#### **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): December 12, 2018



(Exact Name of Registrant as Specified in its Charter)

42-1771610 DELAWARE 001-38241

(State or Other Jurisdiction of Incorporation or Organization)

(Commission File No.)

(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-14(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).

- $\boxtimes$ 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 |X|financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.
On December 12, 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

99.1

Exhibit No. Description

Optinose, Inc. Corporate Presentation dated December 12, 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: December 12, 2018

# Building a Leading ENT / Allergy Specialty Company

# **Corporate Presentation**

December 12, 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: potential benefits of XHANCE® and our EDS technology; potential drivers of future growth; potential benefits of our patient affordability programs; market access objectives; potential effects of INS market seasonality on XHANCE prescriptions; market opportunities; commercial strategies; potential benefits of DTC pilot; 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 grow XHANCE prescriptions and become profitable; 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 <a href="http://www.sec.gov">http://www.sec.gov</a>. 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.

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### **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

~\$220 million of cash as of September 30, 2018

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# **Optinose EDS Technology is a Platform for Development**



Note: The Avanir License Agreement is expected to terminate on March 10, 2019. Optinose is evaluating options including seeking a new license partner.



# 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)

3.5 Million

CRS patients treated by ENT/Allergy specialists

1.2 Million NP patients treated by ENT/Allergy specialists

9.75 Million

CRS patients seek physician care annually

#### 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

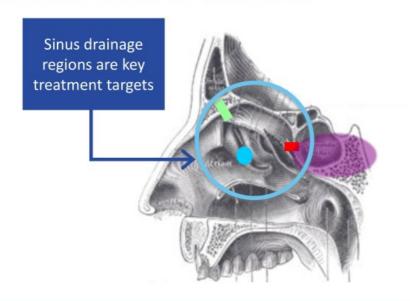
Source: Palmer J et al . A cross-sectional population-based survey of the prevalence, disease burden, and characteristics of the US adult population with symptoms of chronic rhinosinusitis (CRS). Poster session presented at: 62nd Annual Meeting of the American Rhinologic Society; September 16-17, 2016;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

Optinose Market Research. Data on file.

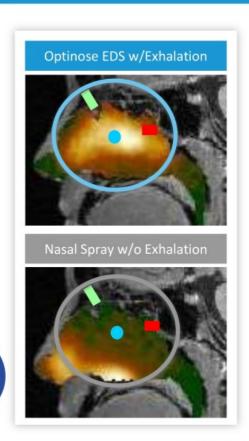


# **Optinose EDS Can Deliver Drug High & Deep in the Nose**

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



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



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# **Optinose Key Priorities**

Accelerate XHANCE® prescription growth

Advance our clinical program for XHANCE for a follow-on indication for the treatment of chronic sinusitis

Support our commercial and development objectives through efficient use of capital

~\$220 Million of cash as of September 30, 2018

optinose<sup>\*</sup>





# **Encouraging Feedback From Xperience Patient Survey**

## Patient responses prior to Month 2 refill from March - August 2018

	Total Respondents (N=2,733)	Prior User of Flonase / Nasonex (n=820)	Prior User 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%

Note: 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.



# **Examples of Positive XHANCE Physician Feedback\***





"The polyps were significantly reduced and patient symptoms improved. The results were dramatic."

- FN7

\*Testimonials and images 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.

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# Our Updated Patient Assistance Program Addresses Physician Perceptions Regarding Affordability and Access





## **XTENDED Patient Support**

- \$0 co-pay for initial Rx for all commercial patients
- Maximum out of pocket of \$30 for refills for covered commercial patients
- Maximum out of pocket of \$50 for non-covered commercial patients through preferred pharmacy network
- Program design driven by patient willingness to pay research and physician willingness to prescribe research

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# **Additional Commercial Updates**



### **Market Access**

- Nationally, we believe more than 75% of commercial lives are in a plan where XHANCE is <u>covered</u> in a Tier 3 formulary position\*
- Recently signed first Part D contract and expanding Medicaid coverage



## Writers

- More than 3,800 physicians have written a prescription through November 2<sup>nd</sup>
- Number of weekly prescribers growing week over week



#### **Direct to Consumer**

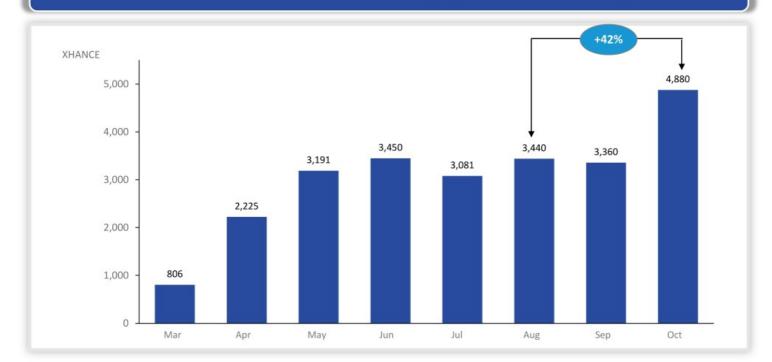
Initiated pilot program in Q4 using digital-only approach for DTC



\* Source: Third party syndicated data and internal analyses as of November 1, 2018. Coverage is subject to change.

# **XHANCE Monthly Prescription Volumes**

New promotional materials and patient affordability program rolled out week of August 17



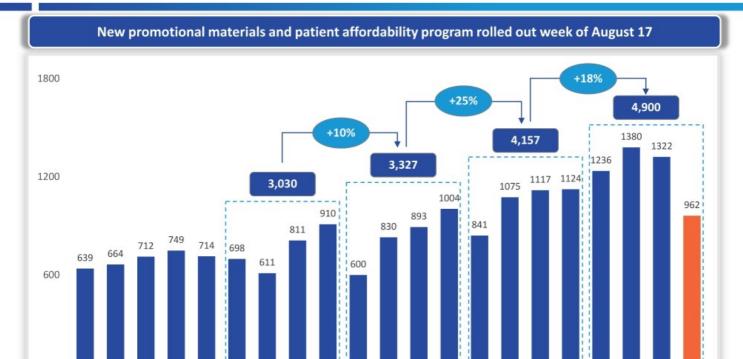
Market TRx for Intranasal Steroids increased 10% from August 2018 to October 2018

Source Monthly prescription data from public sources and preferred pharmacy network.

13



# **XHANCE Weekly Prescription Volumes**



Market TRx for Intranasal Steroids increased 4% and decreased 2% in the four week periods ended Oct. 26 and Nov. 23 respectively

Jul 20 Jul 27 Aug 03 Aug 10 Aug 17 Aug 24 Aug 31 Sep 07 Sep 14 Sep 21 Sep 28 Oct 05 Oct 12 Oct 19 Oct 26 Nov 09 Nov 16 Nov 23



Source Weekly prescription data from public sources and preferred pharmacy network



## Investor Relations - NASDAQ: OPTN

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

**BMO: Gary Nachman** 

Jefferies: David Steinberg

Cantor Fitzgerald: Brandon Folkes

Piper Jaffray: David Amsellem

**RBC: Randall Stanicky** 

At 30 September 2018:

- ~\$220 million in cash
- Long-term debt: \$75 million
- 41.2 million common shares o/s
- 8.0 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



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.

