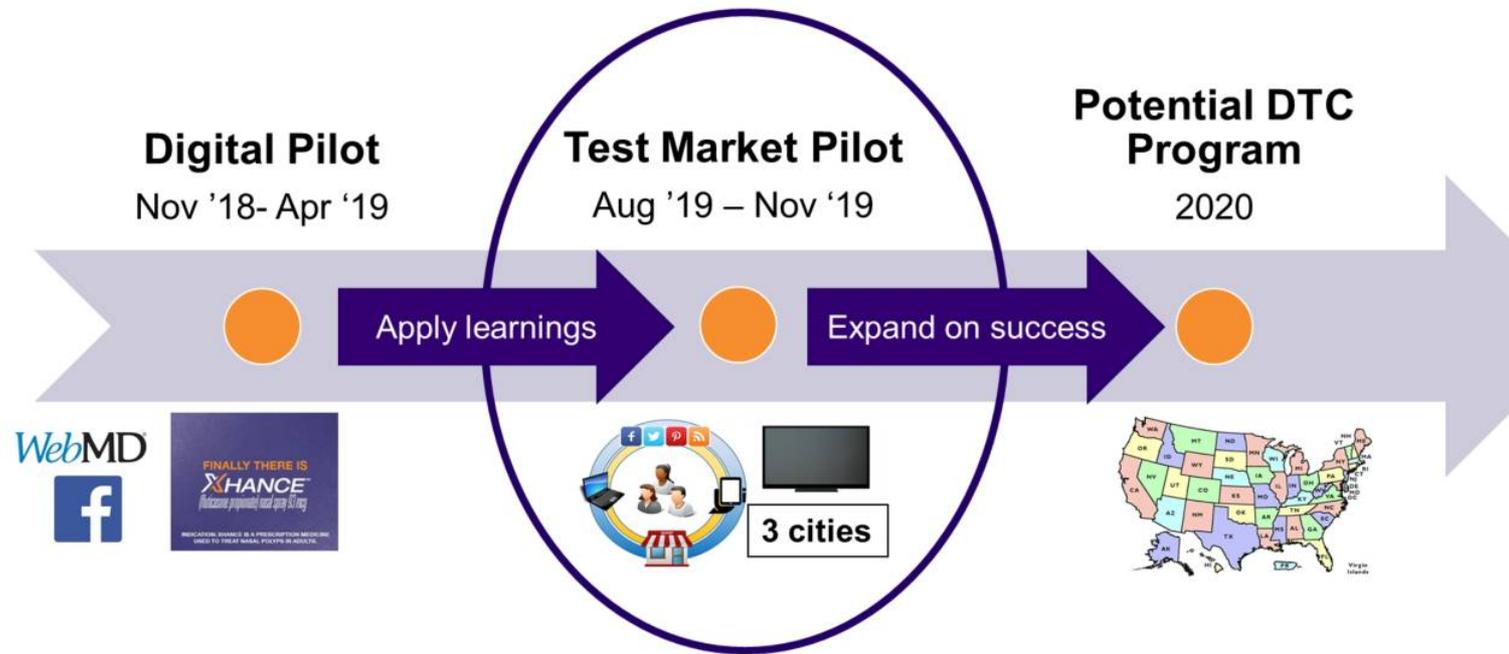
Post-Hoc Analysis of NAVIGATE I/II Pooled Data (n=482): At study entry, a large subgroup (30%) of the patients in the pooled NAVIGATE I/II trials reported using a conventional nasal steroid for a minimum of 30 days prior to study entry.



This analysis was not pre-specified and was not controlled for multiplicity

EDS-PBO: Exhalation Delivery System delivering placebo vehicle; † Based on case record form reports of drug use at study entry, patients reported being on INS or steroid rinse at study entry for a minimum of 30 days and still had moderate-to-severe symptoms and bilateral nasal polyps

