

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): August 11, 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)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

- Emerging growth company
- If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.001 per share	OPTN	Nasdaq Global Select Market

Item 2.02 Results of Operations and Financial Condition.

On August 11, 2022, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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 August 11, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by OptiNose, Inc., dated August 11, 2022
99.2	OptiNose, Inc. Corporate Presentation, dated August 11, 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: August 11, 2022



**Optinose Reports Second Quarter 2022 Financial Results
and Operational Updates**

*Company reports second quarter XHANCE net revenue of \$20.6 million increased 12%
compared to second quarter 2021*

Company plans to submit an sNDA for XHANCE as a treatment for chronic sinusitis by the end of 2022

Company expects full year 2022 XHANCE net revenue to be between \$85 to \$92 million

Company expects full year 2022 and operating expenses to be between \$129 to \$134 million

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

YARDLEY, Pa., Aug. 11, 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 June 30, 2022, and provided operational updates.

"We reported confirmatory, positive topline results from ReOpen2 in June and are further encouraged by the consistency observed in key secondary and pooled results," stated CEO Peter Miller. "These data potentially support a new indication for XHANCE as a treatment for chronic sinusitis which we believe could increase the total addressable market for XHANCE by a factor of approximately ten compared to current indication. Our team plans to submit an sNDA by the end of 2022. Our current business is performing well, XHANCE net revenue increased 12% in the second quarter of 2022 compared to second quarter 2021 and increased 21% on a year-to-date basis. We changed our full year 2022 guidance for net revenue because we experienced greater than expected vacancy rates in our sales territories in recent months and greater than expected summer seasonal volume declines. However, we are optimistic about the impact that filling vacant sales territories, fall seasonal volume increases, and new clinical data showing a reduction in acute exacerbations in nasal polyp patients could have on prescriptions."

Second Quarter 2022 and Recent Highlights

ReOpen2

In June, the Company announced that the ReOpen2 clinical trial met both of its co-primary endpoints. A statistically significant improvement was demonstrated in patients with chronic sinusitis who were treated with XHANCE® (fluticasone propionate), a drug-device combination product with the proprietary Exhalation Delivery System™, in the ReOpen2 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 percentages of opacified volume (APOV) on CT scan across the ethmoid and maxillary sinuses).

"ReOpen2 was the second 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 ReOpen2 we found confirmatory evidence 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. ReOpen2 was exciting news for us and for tens of millions of people suffering from chronic sinusitis and added importantly to the growing body of evidence that may inform 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, COVID-19, headache, and depression.

Detailed results from this trial will be submitted for publication in a peer-reviewed journal and for presentation at

future medical meetings.

Pooled Results from the ReOpen Program

In July, the Company announced selected pooled results from the ReOpen program.

To inform possible differences in response of patients previously using a standard nasal steroid spray, a pre-planned analysis of pooled data assessed symptom improvement for patients entering the trials with at least moderate symptoms despite reporting use of a standard nasal steroid spray. For this subgroup, patients receiving XHANCE improved more from baseline than patients receiving placebo comparator.

In addition, a pooled analysis was performed to assess change in CT scans, measured by APOV at week 24, for the subgroup of patients receiving XHANCE who had chronic sinusitis without nasal polyps. Compared to patients treated with placebo comparator, XHANCE treatment produced greater reduction in sinus opacification in this subgroup. Differences between active and placebo in 186 mcg or 372 mcg XHANCE treatment groups were similar and nominally statistically significant.

Finally, an analysis of pooled data found that the 372 mcg treatment group achieved a type 1 error controlled statistically significant reduction of 66% in the incidence of exacerbations compared to placebo comparator. Reductions in the number of exacerbations, ranging from 53 to 80%, were found for subgroups of chronic sinusitis patients with or without nasal polyps in the 186 mcg or 372 mcg XHANCE treatment groups in additional pre-planned exploratory analyses that were not type 1 error controlled. Exacerbations were defined as a worsening of at least one of the four cardinal symptoms of chronic sinusitis (nasal congestion/obstruction, rhinorrhea, facial pain/pressure, and loss of sense of smell) lasting at least 3 days accompanied by an escalation in medical care, such as doctor visits or antibiotic or steroid prescription.

