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 7, 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 March 7, 2022, OptiNose, Inc. (the Company) issued a press release announcing top-line results from ReOpen1. ReOpen 1 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 with or without nasal polyps. 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 ReOpen1 during an investor call on March 7, 2022. A copy of the presentation 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 March 7, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
99.2	OptiNose, Inc. Corporate Presentation, dated March 7, 2022.

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/ Keith A. Goldan
Keith A. Goldan
Chief Financial Officer

Date: March 7, 2022

Optinose Reports Positive Top-line Results in ReOpen1, a Landmark Phase 3 Trial for XHANCE in Chronic Sinusitis

XHANCE met both co-primary endpoints in the ReOpen1 trial, demonstrating statistically significant benefits on symptoms and CT scans in patients with chronic sinusitis

There are no FDA-approved drug treatments for the 30 million adults in the U.S. with chronic sinusitis

Conference call and webcast to be held today at 4:15 p.m. Eastern Time

YARDLEY, Pa., March 7, 2022— Optinose (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, today announced that the ReOpen1 clinical trial met both of its co-primary endpoints. A statistically significant improvement was demonstrated in patients with chronic sinusitis who were treated with the XHANCE® (fluticasone propionate) Exhalation Delivery System™ in the ReOpen1 clinical trial compared to patients receiving an Exhalation Delivery System placebo as measured by both primary endpoints: first, a composite symptom score (comprising nasal congestion, facial pain or pressure, and nasal discharge) measured at week 4 and second, an objective measure of disease in the sinus cavities at week 24 (measured by average percent of the opacified volume on CT scan, summed across all of the ethmoid and maxillary sinuses).

“In ReOpen1, a large, international, controlled trial, we randomized 332 patients into the first of two trials studying XHANCE for the treatment of patients with chronic sinusitis, a disease for which there are no FDA-approved drug treatments,” said Ramy Mahmoud, MD, MPH, President of Optinose. He went on to say, “In ReOpen1 we found that patients with chronic sinusitis who used XHANCE improved, as measured by both a composite symptom score and as measured by the amount of inflammation in the sinuses themselves. ReOpen1 is exciting news for us and for tens of millions of people suffering from chronic sinusitis. Our team would like to thank the healthcare providers at our investigational sites, and especially the many patients with chronic sinusitis whose participation made this trial possible.”

The Company expects top-line results from ReOpen2, the second of its two phase 3 trials for XHANCE in chronic sinusitis, in the second quarter of 2022.

“Chronic sinusitis is a common, difficult to treat disease that causes a lot of misery. It often leads to severe sinus symptoms requiring repeated courses of antibiotics among other treatments, sometimes requiring surgery,” said James Palmer, M.D., past President of the American Rhinologic Society. “ReOpen1 is the first pivotal registration trial I am aware of that shows significant effects on both subjective and objective endpoints in this disease. In

particular, there are no prior phase 3 trials that show an intranasal drug treatment reduces inflammation inside the sinus cavities of people with chronic sinusitis. If replicated, these findings may lead to XHANCE being the first-ever drug approved for chronic sinusitis and potentially a change in standard of care for chronic sinusitis patients."

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 were: epistaxis, nasopharyngitis, asthma, and cataract (nuclear and cortical).

Detailed results from this trial will be submitted for publication in a peer-reviewed journal and for presentation at future medical meetings.

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 (BID) 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 percent of ethmoid and maxillary sinus volume occupied by disease as measured by CT scan.

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 a period of at least 12 weeks, with most patients suffering with this condition 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 inflammation can lead to polyps in the nasal cavities, referred to as nasal polyps, which can accompany disease in the sinus cavities, with a general umbrella term of "chronic rhinosinusitis" (CRS) often used in medical literature to refer to patients with chronic disease in either the nose or sinuses.

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 4:15 p.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, March 14, 2022 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID #8811908. 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 high and deep regions of the nasal cavity. XHANCE was approved for the treatment of nasal polyps in patients 18 years of age or older by the U.S. Food and Drug Administration in September 2017 and is currently being studied for treatment of chronic sinusitis. If successful, XHANCE may be the first FDA-approved drug product for chronic sinusitis.

