

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): April 25, 2024



OPTINOSE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of Incorporation or Organization)

001-38241
(Commission File No.)

42-1771610
(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-4(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 2.02 Results of Operations and Financial Condition.

On April 25, 2024, OptiNose, Inc. (the "Company") issued a press release to provide corporate updates on the XHANCE launch and outlook and to announce preliminary XHANCE net revenue of \$14.9 million for the three months ended March 31, 2024. The reported XHANCE net revenue for the three months ended March 31, 2024 is preliminary, subject to change, and has not been reviewed by the Company's independent registered public accounting firm.

As set forth in the press release, members of the Company's leadership team will host a conference call to discuss corporate updates at 10:00 a.m. Eastern Time on April 25, 2024.

A copy of the press release and a copy of the Corporate Presentation that will be presented during the update call are furnished as Exhibit 99.1 and Exhibit 99.2, respectively, to this Form 8-K and are incorporated herein by reference.

Item 7.01 Other Events.

The information contained in Item 2.02 above is incorporated herein by reference.

The information included in Item 2.02 and Item 7.01 (including Exhibit 99.1 and Exhibit 99.2) of this Form 8-K, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any Company filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by OptiNose, Inc., dated April 25, 2024.
99.2	OptiNose, Inc. Corporate Presentation, dated April 25, 2024.
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/ Anthony Krick

Anthony Krick

Chief Accounting Officer

Date: April 25, 2024



Optinose Provides Corporate Update on XHANCE Launch and Outlook and Announces Preliminary First Quarter 2024 XHANCE Net Revenue of \$14.9 million

Conference Call and Webcast to be held April 25, 2024, at 10:00 a.m. Eastern Time

YARDLEY, Pa., April 25, 2024— [Optinose](#) (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, today announced corporate updates detailing its commercial plans and expectations for XHANCE® (fluticasone propionate) following the recent FDA approval of a new indication for the treatment of chronic rhinosinusitis without nasal polyps in patients 18 year of age and older. The Company will host an investor call at 10:00 a.m. Eastern Time today to discuss its commercial strategy and financial outlook.

In addition, the Company announced preliminary XHANCE net product revenue of \$14.9 million for the three months ended March 31, 2024, representing growth of approximately 26% over the first quarter of 2023.

“The recent FDA approval of XHANCE as the first and only approved drug treatment for chronic sinusitis (CS) is a landmark achievement,” said Ramy Mahmoud, MD, MPH, CEO of Optinose. “Because we plan to leverage our current commercial infrastructure, including 75 sales territories, we expect to need limited incremental spend to effectively reach the estimated 3 million patients with chronic sinusitis who are cared for by ENT and Allergy specialists. To prepare for an effective launch, we have recently optimized our sales alignment towards a chronic sinusitis call target universe and partnered with a specialty pharmacy hub to improve patient and physician office experience and increase prescription fill and reimbursement rates. Based on our market analysis, we believe that our base planned efforts focused on a specialty prescriber audience can grow XHANCE peak year net revenues to more than \$300 million and allow Optinose to produce positive income from operations (GAAP) for full year 2025. With incremental investments in the future, we believe the market opportunity could be expanded to over 30 million patients through outreach to the 7 million patients being treated by primary care physicians and by direct-to-consumer activation of the 20 million patients who report suffering from chronic sinusitis symptoms,” he concluded.

Financial Outlook:

XHANCE Net Revenue

The Company expects peak XHANCE net revenues to exceed \$300 million based on its current promotional focus on a specialty audience of mostly ENT and Allergy specialists.

Income from Operations

The Company expects to produce positive income from operations (GAAP) for full year 2025.

Company to Host Conference Call

Members of the Company's leadership team will host a conference call to discuss corporate updates. The call is scheduled to start at 10:00 a.m. Eastern Time today.

Participants may access the conference call live via webcast by visiting the Investors section of Optinose's website at <http://ir.optinose.com/event-calendar>. To participate via telephone, please register in advance at this [link](#). Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number and a personal PIN that can be used to access the call. 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 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 [X](#) 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 steroid 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 both the treatment of chronic rhinosinusitis without nasal polyps (also called chronic sinusitis) and chronic rhinosinusitis with nasal polyps (also called nasal polyps) in patients 18 years of age or older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: Hypersensitivity to any ingredient in XHANCE.

