

**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): April 9, 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 7.01 Regulation FD Disclosure.

Corporate Presentation

On April 9, 2018, OptiNose, Inc. 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	Corporate Presentation dated April 9, 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: April 9, 2018

A blue banner image featuring a silhouette of a person's head in profile on the left, looking upwards. A hand is shown holding a string of lightbulbs, with several lightbulbs floating in the air. The text "Building a Leading ENT / Allergy Specialty Company" is overlaid in white.

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

Corporate Presentation

April 9, 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: the initiation and timing of clinical trials for chronic sinusitis; brand awareness and market access objectives; market opportunities; commercial strategies; potential advantages of XHANCE™ and our product candidates; 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: our ability to establish commercial and other capabilities to successfully launch XHANCE; physician and patient acceptance of XHANCE; our ability to obtain adequate third-party reimbursement for XHANCE (market access); uncertainties and delays relating to the initiation, 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.

Emerging Growth Company with Approved Products

BUILDING A LEADING ENT / ALLERGY SPECIALTY COMPANY



XHANCE Represents a Significant Opportunity in Attractive ENT/Allergy Market

- 3.5 Million CRS patients (1.2M with nasal polyps) being treated by 15,000 physicians
- Limited competition anticipated from any pharma companies at launch



“Pipeline Within a Product” Creates Substantial Near-Term Value

- Potential to be first product approved for chronic sinusitis indication—trials planned for 4Q 2018
- Expected to support expansion into primary care treating an additional 6.25M patients



Additional Pipeline Focused on Products for ENT/Allergy to Leverage Infrastructure/Expertise

- Product candidates identified that could be developed using EDS platform for ENT/allergy market
- External pipeline products also identified for potential partnering or acquisition in ENT/allergy



Create Additional Value by Early Development of Additional EDS Platform Products

- Several candidates (Narcolepsy, Prader-Willi) are aimed at innovative “nose-to-brain” delivery approach
- Plan to develop through proof of concept and to seek partnerships for further growth

Our Research on Over 300 Products Suggests Successful Launches are Driven by Four Key Factors



Attractive Market...with High Unmet Need



Differentiated Product



Market Access

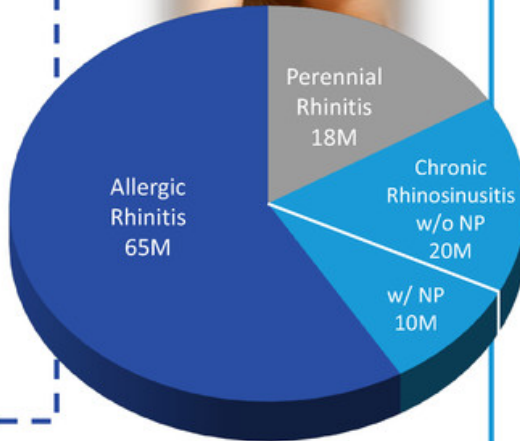


Awareness / Execution

Large CRS Population with Severe Symptoms

Allergic Rhinitis

- Highly prevalent in the United States (~65M)
- Largely OTC / generic market
- Well-treated using INS



Chronic Rhinosinusitis (CRS)

- ~30M US adults suffer from CRS—up to 10M with Nasal Polyps
- 9.75M patients actively seeking physician care annually
- 7M patients have had surgery (frequently non-curative)
- Only one other FDA-approved branded product “for the treatment of nasal polyps” and no FDA-approved product for chronic sinusitis

