

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 15, 2017



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 November 15, 2017, 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 November 15, 2017

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 15, 2017

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate Presentation dated November 15, 2017

A blue banner image featuring a silhouette of a person's head in profile on the left, looking upwards. Several lightbulbs are scattered across the background, with one being held by a hand. The text "Building a Leading Specialty Biopharma Company in ENT / Allergy" is overlaid in white.

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

Company Presentation

15 November 2017

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 launch of XHANCE in the second quarter of 2018; initiation and timing of clinical trials for chronic sinusitis; 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 supply chain, commercial and other capabilities to launch XHANCE; physician and patient acceptance of XHANCE; our ability to obtain adequate third-party reimbursement for XHANCE; uncertainties relating to the initiation, completion and results of pre-clinical and 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 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 to start 2H2018
- Expected to support expansion to primary care physicians treating an additional 6.25M patients



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

- Product candidates have been 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 (eg, Narcolepsy, Prader-Willi) take advantage of “nose-to-brain” delivery concept
- Plan development through proof-of-concept and then to seek partnerships for further growth

Excellent Potential in a Large Market with Unmet Need



Experienced Leadership Team



Peter Miller
Chief Executive Officer and Director



Ramy Mahmoud, MD, MPH, FACP
President & Chief Operating Officer



Tom Gibbs
Chief Commercial Officer

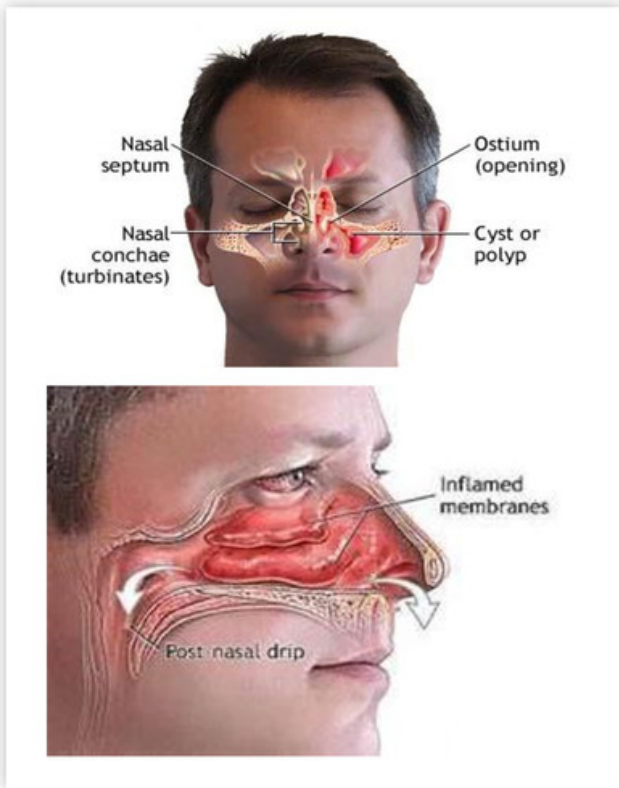


Keith Goldan
Chief Financial Officer



CRS with or without Polyps

THE ROOT ISSUE IS INFLAMMATION (NOT INFECTION)



- A diagnosis characterized by [chronic inflammation](#)
- **Persistent inflammation** causes pain and obstruction deep in the nasal passages and openings to the sinuses
- Primary defining symptoms include congestion, facial pain/pressure, rhinorrhea and loss of smell/taste
- Acute flares are frequent complications of CRS

CRS Patients Suffer High Disease Burden



Patients Frequently Endure Severe Symptoms Throughout the Year

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

Additional Symptoms are Common and can be Serious

- Including chronic sleep disruption, headaches, fatigue and mood disorders

Source: Naïve patient survey, Physician survey.

Existing Treatments are Sub-Optimal

LIMITED EFFICACY, COSTLY, DIFFICULT, PAINFUL, FREQUENTLY NOT CURATIVE

Medical Management

Saline nasal spray, irrigations, neti pots, nebulizers, conventional nasal steroids, oral steroids



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

~75% of physicians believe nasal spray steroids do not work well because they don't sufficiently reach site of inflammation

Limited Efficacy

Sinus Surgery



~80% of patients continue to have symptoms after surgery

Continuing Nasal Steroid use after surgery is typical

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

High Cost, Typically Not Curative

Source: Recurrence of Nasal Polyps After Functional Endoscopic Sinus Surgery Abstract.

