**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): March 15, 2024**

## 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 7.01 Regulation FD Disclosure**

On March 15, 2024, OptiNose, Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration ("FDA") approved its supplemental New Drug Application ("sNDA") for XHANCE for the treatment of chronic rhinosinusitis without nasal polyps in adults. A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

* * *

The information included in Item 7.01 and Item 9.01 (including Exhibit 99.1) of this Form 8-K, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any Company filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 8.01 Other Events.**

On March 15, 2024, the FDA approved the Company's sNDA for XHANCE for the treatment of chronic rhinosinusitis without nasal polyps in adults.

In connection with the FDA's approval of the sNDA and pursuant to the Pediatric Research Equity Act, the Company is required to conduct a randomized, double-blind, placebo-controlled, parallel group clinical study in children and adolescents 12 to 17 years of age with chronic rhinosinusitis without nasal polyps to access the safety, efficacy and pharmacokinetics of XHANCE. The Company is required to initiate this study by December 2024, complete the study by March 2028 and meet with certain other deadlines relating to the conduct of the study and reporting of results to the FDA.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release issued by OptiNose, Inc., dated March 15, 2024 |
| 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

March 15, 2024

**XHANCE Approved by FDA as First and Only Medication Indicated for Treatment of Adults with Chronic Rhinosinusitis without Nasal Polyps**

*ReOpen was the first ever large placebo-controlled clinical trial program to demonstrate statistically significant reduction of symptoms in chronic sinusitis patients without nasal polyps*

*Clinical trial program also showed reduction in sinus inflammation and in acute exacerbations, which frequently result in use of antibiotics*

*XHANCE uses the proprietary Exhalation Delivery System to enable deposition of a proven steroid in target areas of inflammation deep in the nose not typically reached by standard nasal sprays*

*Chronic sinusitis affects approximately 30 million adults in the U.S.*

**YARDLEY, Pa., March 15, 2024** Optinose (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, today announced the U.S. Food and Drug Administration (FDA) has approved XHANCE® (fluticasone propionate) nasal spray for the treatment of chronic rhinosinusitis without nasal polyps in patients 18 years of age and older.

Chronic sinusitis (also called "chronic rhinosinusitis" or "CRS") is one of the most common chronic diseases, affecting approximately 30 million adults in the United States. Research shows that the disease impairs quality of life to a similar degree as other serious chronic conditions, such as chronic obstructive pulmonary disease, sciatica, or migraine. Chronic sinusitis is also one of the most common diagnoses in adult outpatient medicine. Chronic sinusitis is diagnosed in approximately 10 million outpatient visits, of which approximately 70% result in antibiotic prescriptions, and leads to more than 600,000 surgeries annually. Although there are FDA–approved medications to treat nasal polyps, including XHANCE, no medication had ever been approved for the more than two-thirds of chronic sinusitis patients who do not have nasal polyps – until today.[1]

"The FDA approval of XHANCE for the treatment of CRS without nasal polyps is an important milestone," said Rick Chandra, M.D., Professor of Otolaryngology-Head and Neck Surgery, Endowed Director, Roland "Ron" Eavey, MD, SM Endowed Directorship in Leadership and Education, Service Chief, Rhinology and Skull Base Surgery, Vanderbilt University. "Until today, we have been forced to use unproven therapies to try and alleviate the symptoms that these patients suffer. While we often resort to using nasal steroid sprays in this patient population, they have never been shown to be effective in large placebo-controlled clinical studies. XHANCE, which uses the Exhalation Delivery System to enable delivery of an established topical steroid to the areas of the nasal cavity and sinuses we know to be extensively inflamed, is now proven to be effective in treating our CRS patients both with and without nasal polyps."

“People who don’t suffer from chronic sinusitis may not appreciate how burdensome the condition can be. More than 80% of patients with chronic sinusitis report frustration with symptom relief when using a standard-delivery nasal steroid sprays, and patients commonly use multiple unproven over the counter medications in an effort to find symptom relief.” said Ramy Mahmoud, MD, MPH, CEO of Optinose. “Although chronic sinusitis is one of the most common diagnoses in outpatient physician visits, and surgery is available, there has never been a prescription medication approved by the FDA as safe and effective to treat the millions of patients without nasal polyps suffering from this debilitating disease. We are thrilled to now be able to offer new hope to these patients and believe XHANCE has the potential to become part of the standard of care for the treatment of chronic sinusitis.”