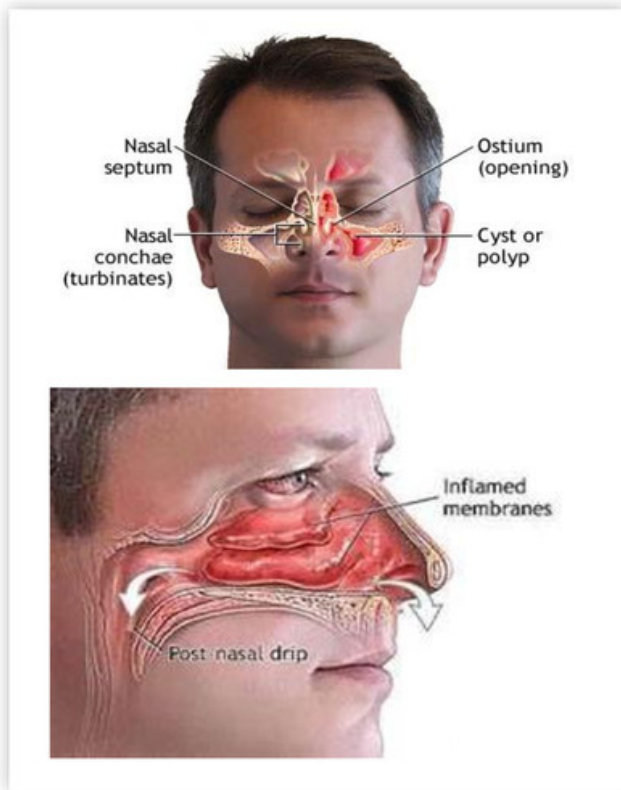
Mild

Moderate

* Based on US Adult Population Survey (n=10,336).

CRS (with or without Polyps)

THE ROOT ISSUE IS INFLAMMATION (NOT INFECTION)



A diagnosis characterized by chronic inflammation

- Disease persists for many years
- Significant quality of life impact (comparable to CHF, COPD, Angina)
- Symptoms Include: congestion and blocked nose, purulent drainage, facial pain/pressure, loss of sense of smell, chronic sleep problems, headaches, fatigue, halitosis, mood disorders

Persistent inflammation causes swelling, pain and obstruction in a high and deep region of the nasal passages where sinuses open

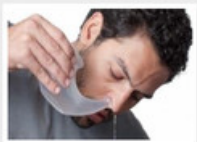
Flares are common and require treatment with antibiotics and other medications

Existing Treatments Are Often Sub-Optimal

LIMITED EFFICACY, HIGH COST, DIFFICULT, PAINFUL, MEDICAL RISKS, FREQUENTLY NOT CURATIVE

Medical Management

Saline nasal sprays, irrigation, neti pot, nebulizers, conventional intranasal steroids (INS)



80% of patients are frustrated with lack of symptom relief with INS

75% of physicians believe INS nasal sprays do not work well because they don't sufficiently reach site of inflammation

Limited Efficacy

Sinus Surgery



Up to **80%** of patients may continue to have symptoms post-surgery

Continued INS use after surgery is typical

\$8,500–\$16,000 per procedure, and repeat surgery is not uncommon

High Cost, Typically Not Curative

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.

A Breakthrough Approach to Nasal Delivery

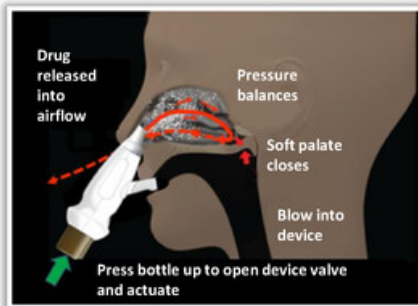
SOLVES A KNOWN MEDICAL PROBLEM IN A UNIQUE NEW WAY

Problem:

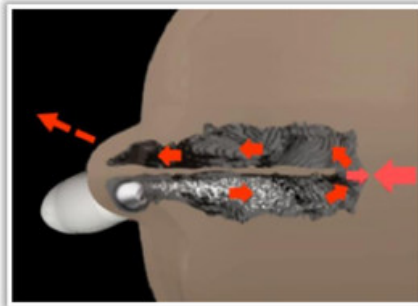
Nasal sprays and aerosols do not effectively place drug high and deep in the nasal passages

Solution:

Unique new concept for delivery gets medicine to targeted sites of inflammation



- Mouthpiece and sealing nosepiece
- Utilizes natural functional behaviors of the upper airway
 - Naturally exhaled breath seals the soft palate
- Drug released into the exhaled breath is **deposited high and deep** in the nasal passages

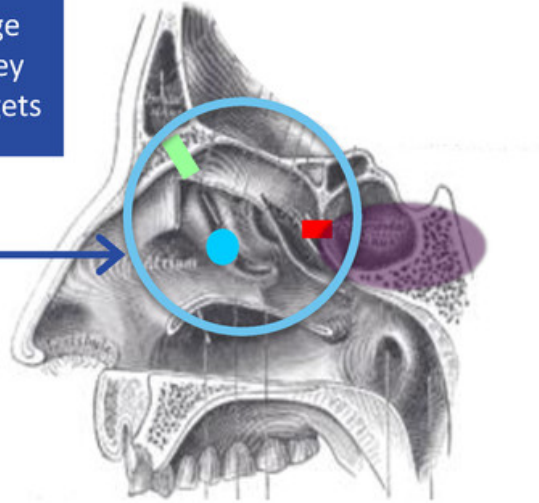


- Exhaled air routed through proprietary exhalation delivery system (EDS)
- "Positive pressure" delivery expands narrow passages
 - Helps the drug flow around anatomical obstructions to broadly fill one side of the nasal cavity
- **Simple, quick use** with limited coordination requirements