Breakthrough Approach to Nasal Delivery

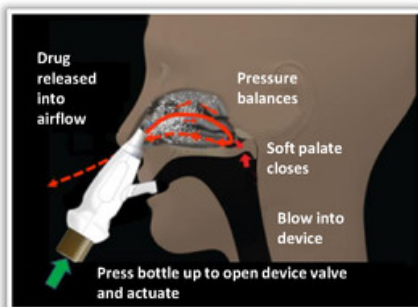
SOLVES A KNOWN MEDICAL PROBLEM WITH A UNIQUE NEW APPROACH

Problem:

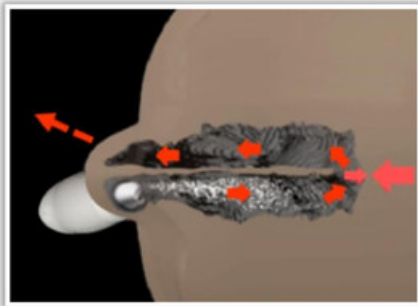
Nasal sprays and aerosols do not effectively place drug high and deep in the nasal passages

Solution:

Unique new concept for delivery gets medicine where it needs to be to work



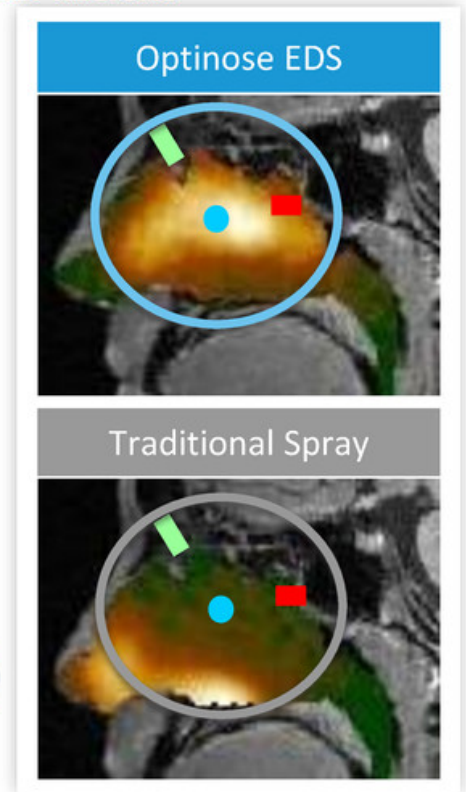
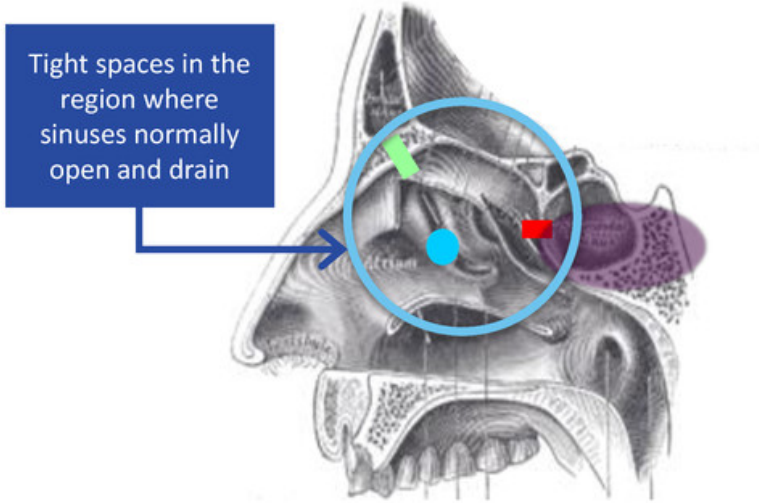
- Proprietary **exhalation delivery systems (EDS)** have a mouthpiece and sealing nosepiece
- Exhaled air passes through the EDS and drug is added
- Delivery takes advantage of natural behaviors of the upper airways
 - Exhaled breath naturally seals the soft palate then flows in one side and then out the opposite side of the nose



- **Simple, quick use** with limited coordination requirements
- "Positive pressure" delivery expands narrow passages
 - Helps "float" drug behind barriers to broadly fill one side of the nasal cavity
- Drug is **deposited high and deep** in the nasal passages

Optinose EDS Delivers Drug High and Deep in the Nose

KEY TO TREATING CS (with or without polyps) IS REACHING TARGET REGIONS



Intranasal steroids are well-tolerated **TOPICAL TREATMENTS** and only work where they are delivered

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 CS w/o polyps
780 CS w/ polyps