WARNINGS AND PRECAUTIONS:

- Local nasal adverse reactions, including epistaxis, erosion, ulceration, septal perforation, Candida albicans infection, and impaired wound healing, can occur. 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.
- Glaucoma and cataracts may occur with long-term use. Consider referral to an ophthalmologist in patients who develop ocular symptoms or use XHANCE long-term.
- 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 infections can occur, including 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.
- Assess for decrease in bone mineral density initially and periodically thereafter.

ADVERSE REACTIONS:

- Chronic rhinosinusitis without nasal polyps: The most common adverse reactions (incidence $\geq 3\%$) are epistaxis, headache, and nasopharyngitis.
- Chronic rhinosinusitis with nasal polyps: The most common adverse reactions (incidence $\geq 3\%$) 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

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 the treatment of chronic sinusitis (also referred to as "chronic rhinosinusitis" and "chronic rhinosinusitis without nasal polyps"); the Company's commercial plans and expectations for XHANCE; preliminary XHANCE net revenue for the three months ended March 31, 2024; the Company's expectation that with only limited incremental spend it can effectively reach the estimated 3 million patients with chronic sinusitis who are cared for by ENT and Allergy specialists; potential market expansion opportunities; the Company's expectation that it will produce positive income from operations (GAAP) for full year 2025; the Company's expectation that its base planned efforts focused on a specialty prescriber audience can grow XHANCE peak year net revenues to more than \$300 million; and other statements regarding the Company's future operations, financial performance, financial position, prospects, objectives, strategies 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: the potential for preliminary XHANCE net product revenue for the three months ended March 31, 2024 to change in connection with the finalization of the Company's financial results for such period and review by the Company's independent registered public accounting firm; physician and patient acceptance of XHANCE for its new indication; the Company's ability to maintain adequate third-party reimbursement for XHANCE (including for its new indication); the prevalence of chronic sinusitis and market opportunities for XHANCE may be smaller than expected; the Company's ability to efficiently generate XHANCE prescriptions and net revenues; unexpected costs and expenses; the ability to cost-effectively activate XHANCE patients through direct-to-consumer promotion; the Company's ability to achieve its financial outlook; potential for varying interpretation of the clinical trial results of XHANCE; the Company's ability to comply with the covenants and other terms of the Amended and Restated Pharmakon Note Purchase Agreement; the Company's

ability to continue as a going concern; risks and uncertainties relating to intellectual property; 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 Contact

Jonathan Neely

jonathan.neely@optinose.com

267.521.0531

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Building a Leading ENT / Allergy Specialty Company

Commercial Launch Call
April 25, 2024

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 the recent FDA approval of XHANCE for the treatment of chronic rhinosinusitis without nasal polyps (also called chronic sinusitis); the benefits of XHANCE for the treatment of chronic sinusitis; the benefits of the Exhalation Delivery System; our commercial plans and expectations for XHANCE; expected benefits of the recently implemented HUB pharmacy; preliminary XHANCE net revenue for the three months ended March 31, 2024; our expectation that our base planned efforts focused on a specialty prescriber audience can grow XHANCE peak year net revenues to more than \$300 million; our expectation that we will produce positive income from operations (GAAP) in full year 2025; potential market expansion and growth opportunities; physician intent to prescribe XHANCE for chronic sinusitis; patent protection for XHANCE; potential for long revenue tail for XHANCE; and other statements regarding to our future operations, financial performance, prospects, intentions, strategies, 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 new indication; the ability to maintain adequate third party reimbursement for XHANCE (including its new indication); the potential for preliminary XHANCE net product revenue for the three months ended March 31, 2024 to change in connection with the finalization of our financial results for such period; the prevalence of chronic sinusitis and market opportunities for XHANCE may be smaller than expected; the ability to efficiently generate XHANCE prescriptions and net revenues; unexpected costs and expenses; the ability to cost-effectively activate XHANCE patients through direct-to-consumer promotion; potential for varying interpretation of clinical trial results and market research results; discrepancies between stated behavior and actual behavior in market research; our ability to comply with the covenants and other terms of the Amended and Restated Pharmakon Note Purchase Agreement; our ability to continue as a going concern; risks and uncertainties relating to intellectual property; 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 (SEC) (including our Form 10-K to be filed with the SEC on March 7, 2024) – 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.

