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 6, 2023

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)
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

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.

Item 8.01 Other Events

On December 6, 2023, OptiNose, Inc. (Optinose) issued a press release announcing that the U.S. Food and Drug Administration (FDA) has extended by three months the review period of its supplemental new drug application (sNDA) requesting approval of XHANCE as a treatment for chronic rhinosinusitis. A copy of the press release is filed as Exhibit 99.1 hereto, and is incorporated by reference herein.

FDA Extension of Prescription Drug User Fee Act (PDUFA) Date

On November 15, 2023, as part of its ongoing review of the XHANCE sNDA, the FDA requested that Optinose submit additional efficacy subset analyses of existing clinical data from one of the two clinical trials submitted in the sNDA: ReOpen1. Optinose submitted the requested analyses on November 22, 2023. On December 4, 2023, the FDA notified Optinose that it will require additional time to review this submission (which the FDA deemed a major amendment), and that the PDUFA goal date for the sNDA would be extended to March 16, 2024.

The FDA request on November 15th was to provide efficacy analyses on a subset of chronic rhinosinusitis patients in ReOpen1 consisting of patients without nasal polyps plus those patients with a nasal polyp grade of 1 or less at baseline.

We believe the results of these additional subset analyses were generally consistent with the previously reported subgroup analyses of patients without nasal polyps from ReOpen1 (summarized below) showing a nominally statistically significant reduction in Composite Symptom Scores (CSS) at week 4 in both the XHANCE 372 mcg and 186 mcg dose groups compared to patients receiving placebo EDS, and an improvement in APOV (defined below) at week 24 in the XHANCE 186 mcg dose group that did not reach statistical significance compared to the placebo EDS. However, in the new subset analyses, the APOV improvement at week 24 was nominally statistically significant for the XHANCE 372 mcg treatment group compared to EDS placebo, while it was not nominally statistically significant in the previous subset analyses consisting solely of patients without nasal polyps.

Background Information on ReOpen1

ReOpen1 was a randomized double-blinded, placebo-controlled Phase 3 clinical trial examining the safety and efficacy of XHANCE versus a placebo Exhalation Delivery System (also referred to as, placebo EDS) in adults with chronic rhinosinusitis (also referred to as, chronic sinusitis) with or without nasal polyps. This clinical trial is intended to serve as one of two pivotal clinical trials included in the sNDA for XHANCE for the treatment of adults with chronic rhinosinusitis.

Study Design

The ReOpen1 clinical trial included a single-blind EDS-placebo lead-in and an EDS-placebo control group, a multi-center, multi-national study population to increase generalizability and an assessment of the safety and efficacy of 186 or 372 mcg twice daily (the 2 currently approved and marketed doses for XHANCE) over a 24-week period. A total of 332 adult subjects were enrolled in this trial.

ReOpen1 had co-primary endpoints of:

- change in a composite score of nasal congestion/obstruction, nasal discharge, and facial pain and pressure symptoms (CSS) from baseline to week 4, and

- change in the average of the percentages of opacified volume in the ethmoid and maxillary sinuses (APOV) from baseline to week 24.

The severity of nasal symptoms was recorded by patients in an electronic diary immediately before dosing in the morning (AM) and evening (PM) and was measured using 7-day average instantaneous AM diary scores. Each symptom was scored from 0-3. The volume of the ethmoid and maxillary sinuses occupied by disease was assessed using computer-assisted assessment of CT scans to determine the percentage (0-100%) of each sinus cavity space that was opacified, with values then averaged across the ethmoid and maxillary sinuses. CT scans were performed at screening and at Week 24.

Previously Reported Primary Endpoint Efficacy Results

In the *a-priori* primary analysis submitted with the sNDA, both the XHANCE 186- and 372-mcg treatment groups achieved statistically significant improvements in both of the co-primary assessments of (i) composite symptom scores (CSS) at week 4, and (ii) average percentage of opacified volume (APOV) of the maxillary and ethmoid sinuses on CT scans at week 24, compared to placebo EDS.

Previously Reported Subgroup Analyses

ReOpen1 was not designed or powered to detect statistical differences between the XHANCE treatment groups and placebo EDS in subgroups of enrolled patients. However, the following planned analyses of the co-primary outcome measures in the patient subgroups with and without nasal polyps, with the definition of subjects "without nasal polyps" excluding subjects with polyp grade 1 or more:

- The subgroup of patients with nasal polyps and the subgroup of patients without nasal polyps were both found to have nominally statistically significant reductions in CSS at week 4 compared to placebo EDS in both the XHANCE 186- or 372-mcg treatment groups.

- The subgroup of patients with nasal polyps was found to have a nominally statistically significant reduction in inflammation inside the sinuses as measured by APOV at week 24 compared to placebo EDS in both the XHANCE 186- or 372-mcg treatment groups. The subgroup of patients without nasal polyps did not have a nominally statistically significant reduction in APOV at week 24 in either the XHANCE 186- or 372-mcg treatment groups compared to placebo EDS.

