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): June 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 June 13, 2022, OptiNose, Inc. (the Company) issued a press release announcing top-line results from ReOpen2. ReOpen 2 was a randomized double-blinded, placebo controlled Phase 3 clinical trial examining the safety and efficacy of XHANCE® versus a 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.

The Company will present top-line results from ReOpen2 during an investor call on June 13, 2022. A copy of the presentation that will be used during the call is attached as Exhibit 99.2 to this report 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 June 13, 2022.
99.2	OptiNose, Inc. Corporate Presentation, dated June 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: June 13, 2022

Optinose Announces Positive Top-line Results of ReOpen2, its second Phase 3 Clinical Trial of XHANCE for Treatment of Chronic Sinusitis

First Ever Phase 3 Program to Show Improvement in Both Symptoms and Inflammation Inside the Sinuses with a Nasal Therapy for Chronic Sinusitis Patients

Physicians Diagnose Chronic Sinusitis 10 Times More Frequently Than XHANCE's Current Nasal Polyps Indication and there is no FDA-Approved Medication for these Patients

Conference call and webcast to be held today at 8:30 a.m. Eastern Time

YARDLEY, Pa., June 13, 2022— Optinose (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, today announced the statistically significant benefits of XHANCE in the ReOpen2 trial for both the symptoms co-primary endpoint and the CT scan co-primary endpoint. Significant improvement was demonstrated in patients with chronic sinusitis who did not have nasal polyps treated with both doses of XHANCE® (fluticasone propionate) nasal spray with the Exhalation Delivery System™ in the ReOpen2 clinical trial compared to patients receiving a vehicle Exhalation Delivery System (placebo). The co-primary endpoints were a patient-reported composite symptom score (comprising nasal congestion, facial pain or pressure, and nasal discharge) measured at week 4 and an objective measure of disease in the sinus cavities at week 24 (measured by average of the percentages of opacified volume on CT scan across the ethmoid and maxillary sinuses).

"ReOpen2 is a large, international, controlled trial, studying 222 patients with chronic sinusitis who did not also have nasal polyps. Currently there are no FDA-approved drug treatments for this large patient population," said Ramy Mahmoud, MD, MPH, President of Optinose. He went on to say, "With top-line results showing that patients with chronic sinusitis experienced significant improvement in both symptoms and inflammation inside the sinuses, ReOpen2 confirms and builds on the positive results from ReOpen1 and, importantly, provides evidence supporting the effectiveness of XHANCE in the very large chronic sinusitis population without nasal polyps. This program provides the first-ever body of controlled trial evidence we are aware of for a nasal medication to produce both improvement in symptoms and reduction of inflammation in the sinus cavities for patients suffering from chronic sinusitis regardless of the presence of nasal polyps. We believe these results are important to the tens of millions of people suffering from chronic sinus disease, so our team is working to quickly complete the analyses of both ReOpen1 and ReOpen2 and have begun the work necessary to seek a new indication that expands access to XHANCE for this broader group of patients. We would like to express our gratitude to the healthcare professionals at our research sites and, most especially,

to all the patients with chronic sinusitis whose altruistic participation made it possible to offer new hope to others who suffer from the same symptoms."

"I see patients every day who suffer greatly from the symptoms of chronic sinusitis, despite availability of current nasal treatments. I'm excited to see this important confirmatory data showing the benefits of XHANCE in this challenging population. This evidence has potential to change the treatment paradigm for chronic sinusitis patients." said Rick Chandra, M.D., professor of otolaryngology, chief of rhinology, sinus & skull base surgery, Vanderbilt University. "The potential addition of the first FDA-approved medication to be an option for chronic sinusitis patients with or without nasal polyps also fits nicely in a stepwise treatment paradigm for those who continue to have symptoms despite trying standard nasal sprays, before they escalate to surgery or other treatments."

The safety profile and tolerability of XHANCE in this trial were generally consistent with its currently labelled safety profile. Adverse events occurring at a rate of more than 3% with XHANCE and more common than the Exhalation Delivery System placebo group in this trial were: epistaxis, COVID-19, headache, and depression.

When pre-planned analyses are completed, detailed results from ReOpen2 will be submitted for publication in a peer-reviewed journal and for presentation at future medical meetings.

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 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) is a serious chronic inflammatory disease that may affect as many as 30 million adults in the United States. 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 chronic sinusitis, 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.

Company to Host Conference Call
Members of the Company's leadership team will host a conference call and presentation to discuss top-line results from this trial today, beginning at 8:30 a.m. Eastern Time.