Market, Industry and Other Data

This presentation and the accompanying remarks contains estimates, projections, market research and other information concerning markets for XHANCE and the size of those markets, the prevalence of certain medical conditions, XHANCE market access, and other physician, patient, payor and prescription data. Unless otherwise expressly stated, we obtain this information from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources, as well as from our own internal estimates and research.

Agenda

Introduction and Corporate Updates	Ramy Mahmoud, MD, MPH
XHANCE Financial Outlook and Clinical Data in Chronic Sinusitis	Ramy Mahmoud, MD, MPH
XHANCE Market Opportunity and Updated Commercial Strategy	Paul Spence
Wrap Up	Ramy Mahmoud, MD, MPH

Optinose Overview:



Differentiated Product: XHANCE is the **First and Only** FDA-approved medicine for chronic sinusitis (also called chronic rhinosinusitis without nasal polyps)

- New market research highlights strong physician preference and intent to use



Significant Near-Term Growth Opportunity: XHANCE 2023 net revenue was \$71M. Recent label expansion provides up to 10x multiple on the TAM which was previously limited promotionally to ~1 million patients with nasal polyps, of which only 600-650k were diagnosed and treated per year

- Launching with current specialty sales force of 75 reps and phased modest incremental investment to expand reach
- Expecting **peak net revenue of \$300M+**
- Expecting **positive income from operations (GAAP) for full year 2025**



Longer-Term Growth Underappreciated: Totality of Addressable Market comprises 30 million patients, of whom 10 million are currently diagnosed and treated; another 20 million patients could be activated via Direct-to-Consumer promotion (DTC)

- Base forecast anticipates access primarily to ~3M currently treated patients in the specialty segment
- Beyond the base forecast: additional growth opportunities include promotional direct-selling partnership (eg, for primary care), digital/non-personal outreach into primary care or DTC segments, leveraging current commercial footprint for additional products, ex-U.S. licensing of rights to XHANCE





Cash flow durability: 13 Orange Book-listed patents (last to expire in 2036), and long revenue tail potential

- Locally acting topical drug supplied as a difficult-to-copy drug/device combination

Optinose – Financial Outlook for XHANCE in Chronic Sinusitis

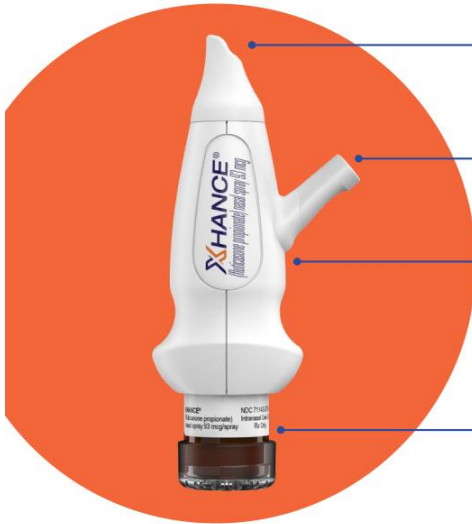
We believe strong growth and profitability are possible in our current ENT and Allergy segment

-  **Growth** With the new CS indication XHANCE has peak **net revenue potential of at least \$300M in specialty physician audience**
-  **Efficiency** XHANCE launching into greatly expanded market with **existing 75 territory sales force and established insurance coverage**
-  **Profitability** Increased revenue opportunity and sales efficiency support expectation of positive income from operations (GAAP) **for Full Year 2025**

Our Leadership team is focused on meeting or exceeding these objectives

XHANCE: Designed to be Meaningfully Different

13 Orange Book listed patents cover XHANCE (last to expire, 2036)



Patented sealing and stenting nosepiece

Specially shaped, it seals tightly in the nostril, stents the narrow nasal valve, especially the superior part, and shifts intranasal soft tissues

Patented translating mouthpiece

Enables proper fit and device orientation across a broad range of patient facial anatomy

Patented internal valve system

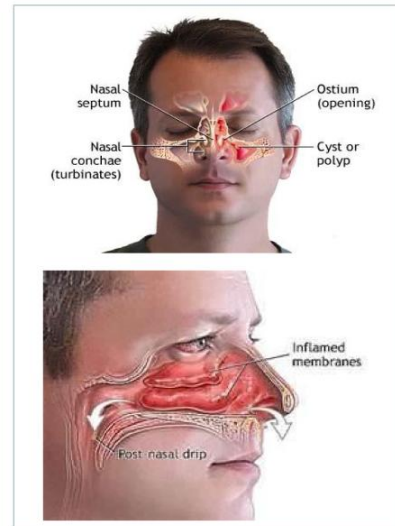
Aids unique deposition profile, ensures consistency of delivery, reduces patient coordination