Second Quarter 2022 Financial Results

Total revenues

The Company reported \$20.6 million in net revenue from sales of XHANCE during the three-month period ended June 30, 2022 an increase of 12% compared to \$18.4 million during the three-month period ended June 30, 2021. For the six-month period ended June 30, 2022 the Company reported \$35.4 million in net revenue from sales of XHANCE an increase of 21% compared to \$29.3 million during the six-month period ended June 30, 2021.

Costs and expenses and net loss

For the three-month period ended June 30, 2022, research and development expenses were \$4.3 million and selling, general and administrative expenses were \$29.5 million. The net loss for the period was \$19.4 million, or \$0.23 per share (basic and diluted). For the six-month period ended June 30, 2022, research and development expenses were \$9.1 million and selling, general and administrative expenses were \$58.9 million. The net loss for the period was \$44.7 million, or \$0.54 per share (basic and diluted).

Cash

The Company had cash and cash equivalents of \$78.3 million as of June 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 \$85 - \$92 million. Previously, the Company expected 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 \$129 - \$134 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 \$135 - \$140 million, of which the Company expected stock-based compensation to be approximately \$10 million.

Chronic Sinusitis Supplemental New Drug Application (sNDA)

The Company plans to submit an sNDA by the end of 2022.

Pharmakon Amendment

On August 10, 2022, the Company entered into the Third Amendment to the Note Purchase Agreement with Pharmakon (the Third Amendment). The Third Amendment reduced the Company's December 31, 2022 trailing twelve month net revenue covenant from \$90 million to \$85 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)

	Three Months Ended		Six Months Ended	
	June 30,	2021	June 30,	2021
	2022		2022	
Revenues:				
Net product revenues	\$ 20,582	\$ 18,357	\$ 35,342	\$ 29,317
Licensing revenues	—	—	—	1,000
Total revenues	<u>20,582</u>	<u>18,357</u>	<u>35,342</u>	<u>30,317</u>
Costs and expenses:				
Cost of product sales	2,143	2,425	4,157	4,165
Research and development	4,270	8,179	9,072	13,404
Selling, general and administrative	29,514	27,308	58,853	54,493
Total costs and expenses	<u>35,927</u>	<u>37,912</u>	<u>72,082</u>	<u>72,062</u>
Loss from operations	<u>(15,345)</u>	<u>(19,555)</u>	<u>(36,740)</u>	<u>(41,745)</u>
Other expense	4,052	3,947	7,990	7,810
Net loss	<u>\$ (19,397)</u>	<u>\$ (23,502)</u>	<u>\$ (44,730)</u>	<u>\$ (49,555)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.23)</u>	<u>\$ (0.44)</u>	<u>\$ (0.54)</u>	<u>\$ (0.93)</u>
Weighted average common shares outstanding, basic and diluted	<u>82,740,096</u>	<u>53,120,574</u>	<u>82,594,786</u>	<u>53,059,492</u>

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

	June 30, 2022 (unaudited)	December 31, 2021
Cash and cash equivalents	\$ 78,264	\$ 110,502
Other assets	44,568	55,569
Total assets	<u>\$ 122,832</u>	<u>\$ 166,071</u>
Total current liabilities	\$ 55,038	\$ 59,235
Long-term debt, net	127,483	126,418
Other liabilities	1,094	2,190
Total stockholders' equity	(60,783)	(21,772)
Total liabilities and stockholders' equity	<u>\$ 122,832</u>	<u>\$ 166,071</u>

