#### 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): November 10, 2022



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)

П 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)) П

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)

X Emerging growth company

X 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 Common stock, par value \$0.001 per share Trading symbol(s) OPTN

Name of each exchange on which registered Nasdag Global Select Market

#### Item 2.02 Results of Operations and Financial Condition.

On November 10, 2022, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 10, 2022, 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 November 10, 2022
99.2	OptiNose, Inc. Corporate Presentation, dated November 10, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

OptiNose, Inc. By: /s/ Michele Janis Michele Janis Chief Financial Officer (acting)

Date: November 10, 2022



#### **Optinose Reports Third Quarter 2022 Financial Results** and Operational Updates

Company plans to submit an sNDA for XHANCE as a treatment for chronic sinusitis in early 2023

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

Company reports third guarter 2022 XHANCE net revenue of \$20.1 million

Company expects full year 2022 XHANCE net revenue to be between \$74 to \$78 million

Company expects full year 2022 operating expenses to be between \$127 to \$131 million; full year 2023 operating expenses expected to decrease materially

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

YARDLEY, Pa., Nov. 10, 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 September 30, 2022, and provided operational updates.

"We are pleased with the progress we made in third quarter of 2022 on our supplemental New Drug Application for XHANCE," stated CEO Peter Miller. "Chronic sinusitis is an enormous opportunity relative to our current business and while our nasal polyps business is facing some headwinds, it is an important product that has achieved a scale that we believe creates an excellent launchpad for achieving the business potential that would be created by a first-ever approval in chronic sinusitis"

#### Third Quarter 2022 and Recent Highlights

Chronic Sinusitis Supplemental New Drug Application (sNDA) In September the Company met with the U.S. Food and Drug Administration (FDA) to discuss its planned efficacy supplement for XHANCE<sup>®</sup> (fluticasone propionate) Exhalation Delivery System<sup>™</sup> as a treatment for adults with chronic sinusitis.

The Company now anticipates submission of the sNDA in early 2023. Previously the Company planned for a submission by the end of 2022. The Company believes the additional time has enabled it to incorporate feedback from the September meeting with FDA into its sNDA submission. Scientific Meeting Presentations

Data from the landmark ReOpen program evaluating the efficacy and safety of XHANCE in adult patients with chronic sinusitis was presented at the American Rhinologic Society (ARS) 68th Annual Meeting on September 9, 2022 and at IDWeek 2022 on October 21, 2022.

ARS Top-Rated Abstracts - Clinical Rhinology Presentation: Re-Open-1: A randomized double-blind placebo-controlled trial of EDS-FLU for CRSwNP or CRSsNP.

IDWeek Late Breaking Presentation: Exhalation Delivery System with Fluticasone (EDS-FLU) Significantly Reduces Acute Exacerbations and Associated Antibiotic Use in Chronic Rhinosinusitis.

In addition, data from the ReOpen program is expected to be presented at the American College of Asthma, Allergy and Immunology (ACAAI) 2022 Annual Scientific Meeting on November 12.

#### Third Quarter 2022 Financial Results

Total revenues

The Company reported \$20.1 million in net revenue from sales of XHANCE during the three-month period ended September 30, 2022, a decrease of 8% compared to \$21.8 million during the three-month period ended September 30, 2021. This decrease was primarily driven by a one-time refund of disputed rebates in the third quarter of 2021 of approximately \$1.6 million that did not repeat in 2022. For the nine-month period ended September 30, 2022, the Company reported \$55.4 million in net revenue from sales of XHANCE, an increase of 8% compared to \$51.1 million during the nine-month period ended September 30, 2022, the Company reported \$55.4 million in net revenue from sales of XHANCE, an increase of 8% compared to \$51.1 million during the nine-month period ended September 30, 2022, the Company reported \$55.4 million in net revenue from sales of XHANCE, an increase of 8% compared to \$51.1 million during the nine-month period ended September 30, 2022, the Company reported \$55.4 million in net revenue from sales of XHANCE, an increase of 8% compared to \$51.1 million during the nine-month period ended September 30, 2022, the Company reported \$55.4 million in net revenue from sales of XHANCE, an increase of 8% compared to \$51.1 million during the nine-month period ended September 30, 2022, the Company reported \$55.4 million in net revenue from sales of XHANCE, an increase of 8% compared to \$51.1 million during the nine-month period ended September 30, 2022, the Company reported \$55.4 million in net revenue from sales of XHANCE, an increase of 8% compared to \$51.1 million during the nine-month period ended September 30, 2022, the Company reported \$55.4 million during the nine-month period ended September 30, 2022, the Company reported \$55.4 million during the nine-month period ended September 30, 2022, the Company reported \$55.4 million during the nine-month period ended September 30, 2022, the Company reported \$55.4 million during the nine-month period ended September 30, 2020, the Company reported \$55.4 million during the n September 30, 2021

