

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): July 11, 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 July 11, 2018, the Company posted an updated Corporate Presentation on its website [www.optinose.com](http://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	<a href="#">Optinose, Inc. Corporate Presentation dated July 11, 2018.</a>

**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

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Chief Financial Officer

Date: July 11, 2018



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

**Corporate Presentation**

**July 12, 2018**

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# Forward Looking Statements

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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 the Xperience program; market access objectives; 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 adequate third-party reimbursement for XHANCE (market access); our ability to successfully commercialize XHANCE without the support provided by the Xperience program; 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.

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 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

# Recent Key Accomplishments

87%

Aided Awareness within ENT / Allergy Specialty\*



Retail Launch April 2, 2018

74%

Commercial Lives Covered (61% Tier 3 Single Step or better)\*



Encouraging Physician Adoption in ENT / Allergy



Submitted CS trial design to FDA

Continued to Build Capabilities to Support a Commercial Stage Company



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

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Attractive Market...with High Unmet Need

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Importantly Differentiated Product

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Awareness / Execution

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Market Access

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## CRS is an Attractive Market...With High Unmet Need

**30 Million**

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

**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 prior intranasal steroids (INS)
- **75% of physicians** believe INS nasal sprays do not work well because they do not sufficiently reach site of inflammation

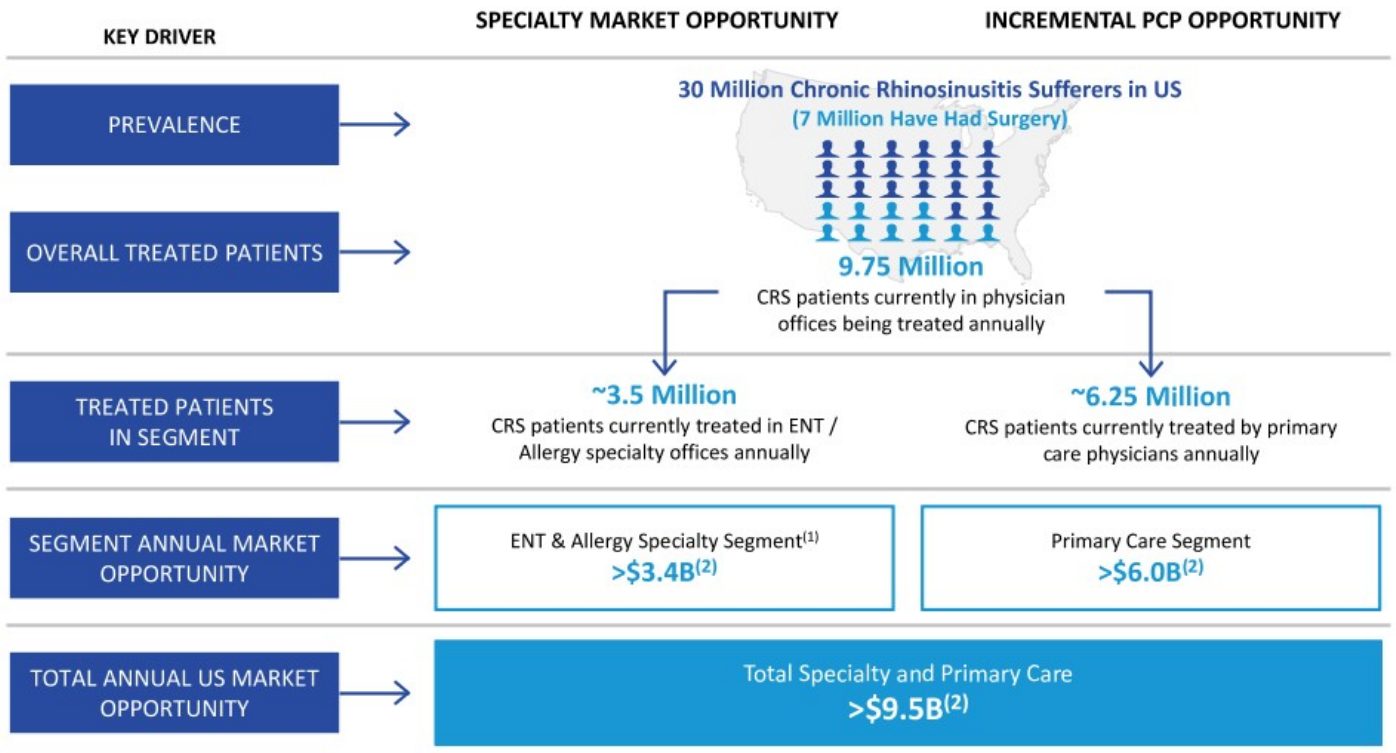
Source: Palmer J et al . A cross-sectional population-based survey of the prevalence, disease burden, and characteristics of the US adult population with symptoms of chronic rhinosinusitis (CRS). Poster session presented at: 62nd Annual Meeting of the American Rhinologic Society; September 16-17, 2016;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