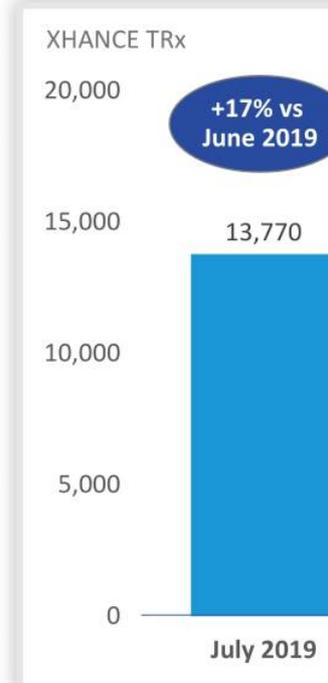
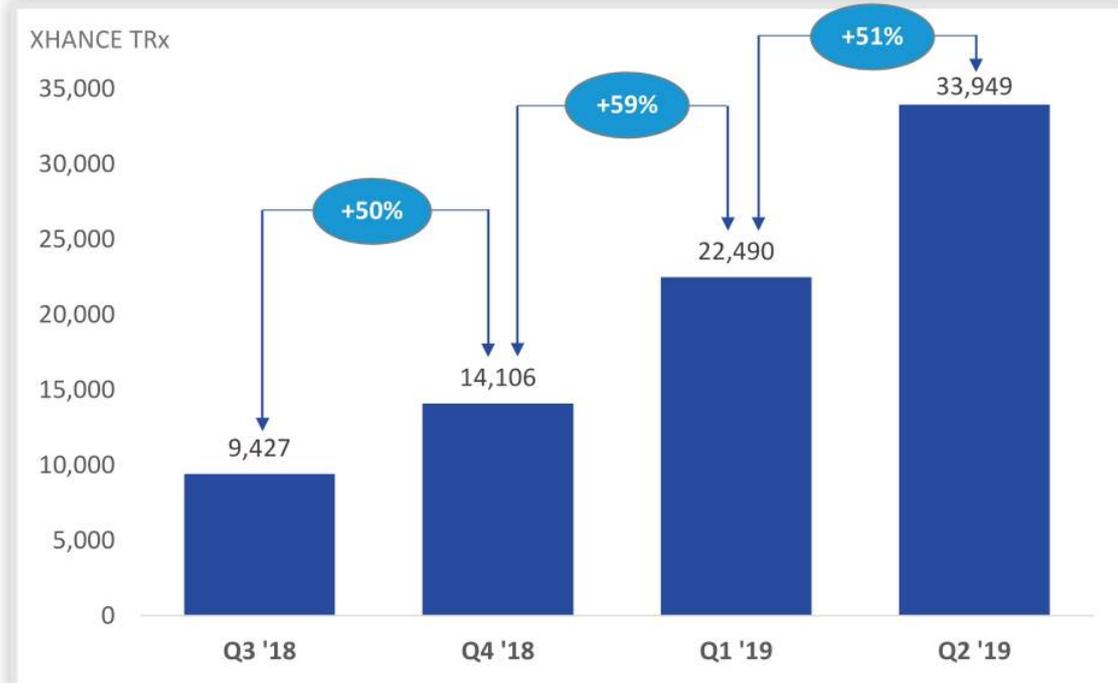
DTC Approach: Pilot. Learn. Expand.



We invite you to view the XHANCE Television Ad starting the week of August 19th on the XHANCE Facebook page, and on YouTube

XHANCE Prescription Volume Grew 51% in Q2 versus Q1 2019 and 17% in July versus June 2019

Strong growth in both new prescriptions and refills drove XHANCE quarterly prescription growth of 51% in Q2 2019.