Key Highlights

Significant benefit on all four defining symptoms of CS

Similar improvements in patients with and without nasal polyps

“Medical” polyp elimination in some patients

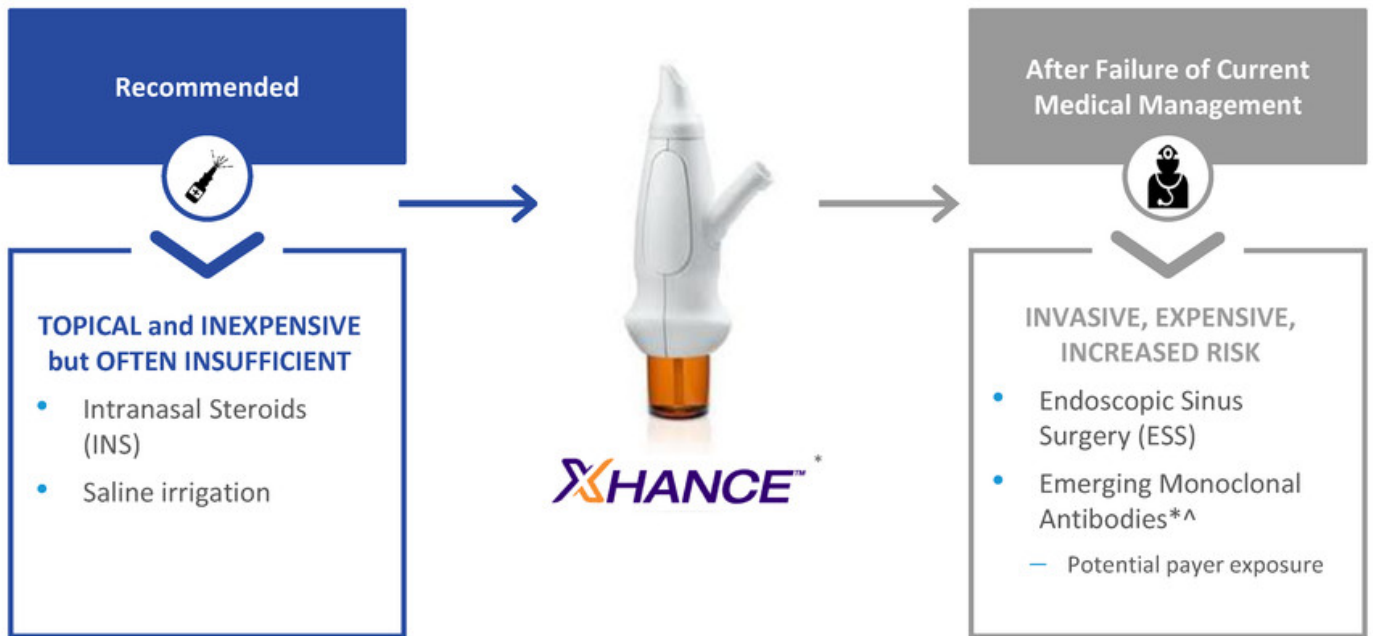
Magnitude of relief comparable to surgery