Nonremovable, drug-filled vial

One month treatment (depending on dose)

Chronic Sinusitis is a common chronic inflammatory disease

- Chronic sinusitis (also called “chronic rhinosinusitis without polyps”) is frequently diagnosed and may or may not be accompanied by comorbid allergies
- Persistent inflammation causes pain, swelling, obstruction in deep nasal passages, sinus drainage tracts, the openings to the sinuses (ostia), and inside the sinuses
- Primary symptoms include congestion/obstruction, facial pain/pressure, rhinorrhea, and loss of smell/taste; sleep loss, persistent fatigue, and recurrent sinus infections are common
- Disease flares (acute exacerbations), often infections, are common, sometimes occurring multiple times per year. They drive many doctor visits and often lead to use of antibiotics and/or oral or systemic steroids



Chronic Sinusitis Is One of The Top 3 Adult Physician Visit Diagnoses¹

CS accounts for
≈10 million annual office visits,
of which
≈70% result in an antibiotic prescription¹

~45% of patients diagnosed with CS
underwent sinus surgery, at a mean duration of
4.7 months after initially meeting diagnostic
criteria for CS²

> **50%** of patients with chronic sinusitis
experience fatigue³

Up to **75%** of CS patients report poor sleep⁴

CS-related work productivity loss
\$20 Billion per year lost in productivity⁵

20+ days per year missed from work / school
(severe CRS with sinus surgery)⁵

1. Smith p1230/col2/para5 and 6, 2. Bhattacharyya 2011, 3. Orlandi RR, et al. *Int Forum Allergy Rhinol.* 2021;11(3):213-739, 4. Alt JA, et al. *Laryngoscope.* 2013;123(10):2364-2370, 5. Rudmik L. *Curr Allergy Asthma Rep.* 2017;17(4):20

XHANCE Significantly Improved Symptoms in Chronic Sinusitis: ReOpen2

Composite Symptom Score Encompassed:



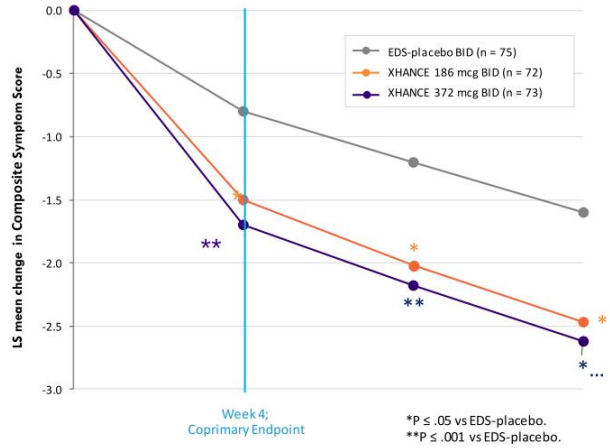
Nasal Congestion



Nasal Discharge



Facial Pain/Pressure

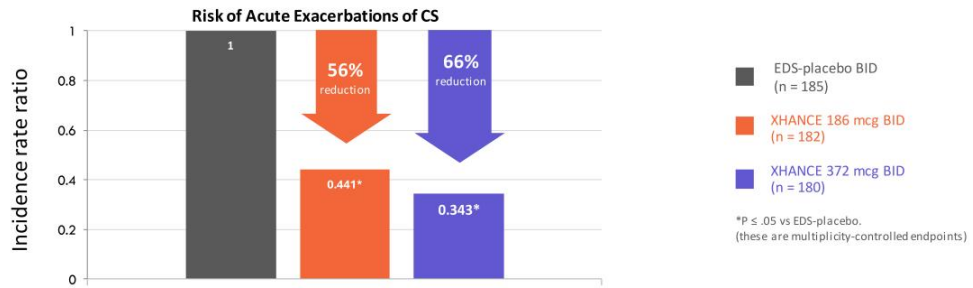


Coprimary Endpoint: LS mean change from baseline to week 4 in composite symptom score (CSS). CSS was the sum of congestion, facial pain/pressure, and nasal discharge scores. For each symptom 0 = no symptoms and 3 = severe. Symptoms were measured in the morning and averaged over the prior 7 days. BID, twice daily; CSS, composite symptom score; EDS, Exhalation Delivery System™; LS, least squares.



