

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): October 1, 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 8.01 Other Events.

On October 1, 2018, the Company posted an updated Corporate Presentation on its website www.optinose.com. A copy of the presentation is furnished hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Optinose, Inc. Corporate Presentation dated October 1, 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: October 1, 2018



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

Corporate Presentation

October 1, 2018

optinose

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 platform, the Xperience program and other patient support programs; market access objectives; potential effects of INS market seasonality and XHANCE sampling on XHANCE prescriptions, market opportunities; commercial strategies; the initiation and timing of clinical trials for chronic sinusitis; 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 successfully commercialize XHANCE without the support provided by the Xperience program and other patient support programs; uncertainties and delays relating to the initiation, enrollment, completion and results of clinical trials; market opportunities for XHANCE may be smaller than we believe; 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.

Emerging Growth Company with Approved Products

BUILDING A LEADING ENT / ALLERGY SPECIALTY COMPANY

-  XHANCE® presents a significant opportunity in the ENT/Allergy market with the current indication
-  XHANCE offers “pipeline within a product” opportunities
-  Additional business development expected to focus on leveraging ENT/Allergy infrastructure and expertise
-  Aim to add value from technology applications outside the ENT/Allergy market by early development and/or licensing
-  \$245 million of cash as of June 30, 2018

Optinose EDS Technology is a Platform for Development

Therapy	Pre-Clinical	Phase 1	Phase 2	Phase 3	NDA	Approved
XHANCE® (Nasal Polyps)						
XHANCE® (Chronic Sinusitis)						
ONZETRA® Xsail® (Migraine)						
OPN-300 (Autism, Prader-Willi Syndrome)						
OPN-021 (Narcolepsy, Parkinson's)						

Chronic Rhinosinusitis (CRS) is an Attractive Market for XHANCE...with High Unmet Need

30 Million

US Adults suffer from CRS and up to 10 million of them have nasal polyps (NP)

9.75 Million

CRS patients seek physician care annually

3.5 Million

CRS patients treated by ENT/Allergy specialists

1.2 Million

NP patients treated by ENT/Allergy specialists

High Burden

- Disease persists for many years
- Significant quality of life impact (comparable to CHF, COPD, Angina)

Recognized Unmet Need

- **80% of patients** are frustrated with lack of symptom relief with standard inhaled nasal steroids (INS)
- **75% of physicians** believe INS nasal sprays do not work well because they do not sufficiently reach site of inflammation

Source: Palmer J et al . A cross-sectional population-based survey of the prevalence, disease burden, and characteristics of the US adult population with symptoms of chronic rhinosinusitis (CRS). Poster session presented at: 62nd Annual Meeting of the American Rhinologic Society; September 16-17, 2016; San Diego, CA
Optinose Market Research. Data on file.

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

Met with FDA regarding CS study design

Selection of CRO and study locations

First patients 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

A silhouette of a person's head and shoulders on the left, holding a string of lightbulbs. The background is a light blue gradient with several lightbulbs floating in the air. The text "XHANCE Launch Update" is centered in white.

XHANCE Launch Update

Early Launch Observations

Critical Insights and Takeaways

- XHANCE is fulfilling its clinical promise (patient)
- Perception of differentiation on device and deposition has been established – can now shift communication emphasis to efficacy (physician)
- Payor coverage is as-expected and continues to improve (access)
- Xperience program succeeded in accelerating broad trial amongst patients and physicians
- Patient support programs are essential to address physician perceptions regarding affordability and access for XHANCE during early launch phase



Encouraging Feedback From Xperience Patient Survey

Patient Responses Prior to Month 2 Refill

	Total Respondents (N=2,733)	Prior User of Flonase / Nasonex (n=820)	Prior User of Budesonide Rinse (N=175)
Patient Satisfaction	89%	90%	90%
Experience Symptom Improvement	80%	79%	68%
Prefer XHANCE	77%	82%	83%
Recommend XHANCE to a Friend	92%	91%	87%
Use without Difficulty	95%	95%	94%

9 Notes: In the same period that the 2,733 responses were received 402 patients declined the opportunity to respond to the survey to receive a second prescription for a \$0 co-pay. Patient entry into Xperience closed at the end of June, and this survey is now complete.