Reduction in eligibility for surgery

Approximately 70% of patients reported being “much” or “very much” improved

Potential to Become Part of Standard of Care

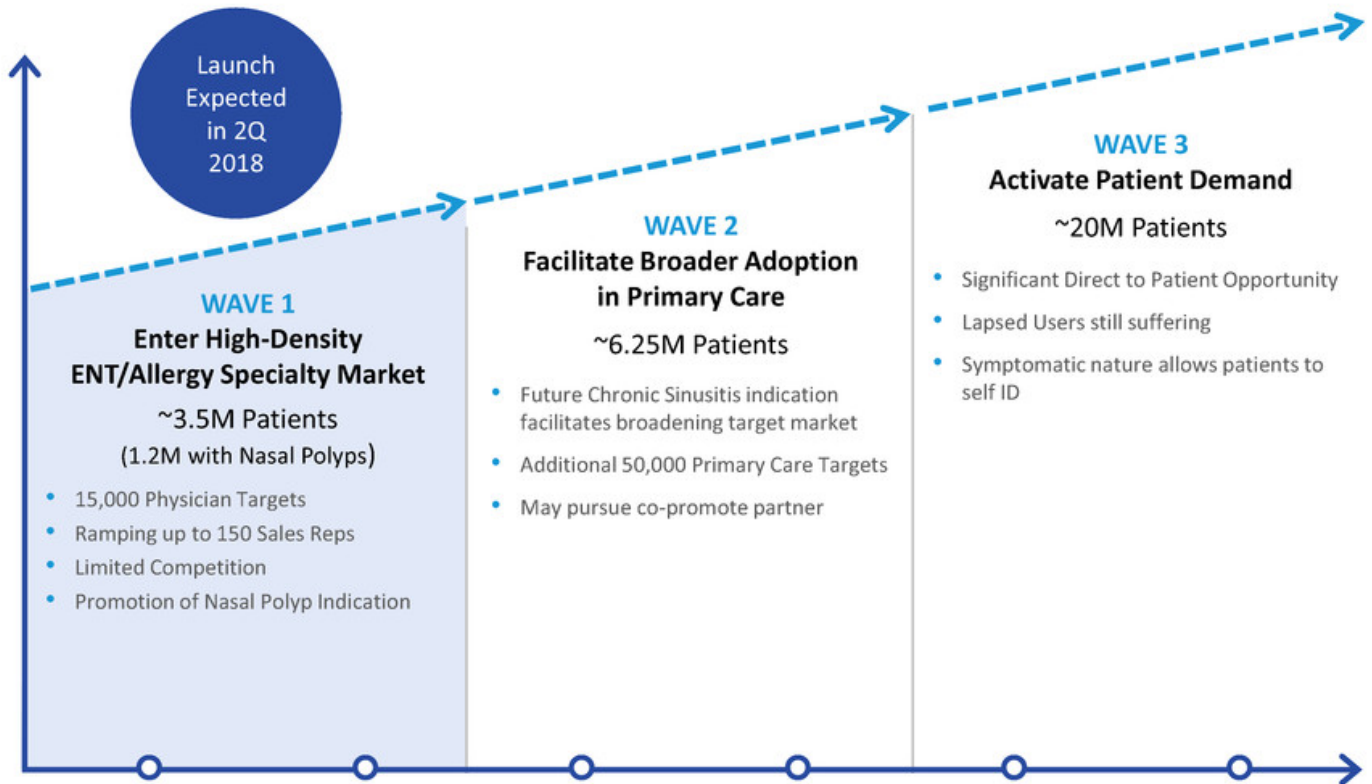
ADAPTED FROM INTERNATIONAL CONSENSUS STATEMENT ON ALLERGY AND RHINOLOGY (ICAR)