XHANCE Produced Breakthrough Reduction in Risk of Acute Exacerbations of Chronic Sinusitis (AECRS) (Pooled data from ReOpen1 and ReOpen2)

AECRS defined as worsening of ≥ 1 cardinal symptom of CS, lasting at least 3 days, that also required initiation of antibiotics or oral corticosteroids or an unscheduled acute care visit or inpatient care for increased sinonasal symptoms



Antibiotics were prescribed in 93% of acute exacerbations in the ReOpen trials

Type-1 error-controlled analysis of pooled data from ReOpen1 and ReOpen2. Total number of AECRS events (percentage of patients who experienced at least 1 event): EDS-placebo, 41 (15.7%); XHANCE 186 mcg, 20 (9.9%); XHANCE 372 mcg, 15 (7.8%). AECRS, acute exacerbation of chronic rhinosinusitis; BID, twice daily; CRS, chronic rhinosinusitis; EDS, Exhalation Delivery System™. 1. Full Prescribing Information for XHANCE (fluticasone propionate). OptiNose US, Inc.; 2023. 2. Data on file. OptiNose US, Inc.

Despite Patient Dissatisfaction, HCPs Have Tended To Cycle Standard-Delivery Nasal Steroids Before Escalating Treatment Or Referring For Surgery



7

double-blind, placebo-controlled, randomized studies have been conducted to **assess effects of nasal steroids in patients with CS (without polyps), but none demonstrated significant benefit**¹

>80%

of patients with CS reported **frustration** with symptom relief when using a **standard-delivery nasal steroid spray**²

75%

of HCPs believe standard-delivery nasal steroid sprays **don't reach target sites of inflammation** and believe they **don't work well** for CS (despite working well for allergic rhinitis)³

CRSsNP, chronic rhinosinusitis without nasal polyps; AR, allergic rhinitis 1. Palmer JN, et al. DOI: <https://doi.org/10.1016/j.jaip.2023.12.0162>. Palmer JN, et al. Allergy Asthma Proc. 2019;40(1):48-56. One study found statistically significant improvement in symptoms with standard-delivery budesonide; however, the benefit was only in patients with atopy (allergic rhinitis) 3. Data on file Optinose survey of ~700 physicians including ~400 ENT and Allergy specialists and ~300 Primary Care

The Breakthrough Innovation is the Device – The Exhalation Delivery System (EDS)

The EDS creates Different Biomechanics During Delivery, Markedly Changing Drug Deposition

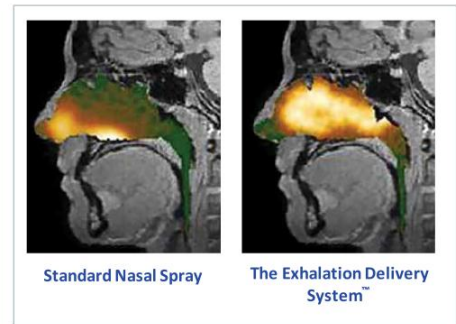
The diagram is divided into two horizontal sections: 'Sagittal Plane' and 'Transverse Plane'. In the Sagittal Plane, a nasal spray bottle is shown being actuated. Three numbered steps are indicated: 1. 'Closed palate' where the soft palate lifts; 2. 'Positive pressure' where air is forced through the nasal cavity; 3. 'Bidirectional flow' where air carries drug particles through the nasal passage and out the opposite nostril. Labels include 'Drug release into airflow', 'Soft palate closes', and 'Press bottle up to open device valve & actuate'. The Transverse Plane shows a cross-section of the nasal cavity with the 'Nasal septum' labeled and bidirectional airflow carrying drug particles.

Unique biomechanics deposit drug in areas where sinuses drain and ventilate. Device shown in human factors and market studies to be easy for patients to use.