Costs and expenses and net loss For the three-month period ended September 30, 2022, research and development expenses were \$3.3 million and selling, general and administrative expenses were \$25.5 million. The net loss for the period was \$15.0 N18 per share (basic and diluted). For the nine-month period ended September 30, 2022, research and development expenses were \$12.3 million and selling, general and administrative expenses were \$84.3 million. The net loss for the period was \$59.7 million, or \$0.72 per share (basic and diluted).

#### **Balance Sheet**

The Company had cash and cash equivalents of \$61.1 million as of September 30, 2022.

In accordance with FASB Accounting Standards, the Company has classified all outstanding principal and fees under its debt as a current liability in the accompanying condensed consolidated balance sheet as of September 30, 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 between \$74 to \$78 million. Previously, the Company expected XHANCE net revenues for the full year of 2022 to be between \$85 to \$92 million. In addition, the Company expected full year 2022 XHANCE average net revenue per prescription to be approximately \$220. Previously, the Company expected full year 2022 XHANCE average net revenue per prescription to be at least \$220.

#### **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 \$127 - \$131 million, of which the Company expects stock-based compensation to be approximately \$9 million.

Previously the Company expected total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2022 to be in the range of \$129 - \$134 million, of which the Company expected stock-based compensation to be approximately \$9 million.

In addition, the Company expects total GAAP operating expenses for full year 2023 to decrease materially compared to full year 2022 total GAAP operating expenses.

#### Pharmakon Amendment

On November 9, 2022, the Company entered into the Fourth Amendment to the Note Purchase Agreement with funds managed by Pharmakon Advisors. The Fourth Amendment waived the trailing twelve month XHANCE net revenue covenant under the Note Purchase Agreement for the periods ended September 30, 2022 and December 31, 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.

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 Nine Months Ended September 30, September 30,			
	2022	2021	2022	2021
Revenues:				
Net product revenues	\$ 20,078	\$ 21,826	\$ 55,420	\$ 51,143
Licensing revenues				1,000
Total revenues	20,078	21,826	55,420	52,143
Costs and expenses:				
Cost of product sales	2,125	2,411	6,282	6,576
Research and development	3,267	6,654	12,339	20,058
Selling, general and administrative	25,486	25,801	84,339	80,293
Total costs and expenses	30,878	34,866	102,960	106,927
Loss from operations	(10,800)	(13,040)	(47,540)	(54,784)
Other expense	4,155	4,077	12,144	11,888
Net loss	\$ (14,955)	\$ (17,117)	\$ (59,684)	\$ (66,672)
Net loss per share of common stock, basic and diluted	\$ (0.18)	\$ (0.32)	\$ (0.72)	\$ (1.25)
Weighted average common shares outstanding, basic and diluted	83,320,704	53,334,669	82,846,868	53,151,730

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

	 ptember 30, 2022 unaudited)	December 31, 2021
Cash and cash equivalents	\$ 61,080 \$	110,502
Other assets	44,190	55,569
Total assets	\$ 105,270 \$	166,071
Total current liabilities	\$ 177,795 \$	59,235
Long-term debt, net	_	126,418
Other liabilities	891	2,190
Total stockholders' equity	(73,416)	(21,772)
Total liabilities and stockholders' equity	\$ 105,270 \$	166,071

