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 12, 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 2.02 Results of Operations and Financial Condition.

On May 12, 2022, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2022. 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 12, 2022, the Company presented 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 12, 2022
99.2	OptiNose, Inc. Corporate Presentation, dated May 12, 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: May 12, 2022

Optinose Reports First Quarter 2022 Financial Results and Operational Updates

Company reports first quarter XHANCE net revenue of $14.8 million increased 35% compared to first quarter 2021

Company expects top-line results from the second of two clinical trials evaluating XHANCE as a potential treatment for Chronic Sinusitis in June 2022

Conference call and webcast to be held today at 8:00 a.m. Eastern Time

YARDLEY, Pa., May 12, 2022 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, 2022, and provided operational updates.

“XHANCE net revenue increased 35% in the first quarter of 2022 compared to first quarter 2021,” stated CEO Peter Miller. “This growth is aligned with our expectation for full year 2022 XHANCE net revenue of at least $90 million. Revenue growth and the completion of our clinical trials evaluating XHANCE for treatment of chronic sinusitis are the two most important objectives for our company this year. We reported positive topline results from ReOpen1 in March and expect to report topline results from ReOpen2 in June. We look forward to sharing detailed results from both trials in peer-reviewed journals and at future medical meetings.”

First Quarter 2022 and Recent Highlights

ReOpen1
In March, the Company 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 the 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 of the percents of opacified volume on CT scan across all of the ethmoid and maxillary sinuses).

"ReOpen1 was 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. "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 was exciting news for us and for tens of millions of people suffering from chronic sinusitis and we believe ReOpen2 also has potential to add importantly to the growing body of evidence informing use of XHANCE to treat sinonasal disease."

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 in the Exhalation Delivery System placebo group were: epistaxis, nasopharyngitis, asthma, and cataract (summed 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.

Total and New XHANCE Prescriptions

The number of XHANCE (fluticasone propionate) prescriptions increased by 11% from 72,600 in the first quarter 2021 to 80,600 in the first quarter 2022.

The number of new prescriptions for XHANCE increased by 9% from 25,900 in the first quarter of 2021 to 28,200 in the first quarter of 2022.

First Quarter 2022 Financial Results

Total revenues
The Company generated $14.8 million in net revenue from sales of XHANCE during the three-month period ended March 31, 2022 an increase of 35% compared to $11.0 million during the three-month period ended March 31, 2021.

Costs and expenses and net loss
For the three-month period ended March 31, 2022, research and development expenses were $4.8 million and selling, general and administrative expenses were $29.3 million. The net loss for the period was $25.3 million, or $0.31 per share (basic and diluted).

Cash
The Company had cash and cash equivalents of $91.4 million as of March 31, 2022.

Corporate Guidance

XHANCE Net Revenue and Average Net Revenue per Prescription
The Company expects XHANCE net revenues for the full year of 2022 to be at least $90 million. In addition, the Company expects full year 2022 XHANCE average net revenue per prescription to be at least $220. Previously the Company expected full year 2022 XHANCE average net revenue per prescription to be at least $210.

Operating Expenses
The Company expects total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2022 to be in the range of $135 - $140 million, of which the Company expects stock-based compensation to be approximately $10 million.

Chronic Sinusitis Clinical Trials
The Company expects top-line results from ReOpen2, the second its two clinical trials evaluating XHANCE as a potential treatment for chronic sinusitis, in June 2022.

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 8:00 a.m. Eastern Time today.

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 May 19, 2022 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID #4999838. 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.

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

	Three Months Ended March 31,	
	2022	**2021**
Revenues:		
Net product revenues	$ 14,760	$ 10,960
Licensing revenues	$ —	1,000
Total revenues	14,760	11,960
Costs and expenses:		
Cost of product sales	2,014	1,740
Research and development	4,802	5,225
Selling, general and administrative	29,339	27,184
Total costs and expenses	36,155	34,149
Loss from operations	(21,395)	(22,189)
Other expense	3,938	3,864
Net loss	$ (25,333)	$ (26,053)
Net loss per share of common stock, basic and diluted	$ (0.31)	$ (0.49)
Weighted average common shares outstanding, basic and diluted	82,447,861	52,997,730

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

	March 31, 2022 (unaudited)	**December 31, 2021**
Cash and cash equivalents	$ 91,367	$ 110,502
Other assets	42,448	55,569
Total assets	$ 133,815	$ 166,071
Total current liabilities	$ 50,023	$ 59,235
Long-term debt, net	126,954	126,418
Other liabilities	1,696	2,190
Total stockholders' equity	(44,858)	(21,772)
Total liabilities and stockholders' equity	$ 133,815	$ 166,071

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 (one or two sprays per nostril) twice daily of OPN-375, marketed as XHANCE, in patients with chronic sinusitis (CS) with or without nasal polyps over 24 weeks. The co-primary efficacy endpoints were the change from baseline in symptoms as measured by a composite score of nasal congestion, facial pain or pressure sensation, and nasal discharge at the end of week 4, and the change from baseline to week 24 in average of the percentages of opacification of the ethmoid and maxillary sinuses 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 or both.

