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): May 14, 2024

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 2.02 Results of Operations and Financial Condition.

On May 14, 2024, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2024. A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

* * *

The information included in Item 2.02 (including Exhibit 99.1) 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 8.01 Other Events.

On May 14, 2024, the Company will present an updated Corporate Presentation during its financial results and corporate updates call. 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 May 14, 2024.
99.2	OptiNose, Inc. Corporate Presentation, dated May 14, 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 J. Krick
Anthony J. Krick
Chief Accounting Officer

Date: May 14, 2024

Optinose Reports First Quarter 2024 Financial Results
and Recent Operational Highlights

Company reports Q1 2024 XHANCE net revenue of $14.9 million, an increase of 26% compared to Q1 2023

Company expects full year 2024 XHANCE net revenues to be between $85.0 to $95.0 million

Company expects peak year XHANCE net revenues of at least $300 million from current specialist focused prescriber audience

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

Conference call and webcast to be held today at 10:00 a.m. Eastern Time

YARDLEY, Pa., May 14, 2024 Optinose (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, today reported financial results for the quarter ended March 31, 2024, and provided recent operational highlights.

“We are proud that in March, based on evidence including multiple randomized placebo-controlled trials, XHANCE was approved by the FDA as the first prescription medication proven safe and effective for the large population with chronic rhinosinusitis who do not have nasal polyps. Millions of people can potentially benefit from this landmark approval because, despite being one of the most common diagnoses in adult outpatient medicine, there has never been an approved prescription treatment for Chronic Sinusitis.” stated CEO Ramy Mahmoud, MD, MPH. “We estimate that the new indication grows the total addressable market by up to ten times and, we've launched into the new opportunity with our current commercial infrastructure aimed primarily at specialty prescribers. We believe that approach will produce positive income from operations for full year 2025, and peak year net revenues of at least $300 million. However, there is considerable incremental potential that could derive from additional efforts in primary care or with activation of tens of millions of people who may have interest in a new and effective treatment option for this disease."

First Quarter 2024 and Recent Highlights

XHANCE Supplemental New Drug Application (sNDA)
On March 15, 2024, the U.S. Food and Drug Administration (FDA) approved XHANCE® (fluticasone propionate) in the Exhalation Delivery System™ as the first and only medication indicated for treatment of chronic rhinosinusitis without nasal polyps in adult patients.

Publication of ReOpen Clinical Program Results
In January 2024, peer-reviewed data from the landmark ReOpen program evaluating the efficacy and safety of XHANCE in adult patients with chronic rhinosinusitis (chronic sinusitis) was published online in the Journal of Allergy and Clinical Immunology: In Practice. As detailed in the publication, both trials showed statistically significant improvement in symptoms, in inflammation inside the sinuses, and in the number of acute disease

exacerbations that occurred in patients treated with XHANCE compared to patients receiving vehicle combined with the Exhalation Delivery System (EDS-placebo).

FDA Approval of Second Manufacturing Site

In March 2024, the FDA approved Hikma Pharmaceuticals USA Inc.'s affiliate West-Ward Columbus Inc., as an additional manufacturing site for finished XHANCE units for commercial sale and sampling. As a result, there are now two sites approved by the FDA for the manufacturer of finished XHANCE units for commercial sale and sampling.

$55 Million Registered Direct Offering

On May 10, 2024 the Company completed a registered direct offering of its common stock and pre-funded common stock warrants to a group of existing and new institutional investors expected to result in approximately $55 million of net proceeds to the Company. The Company expects that its post-offering cash and cash equivalents of approximately $100 million will be sufficient to fund its operations and debt service obligations through 2025.

First Quarter 2024 Financial Results

Total revenues

The Company reported $14.9 million in net revenue from sales of XHANCE during the three-month period ended March 31, 2024, an increase of 26% compared to $11.8 million during the three-month period ended March 31, 2023.

Costs and expenses and net loss

For the three-month period ended March 31, 2024, research and development expenses were $1.2 million and selling, general and administrative expenses were $20.5 million. The net loss for the period was $14.1 million, or $0.12 per share (basic and diluted).

Balance Sheet

The Company had cash and cash equivalents of $51.6 million as of March 31, 2024. The cash and cash equivalents balance of $51.6 million does not include the approximately $55 million of net proceeds expected from the Company's registered direct offering that closed on May 10, 2024.

Financial Guidance

XHANCE Net Revenue and Average

The Company expects XHANCE net revenues for the full year of 2024 to be between $85.0 to $95.0 million.

XHANCE Average Net Revenue per Prescription

The Company expects full year 2024 XHANCE average net revenue per prescription to exceed $230. Previously the Company expected full year 2024 XHANCE average net revenue per prescription to be approximately $220.

Operating Expenses

The Company expects total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2024 to be between $95.0 to $101.0 million, of which the Company expects stock-based compensation to be approximately $6.0 million.