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 FDA approval for a follow-on indication for XHANCE for the treatment of chronic sinusitis; the expectation of top-line results from ReOpen2 in the second quarter of 2022; 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 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 varying interpretation of the top-line results from ReOpen1; potential for the full data set from ReOpen1, when available, to contain results that conflict with or are inconsistent with the top-line results; risks and uncertainties relating to the completion and results of 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); 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
Jonathan Neely
jonathan.neely@optinose.com
267.521.0531

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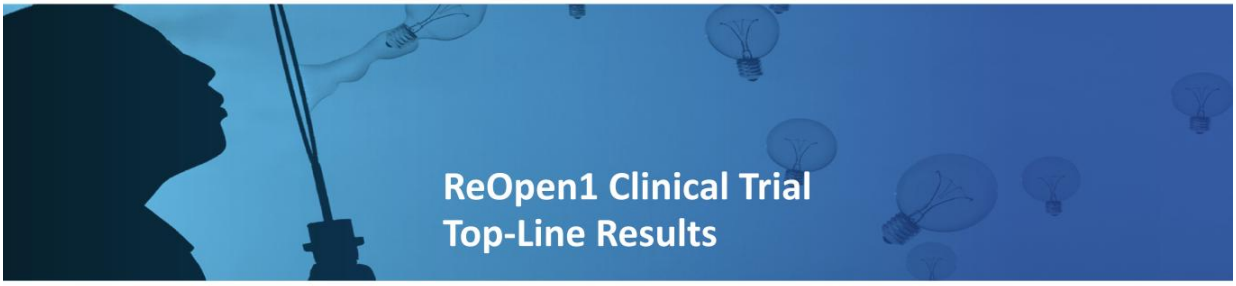

March 7, 2022

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; the expectation of top-line results from ReOpen2 in the second quarter of 2022; 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 for this disease; 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 varying interpretation of the top-line results from ReOpen1; potential for the full data set from ReOpen1, when available, to contain results that conflict with or are inconsistent with the top-line results; risks and uncertainties relating to the completion and results of 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); 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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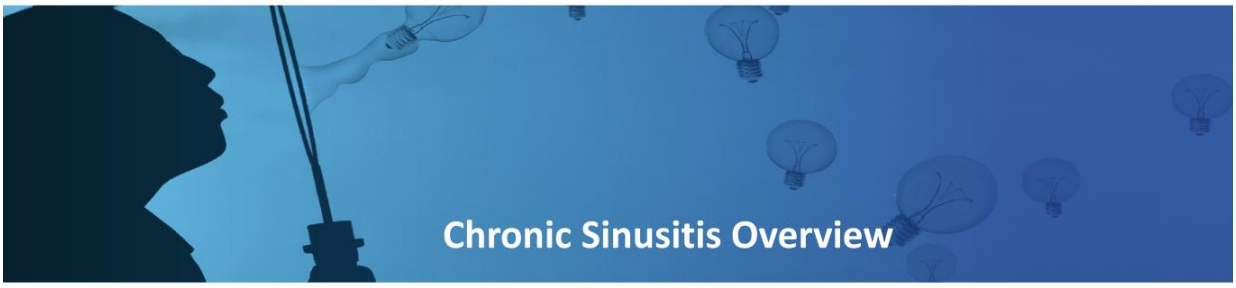

What is Chronic Sinusitis (CS)

