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): June 21, 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):

q Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

q Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

q Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

q 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).

☒ 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 June 21, 2018, OptiNose, Inc. (the “Company”) issued a press release announcing the publication of pivotal efficacy and long-term safety data in peer reviewed journals for the Company's FDA-approved product, XHANCE, for the treatment of nasal polyps. 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

Exhibit No.	Description
99.1	Press Release dated June 21, 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: June 21, 2018

Optinose Announces Publication of Pivotal Efficacy and Long-Term Safety Data for XHANCE in Peer Reviewed Journals

NAVIGATE II: XHANCE produced significant improvement in both co-primary outcome measures, congestion/obstruction at week four and total polyp grade at week 16

EXHANCE-12: Over one year of treatment, XHANCE 372 mcg twice daily was well tolerated in patients with chronic sinusitis with or without nasal polyps

YARDLEY, Pa., June 21, 2018 Optinose (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, today announced that results of the Phase 3 NAVIGATE II trial and the EXHANCE-12 trial were published in peer-reviewed journals: the Journal of Allergy and Clinical Immunology[1] and the International Forum of Allergy & Rhinology[2], respectively.

“We are pleased to announce the peer-reviewed publication of these important data from the development program that supported the FDA approval of XHANCE for the indication ‘treatment for nasal polyps’ in adults,” said Ramy Mahmoud, M.D., MPH, President and Chief Operating Officer of Optinose. “The team at Optinose thanks the investigators and patients involved in NAVIGATE II and EXHANCE-12. Their willingness to conduct and participate in these studies was a crucial element in our success. We look forward to continuing to conduct clinical research with XHANCE, including the planned initiation in the fourth quarter of 2018 of our pivotal program evaluating XHANCE for the new indication ‘treatment of chronic sinusitis,’ an indication that has never previously been achieved for a pharmaceutical product.”

NAVIGATE II and EXHANCE-12 were part of a comprehensive development program consisting of five clinical trials evaluating XHANCE™ in over 1,500 adult patients; including two randomized, double-blinded, placebo-controlled Phase 3 pivotal clinical trials in adults with nasal polyposis and two supportive open-label Phase 3 clinical trials in adults with symptoms of chronic sinusitis with or without nasal polyps. Based upon the results of this program, the U.S. Food & Drug Administration (FDA) approved XHANCE for the treatment of nasal polyps in patients 18 years of age and older in September 2017.

About NAVIGATE II[1]

NAVIGATE II was a 24-week study designed to assess the efficacy and safety of XHANCE versus an Exhalation Delivery System (EDS) with placebo in adults. Patients all had nasal polyps (NP) and moderate-to-severe nasal congestion/obstruction at entry. Patients were randomized to receive XHANCE (including the FDA-approved doses, 186 and 372 mcg) or

EDS-placebo twice daily for the 16-week, double-blind phase. Patients who completed this double-blind phase were permitted to continue in an open-label extension phase in which all patients received 372 mcg of XHANCE twice daily for up to eight additional weeks. All patients and investigators remained blinded to the original treatment during the open-label phase.

At the start of the trial, patients were moderate to severe, with 87% reporting prior corticosteroid treatment for nasal polyps and 51% reporting prior sinus surgery and/or polypectomy.

Both approved doses of XHANCE (186 and 372 mcg) produced statistically significant reductions in both co-primary outcome measures; change in nasal congestion/obstruction symptoms from baseline to week four and change in total nasal polyp grade from baseline to week 16.

In addition to the co-primary efficacy endpoints, NAVIGATE II included assessments of several important secondary endpoints, including the following:

- *Defining Symptoms (congestion, rhinorrhea, facial pain and pressure, loss of sense of smell).* The XHANCE 186- and 372-mcg treatment groups improved more than placebo on all four of the core defining symptoms of nasal polyposis at the end of the double-blinded phase.

- *Complete Response Analysis.* The percentage of patients who had complete response, defined as nasal polyps eliminated (polyp grade of zero) on at least one side of the nose, at the end of the double-blinded phase was 14% in the 372-mcg dose group compared to 4% among EDS-placebo recipients. By the end of 24 weeks, 28% of patients who received the 372-mcg twice daily dose of XHANCE were observed to have polyp elimination in at least one nostril.

- *Sinonasal Outcome Test (22 item).* On the Sinonasal Outcome Test-22, a questionnaire which broadly assesses the impact of nasal polyposis on outcomes including symptoms, functioning and quality of life, the improvement observed with the 186- and 372-mcg doses of XHANCE was superior to the change with EDS-placebo. The magnitude of improvement from baseline associated with XHANCE was approximately 20 points.

- Other secondary endpoints characterizing treatment response included various patient-reported quality of life and functioning outcomes (e.g., SF-36, Rhinosinusitis Disability Index, and others), Patient Global Impression of Change, indicators for potential need for surgery, and others.

Adverse events in this study that were possibly attributable to XHANCE were local (not systemic). Adverse events occurring more often with XHANCE versus EDS-placebo, and in at least 2% of patients, were epistaxis, nasal septal ulceration, nasopharyngitis, nasal erythema/erosion, atypical nasal congestion, nasal septal erythema, and headache.

About EXHANCE-12[2]

EXHANCE-12 was a prospective, 12-month, multicenter, open-label study evaluating the long-term safety and efficacy of XHANCE 372 mcg twice daily in chronic rhinosinusitis (CRS)

patients with or without nasal polyps. Eligible patients were 18 years of age or older and had symptoms of CRS for at least 12 weeks. The presence of nasal polyps was determined by nasal endoscopy at screening. In this study, 96% of patients reported prior use of corticosteroids and 29% reported prior sinus surgery. All patients received XHANCE 372 mcg twice daily.