Net Income from Operations
The Company expects to product 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 and presentation to discuss financial results and corporate updates beginning 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/presentations. 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.

OptiNose, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Revenues:		
Net product revenues	$14,880	$11,846
Total revenues	14,880	11,846
Costs and expenses:		
Cost of product sales	1,231	1,706
Research and development	1,206	1,785
Selling, general and administrative	20,518	22,723
Total costs and expenses	22,955	26,214
Loss from operations	(8,075)	(14,368)
Other expense	5,992	4,479
Net loss	$(14,067)	$(18,847)
Net loss per share of common stock, basic and diluted	$(0.12)	$(0.17)
Weighted average common shares outstanding, basic and diluted	112,594,852	111,774,425

OptiNose, Inc.
Condensed Consolidated Balance Sheet Data
(in thousands)

	March 31 2024 (unaudited)	December 31, 2023
Cash and cash equivalents	$51,644	$73,684
Other assets	32,063	34,045
Total assets	$83,707	$107,729
Total current liabilities [(1)]	$32,705	$176,524
Long term liabilities [(1)]	150,218	17,811
Total stockholders' equity	(99,216)	(86,606)
Total liabilities and stockholders' equity	$83,707	$107,729

(1) – All outstanding debt principal and fees payable upon debt maturity have been classified as a long term liability at March 31, 2024. All outstanding debt principal and fees payable upon debt maturity were classified as a current liability at December 31, 2023. Please refer to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, which will be filed after the issuance of this press release for additional information.

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 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 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 ≥3%) are epistaxis, headache, and nasopharyngitis.
- Chronic rhinosinusitis with nasal polyps: 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, 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 as the first FDA-approved drug treatment for chronic rhinosinusitis without nasal polyps (also referred to as chronic sinusitis); the potential benefits of XHANCE for the treatment of chronic sinusitis and expanded market opportunities relating thereto; the potential benefits of the Exhalation Delivery System; the Company's expectation for XHANCE net revenue and average net revenue per prescription for full year 2024; the Company's expectations for GAAP operating expenses (selling, general and administrative expenses and research & development expenses) and stock-based compensation for 2024; the Company's expectation that it will product positive net income from operations (GAAP) for full year 2025; the Company's expectation that peak year XHANCE net revenues will be at least $300 million from its current specialist physician audience; the expected net proceeds from the May 2024 registered direct offering; the Company's expectation that its post-offering cash and cash equivalents of approximately $100 million will be sufficient to fund its operations and debt service obligations through 2025; 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: physician and patient acceptance of XHANCE for its new indication; the Company's ability to maintain adequate third-party reimbursement for XHANCE (including 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; unanticipated costs and expenses; the Company's ability to achieve its financial guidance; potential for varying interpretation of the results from the ReOpen program; the Company's ability to comply with the covenants and other terms of its Amended and Restated Note Purchase Agreement; risks and uncertainties relating to intellectual property and competitive products; and the risks, uncertainties and other factors discussed under the caption "Item 1A. Risk Factors" and elsewhere in the Company's most recent Form 10-K and Form 10-Q filings with the Securities and Exchange Commission - which are available at www.sec.gov. As a result, you are cautioned not to place undue reliance on any forward-looking statements. Any forward-looking statements made in this press release speak only as of the date of this press release, and the Company undertakes no obligation to update such forward-looking statements, whether as a result of new information, future developments or otherwise.

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267.521.0531

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Building a Leading ENT / Allergy Specialty Company
Corporate Presentation
May 14, 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 referred to as chronic sinusitis); the benefit of XHANCE for treatment of chronic sinusitis; our commercial plans and expectations for XHANCE; the generation of XHANCE prescriptions and net revenues and factors impacting the generation of future prescriptions and net revenues; projected GAAP operating expenses (selling, general and administrative expenses and research and development expenses) and stock-based compensation for 2024; projected XHANCE net revenues for 2024; projected XHANCE average net revenue per prescription for 2024; expectation for positive income from operations (GAAP) for full year 2025; expectation that base planned efforts focused on a specialty prescriber audience can grow XHANCE peak year net revenues to more than $300 million; expected net proceeds from the registered direct offering completed on May 10, 2024; expectation that cash and cash equivalents (including net proceeds from registered direct offering) will be sufficient to fund operations and debt service obligations through 2025; impact of changes to XHANCE co-pay assistance program; potential market expansion and growth opportunities; 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: impact of, and the uncertainties caused by, physician and patient acceptance of XHANCE (including its new indication); our ability to maintain adequate third party reimbursement for XHANCE (including for its new indication); our ability to efficiently generate XHANCE prescriptions and net revenues; the prevalence of chronic sinusitis and market opportunities for XHANCE may be smaller than expected; unexpected costs and expenses; our ability to achieve our financial guidance; potential for varying interpretation of the results from the ReOpen Program; our ability to comply with the covenants and other terms of the A&R Pharmakon Note Purchase Agreement; risks and uncertainties relating to intellectual property and competition; 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 our accompanying remarks contain 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.

