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 9, 2023



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)

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 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 9, 2023, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2023. 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 9, 2023, 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
EXHIDIT NO.	Description
99.1	Press Release issued by OptiNose, Inc., dated November 9, 2023.
99.2	OptiNose, Inc. Corporate Presentation, dated November 9, 2023.
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: November 9, 2023



Optinose Reports Third Quarter 2023 Financial Results and Operational Updates

Company reports third guarter 2023 XHANCE net revenue of \$19.8 million and increases full year 2023 XHANCE net revenue guidance

Strong improvement in operating efficiency as SG&A and R&D expenses decreased by \$32M or 33% year-to-date

PDUFA goal date for XHANCE Chronic Rhinosinusitis sNDA is December 16, 2023

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

YARDLEY, Pa., Nov. 9, 2023 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, 2023, and provided operational updates.

"We are excited as we approach a potentially transformative period for the company," stated CEO Ramy Mahmoud, MD, MPH. Our effort to secure the first-ever drug approval for patients with chronic sinusitis (CS) is progressing towards the FDA's target goal date of December 16, 2023. Claims data suggest that CS is currently being diagnosed by healthcare providers at least 10 times more frequently than nasal polyps, our current indication for XHANCE. We are pleased with the progress we made in the third quarter towards our 2023 operating objectives while sharply reducing expenses. Today's results show that we are outperforming our initial expectations for 2023 XHANCE net revenues while operating far more efficiently and preparing our organization for a successful launch in 2024. This progress positions us well, if the new indication is approved, to achieve rapid adoption of XHANCE for treatment of the tens of millions of chronic sinusitis patients in need of an effective medication."

Recent Highlights

Chronic Rhinosinusitis Supplemental New Drug Application (sNDA) In May the Company announced that the U.S. Food and Drug Administration (FDA) accepted its sNDA for XHANCE® (fluticasone propionate) in the Exhalation Delivery SystemTM seeking a new indication for treatment of adults with chronic rhinosinusitis. The assigned Prescription Drug User Fee Act (PDUFA) goal date is December 16, 2023.

Third Quarter 2023 Financial Results

Total revenues

The Company reported \$19.8 million in net revenue from sales of XHANCE during the three-month period ended September 30, 2023 a decrease of 1% compared to \$20.1 million during the three-month period ended September 30, 2022. For the nine-month period ended September 30, 2023 the Company reported \$51.1 million in net revenue from sales of XHANCE a decrease of 8% compared to \$55.4 million during the nine-month period ended September 30, 2022. The year-over-year decrease in net revenue is consistent with the Company's previously communicated intent to prioritize its capital resources for a potential launch of XHANCE for the treatment of chronic sinusitis.

Costs and expenses and net (loss) income

For the three-month and nine-month periods ended September 30, 2023, research and development expenses were \$1.3 million and \$4.0 million, respectively. Selling, general and administrative expenses were \$18.0 million and \$60.8 million for the three-month and nine-month periods ended September 30, 2023, respectively. In total, SG&A plus R&D expenses decreased by \$31.8 million, or 33%, to \$64.9 million for the nine-month period ended September 30, 2022 total of \$96.7 million. The net loss for the three-month and nine-month period ended September 30, 2023, was \$9.3 million, or \$0.08 per share, and \$25.5 million, or \$0.23 per share (basic and diluted), respectively. Net loss for the three-month and nine-month period ended September 30, 2022 was \$15.0 million, or \$0.18 per share, and \$59.7 million, or \$0.72 per share (basic and diluted), respectively.

Balance Sheet

The Company had cash and cash equivalents of \$66.8 million as of September 30, 2023.

Corporate Guidance

XHANCE Net Revenue and Average Net Revenue per Prescription The Company expects XHANCE net revenues for the full year of 2023 to be between \$66.0 to \$70.0 million. Previously, the Company expected XHANCE net revenues for the full year of 2023 to be between \$64.0 to \$70.0 million. In addition, the Company continues to expect the full year 2023 XHANCE average net revenue per prescription to be approximately \$200.

Operating Expenses The Company continues to expect total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2023 to be in the range of \$88.0 to \$93.0 million, of which the Company expects stock-based compensation to be approximately \$6.0 million.