The approval was based on data from the ReOpen program evaluating XHANCE for treatment of adults with chronic sinusitis. A drug-device combination product, XHANCE uniquely combines a widely used nasal steroid with the Exhalation Delivery System™, an innovative delivery system designed to target the sites where inflammation occurs, especially difficult-to-access sinuses and sinonasal drainage tracts not typically reached by standard-delivery nasal sprays.

The safety profile and tolerability of XHANCE for patients in the ReOpen trials was generally consistent with its currently labeled safety profile. The most common adverse reactions (incidence ≥ 3%) in the ReOpen program were epistaxis, headache, and nasopharyngitis.

**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 X and LinkedIn.

**About XHANCE**
XHANCE® is a drug-device combination product that uses the Exhalation Delivery System™ (also referred to as the EDS®) designed to deliver a topical steroid to the high and deep regions of the nasal cavity where sinuses ventilate and drain. XHANCE is approved by the U.S. Food and Drug Administration for the treatment of chronic rhinosinusitis (with and without nasal polyps) in patients 18 years of age or older.

**About the ReOpen Program** The ReOpen program comprised two global, randomized, double-blind, placebo-controlled Phase 3 trials that evaluated the efficacy and safety of one or two sprays of XHANCE in each nostril twice daily, over 24 weeks, in patients suffering from chronic sinusitis. In ReOpen1, the first of the two trials, 332 chronic sinusitis patients either with or without concurrent nasal polyps were treated. In ReOpen2, 222 chronic sinusitis patients who did not have polyps in the nasal cavity were treated. The co-primary endpoints were change from baseline in symptoms, as measured by composite symptom score (nasal congestion, facial pain or pressure, and nasal discharge) at the end of week 4, and change in inflammation inside the sinus cavities, as measured by CT scans (change in the average of the percentages of volume occupied by disease in the ethmoid and maxillary sinuses) at week 24. The ReOpen trial program is a landmark research program that included the first ever large, placebo-controlled trials we are aware of to demonstrate that any nasal medication produces significant improvement in both symptoms and inflammation inside the sinuses for patients with chronic

sinusitis, regardless of whether or not nasal polyps are present, and to show reduction in the number of acute exacerbations.[1]

**WARNINGS AND PRECAUTIONS:**

- Local nasal adverse reactions, including epistaxis, erosion, ulceration, septal perforation, Candida albicans infection, and impaired wound healing, can occur. 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 until healing has occurred.
- Glaucoma and cataracts may occur with long-term use. Consider referral to an ophthalmologist in patients who develop ocular symptoms or use XHANCE long-term.
- 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 and infections can occur, including 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:**

- Chronic rhinosinusitis without nasal polyps: The most common adverse reactions (incidence ≥3%) are epistaxis, headache, and nasopharyngitis.
- Chronic rhinosinusitis with nasal polyps: 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.

Please see full Prescribing Information, including Instructions for Use

**References**

1- James N. Palmer, Nithin D. Adappa, Rakesh K. Chandra, Greg E. Davis, Mahboobeh Mahdavinia, John Messina, Randall A. Ow, Zara M. Patel, Anju T. Peters, Harry Sacks, Rodney J. Schlosser, Raj Sindwani, Zachary M. Soler, Andrew A. White, Sarah K. Wise, Ramy A. Mahmoud, Efficacy of EDS-FLU for Chronic Rhinosinusitis: Two Randomized Controlled Trials (ReOpen1 and ReOpen2), The Journal of Allergy and Clinical Immunology: In Practice, 2024,, ISSN 2213-2198, https://doi.org/10.1016/j.jaip.2023.12.016. (https://www.sciencedirect.com/science/article/pii/S221321982301365X)

**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 benefits of XHANCE for the treatment of chronic sinusitis (also called chronic rhinosinusitis) with and without nasal polyps; the benefits of the approval of XHANCE for the treatment of chronic rhinosinusitis without nasal polyps; the potential for XHANCE to become part of the standard of care for the treatment of chronic sinusitis; the benefits of the Exhalation Delivery System; 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 new indication (treatment of adults with chronic rhinosinusitis without nasal polyps); the Company's ability to maintain adequate third party reimbursement for XHANCE (including its new indication); potential for varying interpretation of clinical trial results of XHANCE for the treatment of chronic sinusitis; ; the prevalence of chronic sinusitis and market opportunities for XHANCE may be smaller than the Company expects; 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.

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