* Not currently in guidelines.

^ Currently marketed for other indications and in development for nasal polyps indication.

Commercialization Strategy to Build XHANCE into a Leading Product

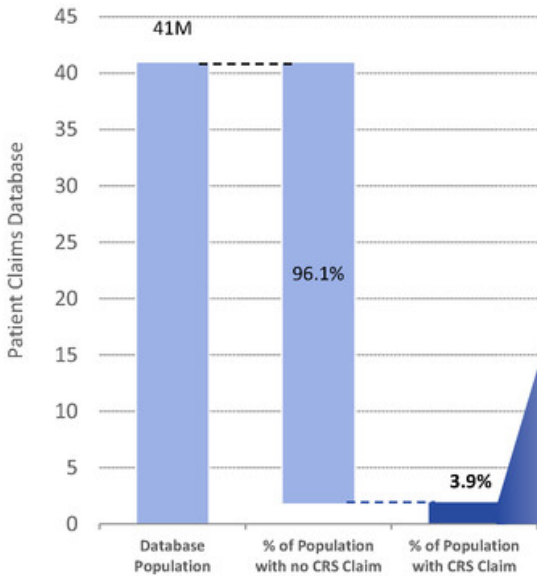


30M US Adults Suffer from Chronic Rhinosinusitis

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

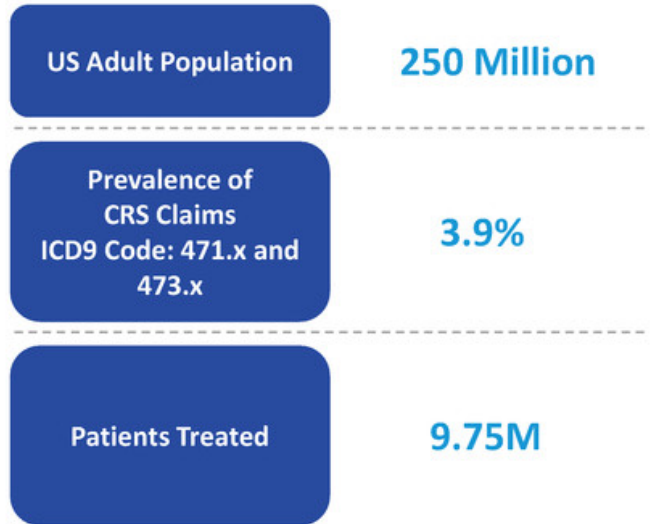
CRS Unique Patient Claims

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



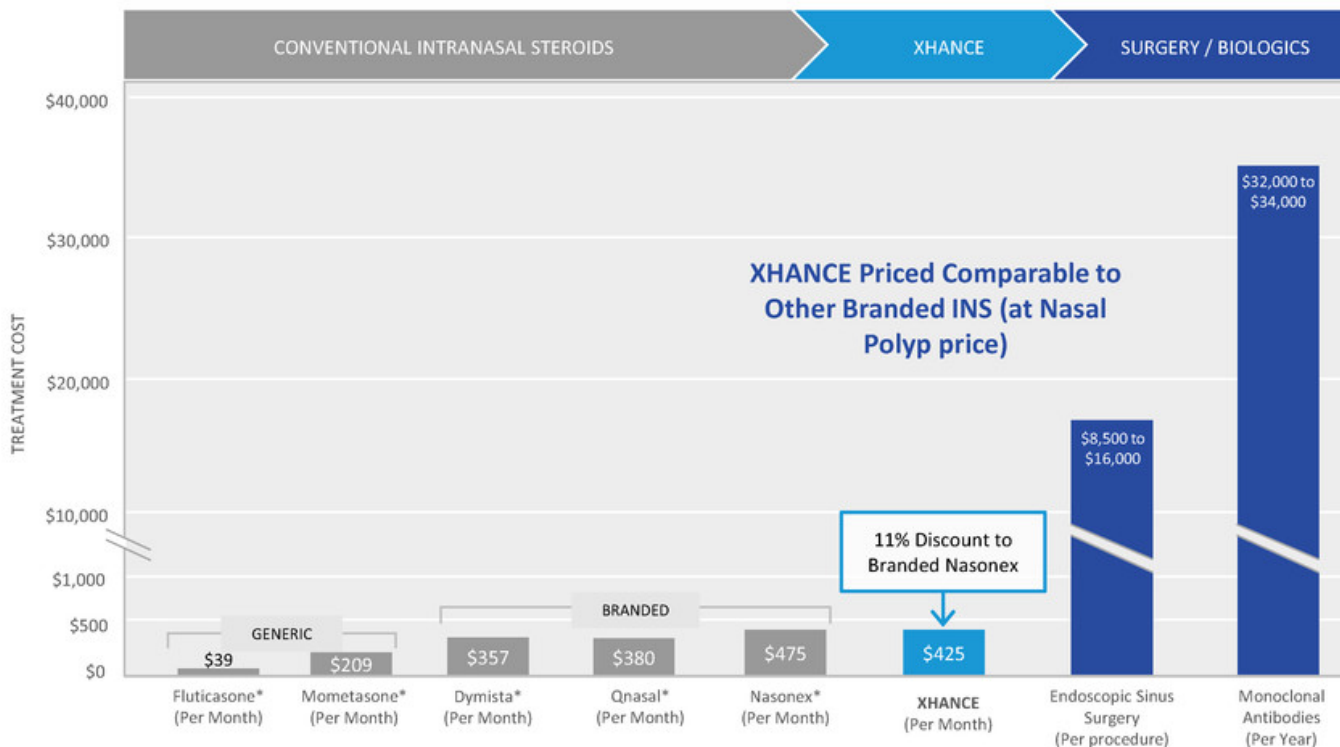
CRS Patients being Treated in Physician Office