**optinose**



# \$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.



# Perceived Differentiation of XHANCE on Key Choice Drivers Translates into High Intention to Prescribe

## XHANCE is Perceived as Differentiated on Key Choice Drivers

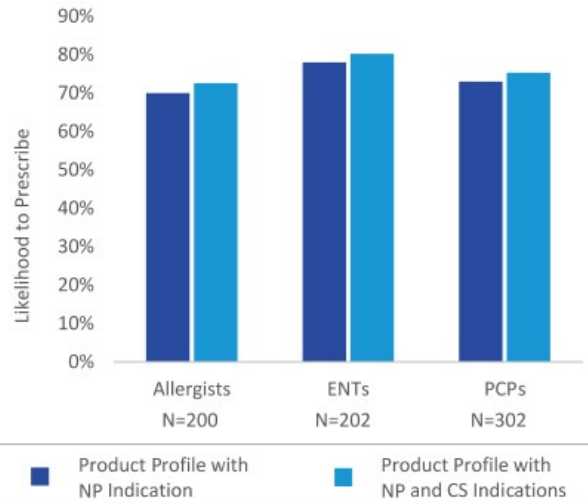
- Improvement in nasal blockage / congestion as early as week 4
- Elimination of polyps at week 24
- Improvement in sense of smell / taste
- Overall Patient Satisfaction

N=200 (100 ENTs and 100 Allergists)



## Physician Stated Interest to Prescribe\*

High Physician Interest in Prescribing is Reported After Presenting Product Profile (With Only Nasal Polyp Indication)