Today's Agenda

Introduction, Key Takeaways and CS Launch Update
Ramy Mahmoud, MD, MPH

Q1 2024 Performance and FY 2024 Financial Guidance
Jonathan Neely

Closing Remarks
Ramy Mahmoud, MD, MPH

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Key Takeaways

XHANCE Chronic Sinusitis Launch

- New indication creates a significant near-term growth opportunity with up to a 10x multiple on the TAM based on patients who are currently treated by a physician
- Current specialty sales force of 75 reps, and phased modest incremental commercial investment, sufficient to achieve peak net revenue of at least $300M and positive income from operations for full year 2025

Building from a stronger base

- Success in 2023 and Q1 2024 with a disciplined approach to operating expenses provided runway to initiate CS launch and supports plan to drive growth with modest incremental investment
- Focus on growing profitable prescriptions is a key driver for Q1 2024 performance and our increase to full year 2024 XHANCE net revenue per prescription guidance

Return to strong growth in 2024

- New indication creates opportunity for commercial team to promote a "first and only" clinical efficacy and safety profile
- Initial expectation for FY 2024 XHANCE net revenue is for growth of 20% to 34%; increasing net revenue per prescription expectation to at least $230 (previously expected to be approximately $220)

Post Offering Cash and Cash Equivalents of ~$100 Million Expected to Fund Operations and Debt Service Obligations Through 2025

Recent $55 million raised in a registered direct offering, priced "at the market" on May 8th

- Post-offering cash and cash equivalents of ~$100 million
- Sufficient to fund operations including re-launching XHANCE and debt service obligations through 2025
- Expected to produce income from operations (GAAP) for full year 2025

Improved Debt Terms

- Waiver on the “going concern” covenant until the filing of December 31, 2025 financial statements
- Reduction of minimum liquidity covenant from $30 million to $20 million following the date of the first quarterly payment of principal due on September 30, 2025
- $4.7 million of outstanding amendment and waiver fees converted to equity

Stronger balance sheet and revised debt terms extend runway to pursue growth opportunities

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Q2 Planned Launch Activities to Drive New Growth

Sales Force

75
Sales Reps Deployed

8.5K
Specialty HCPs Targeted

35K
Total Sales Calls

50%
Increase in Samples

Non-Personal Promotion

22K HCPs targeted through strategic non-personal promotion delivering up to **1.5M HCP impressions and 50K engagements**

Display
SEM
Endemic Media
HCP & Patient Social Media
3rd Party Partnerships

Congress Activity

Attending 10 National and 20 Regional ENT and Allergy Specific Congresses

Exhibits/Booth
Product Theaters
Promotional Dinner Programs

Peer-to-Peer Education

>150
CS Peer-to-Peer Speaker Programs reaching ~ 1K HCPs

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Financial Review – First Quarter 2024

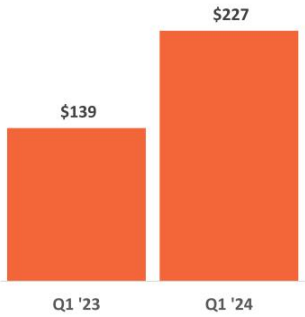
Average net revenue per prescription increased 63% YoY in context of our focus on growing profitable prescriptions

XHANCE Net Revenues of $14.9 million exceeded initial financial guidance and Operating Expenses decreased ~$3M compared to Q1 2023

($M)

Net Revenue

Average Net Revenue per TRx



($M)

SG&A plus R&D Expenses

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Full Year 2024 Financial Guidance

GAAP Operating Expenses (SG&A and R&D Expenses)

Expected to be between $95 to $101 million; approximately $6 million of which represents stock-based compensation

XHANCE Net Revenue

FY 2024 expected to be between $85 to $95 million

XHANCE Average Net Revenue per Prescription

FY 2024 expected to exceed $230

(Previously expected to be approximately $220)


Closing Remarks

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

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Optinose – Incremental Growth Opportunities

Additional growth potential exists both within and beyond our current ENT/Allergy audience

Expand in Specialty: We believe there are ROI positive opportunities to expand sales territories (to as many as ~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, and to 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 our specialty space of ENT and Allergy

Key Takeaways

XHANCE Chronic Sinusitis Launch

- New indication creates a significant near-term growth opportunity with up to a 10x multiple on the TAM based on patients who are currently treated by a physician
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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 March 31, 2024:

$51.6 million in cash

Debt: $130 million

113 million common shares o/s

46 million options, warrants & RSUs o/s

Optinose Investor Contact

Jonathan Neely,

VP, Investor Relations and Business Development

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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.

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Building a Leading ENT / Allergy Specialty Company
Corporate Presentation
May 14, 2024