Optinose EDS Can Deliver Drug High & Deep in the Nose

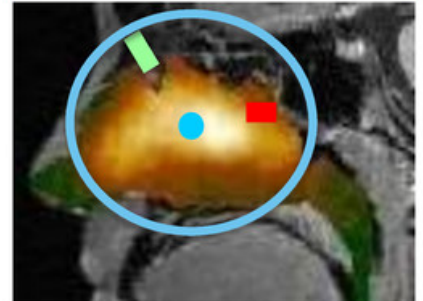
KEY TO TREATING CRS (W OR W/OUT POLYPS)

Sinus drainage regions are key treatment targets

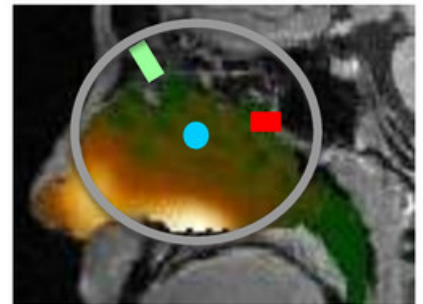


Intranasal steroids are **TOPICALLY ACTING** medications:
Delivery to sites of chronic inflammation and nasal polyp origin is important

Optinose EDS w/Exhalation



Nasal Spray w/o Exhalation



Differentiated Clinical Profile

Global Clinical Program*

Trial	Type	N	Sites
NAVIGATE I	Phase 3 Pivotal	323	54
NAVIGATE II	Phase 3 Pivotal	323	38
EXHANCE-3	Phase 3 open-label 3 month	700	38
EXHANCE-12	Phase 3 open-label 12 month	223	21
Study 1102	Phase 1 bioavailability	112	2