~9.75M CRS Patients being treated in physician offices



Pricing Landscape Offers Attractive Scenarios

FOR NASAL POLYPS

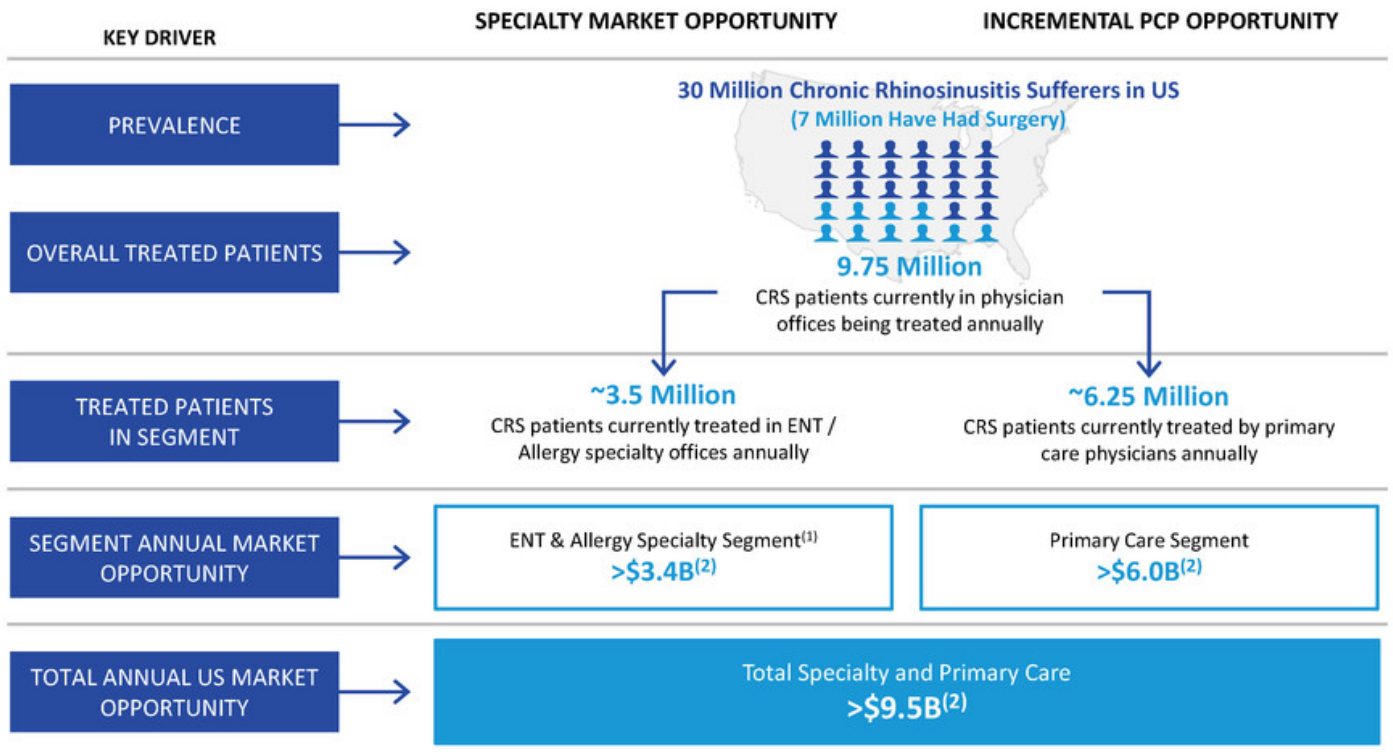


* BID dosing required for the treatment of nasal polyps, based upon Nasonex data and academic literature. WAC prices reflect a 2x multiple on the WAC price for conventional INS due to the approved dose for the treatment of nasal polyps.

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

\$3.4B Market Opportunity Within Specialty (NP and CS Indications)

TOTAL MARKET OPPORTUNITY OF >\$9.5B (NP and CS Indications)



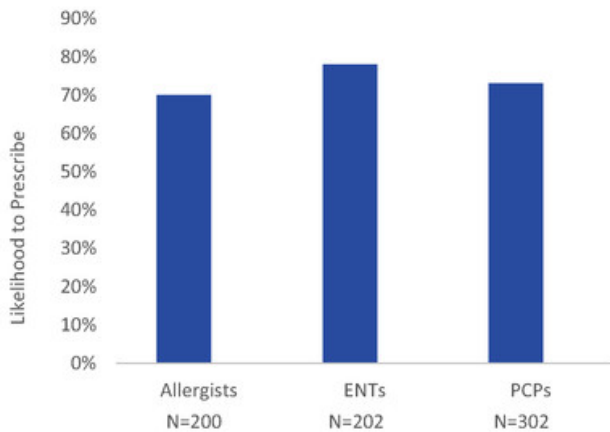
(1) Target market represents ~10,000 ENT and allergy specialists and ~5,000 high-decile INS prescribing primary care physicians.
 (2) Based on our internal estimates.

Differentiated Physician Reaction to Profile

SUGGESTS HIGH LAUNCH INTEREST AND STANDARD OF CARE POTENTIAL

Physician Stated Interest

Physicians of all Specialties Express High Interest in Prescribing



Percent of HCPs stating they will "definitely" or "probably" prescribe XHANCE



...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

Favorable Pharmacoeconomic Profile Offers Promising Market Access Dynamics

RESEARCH* INCLUDING 25 PAYORS REPRESENTING OVER 150M LIVES



PRODUCT

Payors grasp the underlying science/technology of XHANCE



CONTROL

Payors "do not" / "do not want" to manage actively



PRICE

Need to Price "reasonably"



MARKET ACCESS

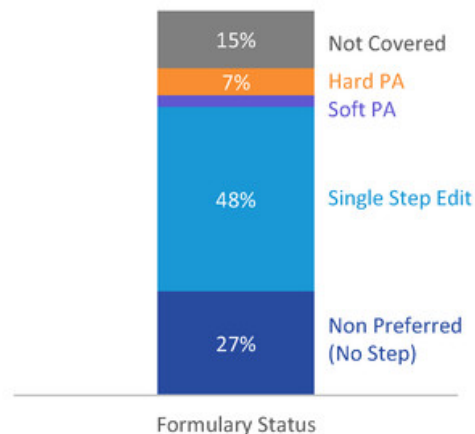
Most commercial lives will have acceptable access if there is comparable pricing to branded INS and utilization is focused on CRS

Across the top 12 payer accounts, for 80% of the total covered lives, payors currently cover INS through open access or step edits

*Q4 2015. Payors Assumed Utilization Both Within NP and More Broadly in CRS.