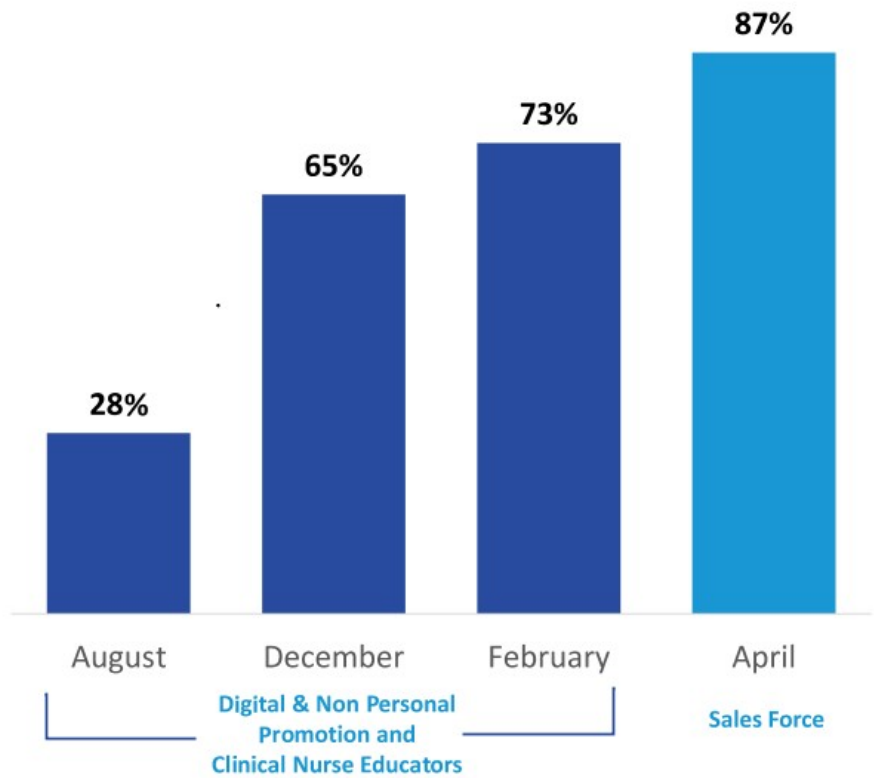




# Multi-Channel Integrated Marketing Program Increased Aided Awareness to 87%

## Awareness & Execution

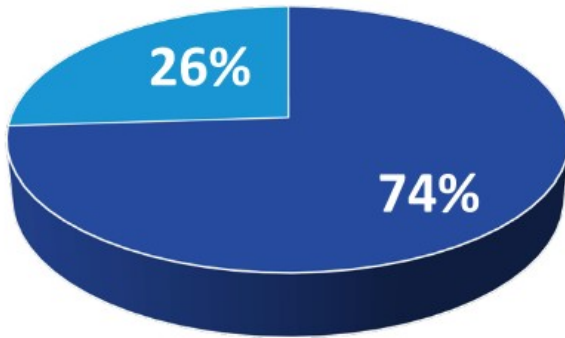
- Digital and Non-Personal Awareness campaign implemented 9/17/2017
- Clinical Nurse Educators deployed 11/18/2017
- Xhance Xperience program introduced in early March
- Approximately **80** Territory Managers deployed on March 5<sup>th</sup>
- TMs have reached **54%** of target Physicians with an average frequency of **3.1** as of May 4







## XHANCE has Good Early Launch Market Access

### XHANCE Overall Access: April 2018



#### Access Key

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

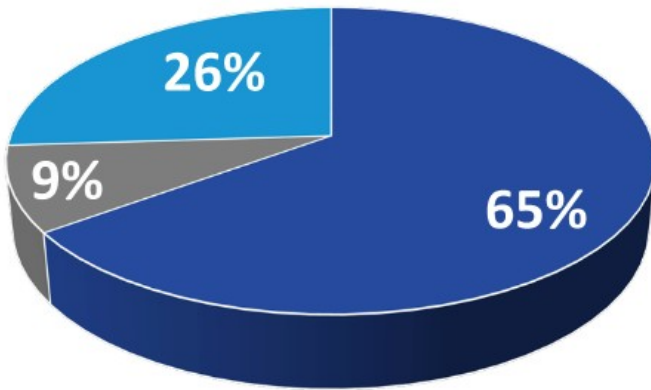
Source: Third party syndicated data and internal analyses as of April 2018

- Nationally, we believe **74% of commercial lives** are in a plan where XHANCE is covered.
- We believe new drugs that launch at approval typically have only **40% of commercial lives covered** and **60% of commercial lives blocked or not covered**.
- XHANCE is available to patients through multiple payers that normally place new-to-market restrictions on access.






## XHANCE National Market Access

### XHANCE Overall Access: April 2018



#### Access Key

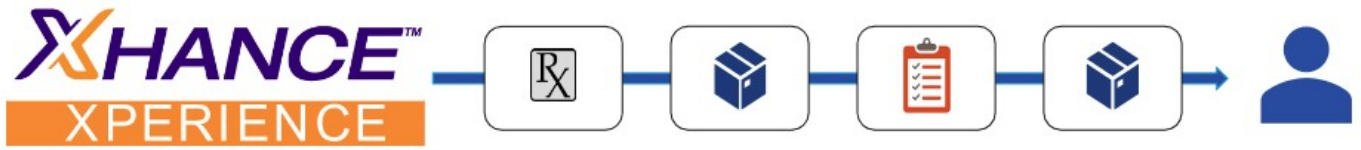
-  NDC Blocked / Not Covered
-  Covered (Double step edit or PA to indication)
-  Covered (Unrestricted, Single step edit, or PA to Prior INS)

Source: Third party syndicated data and internal analyses as of April 2018

- We are focused on creating access for patients that minimizes hassle for prescribers and patients.
- XHANCE is on formulary for **65% of commercial lives** in a Tier 3 position requiring a previous trial of an INS or better.
- Our goal is for **75% of commercial lives** to have “limited hassle” access to XHANCE by the end of 2018.