To participate on the conference call, please dial (866) 916-4761 from the U.S. or +1 (409) 216-6496 from outside the U.S. In addition, following the completion of the call, a telephone replay will be accessible until Monday, June 20, 2022 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID #7793853. A simultaneous webcast of the call and presentation can be accessed by visiting the Investors section of Optinose's website at www.optinose.com. In addition, a replay of the webcast will be available on the Company website for 60 days following the event.

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 corticosteroid 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. Topline results from these trials are the first ever that we are aware of that show improvement in both symptoms and inflammation inside the sinuses with a nasal therapy for chronic sinusitis patients, including those 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 ReOpen2, when available, to contain data that conflicts with or is inconsistent with the announced top-line results; potential for varying interpretation of the results from ReOpen1 and ReOpen2; 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.

Optinose Investor/Media Contact
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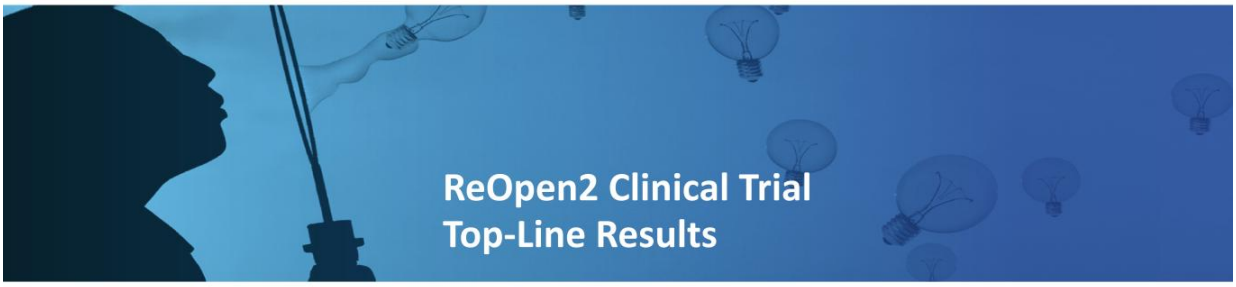

June 13, 2022

Forward-Looking Statements

This presentation and our accompanying remarks contain "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 FDA approval for a follow-on indication for XHANCE for the treatment of chronic sinusitis and the potential submission of a supplemental new drug application by this indication by the end of 2022; the potential for XHANCE to be the first FDA-approved drug product for the treatment of chronic sinusitis and potential benefits of such indication; the potential for XHANCE to become part of the standard of care for this disease; total addressable market opportunities for XHANCE; prospects for potential partnerships to promote XHANCE in primary care; and other statements regarding the Company's future operations, financial performance, prospects, intentions, 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 ReOpen2, when available, to contain results that conflict with or are inconsistent with the top-line results; potential for varying interpretation of the top-line results from ReOpen1 and ReOpen2; 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 potential future indication; the prevalence of chronic sinusitis and XHANCE market opportunities may be smaller than expected; and the risks, uncertainties and other factors discussed in the "Risk Factors" section and elsewhere in our most recent Form 10-K and Form 10-Q filings with the Securities and Exchange Commission – which are available at http://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 presentation speak only as of the date of this presentation, 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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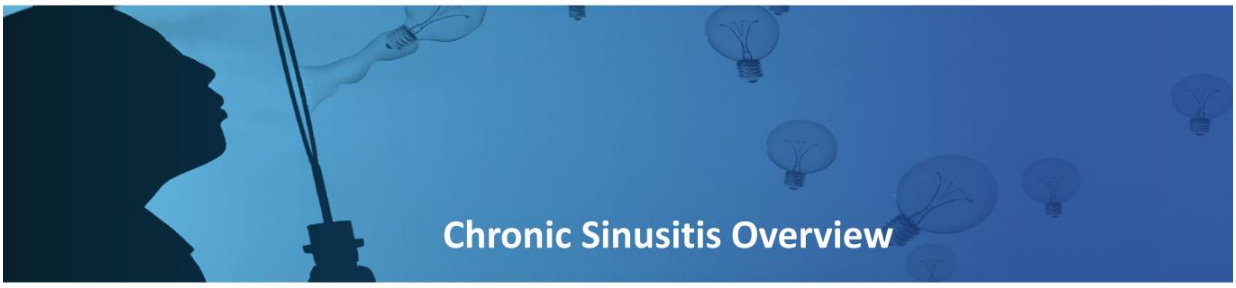