- 1 Closed palate** With EDS, the soft palate lifts/elevates and creates an air-tight seal between the nasal cavity and throat and lungs
- 2 Positive pressure** Widens entry passages and enables air to exit behind the nasal septum
- 3 Bidirectional flow** Exhaled air carries drug through airways and exits from opposite nostril (and not into throat)

The EDS Enables Dramatically Different Deposition vs Standard-Delivery Nasal Spray: with EDS, Topical Drug Can Reach Important Sites of Action

- The EDS deposits drug in high/deep sinonasal spaces to treat sinus drainage tracts and sinuses
- Standard nasal corticosteroid sprays deposit drug almost entirely in the bottom (inferior) and front (anterior) parts of the nasal cavity^{1,2}
- EDS deposition demonstrated in radiolabeled deposition studies³
 - Gamma camera images of distribution of radiolabeled solution after using the EDS (right) versus a standard nasal spray (left)
 - Both images are from the same healthy subject taken over 2 minutes after administration of radiolabeled solution and are representative of the overall findings from ~200 images and ~50 subjects



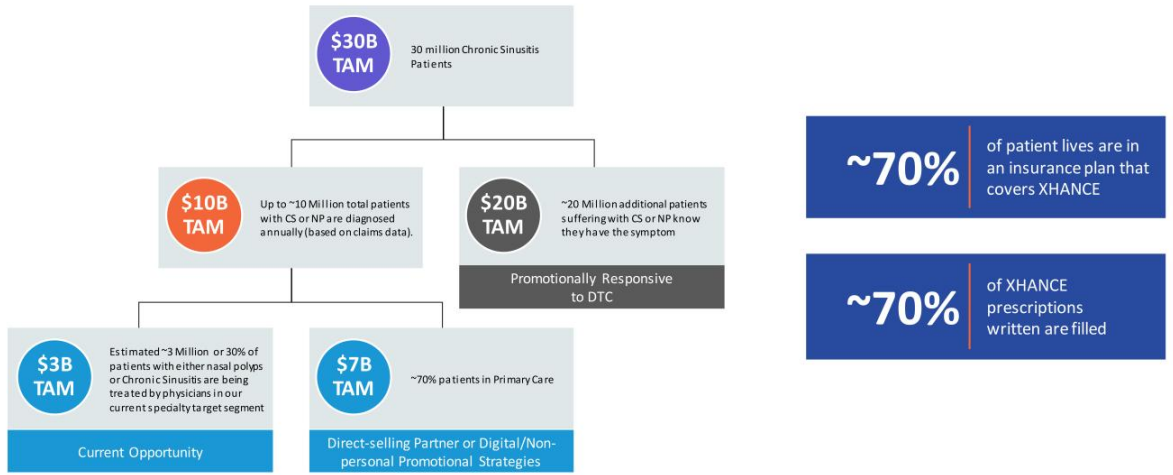
1 - Leach CL, et al. J Aerosol Med. 2015;28(5):334-340. 2. Siu J, et al. Int Forum Allergy Rhinol. 2019;9(9):958-970
3 - Djupesland PG. Drug Deliv Transl Res. 2013;3(1):42-62.



Market Opportunity and Updated Commercial Outlook

Paul Spence
Chief Commercial Officer

FDA Approval of XHANCE Creates Multiple Growth Opportunities



Chronic Sinusitis Launch – Expect to Exceed \$300M Peak Year Sales

Commercial Foundation	Sales Force	Hub Services	CS Clinical Data
<p>Robust domestic supply chain with second source of finished goods approved in March (1.5M units)</p> <p>Insurance Coverage (70%)</p> <p>Sales team (75 territories with ~8,000 targets)</p> <p>Digital Non-Personal Promotion (22,000 high potential CS prescribers)</p> <p>Existing Physician Relationships (60% of 2024 targets)</p>	<p>Optimized prescriber targeting in January using CS claims data instead of NP potential (40% new)</p> <p>Realigned and balanced sales territories to maximize growth potential</p> <p>Improved sales force efficiency and expanded HCP reach to ~105 per Territory Manager</p> <p>Fielded new CS training and promotional materials</p> <p>Inside sales supporting ~1,200 high potential CS prescribers in whitespace</p>	<p>Hub implemented in Jan'24 to support CS launch</p> <p>Improved physician office support</p> <p>Improved patient service</p> <p>Increased approval and fill rates</p> <p>Increased data visibility</p> <p>Increased volume capacity</p> <p>Improved co-pay administration</p>	<p>Key Opinion Leader engagement</p> <p>Speaker's Bureau</p> <p>Presentations at Medical Congresses</p> <p>Continuing Medical Education</p> <p>New Publications</p> <p>Disease burden</p>

XHANCE Patient Support Programs are Designed to Ensure Patients Receive Maximum Possible Coverage and the Lowest OOP Costs

Support Navigating Insurance

Patient support services powered by Asembia through a mix of technology and staffed patient care coordinators dedicated to XHANCE