## XHANCE Xperience Program - Initiated in Market on March 5<sup>th</sup>



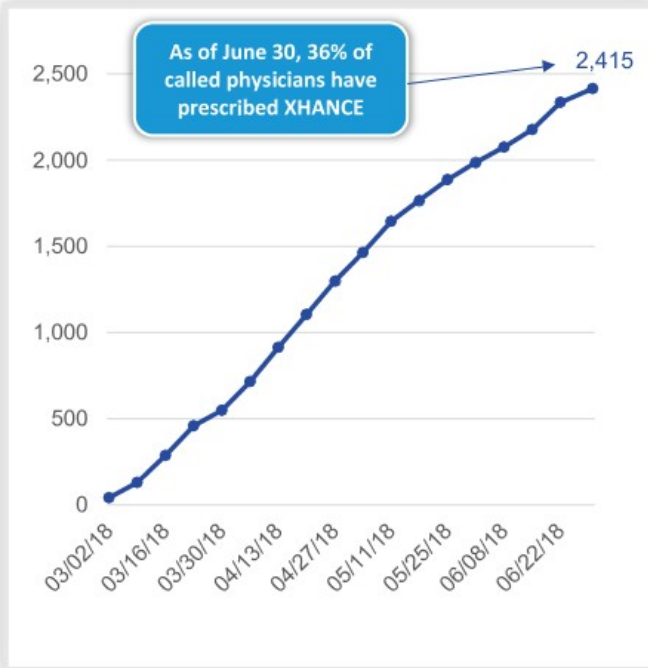
- Innovative launch program, planned for March through June, offering physicians and patients an opportunity to gain initial experience with XHANCE
- Designed to facilitate accelerated trial and adoption, and to help address “practice inertia”
- Eligible patients receive up to two prescription fills of XHANCE at no cost to them (\$0 co-pay)
- Patients required to complete survey for second prescription fill
- A mail-order pharmacy coordinates fulfillment