What is Chronic Sinusitis (CS)

CS is an inflammatory disease of the paranasal sinuses that is defined by the presence of at least two out of four cardinal symptoms (i.e., facial pain/pressure, hyposmia/anosmia, nasal drainage, and nasal obstruction) for at least 12 consecutive weeks, in addition to objective evidence

Prevalence

- Up to **30 Million** US Adults suffer from symptoms of CS and there are no FDA-approved drug treatments for the majority who do not have nasal polyps
- Approximately **10 Million** patients are treated by a physician annually

High Burden

- Disease persists for many years
- Significant harm to quality of life, comparable in magnitude to CHF or COPD

Sources: Sedaghat AR. Chronic Rhinosinusitis. Am Fam Physician. 2017 Oct 15;96(8):500-506. PMID: 29094889. Palmer J et al . A cross-sectional population-based survey of the prevalence, disease burden, and characteristics of the US adult population with symptoms of chronic rhinosinusitis (CRS). Poster session presented at: 62nd Annual Meeting of the American Rhinologic Society; September 16-17, 2016; San Diego, CA. Optinose Market Research. Data on file.

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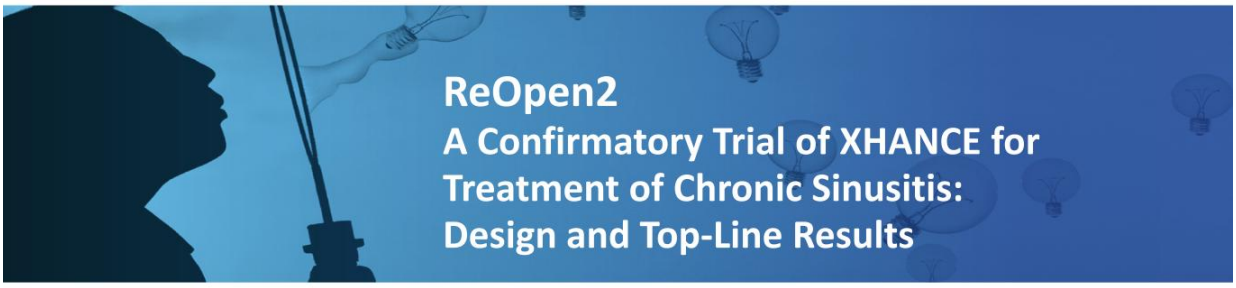
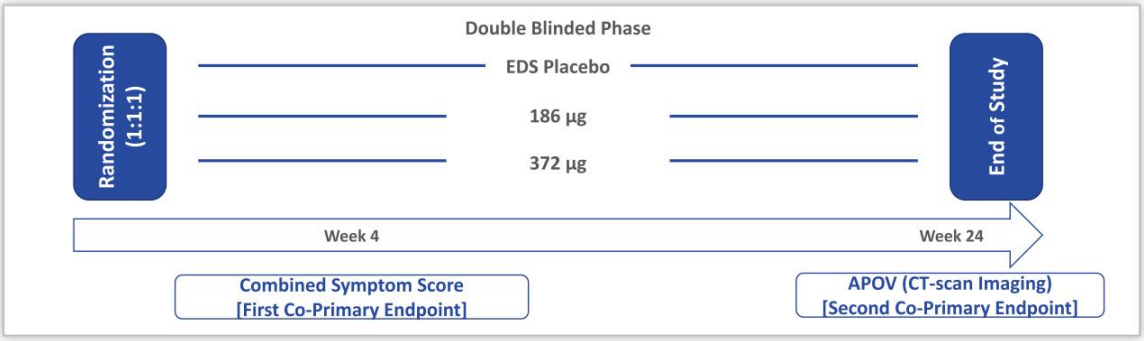


ReOpen2

A Confirmatory Trial of XHANCE for Treatment of Chronic Sinusitis: Design and Top-Line Results

ReOpen2 Trial Design Summary

Randomized, double-blind, EDS-vehicle (placebo) controlled, parallel-group, multicenter study evaluating efficacy and safety of XHANCE 1 or 2 sprays (186 µg or 372 µg) twice daily in subjects with CS who do not have nasal polyps



Additional prespecified Type 1 error-controlled endpoints will include:
change in symptoms in subjects who were symptomatic at trial entry despite using a standard nasal steroid,
frequency of acute exacerbations of CS in pooled data from ReOpen1 and ReOpen2

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ReOpen2: Disposition and Baseline Characteristics