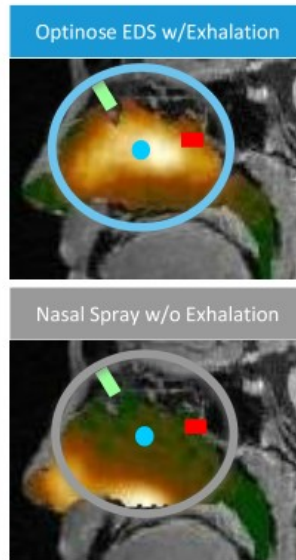


Success in Achieving Strong Perceived Differentiation on Device and Deposition*

Device

Deposition

Data



Specialty-specific detail aids

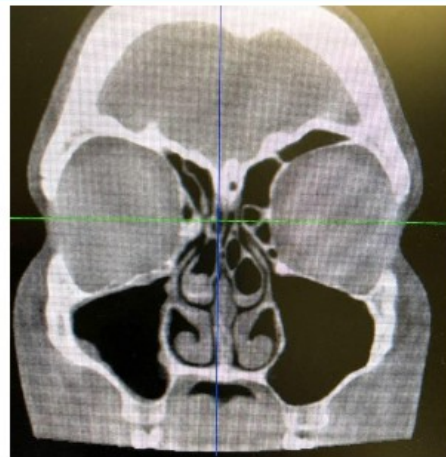
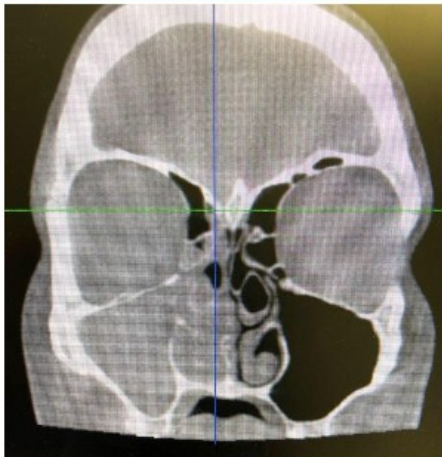


Phase 3 publication dissemination

Communication emphasis now shifting to driving efficacy perceptions of XHANCE

* Based analysis of data from a company survey of 335 target physicians, the deposition attributes of XHANCE are positively differentiated, in a statistically significant manner, when compared to the deposition attributes of traditional INS and steroid rinses

Examples of Positive XHANCE Physician Feedback *



"I had a patient who had been on everything and was begging for surgery. I said let's just try XHANCE for a month. We scheduled surgery but the patient came back very happy and we cancelled the surgery." - ENT

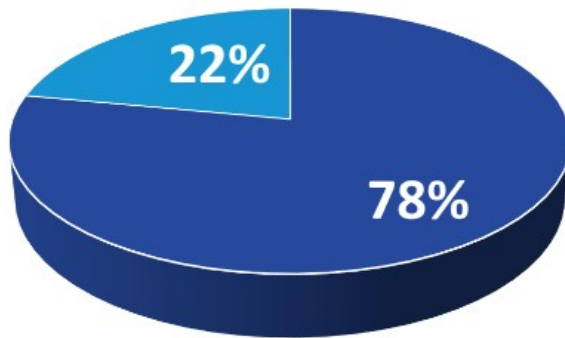
"I had a severe patient and my goal was for the patient's polyps and symptoms to not get any worse. Not only are they not getting worse, he is improving. This patient could be the 'face' of XHANCE!" - ENT

"I prescribed XHANCE for a patient three weeks prior to their scheduled surgery. Due to the patient's vacation, I pushed the surgery out another two weeks. When I went in to do the surgery, the polyps were 80% gone. I could not believe it." - ENT



*Testimonials and CT-scan 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.

XHANCE Commercial Market Access

XHANCE Overall Access: September 2018



Access Key

-  NDC Blocked / Not Covered
-  Covered (Single step edit, double step edit, PA or better)

- Nationally, we believe **78% of commercial lives** are currently in a plan where XHANCE is covered.
- We continue to focus on access with **minimized hassle** for prescribers and patients.
- We are working towards achieving “limited hassle” access to XHANCE for **75% of commercial lives** by year end 2018.

Source: Third party syndicated data and internal analyses as of September 2018. Coverage is subject to change.