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
- 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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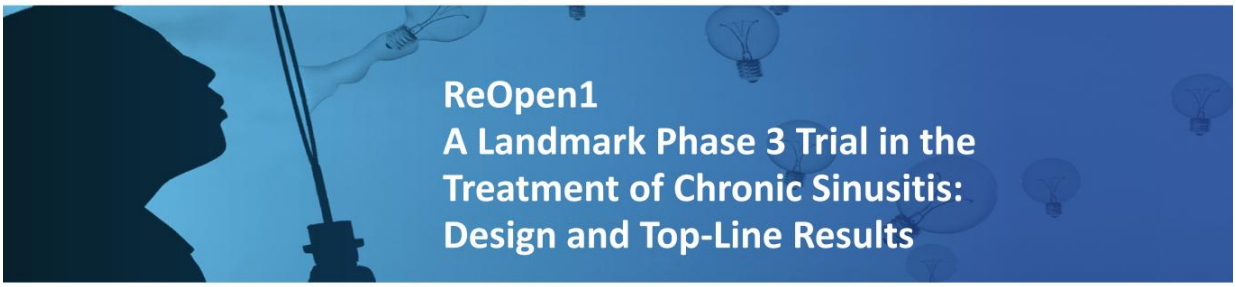
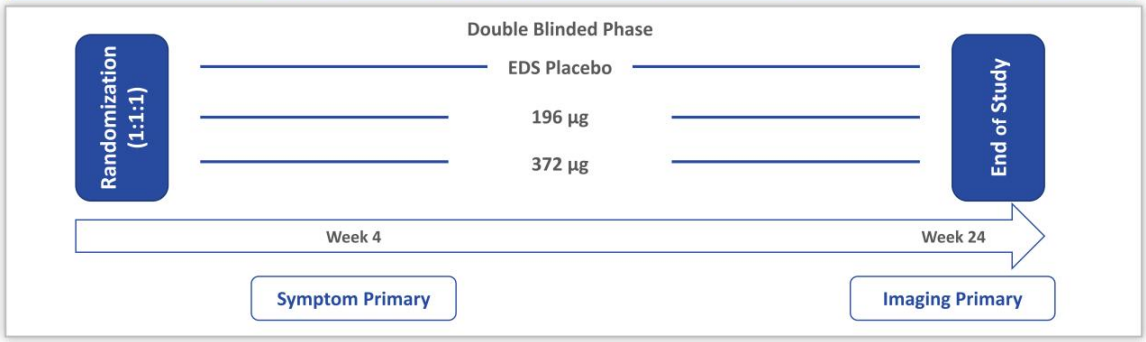

ReOpen1
A Landmark Phase 3 Trial in the
Treatment of Chronic Sinusitis:
Design and Top-Line Results

ReOpen1 Trial Design Summary

Randomized, double-blind, EDS-placebo-controlled, parallel-group, multicenter study to evaluate efficacy and safety of XHANCE 186 µg (1 spray) and 372 µg (2 sprays) BID in subjects with CS (with or without nasal polyps)



Key secondary endpoints: change from baseline to week 4 in CSS in subjects who were symptomatic at trial entry despite reported use of a standard nasal steroid for treatment of CS immediately prior to trial entry, and frequency of acute exacerbations of CS over the 24-week treatment period in pooled dated from ReOpen1 and ReOpen 2

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Re-Open 1: Disposition and Baseline Characteristics

	EDS Placebo	XHANCE 186 mcg	XHANCE 372 mcg
Subjects Randomized	112	111	109
Subjects Who Completed Study	96	102	101
Subjects Discontinuing Early*	16	9	8
Full Analysis Set	110	110	107
Evaluable subjects with NP	69	69	67
Evaluable subjects without NP	41	41	40
Mean Baseline CSS Score	5.77	5.42	5.48
Mean Baseline APOV	68.94	68.88	68.95
Mean Baseline SNOT-22 Score	48.0	50.94	50.81

APOV (average percent of opacified volume); **CSS** (composite symptom score); **SNOT-22** (Sino-Nasal Outcome Test, 22 item)
* Lack of efficacy was the most common reason for early discontinuation

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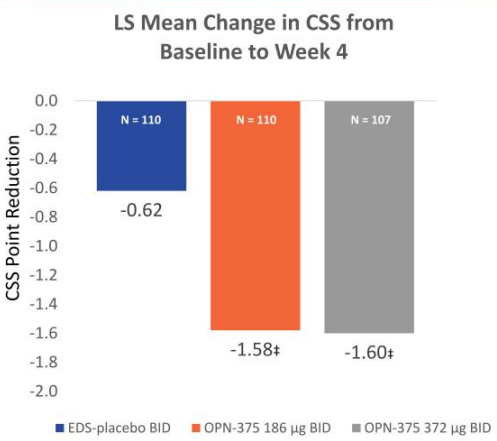
ReOpen-1: Combined Symptom Score Coprimary Endpoint



BID, twice daily; CSNS, composite symptom nasal score.