1,500+ Patients

792 w/o polyps
780 w/ polyps

Key Highlights

Improvement on all four defining symptoms of CRS

“Medical” polyp elimination in some patients

Magnitude of relief comparable to surgery

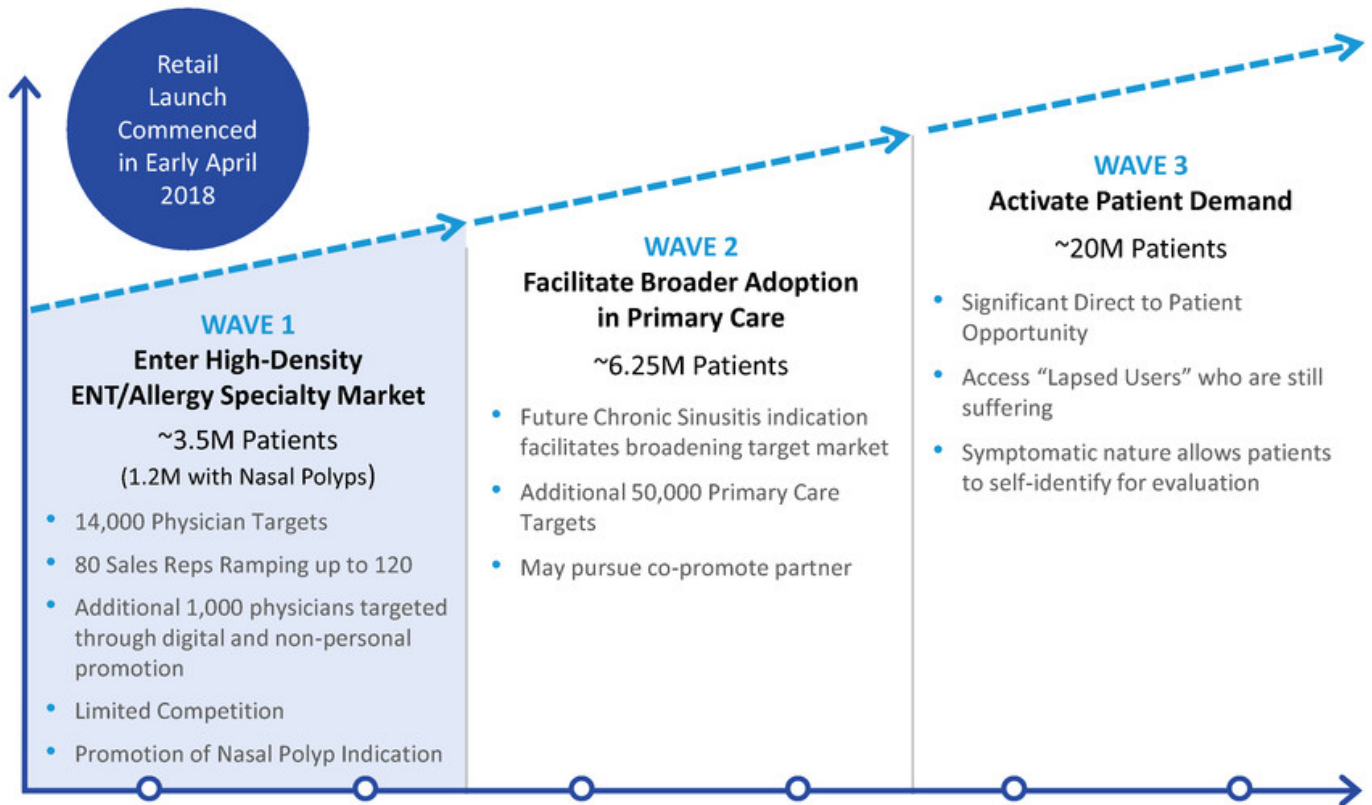
Reduction in the need for surgery

A substantially higher percentage of patients reported being “much” or “very much” improved versus placebo

Similar improvements in patients with and without nasal polyps

* In Navigate I & II, 91% of patients reported previous use of a nasal steroid for the treatment of nasal polyps, and 54% reported previous sinus surgery or polypectomy

Commercialization Strategy - Build XHANCE into a Leading Product

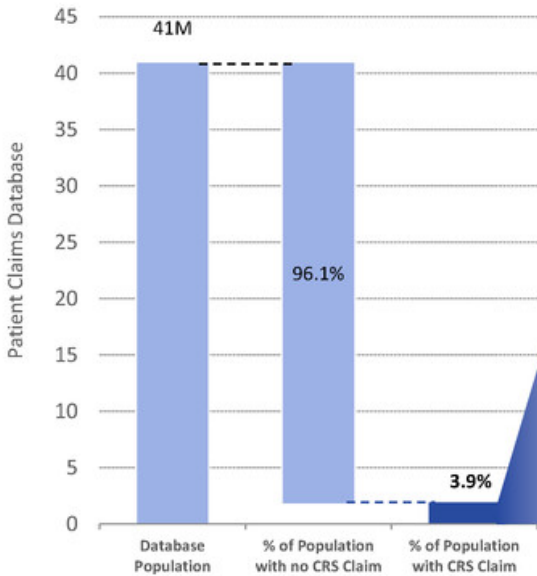


30 Million U.S. Adults Suffer from Chronic Rhinosinusitis

~9.75M PATIENTS CURRENTLY UNDER ACTIVE CARE OF A PHYSICIAN FOR CRS

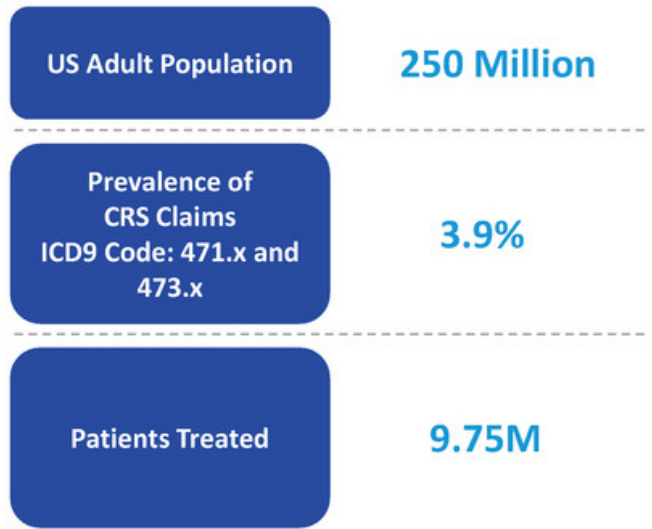
CRS Unique Patient Claims

Approximately 3.9% of patients in claims database have a code for CRS (2010–2012)