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 for continued XHANCE prescription and net revenue growth; the potential benefits of XHANCE for the treatment of chronic sinusitis, the Company's plans to seek approval for a follow-on indication for XHANCE for the treatment of chronic sinusitis and the expectation of top-line results from the second of its two chronic sinusitis trials in June 2022; the potential for XHANCE to be the first FDA-approved drug treatment for chronic sinusitis; projected average net revenue per prescription for full year 2022; projected XHANCE net revenue for full year 2022; projected Company GAAP operating expenses and stock-based compensation for 2022; 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: 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; market opportunities for XHANCE may be smaller than expected; the Company's ability to grow XHANCE prescriptions and net revenues; unanticipated costs and expenses; potential for varying interpretation of results from ReOpen1; 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; the Company's ability to comply with the covenants and other terms of the note purchase agreement entered into with funds managed by Pharmakon Advisors, LP; 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.

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267.521.0531

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Building a Leading ENT / Allergy Specialty Company

Corporate Presentation
May 12, 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: potential for continued XHANCE prescription and net revenue growth and factors supporting such growth; prescription, refill and market share trends; potential effects of INS market seasonality on XHANCE prescriptions; potential early year effects on price and volume related to patient insurance; the effects of changes made to the XHANCE co-pay assistance program in January 2022 and the potential benefits of such changes; projected Company GAAP operating expenses and stock-based compensation for 2022; projected XHANCE net revenues for full year 2022; projected XHANCE average net revenue per prescription for full year 2022; the potential benefits of XHANCE for the treatment of chronic sinusitis; the expectation of having top-line results from ReOpen2 in June of 2022 and, if the results are positive, the potential benefits of such data; the Company's plans to seek approval for a follow-on indication for XHANCE for the treatment of chronic sinusitis; the potential for XHANCE to be the first FDA-approved drug treatment for chronic sinusitis and the potential market expansion opportunities and other benefits of obtaining such indication; the Company's plan to secure a partnership to promote XHANCE in primary care and the prospects for, and potential benefits of, such potential partnership; 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: impact of, and the 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 Company's ability to grow XHANCE prescriptions and net revenues; the prevalence of chronic sinusitis and market opportunities for XHANCE may be smaller than expected; unexpected costs and expenses; potential for varying interpretation of the results from ReOpen1; 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; the Company's ability to comply with the covenants and other terms of the Pharmakon note purchase agreement; 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 – 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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Q1 2022 Performance

Key Takeaways and Q1 2022 Highlights

Achieved Y/Y XHANCE Net Revenue Growth of 35% in Q1 2022

FY 2022 Revenue Guidance Implies Y/Y Growth of at least 22%

Positive Top-Line Results from ReOpen1 Reported in Q1 2022

Top-Line Data from ReOpen2 Expected in June 2022

+35%
XHANCE Net Revenue Growth Q1 2022/Q1 2021

$91M
Cash and equivalents as of March 31, 2022

+11%
XHANCE TRx Growth Q1 2022/Q1 2021

+21%
XHANCE Net Revenue per TRx Growth Q1 2022/Q1 2021

+9%
XHANCE NRx Growth Q1 2022/Q1 2021

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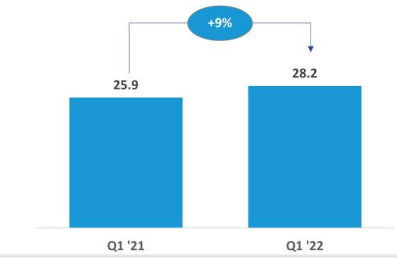
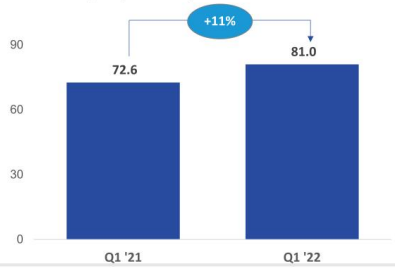
XHANCE New and Total Prescriptions

XHANCE New Prescriptions increased 9% and Total Prescriptions increased 11% from Q1 2021 to Q1 2022