‡$P \leq .001$ vs EDS-placebo

Summary

- Magnitude of improvement comparable to NAVIGATE I and II
- Treatment with XHANCE improved CSS and each of the four cardinal symptoms at week 4

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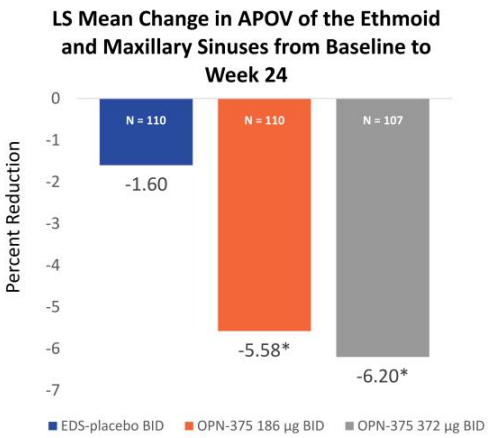
ReOpen-1: Average Percent Opacified Volume (Ethmoid and Maxillary)

Objective CT scan Coprimary Endpoint

Summary

- First phase 3 trial to demonstrate statistically significant improvement in sinus opacification with a nasal treatment
- Represents an average ~20% increase in sinus patency for patients treated with XHANCE



APOV, average percent of opacified volume; BID, twice daily;.
*P ≤ .05 vs EDS placebo.

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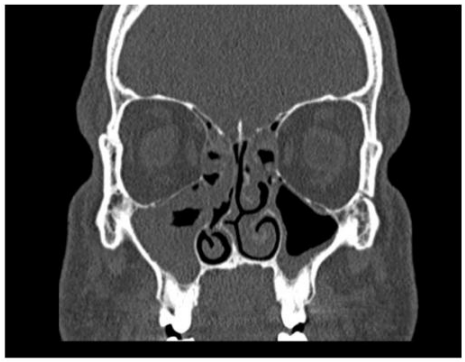
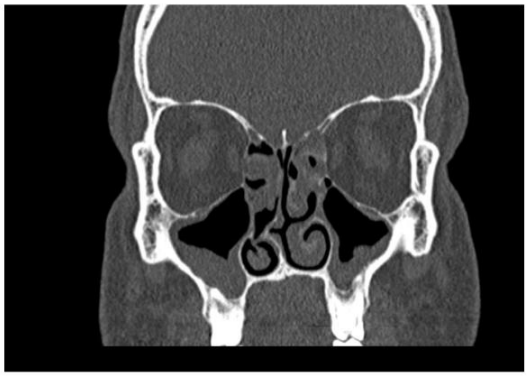
Illustration of APOV Improvement (Patient Receiving XHANCE 186 µg BID)

Baseline



Week 24



6.4% Improvement

Images reflect individual results and results and may not be representative of results generally.

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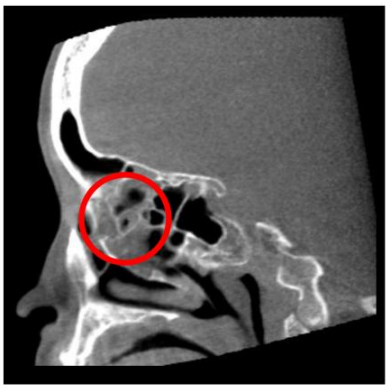
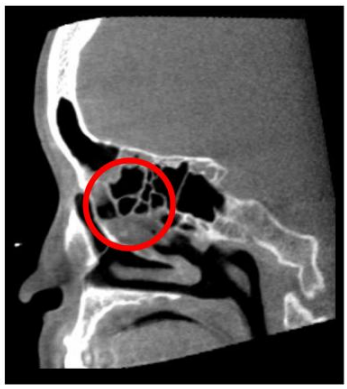
Illustration of APOV Improvement (Patient Receiving XHANCE 372 µg BID)

Baseline



Week 24



7.0% Improvement

Images reflect individual results and results and may not be representative of results generally.