About the ReOpen Program

The ReOpen program comprises two global, randomized, double-blind, placebo-controlled Phase 3 trials that evaluated the efficacy and safety of one or two sprays of XHANCE (OPN-375) in each nostril twice daily, over 24 weeks, in patients suffering from chronic sinusitis (CS). In ReOpen1, the first of the two trials, 332 patients were treated who had CS with or without nasal polyps. In ReOpen2, the second of the two trials, 222 patients were treated who had CS without nasal polyps. The co-primary endpoints were change from baseline in symptoms, as measured by a composite score of patient-reported symptoms (including nasal congestion, facial pain or pressure sensation, and nasal discharge) at the end of week 4, and objective change in inflammation inside the sinus cavities, as measured by the change in average of percentages of volume occupied by disease across the ethmoid and maxillary sinuses as measured by CT scan. The ReOpen trial program is a landmark research program because these are the first ever large, controlled trials we are aware of with any nasal medication to demonstrate significant improvement of both symptoms and inflammation inside the sinuses and to show reduction in the number of acute exacerbations.

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 costing 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 a nasal 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 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 $\geq 3\%$) are epistaxis, nasal septal ulceration, nasopharyngitis, nasal mucosal erythema, nasal mucosal ulcerations, nasal congestion, acute sinusitis, nasal septal erythema, headache, and pharyngitis.

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

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

Please see full [Prescribing Information](#).

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 impact that filling vacant sales territories, fall seasonality, and new clinical data showing a reduction in acute exacerbations in nasal polyp patients with XHANCE use could have on XHANCE prescriptions; 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 by the end of 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 and 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.

Optinose Investor Contact
Jonathan Neely
jonathan.neely@optinose.com
267.521.0531

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**Building a Leading ENT / Allergy
Specialty Company**

Corporate Presentation
August 11, 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; 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 Company’s plans to seek approval for a follow-on indication for XHANCE for the treatment of chronic sinusitis and its plan to submit an sNDA by the end of 2022; 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 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 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.



