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 13, 2022

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

On July 13, 2022 OptiNose, Inc. (the "Company") issued a press release announcing that an analysis of pooled data from the ReOpen1 and ReOpen2 trials found that the 372-mcg treatment group achieved a type 1 error controlled statistically significant reduction of 66% in the incidence of exacerbations compared to placebo comparator. Reductions in the number of exacerbations, ranging from 53 to 80%, were found for subgroups of chronic sinusitis patients with or without nasal polyps receiving one or two sprays per nostril of XHANCE twice daily (186 mcg or 372 mcg BID) in additional pre-planned exploratory analyses that were not type 1 error controlled. Exacerbations were defined as a worsening of at least one of the four cardinal symptoms of chronic sinusitis (nasal congestion/obstruction, rhinorrhea, facial pain/pressure, and loss of sense of smell) lasting at least 3 days accompanied by an escalation in medical care, such as doctor visits or antibiotic or steroid prescription. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Additional detail regarding these findings is set forth below.

Treatment Group	n	Events	LS Mean	Incidence Rate Ratio (Active/PBO)	P-value [1]
Frequency of Exacerbations over 24 Weeks (Full Analysis Set/All Patients)					
XHANCE 186 or 372 mcg	362	35	0.081	0.389	0.001
XHANCE 372 mcg	180	15	0.072	0.343	0.002[2]
XHANCE 186 mcg	182	20	0.092	0.441	0.012
Placebo EDS	185	41	0.208	-	-
Frequency of Exacerbations over 24 Weeks (Patients with Nasal Polyps)					
XHANCE 186 or 372 mcg	137	12	0.052	0.276	0.005
XHANCE 372 mcg	68	4	0.038	0.203	0.010
XHANCE 186 mcg	69	8	0.070	0.376	0.055
Placebo EDS	69	17	0.187	-	-
Frequency of Exacerbations over 24 Weeks (Patients without Nasal Polyps)					
XHANCE 186 or 372 mcg	225	23	0.113	0.472	0.032
XHANCE 372 mcg	112	11	0.113	0.470	0.077
XHANCE 186 mcg	113	12	0.113	0.474	0.076
Placebo EDS	116	24	0.239	-	-

a. The p-value, or probability value, is a measure of statistical significance reflecting the likelihood that an observed result occurred by chance and compares the indicated group to the relevant placebo EDS group. Unless otherwise noted, all p-values shown in this table represent nominal p-values (meaning they are exploratory, not type 1 error controlled) and therefore have an increased possibility of being a chance finding

b. This p-value for all patients receiving XHANCE 372 mcg in the ReOpen Program is a type 1 error controlled statistically significant result. All other p-values shown in this table are nominal p-values.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by OptiNose, Inc., dated July 13, 2022.
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

Date: July 13, 2022

Optinose Announces that XHANCE Significantly Reduced Incidence of Exacerbations for Patients with Chronic Sinusitis in Landmark ReOpen Program

XHANCE is the first and only nasal medication ever shown in Phase 3 controlled trials to reduce exacerbations for patients with chronic sinusitis

Pre-planned analysis of pooled data from the landmark ReOpen trials reveals 66% reduction in sinusitis exacerbations (flares) with use of XHANCE 372 mcg for patients with Chronic Sinusitis

Chronic sinusitis exacerbations lead to doctor visits, antibiotic use, steroid use, surgery, and important morbidity and loss of quality of life

There are approximately 10 million outpatient visits for chronic rhinosinusitis per year, antibiotics are prescribed in 70% of visits, and chronic rhinosinusitis is reported to be the number one reason for outpatient adult antibiotic prescriptions in the United States[1]

YARDLEY, Pa., July 13, 2022— Optinose (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, today announced results of pre-planned analyses from the ReOpen trial program evaluating XHANCE for treatment of patients with chronic sinusitis. XHANCE® (fluticasone propionate) nasal spray is a drug-device combination product combining its proprietary Exhalation Delivery System™ (EDS™) designed to uniquely deliver drug high and deep in nasal passages with an anti-inflammatory drug. These analyses of pooled data from the ReOpen1 and ReOpen2 trials found that over 24 weeks of follow-up, patients using XHANCE two sprays per nostril (372 mcg) twice daily had 66% reduction in the number of disease exacerbations compared to patients receiving a placebo comparator.

Acute exacerbations, or “flares”, are a major source of disability for the roughly 30 million patients in the United States who suffer from chronic sinusitis (also called “chronic rhinosinusitis”). There are approximately 10 million office visits for chronic rhinosinusitis every year, and approximately 70% of patients who visit a doctor for chronic rhinosinusitis receive an antibiotic. Reducing widespread use of antibiotics is important because frequent use of antibiotics poses risks to the individuals using them, including adverse changes to the microbiome of the nose or gut, and because of societal risks, such as emergence of drug-resistant organisms. ReOpen1 and ReOpen2 are controlled clinical trials in patients with CT-scan proven chronic sinusitis. Both trials were previously reported to have shown that XHANCE

treatment resulted in reduction of inflammation inside the sinus cavities and reduction in a combined symptom score. Analysis of pooled data from the 2 trials found a statistically significant reduction of 66% in the incidence of exacerbations for patients receiving 2 sprays twice daily of XHANCE compared to placebo comparator. In additional exploratory pre-planned analyses, similar reductions (ranging from 53 to 80%) in the number of exacerbations were also found for patients taking XHANCE one spray per nostril (186 mcg) twice daily, and in subgroups either with or without nasal polyps. Exacerbations were defined as a worsening of at least one of the four cardinal symptoms of chronic sinusitis (nasal congestion/obstruction, rhinorrhea, facial pain/pressure, and loss of sense of smell) lasting at least 3 days accompanied by an escalation in medical care, such as doctor visits or antibiotic or oral steroid prescriptions.