	EDS-vehicle (Placebo)	XHANCE 186 mcg	XHANCE 372 mcg
Subjects Randomized	75	74	74
Subjects Treated	75	73	74
Subjects Who Completed Study	69	70	71
Subjects Discontinuing Early*	6 (8%)	3 (4.1%)	3 (4.1%)
Full Analysis Set	75	72	73
Mean Baseline CSS Score	6.15	5.87	5.97
Mean Baseline APOV	64.09	60.51	61.50

APOV (average of percentages of opacified volume across ethmoid and maxillary sinuses); **CSS** (composite symptom score)
* Adverse events were the most common reason for early discontinuation

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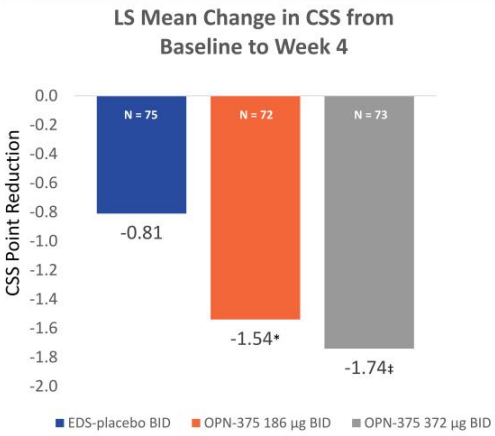
ReOpen2: Combined Symptom Score (Co-Primary Endpoint)



BID, twice daily; CSNS, composite symptom nasal score.
*$P \leq .05$ vs EDS placebo.
‡$P \leq .001$ vs EDS-placebo.

Summary

- Confirmatory Phase 3 results demonstrate statistically significant improvement in combined symptoms with XHANCE
- Magnitude of improvement comparable to ReOpen1, NAVIGATE I, and NAVIGATE II

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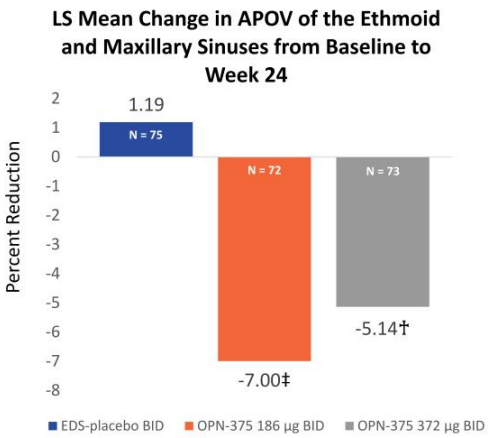
ReOpen2: Average of Percentages of Opacified Volume (Ethmoid and Maxillary)

Objective Evidence of Effect in Sinus Cavities by CT Scan; Co-Primary Endpoint

Summary

- Confirmatory Phase 3 results demonstrate statistically significant improvement inside the sinus cavities with XHANCE
- Magnitude of improvement similar to ReOpen1
- First ever replicated large controlled trial evidence for a nasal treatment to improve both symptoms and inflammation inside the sinuses



OPN-375 is XHANCE; APOV, average percent of opacified volume; BID, twice daily.

†$P \leq .01$ vs EDS-placebo.

‡$P \leq .001$ vs EDS-placebo.

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AEs Occurring in ≥3% of Patients and More Common Than Placebo

Adverse Event (AE)	EDS-placebo BID (N =75) n (%)	XHANCE 186 mcg BID (N =73) n (%)	XHANCE 372 mcg BID (N =74) n (%)
COVID-19	2 (2.7)	3 (4.1)	7 (9.5)
Epistaxis	0 (0.0)	4 (5.5)	7 (9.5)
Headache	6 (8.0)	2 (2.7)	7 (9.5)
Depression	1 (1.3)	0 (0.0)	3 (4.1)

Anticipated Next Steps

- Complete analysis of ReOpen2
- Complete pre-specified pooled analyses of ReOpen1/2 data
  - Notably, reduction of disease exacerbations is an important endpoint pre-specified to be evaluated in pooled data
- Meeting with FDA prior to data submission
- Development of sNDA underway with a target of submitting by the end of 2022
- FDA notification on acceptance due within 74 days of submission date
  - If sNDA accepted, action date is provided at that time