Patient support services are available to patients through mail order AND for patients who prefer to pick up Rx at retail

Patient Affordability Solutions

Current offerings for commercially insured patients through hub and specialty pharmacy:

- \$0 copay first fill (bridge program)
- \$25 copay for covered patients
- \$0 copay for covered patients enrolled in pharmacy's refill program
- \$99 direct to patient (DTP/cash price) for patients without coverage or high deductible

Current offering for commercially insured patients through retail:

- \$0 to \$24.99 copay through relay health (for covered patients)
- Offer also promoted through GoodRx

Finally, a solution to help you get XHANCE for patients who need it

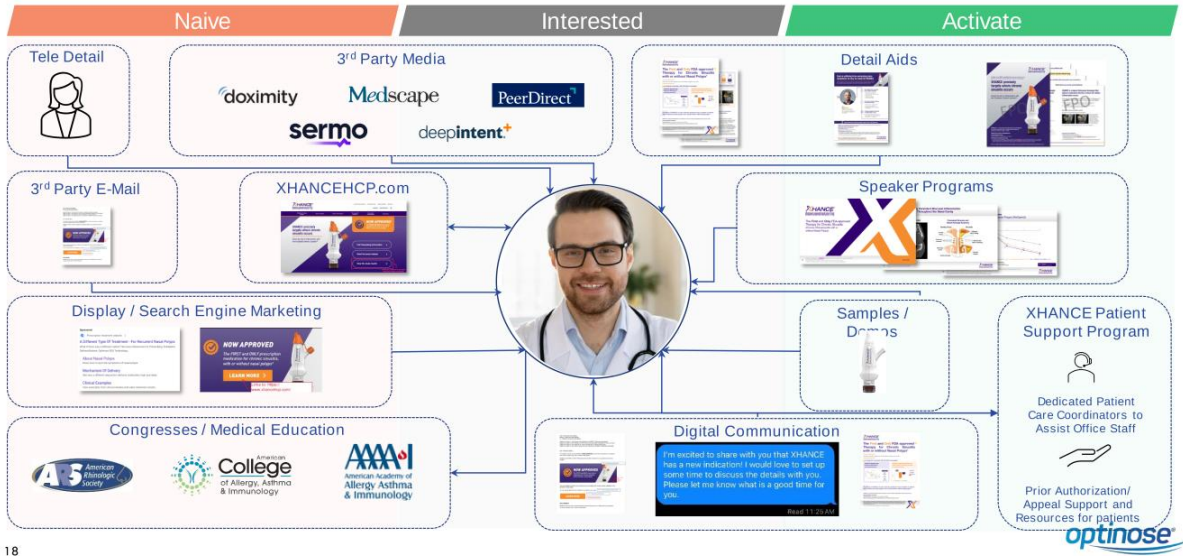
Access in 3 steps:

- 1 Send XHANCE Rx to ASPN Pharmacies**
 aPharmacia via EMR
 ASPN Pharmacy, LLC
 290 W. Mount Pleasant Ave.
 Longwood, NJ 07039
 NPI: 1028393690
 XHANCE delivery preferred
 Postal Service 87 only
 Do not use for 180-day supply
 NDC 71432-019-01
 Prescriptions are also to be sent to ASPN Pharmacies at 1-800-866-0266
- 2 Include as much detail as possible with your Rx**
 - ICD-10-CM codes
 - Relevant medical notes
 - Treatment history
- 3 Get assistance and support**
 Our trained staff is available to guide you through the prior authorization process

For Eligible Commercially Insured Patients
Pay As Little As \$0 for your prescription*
*For patients that are 18+ years of age.
[View program card](#)

XHANCE Pay as little as \$0*
Prescription Card
 Patient Name: _____
 Date: _____
 NPI: 1028393690
 NDC: 71432-019-01
*See back for terms and conditions. © 2016 Optinose

Employing Multiple Channels to Move Targeted HCPs from Awareness to Action



More than 87% of HCPs Indicate They are Likely to Prescribe XHANCE for CS Patients¹

Likelihood to Prescribe

Allergist (n=30)



ENT (n=30)



PCP (n=30)



- 1= Completely unlikely
- 2= Somewhat unlikely
- 3= Neither unlikely nor likely
- 4= Somewhat likely
- 5= Completely likely

Market research shows that HCP's intent to prescribe XHANCE increased up to 4-fold for both first-and second-line use after exposure to the Chronic Sinusitis Therapeutic Product Profile

¹ Source: CS Choice Drivers & Unmet Need Study; Aug 23, 2023. Optinose market research of ~100 HCPs who treat patients with CS. Respondents were asked to review a Chronic Sinusitis Therapeutic Product Profile (meant to represent XHANCE) and to assume access, pricing and reimbursement comparable to existing branded intranasal steroids, prior to making a prescribing decision for a patient suffering from the symptoms of chronic sinusitis and a history of over-the-counter treatment.