About Chronic Sinusitis Chronic sinusitis (CS), cited as the second most common chronic disease of adults in the US, is a serious chronic inflammatory disease affecting as many as 30 million adults in the United States and cost the U.S. economy over \$30 billion in direct and indirect costs every year. CS is characterized by chronic inflammation affecting the paranasal sinuses and the nasal cavity, where the openings from the sinuses normally ventilate and drain. Chronic sinusitis is associated with symptoms that persist for at least 12 weeks, with most patients suffering for many years. In addition, the condition is often associated with multiple acute exacerbations that result in substantial use of antibiotics. In some patients, chronic sino-nasal inflammation is accompanied by development of polyps in the nasal

cavities, referred to as nasal polyposis. Today, there are no FDA-approved drug treatments for the majority of chronic sinusitis patients who do not have nasal polyps, though there are medications, including XHANCE, approved by FDA for treatment of nasal polyps. The term "chronic rhinosinusitis" is also often used as an umbrella term in medical literature to refer to patients with chronic inflammatory disease in the nose and sinuses, with or without nasal polyps

#### 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. 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 to the high and deep regions of the nasal cavity where sinuses ventilate and drain. XHANCE is approved by U.S. Food and Drug Administration for the treatment of nasal polyps in patients 18 years of age or older and has been studied for treatment of chronic sinusitis in two phase 3 trials, ReOpen1 and ReOpen2. The results from these trials are the first ever that we are aware of that show improvement in both symptoms and inflammation inside the sinuses, and reduction in acute exacerbations of disease, with an intranasal therapy for chronic sinusitis patients, including those with and without nasal polyps. If approved, XHANCE may be the first drug ever FDA-approved for treatment of chronic sinusitis either with or without nasal polyps.

#### Important Safety Information

CONTRAINDICATIONS: Hypersensitivity to any ingredient in XHANCE.

#### WARNINGS AND PRECAUTIONS:

- Local Nasal Effects: epistaxis, erosion, ulceration, septal perforation, Candida albicans infection, and impaired wound healing. Monitor patients periodically for signs of possible changes on the nasal nucosa. Avoid use in patients with recent nasal ulcerations, nasal surgery, or nasal trauma. Close monitoring for glaucoma and cataracts is warranted.
- Hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, contact dermatitis, rash, hypotension, and bronchospasm) have been reported after administration of fluticasone propionate. Discontinue XHANCE if such reactions occur.
- Immunosuppression: potential increased susceptibility to or worsening of infections (e.g., existing tuberculosis; fungal, bacterial, viral, or parasitic infection; ocular herpes simplex). Use with caution in
- patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue XHANCE slowly. Patients with major risk factors for decreased bone mineral content should be monitored and treated with established standards of care.

ADVERSE REACTIONS: The most common adverse reactions (incidence ≥ 3%) are epistaxis, nasal septal ulceration, nasopharyngitis, nasal mucosal erythema, nasal mucosal ulcerations, nasal congestion, acute sinusitis, nasal septal erythema, headache, and pharyngitis.

DRUG INTERACTIONS: Strong cytochrome P450 3A4 inhibitors (e.g., ritonavir, ketoconazole): Use not recommended. May increase risk of systemic corticosteroid effects.

USE IN SPECIFIC POPULATIONS: Hepatic impairment. Monitor patients for signs of increased drug exposure.

Please see full Prescribing Information.

#### Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. All statements that are not historical facts are hereby identified as forward-looking statements for this purpose and include, among others, statements relating to the potential benefits of XHANCE for 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 to submit an sNDA in early 2023; 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 not revenue for full year 2022; projected CMANCE not revenue for full year 2022; projected company GAAP operating expenses and stock-based compensation for 2022 and 2023; 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; 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 factors the note purchase agreement entered into with funds managed by Pharmakon Advisors, LP; the Company's ability to continue as a going concern; risks and uncertainties relating to intellectual property; and the risks, uncertainties relating to a fund 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 development for therwise.