Key Focus Areas Addressed in Late August to Accelerate XHANCE Performance

1

Prioritized Patient Type within ENT / Allergy

- Taking advantage of early in-market experience with XHANCE, an updated and rigorous market analysis and segmentation was performed to define specific, readily-identifiable, patient types within ENT and Allergy where XHANCE is perceived as disproportionately beneficial vs other treatments

2

Enhanced Efficacy Communication Platform

- Inclusion of important secondary endpoints, consistent with updated FDA guidance, that communicate an interpretable and large magnitude of effect (eg, SNOT-22)
- Publication and dissemination of Phase 3 trial publications (NAVIGATE-2 and EXHANCE-12)

3

Patient Affordability and Access

- \$0 co-pay for first prescription (in lieu of sample) implemented August 6th
- \$30 maximum co-pay for commercial covered patients and \$50 maximum co-pay for commercial uncovered patients through preferred pharmacy network implemented August 20th
- Approximately a 65% reduction in sample volume beginning ~end of July

Patient Support Programs are Essential to Address Physician Perceptions Regarding Affordability and Access for XHANCE

March through June

XHANCE™

- \$0 for the first two prescriptions
- Up to \$120 co-pay assistance for covered patients
- Co-pay program driven by patient willingness to pay research

July through mid-August



- Leverage samples for initial use (over 200% increase in weekly sample volume)
- \$30 for first Rx for covered patients
- Maximum out of pocket of \$99 for covered patients

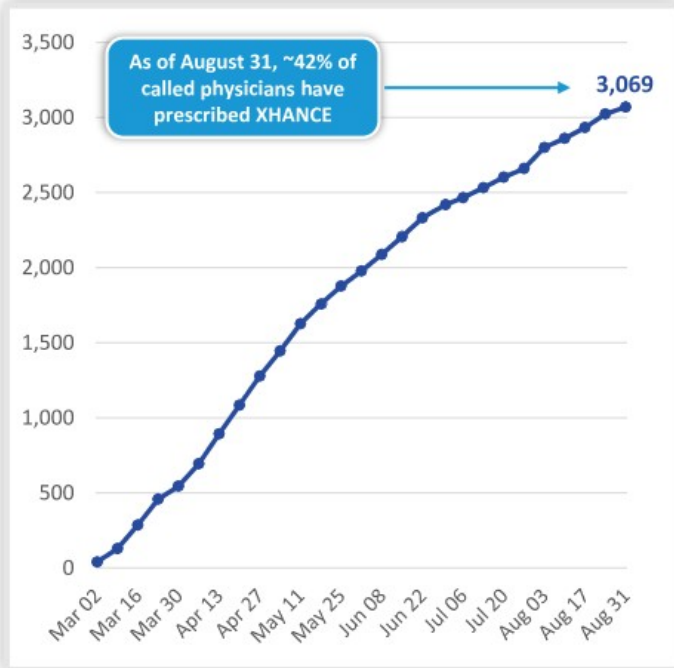
Mid-August forward

XHANCE™

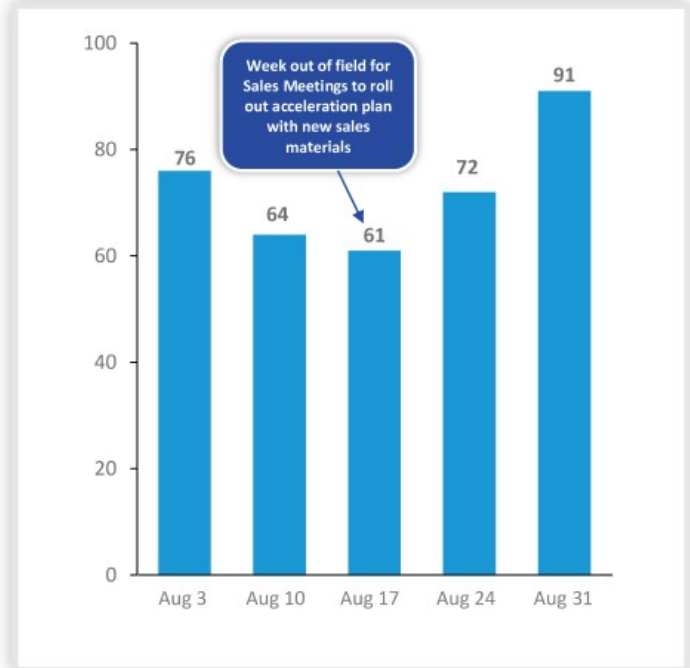
- \$0 co-pay for initial Rx (in lieu of samples) for all patients (65% reduction in weekly sample volume)
- Maximum out of pocket of \$30/\$50 for refills for covered/non-covered patients
- Decision driven by patient willingness to pay research and physician willingness to prescribe research