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)

2	2023				Nine Months Ended September 30,			
			2022	2023		2022		
\$	19,823	\$	20,078	\$ 51,1	22 \$	55,420		
	19,823		20,078	51,1	22	55,420		
\$	2,225	\$	2,125	6,5	02	6,282		
\$	1,281	\$	3,267	4,0	L7	12,339		
	18,011		25,486	60,8	39	84,339		
	21,517		30,878	71,3	58	102,960		
	(1,694)		(10,800)	(20,2	36)	(47,540)		
	7,600		4,154	5,2	30	12,144		
\$	(9,294)	\$	(14,954)	\$ (25,5	L6) \$	(59,684)		
\$	(0.08)	\$	(0.18)	\$ (0	23) \$	(0.72)		
	112,230,155		83,320,704	111,996,4	56	82,846,868		
	\$ \$ \$ \$	19,823 \$ 2,225 \$ 1,281 18,011 21,517 (1,634) 7,600 \$ (9,294) \$ (0.08)	19,823 \$ 2,225 \$ 1,281 18,011 21,517 (1,694) 7,600 \$ (9,294) \$	19,823 20,078 \$ 2,225 \$ 2,125 \$ 1,281 \$ 3,267 18,011 25,486 21,517 30,878 (1,694) (10,800) 4,154 \$ (9,294) \$ (14,954) \$ (0,08) \$ (0,18)	$\begin{array}{ c c c c c c c c c c c c c c c c c c c$	19,823 20,078 51,122 \$ 2,225 \$ 2,125 6,502 \$ 1,281 \$ 3,267 4,017 18,011 25,486 60,839 71,358 21,517 30,878 71,358 (10,800) (20,236) 5,280 \$ (9,294) \$ (14,954) \$ (0.08) \$ (0.18) \$		

OptiNose, Inc. Condensed Consolidated Balance Sheet Data

	September 30 2023 (unaudited)			
Cash and cash equivalents	\$	66,845	\$	94,244
Other assets		34,562		49,978
Total assets	\$	101,407	\$	144,222
Total current liabilities ⁽¹⁾ Other liabilities Total stockholders' equity	\$	163,981 15,041 (77,615)	\$	178,730 22,116 (56,624)
Total liabilities and stockholders' equity	\$	101,407	\$	144,222

(1) – All outstanding principal and fees payable upon maturity have been classified as a current liability in accordance with Generally Accepted Accounting Principles ("GAAP") because, as of the date hereof, the Company believes that it is probable that it will not maintain compliance with certain financial and liquidity covenants contained in its Amended and Restated Note Purchase Agreement for at least the next 12-months. As a result, the Company's unaudited financial statements for the three and nine months ended September 30, 2023 (2023 Financial Statements) will state that there is substantial doubt about the Company's ability to continue as a going concern (Le., a 'going concern' paragraph). Please refer to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 (2023 Financial Statements) which will be filed after the issuance of this press release for additional information.

About Optinose

Optinose is a speciality 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 anti-inflammatory 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 the treatment of chronic rhinosinusitis with nasal polyps in patients 18 years of age or older and has been studied for treatment of chronic sinusitis (notably including patients without polyps in the nasal cavity) 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 a nasal therapy for chronic sinusitis patients, including patients with or without nasal polyps. If approved, XHANCE may be the first drug ever FDA-approved for treatment of chronic rhinosinusitis either with or without nasal polyps.

Important Safety Information

CONTRAINDICATIONS: Hypersensitivity to any ingredient in XHANCE.

WARNINGS AND PRECAUTIONS

- Local Nasal Adverse Reactions; 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 until healing has occurred. 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 and Risk of Infection: 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, nasopharynoitis, nasal mucosal erythema, nasal mucosal ulcerations, nasal concestion, 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 without nasal polyps (also referred to as, chronic looking statements for this purpose and include, among others, statements relating to the potential benefits of XHANCE for the treatment of chronic sinusitis without nasal polyps (also referred to as, chronic sinusitis or chronic rhinosinusitis); the potential for XHANCE to be the first FDA-approved drug treatment for chronic sinusitis and the potential benefits thereof; objectives and preparations to launch XHANCE, if approved, for the treatment of chronic sinusitis; potential for an FDA action on the sNDA in December 2023; projected XHANCE net revenue and average net revenue per prescription for full year 2023; projected Company GAAP operating expenses (selling, general and administrative expenses and research & development expenses) and stock-based compensation for 2023; potential non-compliance with certain covenants under the Amended and Restated Pharmakon Note Purchase Agreement and the consequences thereof; 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 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 AtNANCE for its current and any potential future indication; the Company's ability to maintain adequate third-party reimbursement for XHANCE (market access) including any future indication; the potential for XHANCE may be smaller than expected; the Company's ability to face the reatment of chronic sinusitis 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; uncertainties related to the clinical development program and regulatory approval of XHANCE for the treatme 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