XHANCE NRx *(in thousands)*



XHANCE Prescriptions *(in thousands)*



NRx for Intranasal Steroids Market increased 14% from Q1 2021 to Q1 2022 and TRx for Intranasal Steroids Market increased 8% from Q1 2021 to Q1 2022

Estimated based on monthly prescription data from third parties and XHANCE preferred pharmacy network. The Market on this slide is defined as the sum of all intranasal steroid prescriptions based on monthly prescription data from third parties

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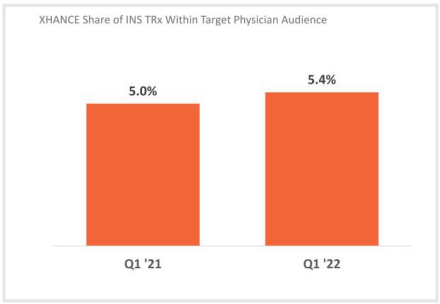
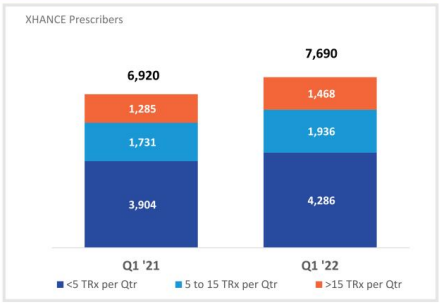
XHANCE Market Share & Prescribers by Prescribing Frequency

XHANCE market share increased from 5.0% to 5.4% and HCPs who had more than 15 XHANCE prescriptions filled by their patients in a quarter increased by 14% (1,468 versus 1,285) from Q1 2021 to Q1 2022





The Market on this slide is defined as the sum of all intranasal steroid prescriptions written by physicians in the XHANCE target physician audience of approximately 21,000 physicians. Estimated based on monthly prescription data from third parties and XHANCE preferred pharmacy network.

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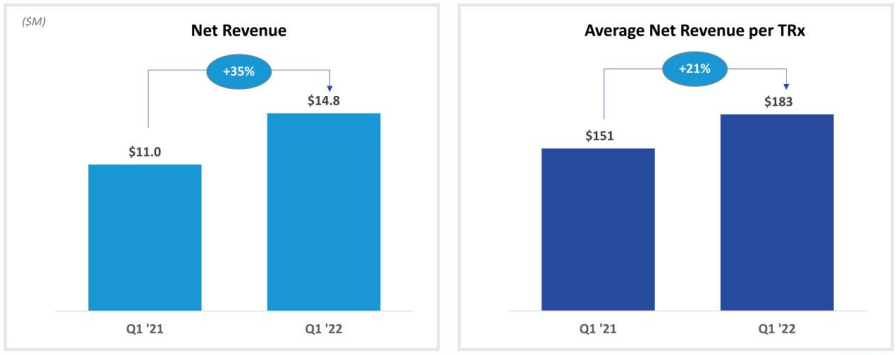
Q1 2022 Financial Update

Financial Review – First Quarter 2021

XHANCE Net Revenue Increased 35% and Average Net Revenue per TRx Increased from $151 to $183 from Q1 2021 to Q1 2022



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Full Year 2022 Financial Guidance

- **XHANCE Net Revenue**
  - Expected to be at least $90 million
- **XHANCE Average Net Revenue per Prescription**
  - FY 2022 expected to exceed $220; previously expected to exceed $210
- **Operating Expense (GAAP)**
  - Expected to be between $135 – $140 million; approximately $10 million of which represents stock-based compensation

Additional Phase 3b Clinical Trial Data Expected in Q2 2022

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Closing Remarks

Key Takeaways and Q1 2022 Highlights

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FY 2022 Revenue Guidance Implies Y/Y Growth of at least 22%

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Top-Line Data from ReOpen2 Expected in June 2022

+35%
XHANCE Net Revenue Growth Q1 2022/Q1 2021

$91M
Cash and equivalents as of March 31, 2022

+11%
XHANCE TRx Growth Q1 2022/Q1 2021

+21%
XHANCE Net Revenue per TRx Growth Q1 2022/Q1 2021

+9%
XHANCE NRx Growth Q1 2022/Q1 2021

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Investor Relations – NASDAQ: OPTN

Analyst Coverage [1]
BMO: Gary Nachman
Cantor Fitzgerald: Brandon Folkes
Cowen: Ken Cacciatore
Jefferies: Caleb Ezell
Piper Sandler: David Amsellem

At 31 March 2022:

- **$91.4 million** in cash
- Long-term debt: **$130 million**
- **82.7 million** common shares o/s
- **15.7 million** options, warrants & RSUs o/s

Optinose Investor Contact

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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 12, 2022