Potential Commercial Coverage Reported by Surveyed Payors

Percentage of Commercial Lives



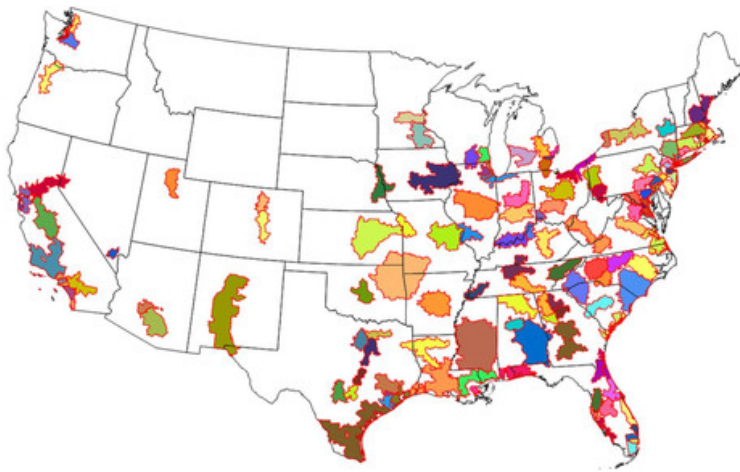
Efficient, Specialty-Focused, Go-to-Market Commercialization Model to Launch XHANCE



Approximately 75 designated territory managers at launch growing to 150 based on expansion of market access

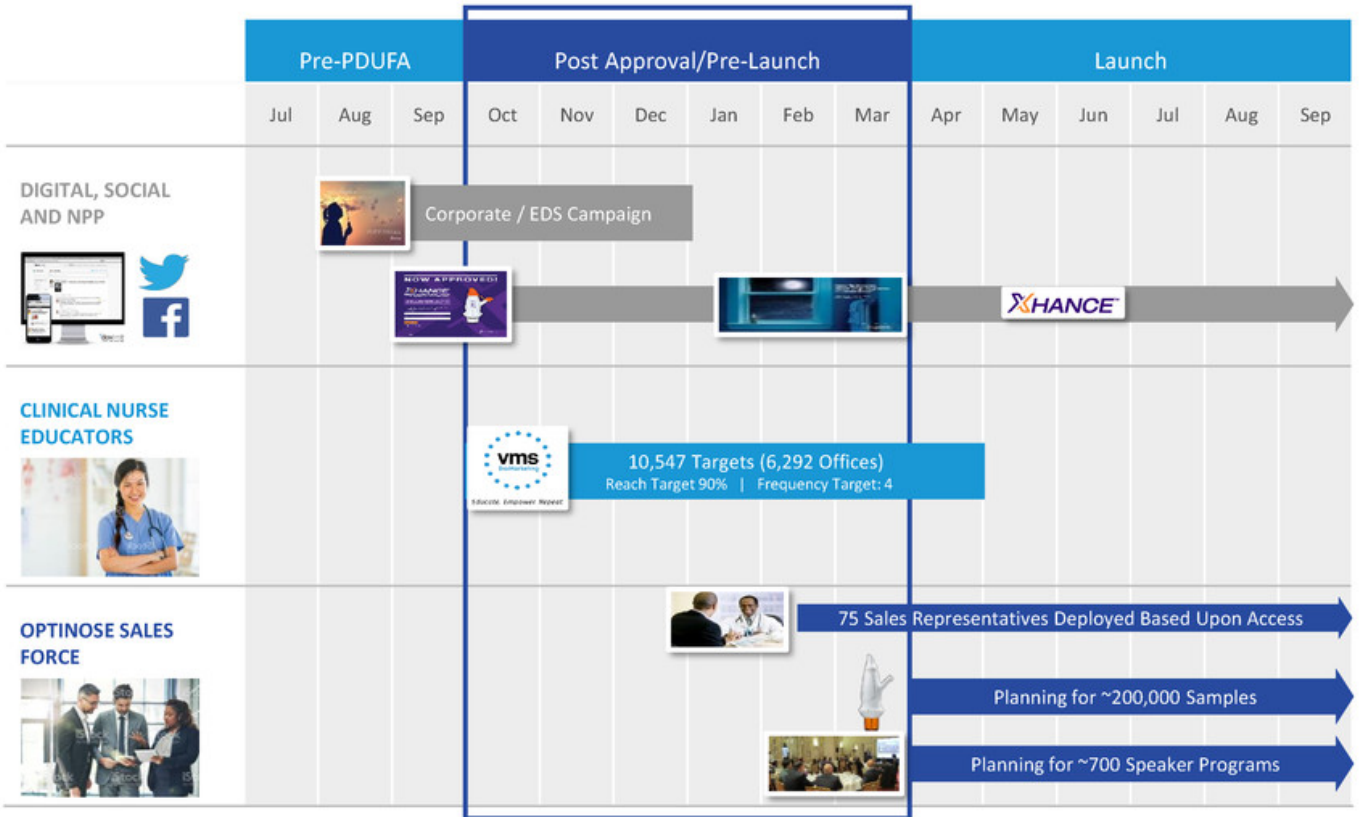
Specialties:
ENT, allergists and high-decile, INS-prescribing primary care physicians