Strong Initial Breadth of XHANCE New Prescribers

Cumulative Physician Trialists (Through the Week Ended August 31, 2018)



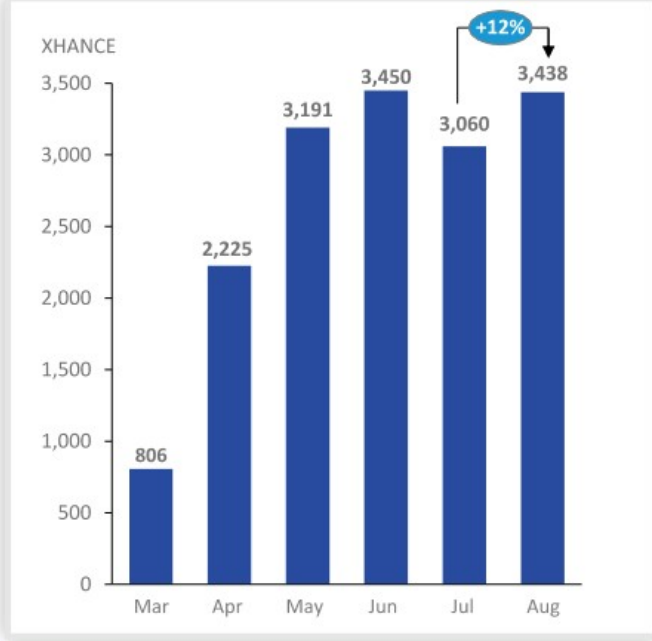
August Weekly New Prescribers (Through the Week Ended August 31, 2018)



Source: cumulative physician trialists based on preferred pharmacy network data under Xperience program and available retail data.

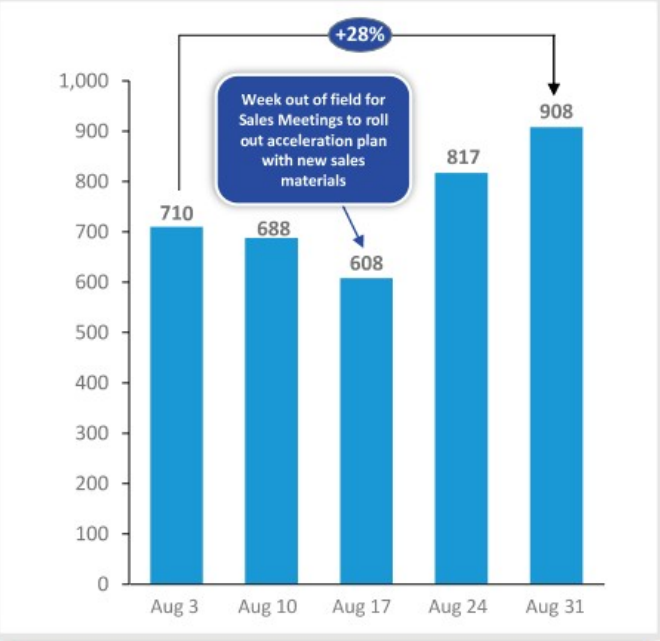
Impact of market seasonality, heavy sampling, and sunsetting of XPERIENCE program was absorbed in July: encouraging early signals of growth following late-August implementation of acceleration plan

XHANCE Monthly TRx Volume (Through August 2018)



Market TRx for Intranasal Steroids increased 9% From July 2018 to August 2018

August Weekly TRx Volume (Through August 31, 2018)



Market TRx for Intranasal Steroids increased 7% from the week ended Aug. 3 to the week ended Aug. 31

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 June 2018:

- \$245 million in cash
- Long-term debt: \$75 million
- 41.1 million common shares o/s
- 8.0 million options & warrants o/s

Optinose Investor Contact

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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 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.



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