Corporate Presentation November 9, 2023

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 generation of XHANCE prescriptions and net revenues and factors impacting the generation of future prescriptions and net revenues; prescription, net revenue, prescription, and net revenues and factors impacting the generation of future prescriptions and net revenues; prescription, net revenue, prescription, and net revenues; projected SAANCE prescriptions; potential effects of INS market seasonality on XHANCE prescriptions; potential early year effects on price and volume related to patient insurance; impact of payor utilization management criteria; commercial strategies; projected GAAP operating expenses (selling, general & administrative expenses and research & development expenses) and stock-based compensation for 2023; projected XHANCE for the treatment of chronic sinusitis; the potential for an FDA action on the SNDA in December 2023; her potential for XHANCE to reatement of chronic sinusitis; the potential for an FDA action on the sNDA in December 2023; her potential for XHANCE to reatement for chronic sinusitis; the potential market expansion opportunities and other benefits of obtaining such indication; our plan to seek a partner to promote XHANCE in primary care and the prospects for, and potential benefits of, such potential partnership; potential non-compliance with certain covenants under the A&R Pharmakon Note Purchase Agreement and the potential consequences thereof; 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 for its current and any potential future indication; our ability to maintain adequate third party reimbursement for XHANCE for its current and any potential future indication; our ability to maintain adequate third party reimbursement for XHANCE for its current and any potential future 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; uncertainties related to the clinical development program and regulatory approval of XHANCE for the treatment of chronic rhinosinusitis; 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 – which are available at http://www.sec.gov. As a result, you are cautioned not to place undure reliance on any forward-looking statements, dure reliance on other securities and students, on your object on other was a secult of new information, future developments or otherwise.

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Key Takeaways

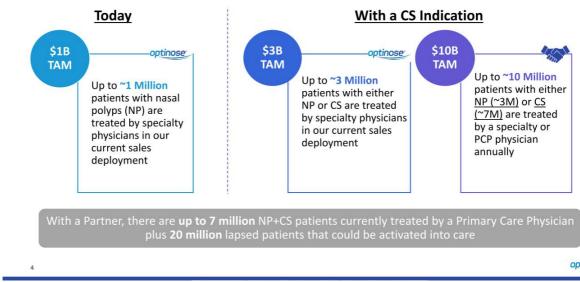
Chronic sinusitis is a 10-fold market opportunity for XHANCE

sNDA target action date in December 2023

Executing our strategy to prioritize the potential launch of XHANCE as the first-ever FDA approved drug treatment for CS



Successful Development of XHANCE as the <u>First and Only</u> FDA-approved Drug Treatment for Chronic Sinusitis Would Create Multiple New Growth Opportunities







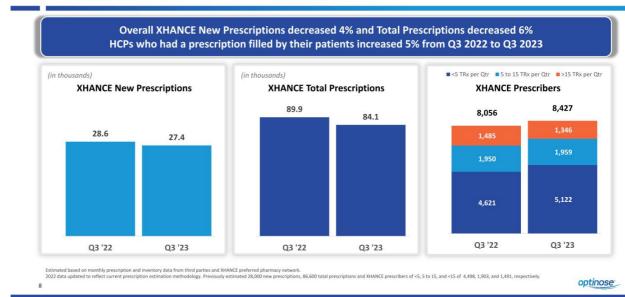
CS Supplemental NDA - Anticipated Next Steps



- FDA accepted for review our supplemental new drug application (sNDA) in pursuit of a new indication
- PDUFA target action date is December 16, 2023
 - Standard review period was applied