For additional information regarding the ReOpen clinical trial program, see "*Business - XHANCE Clinical Development – Chronic Sinusitis Program*" section of Optinose's Annual Report on Form 10-K, filed with the Securities and Exchange Commission on March 7, 2023.

* * *

Cautionary Note on Forward-Looking Statements
This Current Report on Form 8-K 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 potential benefits of XHANCE for the treatment of chronic sinusitis (also referred to as, chronic rhinosinusitis without nasal polyps); the potential for XHANCE to be the first FDA approved drug product for chronic sinusitis and the potential benefits of such label expansion; the potential for an FDA action on the sNDA in March 2024; and other statements regarding Optinose'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: physician and patient acceptance of XHANCE for its current and any potential future indication; Optinose's ability to maintain adequate third-party reimbursement for XHANCE (market access) including any future indication; the prevalence of chronic sinusitis and market opportunities for XHANCE may be smaller than expected; potential for varying interpretation of the results from the ReOpen program; uncertainties related to the clinical development program and regulatory approval of XHANCE for the treatment of chronic rhinosinusitis; the potential that the FDA does not meet the PDUFA goal date; Optinose's ability to comply with the covenants and

other terms of the Amended and Restated Pharmakon Note Purchase Agreement; Optinose's ability to continue as a going concern; 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 Optinose'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 Form 8-K speak only as of the date of this Form 8-K, and Optinose undertakes no obligation to update such forward-looking statements, whether as a result of new information, future developments or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated December 6, 2023, issued by OptiNose, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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/ Michael F. Marino
Michael F. Marino
Chief Legal Officer

December 6, 2023

Optinose Announces 3-Month Extension of FDA Review Period for the Supplemental New Drug Application for XHANCE

The application is based on phase 3 results from the ReOpen clinical trial program showing XHANCE significantly reduced symptoms and sinus opacification in participants with chronic rhinosinusitis

If approved, XHANCE is expected to be the first and only drug indicated for the treatment of chronic rhinosinusitis, a diagnosis which is assigned at approximately 10 million patient visits annually

YARDLEY, Pa., Dec. 06, 2023— Optinose (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, today announced that the U.S. Food and Drug Administration (FDA) has extended by three months the review period of its supplemental new drug application (sNDA) requesting approval of XHANCE as a treatment for chronic rhinosinusitis. The updated Prescription Drug User Fee Act (PDUFA) goal date is March 16, 2024.

On November 15, 2023, as part of the ongoing sNDA review, the FDA requested that Optinose submit additional efficacy subset analyses of existing clinical data from one of the two trials submitted in the sNDA: ReOpen1. Optinose submitted the requested analyses on November 22, 2023. On December 4, 2023, the FDA notified Optinose that it will require additional time to review this submission (which the FDA deemed a major amendment), and that the PDUFA goal date would be extended to March 16, 2024. The additional efficacy subset analyses requested by the FDA evaluated the subgroup of patients in ReOpen1 consisting of patients without nasal polyps plus those patients with a nasal polyp grade of one or less at trial entry.

“Chronic sinusitis is one of the top diagnoses made in adult outpatient visits, with approximately 10 million physician office visits coded annually, yet there is a high level of morbidity and no FDA approved drug treatments for the majority of chronic sinusitis patients, those who do not have nasal polyps,” stated Ramy Mahmoud, MD, MPH, CEO of Optinose. “We believe the ReOpen trials demonstrated important clinical benefits XHANCE could offer chronic sinusitis patients and, if approved, we look forward to providing doctors and their patients the first-ever medication to treat all chronic sinusitis patients, including those with or without nasal polyps.”

XHANCE® (fluticasone propionate) nasal spray is a drug-device combination product that combines the most widely used nasal anti-inflammatory drug with the innovative Exhalation Delivery System™ (EDS™). The EDS is designed to uniquely deliver drug high and deep into difficult-to-access sinuses and sinonasal drainage tracts.

For additional information regarding the subset analyses described in this release please refer to Optinose's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 6, 2023.

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 X 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 potential benefits of XHANCE for the treatment of chronic sinusitis (also referred to as, chronic rhinosinusitis without nasal polyps); the potential for XHANCE to be the first FDA approved drug product for chronic sinusitis and the potential benefits of such label expansion; the potential for an FDA action on the sNDA in March 2024; 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: 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) including any future indication; the prevalence of chronic sinusitis and market opportunities for XHANCE may be smaller than expected; potential for varying interpretation of the results from the ReOpen program; uncertainties related to the clinical development program and regulatory approval of XHANCE for the treatment of chronic rhinosinusitis; the potential that the FDA does not meet the PDUFA goal date; the Company's ability to comply with the covenants and other terms of the Amended and Restated Pharmakon Note Purchase Agreement; the Company's ability to continue as a going concern; 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 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 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
Jonathan Neely
jonathan.neely@optinose.com
267.521.0531

###