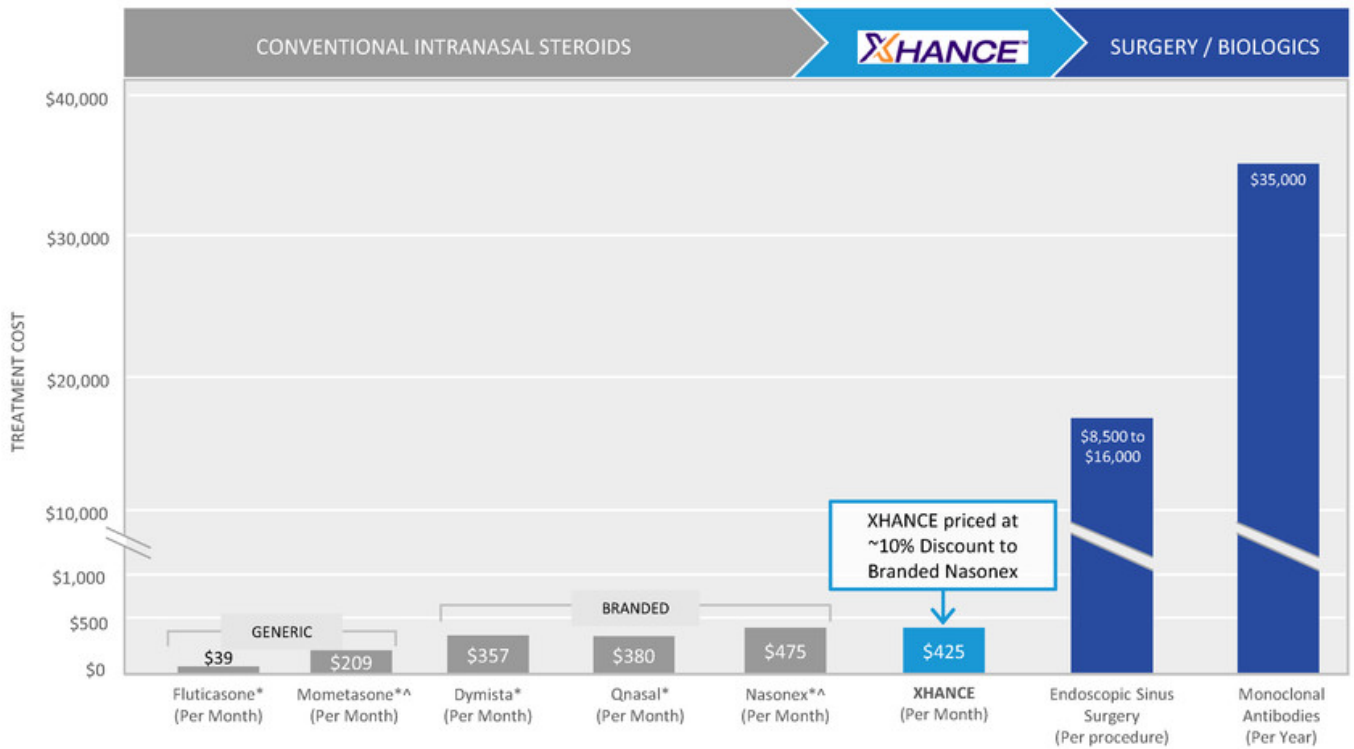
CRS Patient being Treated in Physician Office