The majority of spontaneously reported AEs were local in nature, mild in severity, and resolved spontaneously with continued use of XHANCE. The most common AEs (5%) included those coded as epistaxis (11.2%); nasal erythema (17.5%); nasal septum disorder (nasal septal erythema, 14.3%); acute sinusitis (13.9%); nasal septal erosion or ulceration (11.2%); headache (9.4%); and upper respiratory infection (7.6%).

Important efficacy measures in EXHANCE-12 included:

- *Sinonasal Outcome Test-22:* The average total score improved throughout the clinical trial. After 12 months of treatment with XHANCE, at least 50% of patients had a score that was at or below 9.0, which is less than the average score of 9.3 that has been reported for healthy individuals.

- *Complete Response Analysis:* After 12 months of treatment with XHANCE, approximately 54% of the patients who started the study with polyps were observed to have polyp elimination (polyp grade of zero) in at least one nostril.

Patient Global Impression of Change: At month 12, more than 85% of patients reported improvement and more than 64% reported being ‘‘much’’ or ‘‘very much’’ improved. Other efficacy measures included: Lund-Kennedy scoring of endoscopically observed nasal pathology, indicators of potential need for surgery, and others.

About CRS with and without nasal polyps
Chronic rhinosinusitis (CRS) is a chronic inflammatory condition affecting 10%-15% of the population. Chronic rhinosinusitis is divided into two common subtypes: with or without nasal polyps (CRSwNP, CRSsNP). Nasal polyps are benign lesions developing from the chronically inflamed surfaces deep in the nose.

About XHANCE
XHANCE (fluticasone propionate) nasal spray, 93 mcg is a corticosteroid indicated for the treatment of nasal polyps in patients 18 years of age or older. XHANCE combines an Optinose Exhalation Delivery System (EDS) with an aqueous suspension of microfine fluticasone propionate for topical intranasal administration by means of an atomizing spray pump and exhaled breath. Local exposure within the nasal cavity with XHANCE will differ when used without exhalation through the device.

IMPORTANT SAFETY INFORMATION for XHANCE

CONTRAINDICATIONS:
Hypersensitivity to any ingredient in XHANCE.

WARNINGS AND PRECAUTIONS:
- Local Nasal Effects: epistaxis, erosion, ulceration, septal perforation, Candida albicans infection, and impaired wound healing. Monitor patients periodically for signs of possible

changes on the nasal mucosa. Avoid use in patients with recent nasal ulcerations, nasal surgery, or nasal trauma.

- Close monitoring for glaucoma and cataracts is warranted.
- Hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, contact dermatitis, rash, hypotension, and bronchospasm) have been reported after administration of fluticasone propionate. Discontinue XHANCE if such reactions occur.
- Immunosuppression: potential increased susceptibility to or worsening of infections (e.g., existing tuberculosis; fungal, bacterial, viral, or parasitic infection; ocular herpes simplex). Use with caution in patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients.
- Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue XHANCE slowly.
- Assess for decrease in bone mineral density initially and periodically thereafter.

ADVERSE REACTIONS:
The most common adverse reactions (incidence ≥ 3%) are epistaxis, nasal septal ulceration, nasopharyngitis, nasal mucosal erythema, nasal mucosal ulcerations, nasal congestion, acute sinusitis, nasal septal erythema, headache, and pharyngitis.

DRUG INTERACTIONS:
Strong cytochrome P450 3A4 inhibitors (e.g., ritonavir, ketoconazole): Use not recommended. May increase risk of systemic corticosteroid effects.

USE IN SPECIFIC POPULATIONS
Hepatic impairment. Monitor patients for signs of increased drug exposure.

INDICATIONS AND USAGE:
XHANCE is a corticosteroid indicated for the treatment of nasal polyps in patients 18 years of age or older.

Please see full Prescribing Information at www.xhance.com.

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. Optinose has offices in the U.S., the U.K. and Norway. 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 initiation and timing of a clinical program of XHANCE for chronic sinusitis and other statements regarding the Company's future operations, prospects, 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: the Company's ability to successfully commercialize XHANCE; physician and patient acceptance of XHANCE; the Company's 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; market opportunities for XHANCE may be smaller than expected; uncertainties and delays relating to the initiation, enrollment and completion of clinical trials; unanticipated costs; and the risks, uncertainties and other factors discussed under the caption "Item 1A. Risk Factors" and elsewhere in our 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 we undertake no obligation to update such forward-looking statements, whether as a result of new information, future developments or otherwise.

References

1 - Leopold DA, Elkayam D, Messina JC, Kosik-Gonzalez C, Djupesland PG, Mahmoud RA, NAVIGATE II: randomized, double-blind trial of the exhalation delivery system with fluticasone (EDS-FLU) for nasal polyposis, Journal of Allergy and Clinical Immunology (2018), doi:10.1016/j.jaci.2018.06.010.

2 - Palmer JN, Jacobsen KW, Messina JC, Kosik-Gonzalez C, Djupesland PG, Mahmoud RA. EXHANCE-12: 1-Year Study of the exhalation delivery system with fluticasone (EDS-FLU) in chronic rhinosinusitis. *Int Forum Allergy Rhinol.* 2018;00:1-8.

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