Q2 2022 Performance

Key Takeaways and Q2 2022 Highlights



Completed Landmark ReOpen Trials in Q2 2022

Plan to Submit sNDA by the end of 2022

Improved Profitability of XHANCE Prescriptions by 12% in H1 2022

Revised FY 2022 Net Revenue and Operating Expense Guidance

+21%

XHANCE Net
Revenue Growth
H1 2022/H1 2021

+12%

XHANCE Net
Revenue per TRx
Growth
H1 2022/H1 2021

1,500

Physicians in
15+ TRx Segment
in Q2 2022

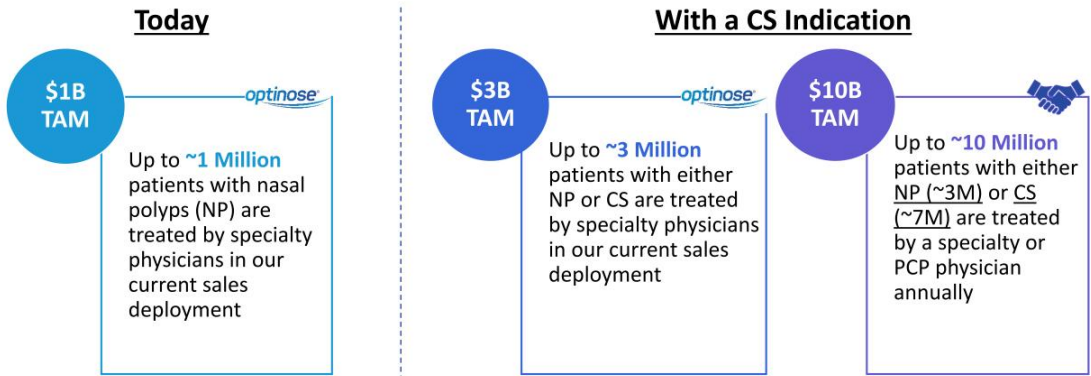
5.6%

Q2 2022 market share
an increase of 0.4%
compared to Q2 2021

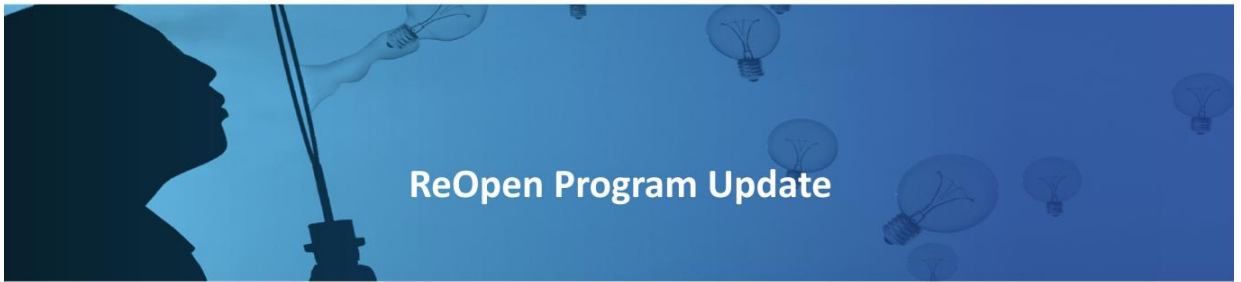
\$78M

Cash and equivalents
as of
June 30, 2022

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



For a Partner, there are **6 to 7 million** NP+CS patients currently treated by a Primary Care Physician plus **20 million** lapsed patients that could be activated into care



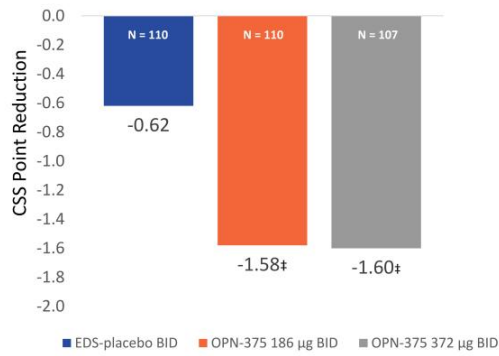
ReOpen Program Update

Combined Symptom Score (Co-Primary Endpoint)

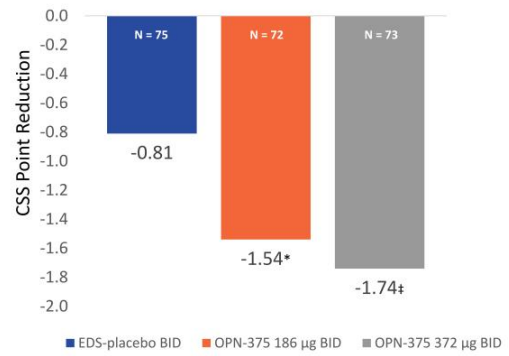
Improvement in combined symptoms with XHANCE; Consistent with NAVIGATE I and II



LS Mean Change in CSS from Baseline to Week 4



LS Mean Change in CSS from Baseline to Week 4



OPN-375 is XHANCE; BID, twice daily; CSNS, composite symptom nasal score.

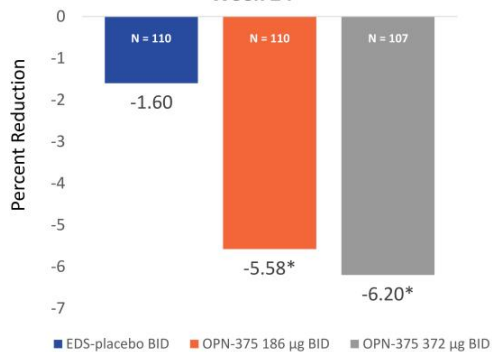
^{*}P ≤ .05 vs EDS placebo.

[‡]P ≤ .001 vs EDS-placebo.

Average of Percentages of Opacified Volume (Ethmoid and Maxillary)

Objective Evidence of Effect in Sinus Cavities by CT Scan; Co-Primary Endpoint

ReOpen-1 LS Mean Change in APOV of the Ethmoid and Maxillary Sinuses from Baseline to Week 24



■ EDS-placebo BID ■ OPN-375 186 µg BID ■ OPN-375 372 µg BID

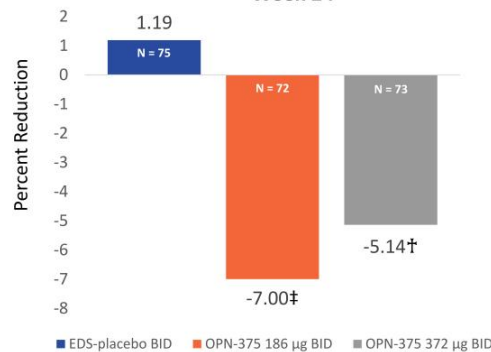
OPN-375 is XHANCE; BID, twice daily; CSNS, composite symptom nasal score.

