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): May 4, 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 May 4, 2023, OptiNose, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) accepted for review its supplemental new drug application (sNDA) requesting approval of XHANCE as a treatment for chronic rhinosinusitis, and assigned the sNDA a Prescription Drug User Fee Act (PDUFA) target goal date of December 16, 2023. A copy of the press release is furnished hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by OptiNose, Inc., dated May 4, 2023.
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

May 4, 2023

Optinose Announces FDA Acceptance of 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., May 4, 2023 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) accepted for review its supplemental new drug application (sNDA) requesting approval of XHANCE as a treatment for chronic rhinosinusitis. 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. The sNDA submission is based on data from the two Phase 3 clinical trials in patients with chronic sinusitis from the ReOpen Program and has been assigned a Prescription Drug User Fee Act (PDUFA) target goal date of December 16, 2023.

“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 patient dissatisfaction and suffering and no FDA approved drug treatments except for patients who also have nasal polyps,” stated Ramy Mahmoud, MD, MPH, CEO of Optinose. “We are excited to see our study data under FDA review as we believe the ReOpen trials found important benefits that XHANCE could offer to physicians and their patients as a first-ever drug approved to treat chronic rhinosinusitis.”

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 (OPN-375) in each nostril twice daily, over 24 weeks, in patients suffering from chronic sinusitis (CS). In ReOpen1, the first of the two trials, 332 CS patients were treated, either with or without concurrent nasal polyps. In ReOpen2, the second of the two trials, 222 CS patients were treated, all of whom did not have polyps in the nasal cavity. The co-primary endpoints were change from baseline in symptoms, as measured by a composite score of patient-reported symptoms (including nasal congestion, facial pain or pressure, and nasal discharge) at the end of week 4, and objective change in inflammation inside the sinus cavities,

as measured by CT scans assessing the change in the average of the percentages of volume occupied by disease across the ethmoid and maxillary sinuses. The ReOpen trial program is a landmark research program because these are the first ever large, controlled trials we are aware of with any nasal medication to demonstrate significant improvement of both symptoms and inflammation inside the sinuses and to demonstrate reduction in the number of acute exacerbations.

About Chronic Sinusitis
Chronic sinusitis (CS), also called “chronic rhinosinusitis”, has been cited as the second most common chronic disease of adults in the US[1]. It is a serious chronic inflammatory disease affecting as many as 30 million adults in the United States and burdens the U.S. economy with over $30 billion in direct and indirect costs every year.[2] CS is characterized by chronic inflammation affecting the paranasal sinuses and the nasal cavity, where the openings from the sinuses normally ventilate and drain. Chronic sinusitis is associated with symptoms that persist for at least 12 weeks, with many patients suffering for years. In addition, the condition is often associated with multiple acute exacerbations that require medical care and result in substantial use of antibiotics. In some patients, chronic sino-nasal inflammation is accompanied by development of polyps in the nasal cavities, referred to as nasal polyposis. Today, there are no FDA-approved drug treatments for the majority of chronic sinusitis patients, those who do not have polyps in the nasal cavity, although there are medications, including XHANCE, that have been approved by FDA for treatment of the smaller population of chronic rhinosinusitis patients who also have nasal polyps. The term “chronic rhinosinusitis” is sometimes used instead of “chronic sinusitis” to acknowledge that inflammation inside the sinuses is typically accompanied by inflammation in the nasal cavity.

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.

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 anti-inflammatory 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 nasal polyps in patients 18 years of age or older and has been studied for treatment of chronic sinusitis (notably including patients without polyps in the nasal cavity) in two phase 3 trials, ReOpen1 and ReOpen2. These trials are the first ever that we are aware of that show improvement in both symptoms and inflammation inside the sinuses, and reduction in acute exacerbations of disease, with a nasal therapy for chronic sinusitis patients, including patients with or without nasal polyps. If approved, XHANCE may be the first drug ever FDA-approved for treatment of chronic rhinosinusitis either with or without nasal polyps.

Important Safety Information

CONTRAINDICATIONS: Hypersensitivity to any ingredient in XHANCE.

WARNINGS AND PRECAUTIONS:

- Local Nasal Adverse Reactions: 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 until healing has occurred.
- 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 and Risk of Infection: 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.

Please see full Prescribing Information, including Instructions for Use

References

1. Hamilos DL. Chronic rhinosinusitis: epidemiology and medical management. J Allergy Clin Immunol. 2011 Oct;128(4):693-707; quiz 708-9. doi: 10.1016/j.jaci.2011.08.004. Epub 2011 Sep 3. PMID: 21890184.
2. Palmer JN, Messina JC, Biletch R, Grosel K, Mahmoud RA. A cross-sectional, population-based survey of U.S. adults with symptoms of chronic rhinosinusitis. Allergy Asthma Proc. 2019 Jan 14;40(1):48-56. doi: 10.2500/aap.2019.40.4182. PMID: 30582496.

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 for XHANCE to be the first FDA approved drug product for chronic rhinosinusitis and the potential benefits of such label expansion; 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; potential for varying interpretation of clinical trial results of XHANCE for the treatment of chronic rhinosinusitis; potential that the FDA does not meet the PDUFA target goal date; risks and uncertainties relating to FDA approval of XHANCE for the treatment of chronic rhinosinusitis; 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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