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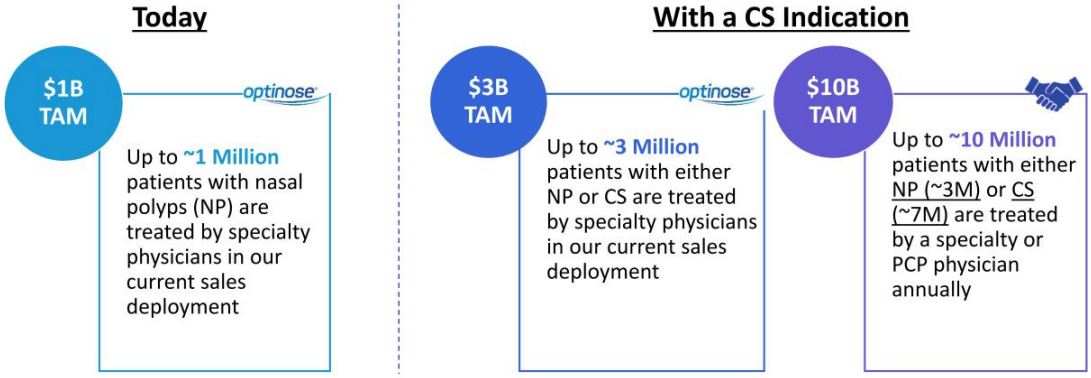
Successful Development of XHANCE as the First FDA-approved Drug Treatment for Chronic Sinusitis Creates Multiple New Opportunities for Growth



For a Partner, there are **6 to 7 million** NP+CS patients currently treated by a Primary Care Physician plus **20 million** lapsed patients that could be activated into care

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Successful Development of XHANCE as a Treatment for Chronic Sinusitis Would Increase Opportunity and Address Certain Barriers to Broader Prescribing that Exist Today

Insurance

- Today, **~80%** of commercial lives are in plans that cover XHANCE, but **~half** require physicians to attest that they are prescribing for the approved indication
- This is important because chronic sinusitis (CS) is diagnosed much more frequently than nasal polyps (NP)
- **~10 million** patients diagnosed with CS are actively treated by physicians compared to **~1 million** with NP

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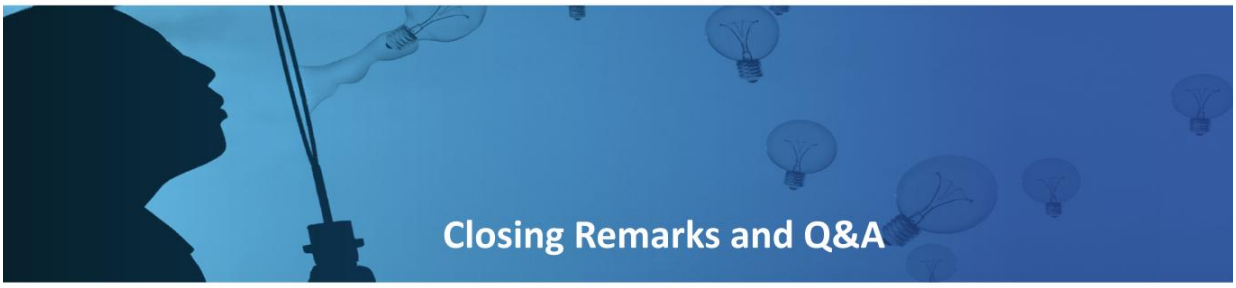

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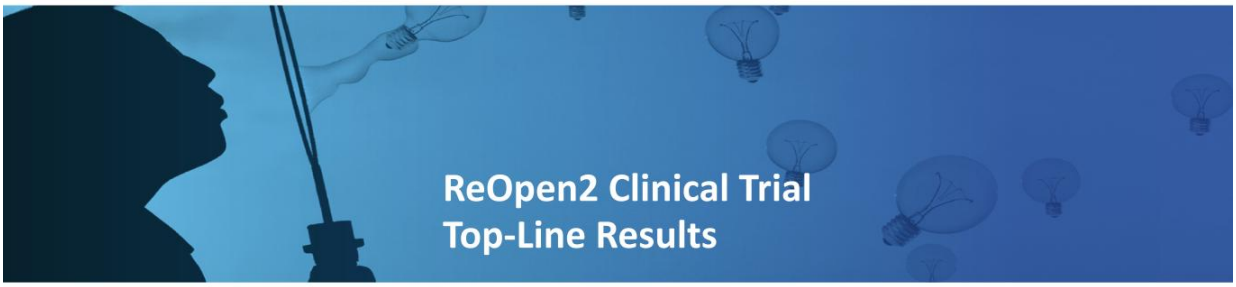

June 13, 2022