“This is the first Phase 3 program we are aware of showing that a nasal medication can significantly reduce the number of acute exacerbations of chronic sinusitis,” said Ramy Mahmoud, MD, MPH, President of Optinose. He went on to say, “This is important because these episodes not only lead to poor quality of life but also often push people to frequent use of antibiotics, oral steroids, or even surgery.[2] If a new treatment can prevent these events from occurring and reduce use of antibiotics, oral steroids, or even sinus surgery, it could be very meaningful for a large population of sufferers and for society.”

“Acute symptom flares of chronic sinusitis are a major reason for patients to come to see me and many other doctors,” said Anju Peters, M.D., Professor of Medicine and Director of Clinical Research, Division of Allergy and Immunology, Northwestern University Feinberg School of Medicine. “Data show that nationwide, chronic sinusitis patients receive antibiotics at a vast majority of office visits, and it is one of the most common reasons for antibiotic prescribing in outpatient adult care. Excessive antibiotic use can drive emergence of antibiotic resistance and can lead to allergic reactions, adverse effects, and unnecessary costs, so preventing exacerbations and reducing antibiotic use in chronic sinusitis is very important. These data suggest a potential new evidence-based best practice paradigm where we use medical treatment to treat chronic sinusitis and reduce the frequency of acute exacerbations.”

As previously reported, the safety profile and tolerability of XHANCE in the ReOpen Program were generally consistent with its currently labelled safety profile. Individual adverse event terms occurring at a rate of more than 3% in pooled data from both trials and both dose groups receiving active treatment with XHANCE that were also more common than in the group receiving EDS-placebo were epistaxis, COVID-19, nasopharyngitis, and headache.

About the ReOpen Program

The ReOpen program comprises 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 patients were treated who had CS with or without nasal polyps. In ReOpen2, the second of the two trials, 222 patients were treated who had CS without nasal polyps. 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 sensation, and nasal discharge) at the end of week 4, and objective change in inflammation inside the sinus cavities, as measured by the change in average of percentages of volume occupied by disease across the ethmoid and maxillary sinuses as measured by CT scan. 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 show reduction in the number of acute exacerbations.

About Chronic Sinusitis
Chronic sinusitis (CS), cited as the second most common chronic disease of adults in the US[3], is a serious chronic inflammatory disease affecting as many as 30 million adults in the United States and costing the U.S. economy over $30 billion in direct and indirect costs every year.[4] 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 most patients suffering for many years. In addition, the condition is often associated with multiple acute exacerbations that 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 who do not have nasal polyps, though there are medications, including XHANCE, approved by FDA for treatment of nasal polyps. The term "chronic rhinosinusitis" is also often used as an umbrella term in medical literature to refer to patients with chronic inflammatory disease in the nose and sinuses, with or without nasal polyps.

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.

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 U.S. Food and Drug Administration for the treatment of nasal polyps in patients 18 years of age or older and has been studied for treatment of chronic sinusitis in two phase 3 trials, ReOpen1 and ReOpen2. Top-line results from 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 those with and without nasal polyps. If approved, XHANCE may be the first drug ever FDA-approved for treatment of chronic sinusitis either with or without nasal polyps.

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.

Please see full Prescribing Information.

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 treating chronic sinusitis and reducing disease exacerbations; 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 FDA-approved drug product for the treatment of chronic sinusitis and the potential for XHANCE to become part of the standard of care and a stepwise treatment paradigm for this disease; and 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: potential for the full data set from the ReOpen Trial program, when available, to contain data that conflicts with or is inconsistent with the announced results; potential for varying interpretation of the results from the ReOpen Trial program; 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) for its current and any potential future indication; prevalence of chronic sinusitis and XHANCE market opportunities may be smaller

than expected; 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.

References

1. Smith SS, Evans CT, Tan BK, Chandra RK, Smith SB, Kern RC. National burden of antibiotic use for adult rhinosinusitis. J Allergy Clin Immunol. 2013 Nov;132(5):1230-2. doi: 10.1016/j.jaci.2013.07.009. Epub 2013 Aug 26. PMID: 23987794; PMCID: PMC3815964.
2. Phillips KM, Hoehle LP, Bergmark RW, Caradonna DS, Gray ST, Sedaghat AR. Acute Exacerbations Mediate Quality of Life Impairment in Chronic Rhinosinusitis. J Allergy Clin Immunol Pract. 2017 Mar-Apr;5(2):422-426. doi: 10.1016/j.jaip.2016.09.015. Epub 2016 Nov 7. PMID: 27839750.
3. 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.
4. 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.

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