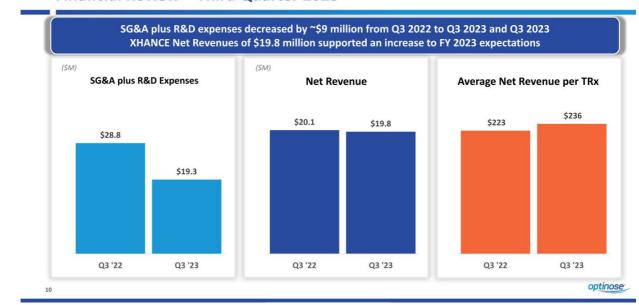




XHANCE Prescriptions – Third Quarter 2023







Financial Review – Third Quarter 2023





Full Year 2023 Financial Guidance

- XHANCE Net Revenue
 - FY 2023 expected to be between \$66 to \$70 million
 - Previously expected to be between \$64 to \$70 million
 - FY 2023 expectation does not include net revenues from a CS launch
- XHANCE Average Net Revenue per Prescription
 - FY 2023 expected to be approximately \$200
- GAAP Operating Expenses (SG&A and R&D Expenses)
 - Expected to be between \$88 to \$93 million; approximately \$6 million of which represents stock-based compensation

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Key Takeaways

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Chronic sinusitis is a 10-fold market opportunity for XHANCE

sNDA target action date in December 2023

Executing our strategy to prioritize the potential launch of XHANCE as the first-ever FDA approved drug treatment for CS



Investor Relations – NASDAQ: OPTN

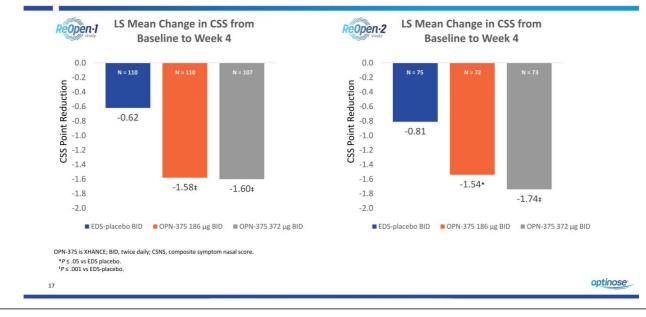




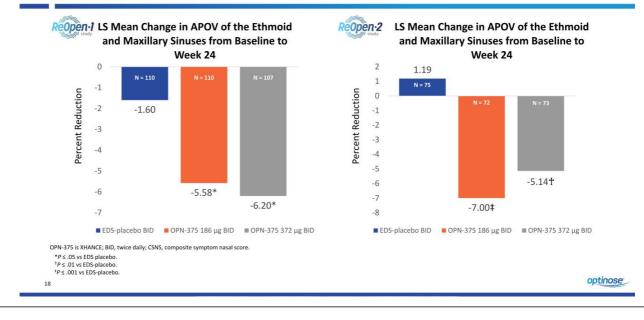




Combined Symptom Score (Co-Primary Endpoint) Improvement in combined symptoms with XHANCE; Consistent with NAVIGATE I and II

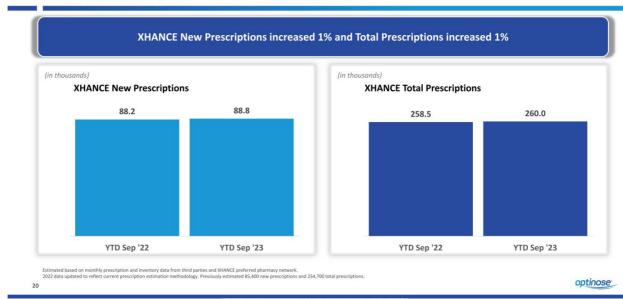


Average of Percentages of Opacified Volume (Ethmoid and Maxillary) Objective Evidence of Effect in Sinus Cavities by CT Scan; Co-Primary Endpoint

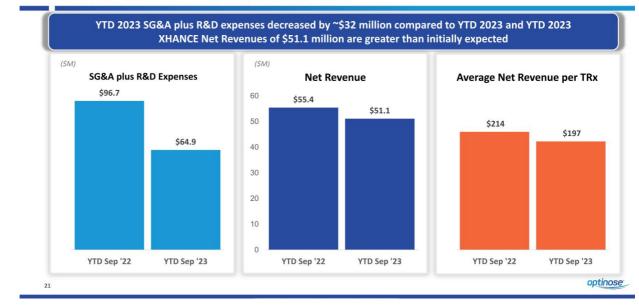








XHANCE Prescriptions – YTD September 2023



Financial Review – YTD September 2023





Corporate Presentation November 9, 2023