~9.75M CRS Patients being treated in physician offices



Pricing Landscape Offers Attractive Scenarios

FOR NASAL POLYPS

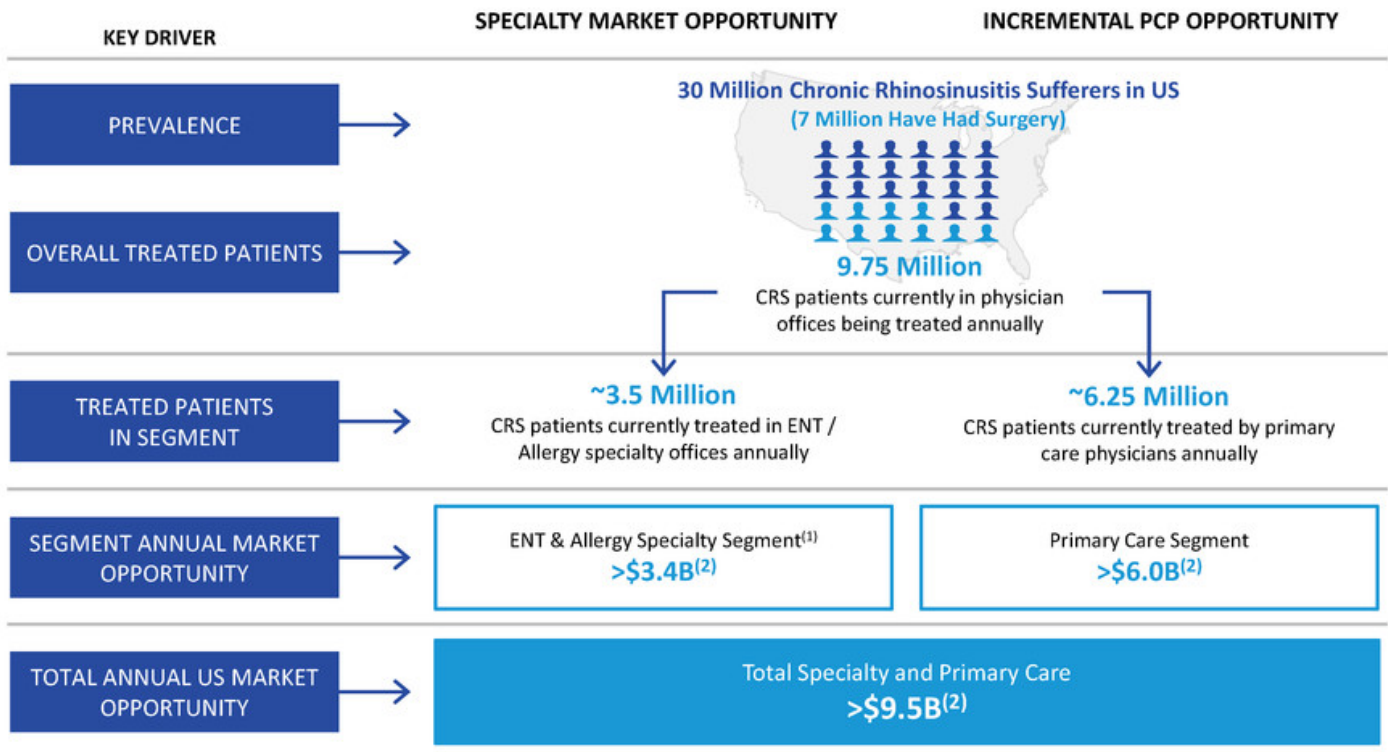


* BID dosing required for the treatment of nasal polyps, based upon Nasonex data and academic literature. WAC prices reflect a 2x multiple on the WAC price for conventional INS due to the approved dose for the treatment of nasal polyps.

** Nasonex and Mometasone are currently the only other intranasal steroids approved for the treatment of nasal polyps.

\$3.4B Market Opportunity Within Specialty

TOTAL MARKET OPPORTUNITY OF >\$9.5B (Nasal Polyps + CS Indications)



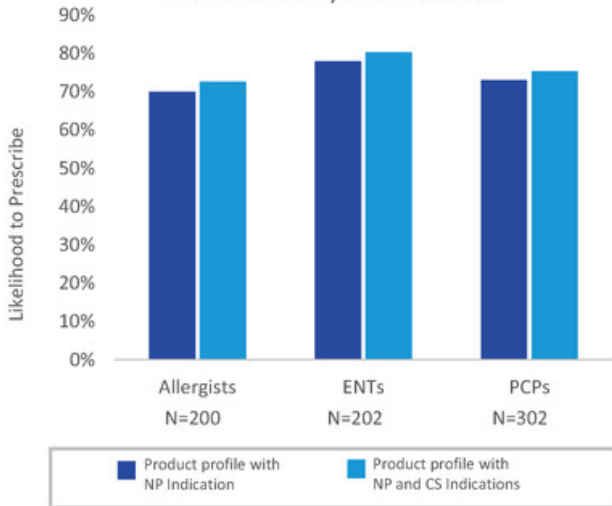
(1) Target market represents ~10,000 ENT and allergy specialists and ~5,000 high-decile INS prescribing primary care physicians.
 (2) Based on our internal estimates.

Differentiated Physician Reaction to Profile

SUGGESTS HIGH LAUNCH INTEREST AND 'STANDARD OF CARE' POTENTIAL

Physician Stated Interest

Majority of Physician Interest in Prescribing Is Reported After Presenting a Product Profile with Only a NP Indication



Percent of HCPs stating they will definitely or probably prescribe a product profile similar to XHANCE

Source: Optinose Market Research (2015). Data on file.



