

**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 10, 2018



OPTINOSE, INC.

(Exact Name of Registrant as Specified in its Charter)

DELAWARE

001-38241

42-1771610

(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-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 December 10, 2018, OptiNose, Inc. (the "Company") issued a press release announcing the enrollment of the first patient in a global clinical trial to evaluate the safety and efficacy of XHANCE® (fluticasone propionate) nasal spray as a treatment for patients with chronic sinusitis. A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated December 10, 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 10, 2018



Optinose Announces First Patient Enrolled in Clinical Trial of XHANCE for Chronic Sinusitis

- *Company also announces first patient enrolled in clinical trial of XHANCE for treatment of nasal polyps in pediatric patients*

YARDLEY, Pa., Dec. 10, 2018— [Optinose](#) (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, announced today the enrollment of the first patient in a global clinical trial to evaluate the safety and efficacy of XHANCE® (fluticasone propionate) nasal spray as a treatment for patients with Chronic Sinusitis.

The trial is a randomized, double-blind, placebo-controlled study of approximately 400 patients across 50 sites.

In addition, the Company announced the enrollment of the first patient in a clinical trial to evaluate the safety and efficacy of XHANCE for treatment of adolescent pediatric patients with nasal polyps.

The pediatric trial is a randomized, double-blind, placebo-controlled study of approximately 120 patients across 30 sites.

"We are particularly pleased to be initiating our clinical program in pursuit of an indication for treatment of Chronic Sinusitis because we are aware of no approved drugs for that indication, and we believe there is a very large population in need of treatment," said Dr. Ramy Mahmoud, President and Chief Operating Officer of Optinose. "We anticipate starting the second trial in the program in 2019 and hope to achieve the first ever approval for this indication."

About Optinose

Optinose is a global specialty pharmaceutical company focused on serving the needs of patients cared for by ear, nose and throat (ENT) and allergy specialists. To learn more, please visit www.optinose.com or follow us on Twitter and LinkedIn.

Cautionary Note on Forward-Looking Statements

This press release contains 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 anticipated commencement of the second chronic sinusitis trial in 2019; the

potential to achieve the first ever drug approval for chronic sinusitis; 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: uncertainties and delays relating to the initiation, enrollment, completion and results of clinical trials; risks relating to regulatory approval of XHANCE for chronic sinusitis; market opportunities for XHANCE may be smaller than the Company believes; and the risks, uncertainties and other factors discussed under the caption "Item 1A. Risk Factors" and elsewhere in the Company's most recent Form 10-K and Form 10-Q filings with the Securities and Exchange Commission - which are available at 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 press release speak only as of the date of this press release, and the Company undertakes no obligation to update such forward-looking statements, whether as a result of new information, future developments or otherwise.

Optinose Investor Contact

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