~15,000
Targets



XHANCE Territories
(assuming full deployment)

Multi-Channel Approach to Drive Rapid Trial and Adoption



Optinose EDS Finally Enables Delivery of Drug to Target Sites High/Deep in the Nose: Differentiated Clinical Profile

XHANCE™

**Brand
Differentiation**



Unmet Need

- Patients and physicians cite limited efficacy as the most important unmet need for treating CS with or without Nasal Polyps

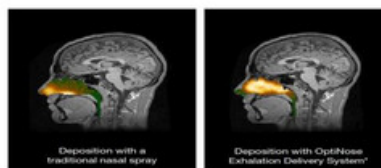


Unsatisfied / engaged patient

- Target patient type is patients who have already tried and failed on a traditional intranasal steroid



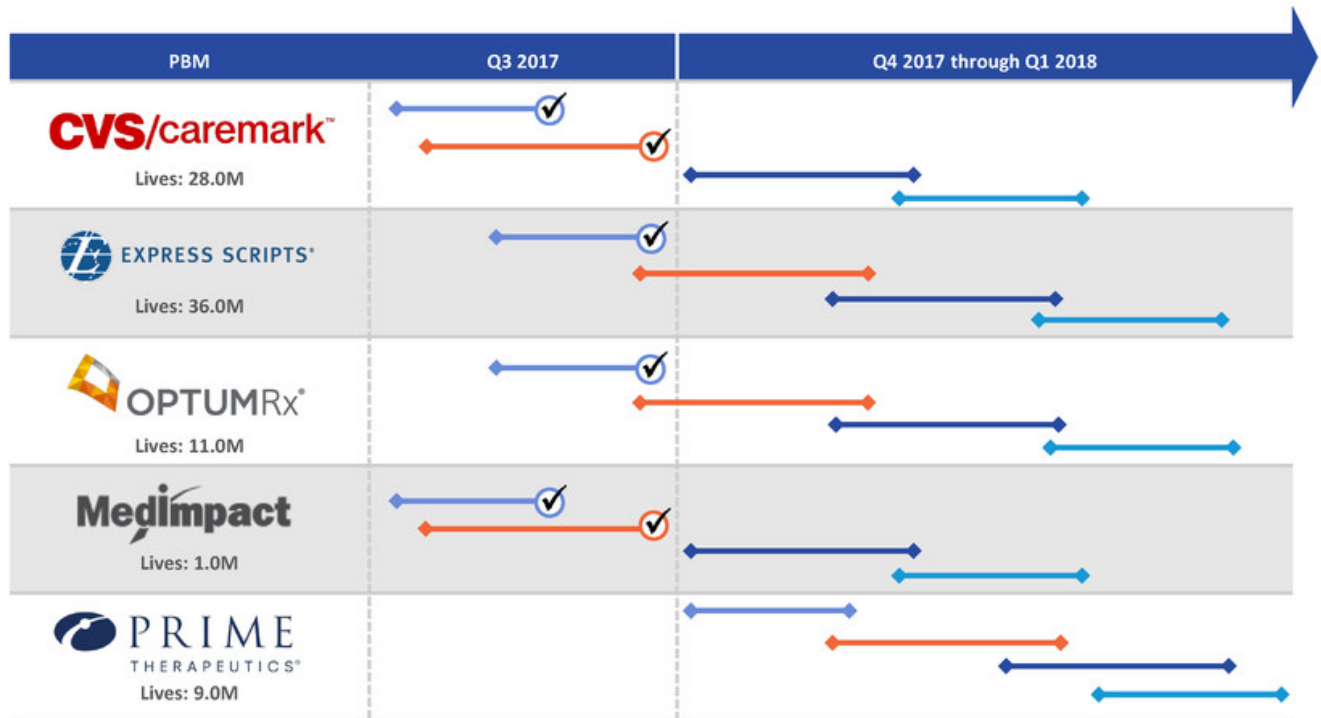
Innovative delivery system



Delivers excellent clinical benefit

- Significant improvement on all 4 defining symptoms of CS
- “Medical” polyp elimination in some patients
- Magnitude of efficacy similar to surgery (SNOT-22)
- Reduction in surgical eligibility

PBM Access Planning Scorecard



Key

- ✓ Task Completed
- ◆ Complete introductory presentation
- ◆ Complete clinical presentation
- ◆ Submit term sheet
- ◆ Potential formulary approval

Excellent Potential in a Large Market with Unmet Need