...There is a real need in the medical community to be able to deliver intranasal steroids higher and deeper in the nasal cavity...



Allergist / Immunologist



... The Optinose Device will be a game changer... and will really improve our ability to care for patients....



Director, Division of Rhinology



...If the Optinose Device is approved, I will definitely use it in my practice; no question....



Otolaryngologist



Introducing XHANCE™

For the treatment of nasal polyps in patients 18 years of age or older

XHANCE™

(Fluticasone propionate) nasal spray 93 mcg



XHANCE uses an Optinose® Exhalation Delivery System (EDS) that is designed to deliver medication^{1,2}:

- High and deep in the nasal passages
- To regions where nasal polyps originate and sinuses drain and ventilate

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS:
Hypersensitivity to any ingredient in XHANCE.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information and Instructions for Use in pocket.

Retail Launch Commenced in Early April

LAUNCH EXECUTION PRIORITIES



XTEND

**Commercial
Capabilities**



XCCENTUATE

**Brand
Differentiation**



XCCELERATE

**Awareness,
Trial and
Adoption**



XPAND

**Market
Access**

Experienced Sales Team Optimally Deployed to Accelerate Adoption of XHANCE at Launch



Commercial
Capabilities



Hired an experienced first-line sales leadership team

Recruited & trained fully-dedicated contract territory managers (TMs)

~80 TMs deployed on March 5th
Growing to ~120 based on expansion of market access

~8,000 HCPs targeted at launch
Growing to ~14,000 based on expansion of market access
(additional 1,000 physicians targeted through digital and non-personal promotion)

Multi-Channel Integrated Marketing Program Increased Aided Awareness to Over 73% in the Past 4 Months



Awareness,
Trial and
Adoption



Social media: reached 10,000 ENTs and allergists and delivered 700,000 impressions



Clinical Nurse Educators: reached ~5,000 ENT/allergy physicians and delivered over 10,000 presentations

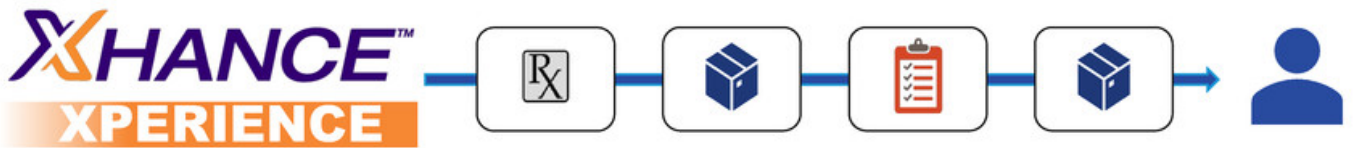


Initial reaction from target physicians to core brand messages is positive



Launched Xhance Xperience program in early March

XHANCE Xperience Program - Initiated in Market on 3/5



- Limited availability program offering select physicians and their patients an opportunity to gain initial experience with XHANCE
- Enrolled patients receive up to two prescription fills of XHANCE at no cost to them (\$0 co-pay)
- A full-service pharmacy coordinates fulfillment

As of March 31st, more than 530 unique physicians have written a total of 1,200+ prescriptions

Market Access on Track to Support Retail Launch



**Market
Access**



Covered Commercial Lives at Launch

Engaged with 40 payers representing
85% of commercial lives

Expect \geq 65% tier 3 market access for
commercial lives during retail launch

Objective is to achieve 75% tier 3 market
access for commercial lives by YE 2018

Favorable health system economics
(e.g., surgical cost savings) suggest potential to
more than offset drug acquisition cost

Market Dynamics, Product Characteristics and Execution to Date Provide a Strong Foundation for a Successful Launch



	Indicator/Objective	Assessment
Attractive Market...with High Unmet Need Current Patients Dissatisfied with Existing Treatment	>80% >80% of patients frustrated with lack of symptom relief with their current INS	
	75% >75% of physicians agree, in part, that INS medications do not work because they do not reach the site of inflammation	
Differentiated Product Physician Stated Interest to Prescribe	70%–80% Physicians' stated interest to prescribe based on product profile similar to XHANCE	
Market Access Covered Commercial Lives at Launch	65% T3 Coverage at Launch	On Target
Awareness / Execution Awareness During Launch	85% Aided awareness within 8,000 target ENT and allergists during launch	On Target

Chronic Sinusitis Follow-on Indication (sNDA)