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Secondary Endpoints and Subgroup Analysis

Top-line results are limited: full analysis is still ongoing

Secondary Endpoints

Exploratory and Subject to Nominal Statistical Testing

- **Four defining symptoms of Chronic Sinusitis -** XHANCE-treated patients had statistically significant improvement over EDS-placebo treated patients on each of the four symptoms (congestion, rhinorrhea, facial pain/pressure, and sense of smell) at week 4
- **Acute Exacerbations -** XHANCE-treated patients had a reduced occurrence of acute disease exacerbation which reached statistical significance in the high dose group
- **SNOT-22 -** XHANCE-treated patients had statistically significant improved SNOT-22 scored by week 4 compared to EDS-placebo treated patients

Subgroup Analyses

Exploratory and Nominal Statistical Testing
Underpowered to Detect Statistically Significant Differences

- **CSS Outcome –** the subgroup of chronic sinusitis patients without nasal polyps receiving XHANCE and the subgroup with concomitant nasal polyps receiving XHANCE had statistically significant improvement in CSS over EDS-placebo treated patients
- **APOV Outcome –** the subgroup of chronic sinusitis patients without nasal polyps receiving XHANCE was not statistically different from those receiving EDS-placebo and the subgroup with concomitant nasal polyps receiving XHANCE was statistically significantly improved over EDS-placebo patients

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

Adverse Event (AE)	EDS-placebo BID (N =112) n (%)	XHANCE 186 mcg BID (N =111) n (%)	XHANCE 372 mcg BID (N =109) n (%)
Epistaxis	1 (0.9)	5 (4.5)	13 (11.9)
Nasopharyngitis	3 (2.7)	6 (5.4)	3 (2.8)
Asthma	1 (0.9)	5 (4.5)	4 (3.7)
Nuclear Cataract	0	5 (4.5)	4 (3.7)
Cortical Cataract	1 (0.9)	6 (5.4)	2 (1.8)
Subcapsular Cataract	2 (1.8)	1 (0.9)	1 (0.9)

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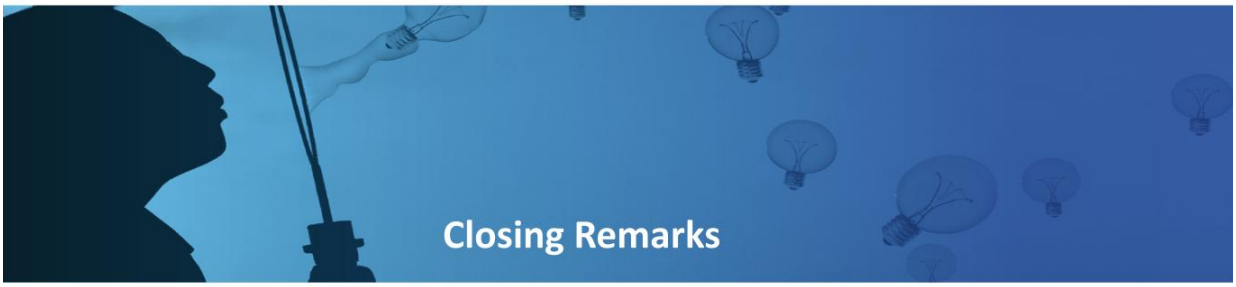

Additional Phase 3b Clinical Trial Data Expected in Q2 2022

Recruitment Completed July 2021

Top-line results expected in Q1 2022

Recruitment Completed October 2021

Top-line results expected in Q2 2022

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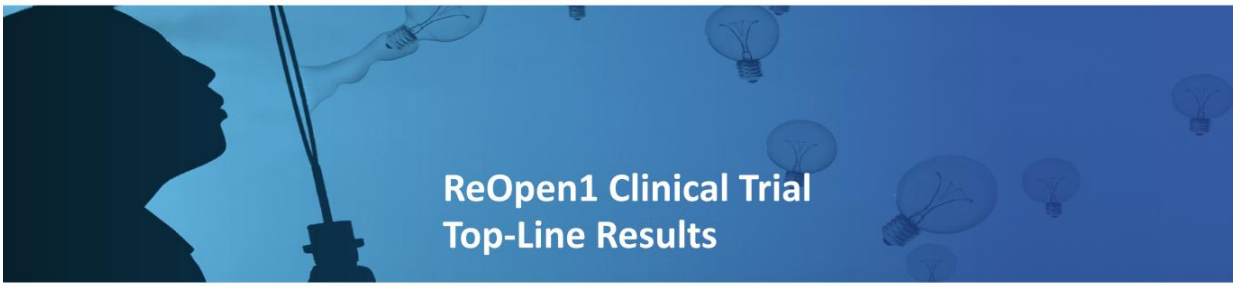

March 7, 2022