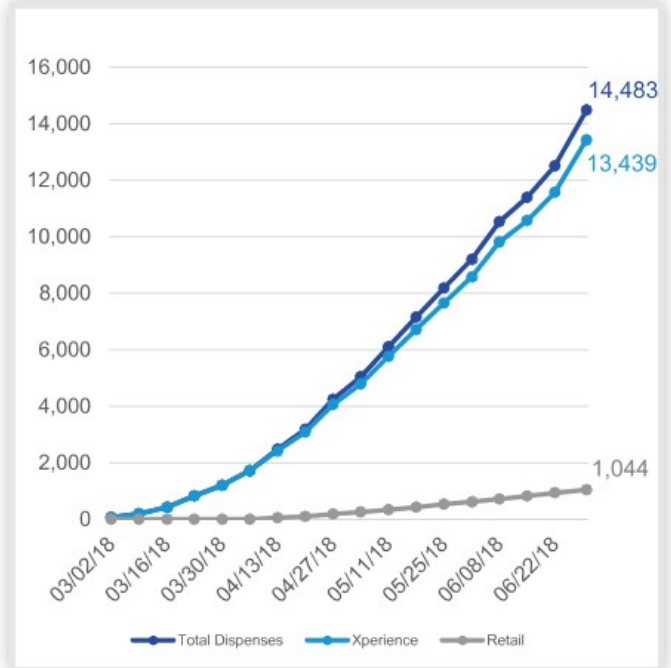


# XHANCE Launch Accelerated by Xperience (Week ending June 30, 2018)

## Cumulative Physician Trialists



## Cumulative Units Dispensed

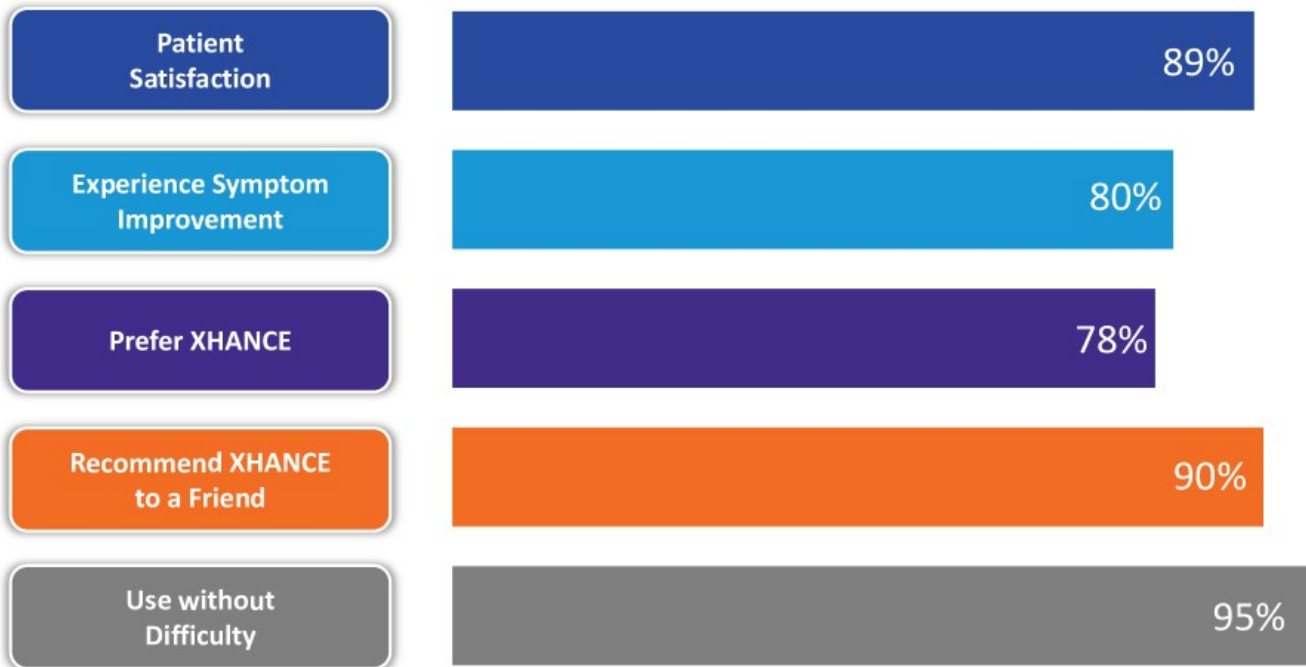


Source: cumulative physician trialists and cumulative units dispensed based on mail order pharmacy data under Xperience program and available retail data.



# Encouraging Feedback From Xperience Program Survey

## Patient Responses Prior to Month 2 Refill (N=1,470)



Note: in the same period that the 1,470 responses were received, 332 patients declined the opportunity to respond to the survey.

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



	Indicator/Objective	Assessment
<b>Attractive Market...with High Unmet Need</b> 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	
<b>Differentiated Product</b> Physician Stated Interest to Prescribe	70%–80% Physicians' stated interest to prescribe based on product profile similar to XHANCE	
<b>Awareness / Execution</b> Awareness During Launch	87% Aided awareness within ENTs and allergists during launch	
<b>Market Access</b> Covered Commercial Lives at Launch	65% Tier 3 coverage at launch (As of April 2018: 74% T3 coverage; 61% T3 unrestricted or single-step)	

# Financial Review

## Q1 2018 Revenues and Average Selling Price (ASP)

- A large majority of Q1 revenue is related to inventory shipped in late-March to support retail pharmacy availability of XHANCE in April.
- In accordance with GAAP accounting rules, we estimated ASP for XHANCE, with specific assumptions for units sold into the retail channel as well as units sold through the Xperience program.
- The ASP for the Xperience program is significantly less than the ASP for the retail channel.

## Q2 and Full Year 2018 Perspectives

- As planned, we expect the Xperience program to be the primary source of demand for XHANCE in Q2.
- We believe the Xperience program will help accelerate demand in the early phase of launch.
- As a result of this program, we expect ASP and Gross Margin percentage in Q2 to be significantly less than in Q1.
- We are focused on maximizing patient retention following the Xperience program.