#### **Optinose Investor Contact**

Jonathan Neely jonathan.neely@optinose.com 267.521.0531

Exhibit 99.2





Corporate Presentation November 10, 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 XHANCE prescription, and net revenue growth and factors supporting such growth; potential to increase insurance coverage for XHANCE in the future; XHANCE prescription, refill and market share trends; potential effects of INS market seasonality on XHANCE prescriptions; 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 and 2023; projected XHANCE net revenues for full year 2022; projected XHANCE average net revenue per prescription for full year 2022; the potential benefits of such changes; projected 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; the Company's plans to submit an sNDA in early 2023 resulting in an expected target FDA action date in December 2023; the potential for XHANCE to be the first FDA-approved drug treatment for chronic sinusitis and ther 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 changes 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 and 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 sinusits and market opportunities for XHANCE may be smaller than expected; unexpected costs and expenses; potential for varying interpretation of the results from the ReOpen program; 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 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 <a href="http://www.sec.gov">http://www.sec.gov</a>. As a result, you are cautioned not to place undue reliance on any forward-looking statements. Any forward-looking statements whether as a result of new information, future developments or otherwise.

2





## **Key Takeaways**



optinose





## **CS Supplemental NDA - Anticipated Next Steps**

- As planned, we met with FDA in September to discuss submission of our upcoming supplemental new drug application (sNDA) in pursuit of a new indication
  - We believe it was a positive meeting
- Submission of the sNDA now expected in early 2023
  - Previously expected by the end of 2022
  - Additional time has enabled us to incorporate the feedback received in September into the preparation of the sNDA submission
- We believe the clinical safety and efficacy database is sufficient to support the filing of the sNDA

### **ReOpen Program at Conferences**



### American Rhinologic Society (ARS)

- Re-Open-1: A randomized double-blind placebo-controlled trial of EDS-FLU for CRSwNP or CRSsNP
- Abstract presented at 68<sup>th</sup> Annual Meeting on September 9<sup>th</sup>

### IDWeek 2022

- Pooled Data: Exhalation Delivery System with Fluticasone (EDS-FLU) Significantly Reduces Acute Exacerbations and Associated Antibiotic Use in Chronic Rhinosinusitis
- Late Breaking Abstract presented on October 21<sup>st</sup>

### American College of Asthma, Allergy and Immunology (ACAAI)

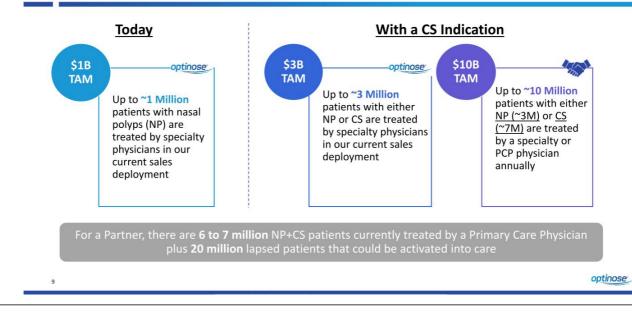
- Re-Open-2: A randomized double-blind placebo-controlled trial of EDS-FLU for CRSsNP
- Poster presentation on November 12<sup>th</sup>

optinose

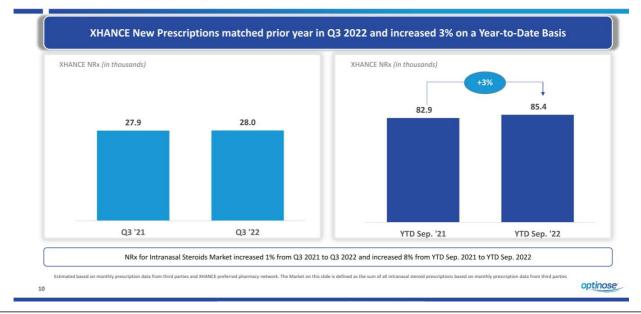




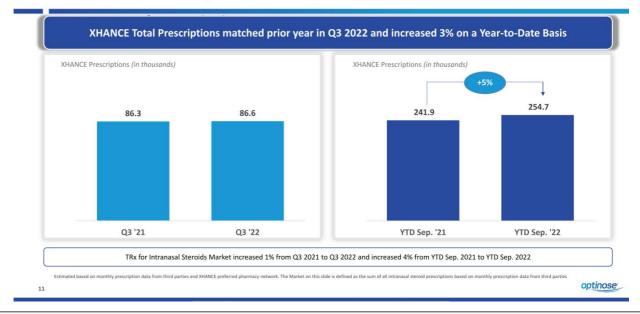
# Successful Development of XHANCE as the <u>First</u> FDA-approved Drug Treatment for Chronic Sinusitis Creates Multiple <u>New</u> Opportunities for Growth

