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 8, 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 8, 2022, OptiNose, Inc. (the Company) issued a press release announcing additional results from ReOpen2 as well as initial pooled results from ReOpen1 and ReOpen2. ReOpen1 and ReOpen 2 were randomized double-blinded, placebo-controlled Phase 3 clinical trials examining the safety and efficacy of XHANCE® versus the placebo Exhalation Delivery System™ in adults with chronic sinusitis. 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.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by OptiNose, Inc., dated July 8, 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 8, 2022

Optinose Announces Additional Positive Results from ReOpen2 and Initial Results from Pooled Analyses of Both Trials in the ReOpen Program

Company previously announced positive top-line results from both ReOpen1 and ReOpen2, the landmark trials evaluating XHANCE as a treatment for chronic sinusitis

Multiple secondary endpoints from ReOpen2 indicate patients treated with XHANCE experienced improvement in symptoms and quality of life when compared to patients treated with placebo

In pooled data from ReOpen1 and ReOpen2, XHANCE demonstrated a benefit relative to placebo on CT scans in patients with chronic sinusitis without nasal polyps

YARDLEY, Pa., July 8, 2022— Optinose (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, today announced additional results 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 pre-planned secondary analyses of data from the ReOpen2 trial as well as pooled data from both ReOpen1 and ReOpen2 found that patients using XHANCE in these trials experienced a spectrum of benefits on symptoms and quality of life, as well improvement in objective measures of disease, relative to patients receiving a placebo comparator.

As previously disclosed, both co-primary endpoints in ReOpen2 showed significant improvement among patients treated with XHANCE versus placebo comparator, including combined symptom score at 4 weeks and average of percentages of opacified volume (APOV) at 24 weeks. In pre-planned, exploratory, secondary analyses of ReOpen2, patients treated with XHANCE were also found to have larger improvements than patients receiving placebo comparator at the 4-week time point on each of the four individual defining symptoms of chronic rhinosinusitis, including congestion/obstruction, rhinorrhea (thick drainage), facial pain or pressure, and loss of sense of smell. Pre-planned secondary analyses also revealed greater improvement on the sinonasal outcomes test (22 item), a commonly used measure of symptoms, quality of life, and functioning in chronic rhinosinusitis, at week 24 for patients receiving XHANCE then placebo comparator. Nominal p-values for the differences between the group of patients receiving XHANCE and the group of patients receiving placebo were less than 0.05 on each of these measures.

Many people with chronic rhinosinusitis have tried and are frustrated with standard nasal steroid sprays. To inform possible differences in response of patients previously using a standard nasal steroid spray, a pre-planned analysis of pooled data from ReOpen1 and ReOpen2 assessed symptom improvement for patients entering the trials with at least moderate symptoms despite reporting use of a standard nasal steroid spray. For this subgroup, patients receiving XHANCE improved more from baseline than patients receiving placebo comparator. Additionally, a pooled analysis was performed to assess change in CT scans, measured by APOV at week 24, for the subgroup of patients receiving XHANCE who had chronic sinusitis without nasal polyps. Compared to patients treated with placebo comparator, XHANCE treatment produced greater reduction in sinus opacification in this subgroup (-6.31% vs -1.55%, nominal p-value of 0.004). Differences between active and placebo in the groups receiving one or two sprays per nostril twice daily were similar and nominally statistically significant.

“We are pleased to see new evidence from ReOpen2 suggesting XHANCE treatment produces benefits on each of the cardinal symptoms of chronic rhinosinusitis and on a measure of quality of life. Symptom relief and quality of life represent the main treatment goals for patients with chronic rhinosinusitis and their doctors,” said Ramy Mahmoud, MD, MPH, President of Optinose. “In addition, we now have pooled data showing that the subgroup of patients receiving XHANCE in the ReOpen trials who had chronic sinusitis without nasal polyps experienced improvement on the APOV endpoint.”

The safety profile and tolerability of XHANCE in these trials were consistent with its currently labelled safety profile. In pooled data from both trials inclusive of both dose groups, adverse events occurring at a rate of more than 3% in patients receiving XHANCE that were also more common than in the group receiving the EDS-placebo were epistaxis, COVID-19, nasopharyngitis, and headache.

Summary of Efficacy Results

				Difference from Placebo EDS	
Treatment	**n**	**Baseline Score**	**LS Mean Change from Baseline**	**LS Mean**	**Nominal P-value (1)**
Change in SNOT-22 from Baseline to Week 24 (ReOpen2)					
XHANCE 186 or 372 mcg	145	48.57	-17.49	-8.77	0.001
Placebo EDS	75	51.11	-8.72	-	-
Change in Symptoms in Prior Nasal Steroid Users from Baseline to Week 4 (Pooled)					
XHANCE 186 or 372 mcg	172	5.63	-1.46	-0.70	<0.001
Placebo EDS	108	5.84	-0.77	-	-
Change in APOV in CS Patients without Nasal Polyps from Baseline to Week 24 (Pooled)					
XHANCE 186 or 372 mcg	225	61.33	-6.31	-4.76	0.004
XHANCE 372 mcg	112	61.26	-6.50	-4.95	0.010
XHANCE 186 mcg	113	61.40	-6.12	-4.57	0.019
Placebo EDS	116	63.32	-1.55	-	-

Summary of Safety Results

Summary of Adverse Events with XHANCE Reported in ≥ 3% and More Common Than Placebo EDS in Pooled data			
Adverse Event (AE)	**Placebo EDS BID (N =187) n (%)**	**XHANCE 186 mcg BID (N =184) n (%)**	**XHANCE 372 mcg BID (N =183) n (%)**
Epistaxis	1 (0.5)	9 (4.9)	20 (10.9)
COVID-19	8 (4.3)	5 (2.7)	12 (6.7)
Nasopharyngitis	8 (4.3)	9 (4.9)	7 (3.8)
Headache	7 (3.7)	4 (2.2)	10 (5.5)

About ReOpen1
The global, randomized, double-blind, placebo-controlled Phase 3 ReOpen1 trial evaluated the efficacy and safety of intranasal administration of 186 and 372 mcg twice daily of OPN-375, marketed as XHANCE, in patients with chronic sinusitis (CS) with or without nasal polyps over 24 weeks. The co-primary efficacy endpoints were the change from baseline in symptoms as measured by a composite score of nasal congestion, facial pain or pressure sensation, and nasal discharge at the end of week 4, and the change from baseline to week 24 in the average of the percentages of ethmoid and maxillary sinus volume occupied by disease as measured by CT scan.

About ReOpen2
The global, randomized, double-blind, placebo-controlled Phase 3 ReOpen2 trial evaluated the efficacy and safety of one and two sprays of XHANCE (OPN-375) in each nostril twice daily, over 24 weeks in patients with chronic sinusitis (CS) who did not have 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 that show significant improvement of both symptoms and inflammation inside the sinuses with a nasal therapy.

About Chronic Sinusitis
Chronic sinusitis (CS), cited as the second most common chronic disease of adults in the US, is a serious chronic inflammatory disease that may affect as many as 30 million adults in the United States and cost the U.S. economy over $30 billion in direct and indirect costs every year. 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, those 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. Optinose has offices in the U.S. and Norway. 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 for patients either with or 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; 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.

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