Plan to submit
protocol to FDA
in 1H 2018

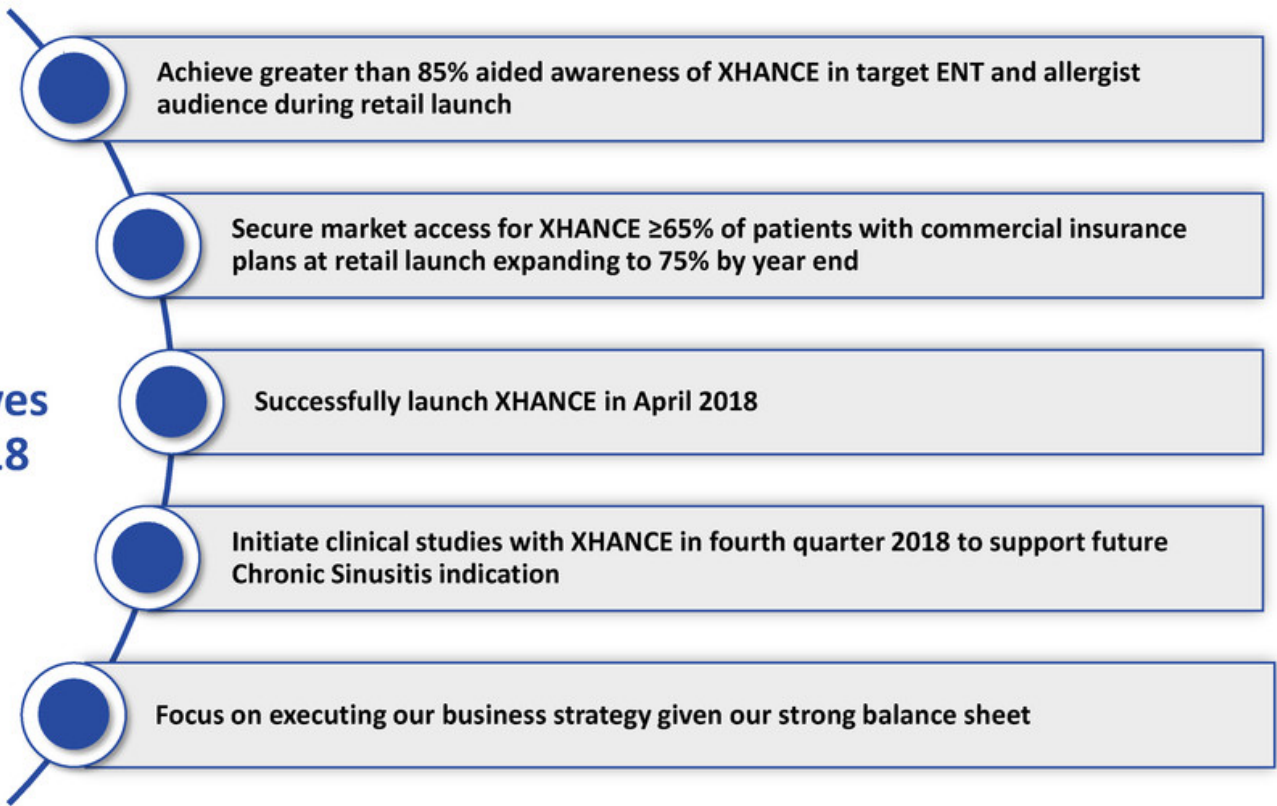
Selection of CRO
and study
locations

First patients
expected to
enroll in 4Q 2018

Phase 3b trial design expected to include co-primary endpoints: both an objective measure of inflammation and a subjective measure of symptom relief

2018 Stands to be an Important Year

Key Objectives For 2018



Investor Relations – NASDAQ: OPTN

Analyst Coverage¹

BMO: Gary Nachman

Jefferies: David Steinberg

Piper Jaffray: David Amsellem

RBC: Randall Stanicky

At 31 December 2017:

- \$234.5 million in cash
- 37.9 million common share o/s
- Long-term debt, net: \$71.9 million

Optinose Investor Contact

Jonathan Neely, VP, Investor Relations
and Business Operations
267-521-0531



investors@optinose.com



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[@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.

A horizontal banner with a blue background. On the left, there is a dark silhouette of a person's head in profile, looking upwards. A hand is shown holding a string that goes up to a lightbulb. Several other lightbulbs are scattered across the background, some appearing to float or be part of a larger structure. The text "Building a Leading ENT / Allergy Specialty Company" is written in white, bold, sans-serif font in the center of the banner.

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

Corporate Presentation

April 9, 2018