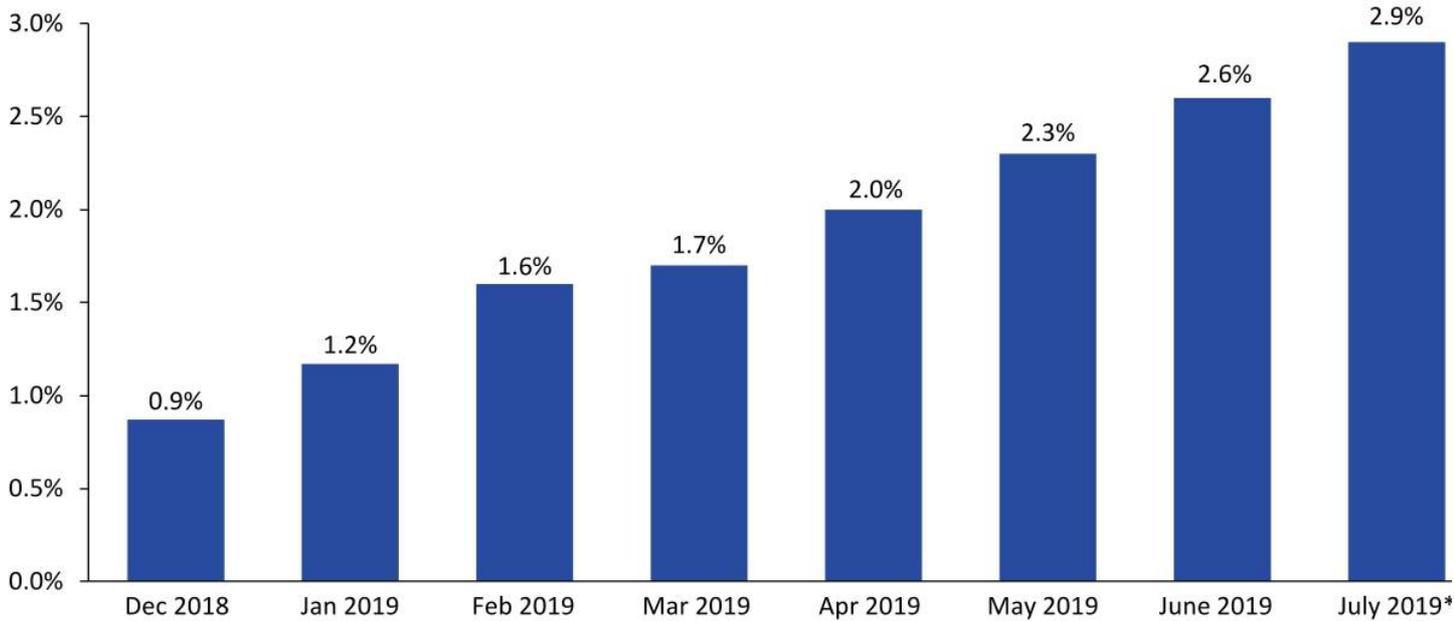


TRx for Intranasal Steroids Market increased 11% from Q3 to Q4 2018, increased 3% from Q4 2018 to Q1 2019, increased 1% from Q1 to Q2 2019 and changed 0% from June to July 2019

XHANCE Share of INS Prescriptions Within the Target Physician Audience is Growing and the Remaining Opportunity is Large

Market share within target physician audience has increased consistently in 2019

XHANCE Share of INS TRx Within Target Physician Audience



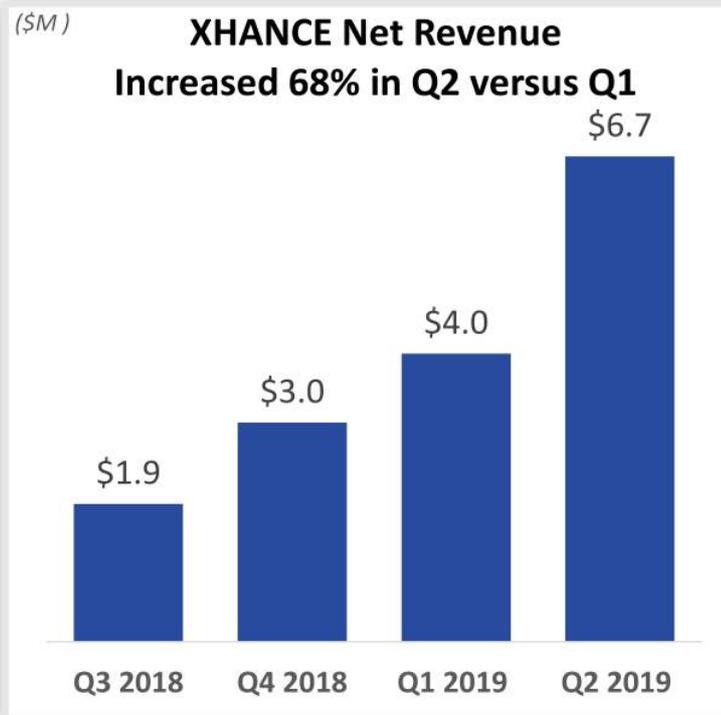
The Market on this slide is defined as the sum of all intranasal steroid prescriptions written by physicians in the XHANCE target physician audience. Estimated based on monthly prescription data from public source (IQVIA) and XHANCE preferred pharmacy network.

* July market share estimated as of July 26, 2019

Q2 2019 Financial Update

Financial Review – Second Quarter 2019

Q2 2019 XHANCE Net Revenues and Average Net Revenue per TRx



Average Net Revenue per TRx

- Average XHANCE net revenue of \$197 per TRx in Q2 2019
 - 11% Increase compared to \$177 in Q1 2019
- Average XHANCE net revenue of \$189 per TRx in H1 2019
 - Within full year guidance range of \$185 to \$205

2019 Financial Guidance

- Full Year XHANCE net revenue expected to be in the range of \$29 - \$34 million
- Continue to expect Full Year 2019 average net revenue per prescription of XHANCE to be in the range of \$185 - \$205
- Full Year 2019 Operating Expenses (GAAP) expected to be in the range of \$128 – \$133 million
 - \$10 – \$11 million of which represents stock-based compensation
 - Second Quarter 2019 Operating Expenses of \$31.3 million