Ramy Mahmoud, MD, MPH
Chief Executive Officer

Optinose – Incremental Growth Opportunities

There is additional growth potential within and beyond our current ENT/Allergy audience



Expand in Specialty: We believe there are ROI positive opportunities to expand sales territories (to ~115) in ENT and Allergy based on success/capital availability



PCP and DTC: Potential to secure a partner with direct sales infrastructure, and/or create value with other selling models, targeting the ~7 million CS patients in primary care today, then use DTC to activate the ~20 million people with CS not actively seeking care



Major Markets Outside the USA: The first-ever CS approval may create opportunities for value creation outside the U.S. and we have maintained patents in select major markets



Leverage: Our capabilities and infrastructure make Optinose an ideal partner to develop and/or commercialize additional products in ENT and Allergy

Differentiated Product Offers Significant Opportunity Fueled by Large Market, High Unmet Need that Is Recognized by Patients and HCPs, Strong Promotional Responsiveness, Limited Competition



Large Market Potential

CS represents a ~\$10 billion annual addressable market potential



Significant Unmet Need

>80% of patients with CS reported frustration with symptom relief when using a standard-delivery nasal steroid



Promotionally Responsive

After exposure to the XHANCE TPP, HCPs increase intent to prescribe by 4-fold¹



Highly Differentiated

Significantly reduced CS symptoms, regardless of phenotype, and reduced exacerbations by up to 66%

1. Source: CS Choice Drivers & Unmet Need Study; Aug 23, 2023. Optinose market research of ~100 HCPs who treat patients with CS.

Optinose Overview:



Differentiated Product: XHANCE is the **First and Only** FDA-approved medicine for chronic sinusitis (also called chronic rhinosinusitis without nasal polyps)

- New market research highlights strong physician preference and intent to use



Significant Near-Term Growth Opportunity: XHANCE 2023 net revenue was \$71M. Recent label expansion provides up to 10x multiple on the TAM which was previously limited promotionally to ~1 million patients with nasal polyps, of which only 600-650k were diagnosed and treated per year

- Launching with current specialty sales force of 75 reps and phased modest incremental investment to expand reach
- Expecting **peak net revenue of \$300M+**
- Expecting **positive income from operations (GAAP) for full year 2025**



Longer-Term Growth Underappreciated: Totality of Addressable Market comprises 30 million patients, of whom 10 million are currently diagnosed and treated; another 20 million patients could be activated via Direct-to-Consumer promotion (DTC)

- Base forecast anticipates access primarily to ~3M currently treated patients in the specialty segment
- Beyond the base forecast: additional growth opportunities include promotional direct-selling partnership (eg, for primary care), digital/non-personal outreach into primary care or DTC segments, leveraging current commercial footprint for additional products, ex-U.S. licensing of rights to XHANCE



Cash flow durability: 13 Orange Book-listed patents (last to expire in 2036), and long revenue tail potential

- Locally acting topical drug supplied as a difficult-to-copy drug/device combination



Q&A

Investor Relations – NASDAQ: OPTN

Analyst Coverage ¹

Jefferies: Glen Santangelo

Lake Street: Thomas Flaten

Piper Sandler: David Amsellem

H. C. Wainwright: Matthew Caufield

As of December 31, 2023:

- **\$73.7 million** in cash
- **Debt: \$130 million**
- **112 million** common shares o/s
- **46 million** options, warrants & RSUs o/s

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¹ - Optinose is followed by the analysts listed above. Please note that any opinions, estimates or forecasts regarding the Company's performance made by these analysts are theirs alone and do not represent opinions, forecasts or predictions of Optinose or its management. Optinose does not by its reference above or distribution imply its endorsement of or concurrence with such information, conclusions or recommendations.



Building a Leading ENT / Allergy Specialty Company

Commercial Launch Call
April 25, 2024