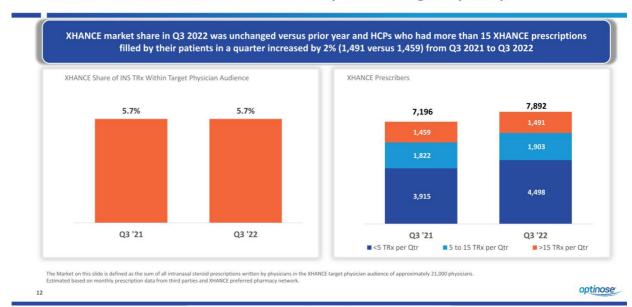


## **XHANCE New Prescriptions**



## **XHANCE Total Prescriptions**





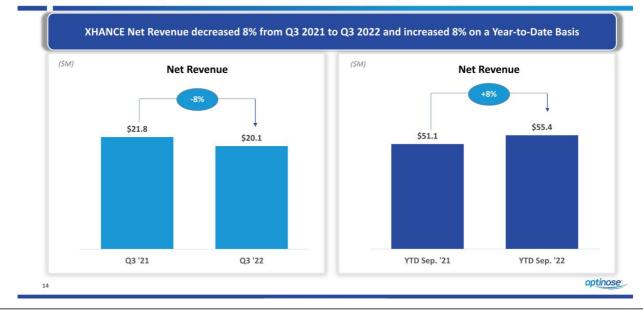
## **XHANCE Market Share & Prescribers by Prescribing Frequency**



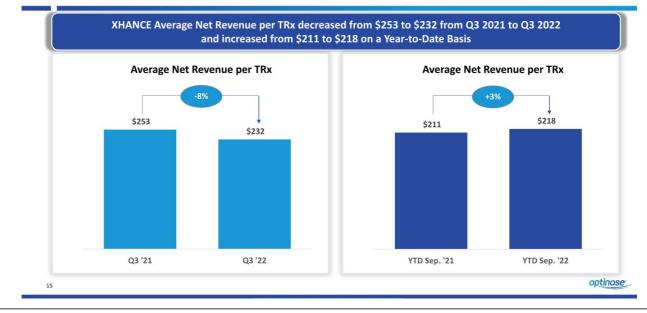


### **Financial Review – XHANCE Net Revenue**

One-time refund of disputed rebates of ~\$1.6M in Q3 2021 is the primary driver of Y/Y decrease in Q3 2022



Financial Review – XHANCE Average Net Revenue per Prescription One-time refund of disputed rebates of ~\$1.6M in Q3 2021 is the primary driver of Y/Y decrease in Q3 2022



### **Financial Guidance**

### XHANCE Net Revenue

- Expected to be between \$74 \$78 million
- Previously expected to be between \$85 \$92 million
- XHANCE Average Net Revenue per Prescription
  - FY 2022 expected to be approximately \$220
  - Previously expected to exceed \$220

### Operating Expense (GAAP)

- Expected to be between \$127 \$131 million; approximately \$9 million of which represents stock-based compensation;
- Previously expected to be between \$129 \$134 million; approximately \$9 million of which represents stock-based compensation;
- FY 2023 expected to decrease materially compared to FY 2022

16





## **Key Takeaways**



18

## Investor Relations – NASDAQ: OPTN

Analyst Coverage <sup>1</sup>	As of September 30, 2022: – \$61.1 million in cash – Debt: \$130 million – 83.5 million common shares o/s – 14.0 million options, warrants & RSUs o/s		
BMO: Gary Nachman			
Cantor Fitzgerald: Brandon Folkes			
Cowen: Ken Cacciatore	Optinose Investor Contact		
Jefferies: Glen Santangelo	Jonathan Neely, VP, Investor Relations and Business Development		
Piper Sandler: David Amsellem	267-521-0531 Investors@optinose.com		
investors@optinose.com	www.optinose.com		
	vions, estimates or forecasts regarding the Company's performance made by these analysts of Optinose or its management. Optinose does not by its reference above or distribution ons or recommendations.		
19		optinos	





Corporate Presentation November 10, 2022