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

- First patient enrolled in Q4 2018
- Estimated enrollment: 378 patients
- ClinicalTrials.gov Identifier: NCT03781804

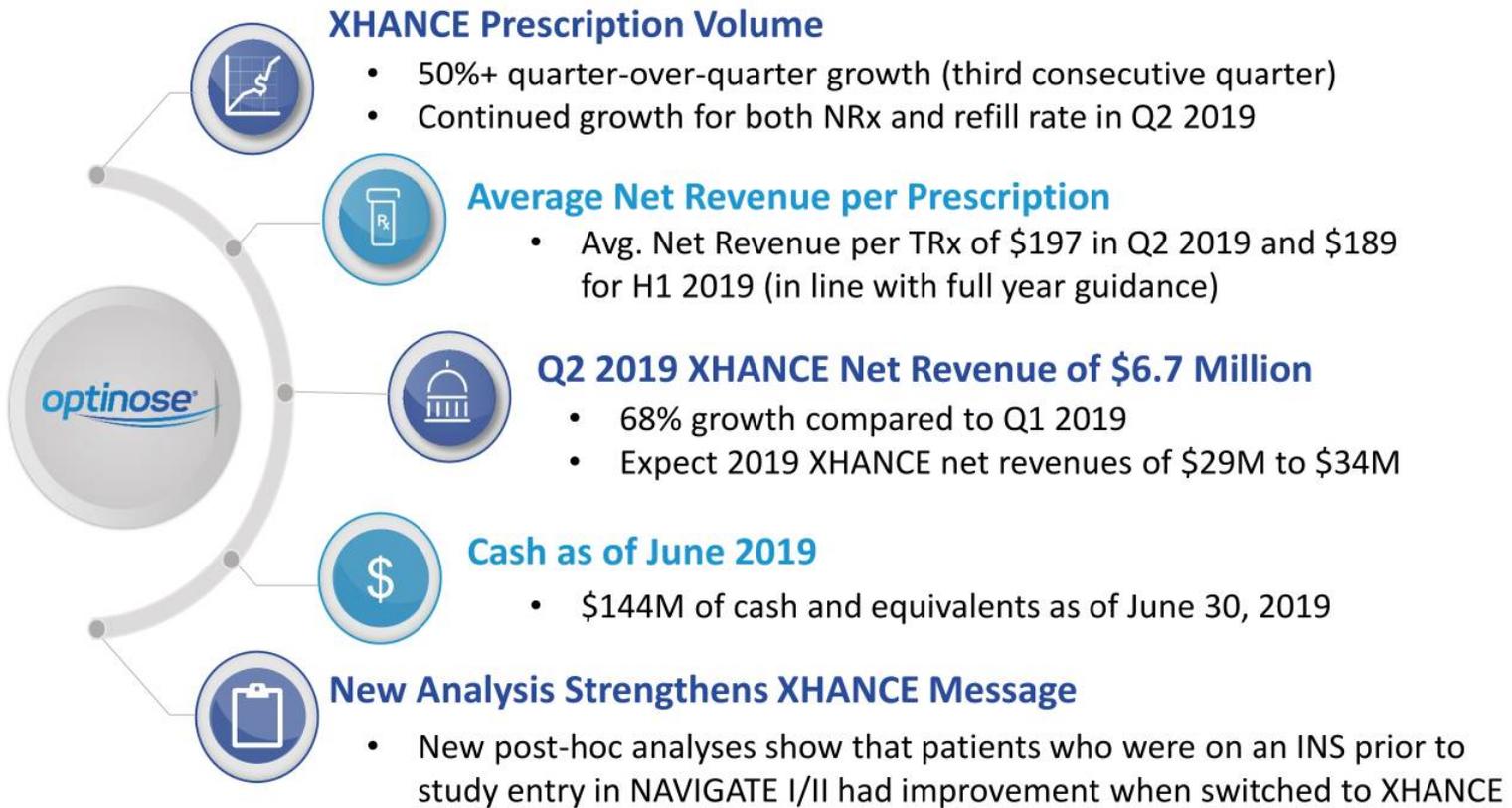
Study 3206

- 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

Q2 2019 Key Highlights



Investor Relations – NASDAQ: OPTN

Analyst Coverage¹

BMO: Gary Nachman

Jefferies: David Steinberg

Cantor Fitzgerald: Brandon Folkes

Piper Jaffray: David Amsellem

RBC: Randall Stanicky

At 30 June 2019:

- **\$144 million** in cash
- **Long-term debt: \$75 million**
- **41.4 million** common shares o/s
- **9.9 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

August 12, 2019

