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 30, 2021

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-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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	OPTN	Nasdaq Global Select Market

Item 8.01 Other Events.

As previously reported, the Company completed an interim analysis to access the variance in one of the two co-primary endpoints in its first CS trial - change in Composite Score of Nasal Symptoms from baseline to week 4. The analysis was performed on blinded interim data from approximately half of the initial estimated enrollment of 378 patients. The result of this interim analysis was that the observed variance in this endpoint was lower than the variance assumed when the Company estimated sample size during the design of the study.

The Company is now reporting that it has completed a previously planned, blinded interim analysis to access the variance in the other co-primary endpoint in this trial – change in average percent opacification of volume by CT scan from baseline to week 24. The analysis was performed on blinded interim data from approximately one-third of the initial estimated enrollment of 378 patients for whom 6-month CT scan data was available. The result of this interim analysis was that the observed variance in this endpoint was also lower than the variance assumed when the Company estimated sample size for statistical powering during the initial design of the study. Based on the results of these two interim analyses, and the Company's assumptions and estimates relating to the study, the Company anticipates that the initial targeted statistical power will be achieved with the approximately 330 patients currently enrolled in the study. As a result, the Company has closed enrollment in the first CS trial and is now focusing all of its recruitment efforts on the second CS trial. For clarity, both of the referenced interim analyses were blinded to treatment group and therefore could not evaluate the magnitude of difference, if any, between treatment groups. Accordingly, these interim analyses were not designed to, and do not, provide evidence regarding possible superiority of active treatment over placebo or success of the trials.

*****

On July 30, 2021, the Company issued a press release announcing the completion of patient recruitment in one of its chronic sinusitis trials. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

*****

Item 9.01 Financial Statements and Exhibits.

Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by OptiNose, Inc., dated July 30, 2021.

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:July 30, 2021

Optinose Completes Patient Recruitment in Pivotal Trial for XHANCE in Chronic Sinusitis

Company Expects Top-Line Results in First Quarter 2022

XHANCE Reaches Important Milestone on Path to be the First FDA-Approved Drug Treatment for the Approximately 30 million Chronic Sinusitis Sufferers in the U.S.

YARDLEY, Pa., July 30, 2021 — Optinose (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, today announced it has successfully completed recruitment in the first of two pivotal clinical trials to evaluate the safety and efficacy of XHANCE® (fluticasone propionate) nasal spray as a treatment for patients with chronic sinusitis (CS).

“Today we are announcing completion of recruitment in the first of our pivotal CS trials,” stated Ramy Mahmoud, M.D., MPH, President and Chief Operating Officer of Optinose. “Our clinical team is now focusing all of its recruitment effort on the second of our two pivotal CS trials, and we expect to complete enrollment in that trial before year-end. We are grateful to the patients, investigators, and clinical trial site staff who are participating in this research as we work to bring the first FDA-approved drug therapy for chronic sinusitis to patients who need it.”

“The completion of recruitment for this trial keeps us on track to have top-line results in the first quarter of 2022,” said CEO Peter Miller. “Approximately 30 million adults in the U.S. suffer from CS and there are no FDA-approved drug treatments for the disease today. If successfully developed, we believe our business potential with XHANCE will expand multi-fold with the new indication in terms of the number of patients who can be reached promotionally, the size of the physician audience that can be productively engaged, and the potential for commercial partnerships.”

About XHANCE
XHANCE is a drug-device combination product that uses an Optinose Exhalation Delivery System (EDS™) device designed to deliver a topical anti-inflammatory corticosteroid to high and deep regions of the nasal cavity. XHANCE was approved for the treatment of nasal polyps in patients 18 years of age or older by the U.S. Food and Drug Administration in September 2017 and is currently being studied for treatment of chronic sinusitis. If successful, XHANCE may be the first FDA-approved drug product for chronic sinusitis.

Important Safety Information

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.
- Patients with major risk factors for decreased bone mineral content should be monitored and treated with established standards of care.

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.

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

About Optinose

Optinose is a 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 Company's plans to seek approval for a follow-on indication for XHANCE for the treatment of chronic sinusitis and the potential benefits of such indication; the potential for XHANCE to be the first drug treatment approved by the FDA for chronic sinusitis; the Company’s expectation of top-line results in the first quarter of 2022 from its first chronic sinusitis trial and the completion of enrollment in its second chronic sinusitis trial by year-end;

the Company’s believe that, if an indication for chronic sinusitis is successfully obtained, its business potential with XHANCE will expand multi-fold with the new indication in terms of the number of patients who can be reached promotionally, the size of the physician audience that can be productively engaged, and the potential for commercial partnerships, other statements regarding the Company's future operations, financial performance, financial position, 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: risks and uncertainties relating to the enrollment, completion, and results of the clinical trials evaluating XHANCE for the treatment of chronic sinusitis; risks and uncertainties related to the clinical development program and regulatory approval of XHANCE for the treatment of chronic sinusitis; impact of, and uncertainties caused by the COVID-19 pandemic; physician and patient acceptance of XHANCE for its current and any potential future indication; the Company’s ability to maintain adequate third-party reimbursement for XHANCE (market access); market opportunities for XHANCE may be smaller than expected; risks and uncertainties relating to intellectual property; 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.

Investor Relations Contact
Jonathan Neely
jonathan.neely@optinose.com
267-521-0531

###