## Chronic Sinusitis Supplemental Indication (sNDA)

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CS study design submitted to FDA, meeting requested

Selection of CRO and study locations

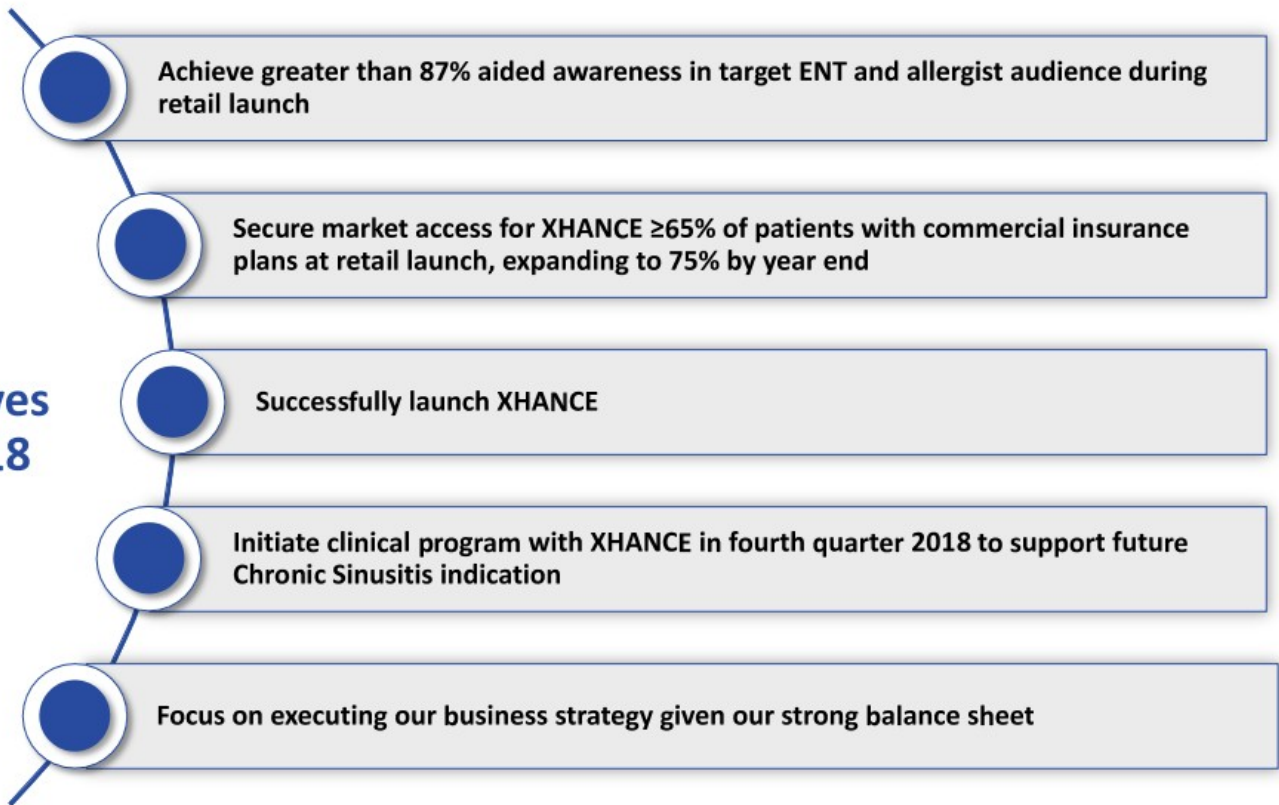
First patients expected to enroll in 4Q 2018

**Chronic Sinusitis trial design expected to include co-primary endpoints: both an objective measure of inflammation and a subjective measure of symptom relief**

## 2018 Stands to be an Important Year

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### Key Objectives For 2018



## Investor Relations – NASDAQ: OPTN

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### Analyst Coverage<sup>1</sup>

BMO: Gary Nachman

Jefferies: David Steinberg

Piper Jaffray: David Amsellem

RBC: Randall Stanicky

### At 31 March 2018:

- \$210 million in cash
- Long-term debt: \$75 million

### June 2018 Offering:

- Net proceeds of \$60 million in cash
- 40.8 million common shares o/s
- 8.2 million options & warrants o/s

### Optinose Investor Contact

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



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