* $p \leq .05$ vs EDS placebo.

† $p \leq .01$ vs EDS-placebo.

‡ $p \leq .001$ vs EDS-placebo.

ReOpen-2 LS Mean Change in APOV of the Ethmoid and Maxillary Sinuses from Baseline to Week 24

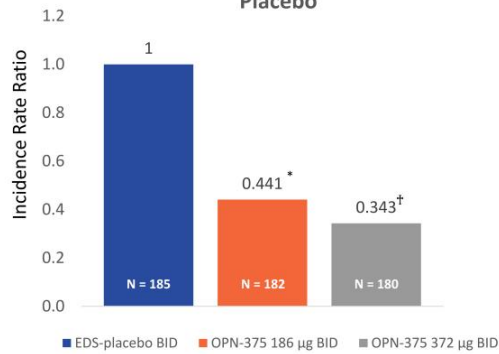


■ EDS-placebo BID ■ OPN-375 186 µg BID ■ OPN-375 372 µg BID

Pooled Analysis Exacerbations (Key Secondary Endpoint)

XHANCE is the first and only nasal medication ever shown in Phase 3 controlled trials to reduce exacerbations for patients with chronic sinusitis

LS Mean Frequency of Exacerbations through 24 Weeks relative to EDS-Placebo



BID, twice daily; CSNS, composite symptom nasal score.

* $P \leq .05$ vs EDS placebo. This is a nominal p-value.

† $P \leq .01$ vs EDS-placebo. This is a type-1 error controlled p-value.

Summary

- Acute exacerbations are a major source of disability for the roughly 30 million patients in the United States who suffer from chronic sinusitis.
- There are approximately 10 million office visits for chronic rhinosinusitis every year, and approximately 70% of patients who visit a doctor for chronic rhinosinusitis receive an antibiotic.
- Reducing widespread use of antibiotics is important because frequent use of antibiotics poses risks to the individuals using them, and because of societal risks, such as emergence of drug-resistant organisms.

Anticipated Next Steps



- Meeting with FDA prior to data submission scheduled for the end of September
 - Meeting minutes available in fourth quarter
- Plan to submit sNDA by the end of 2022

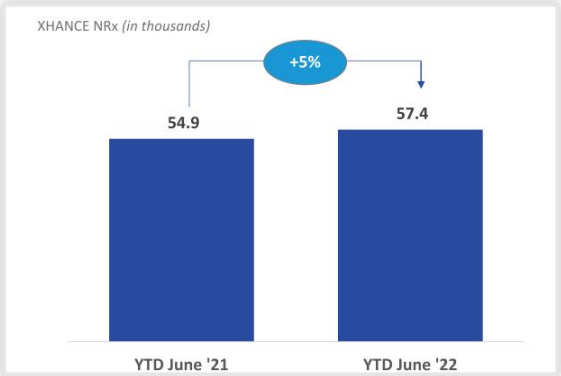
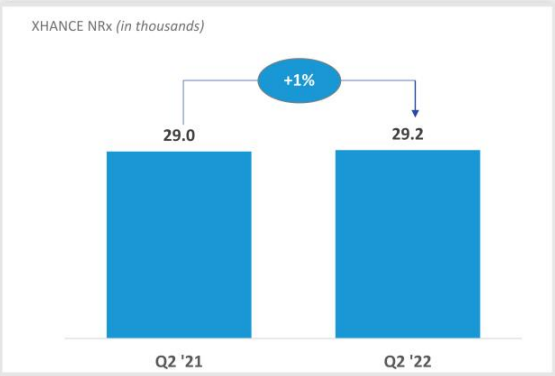


Q2 2022 Commercial Update

XHANCE New Prescriptions

Revised Co-Pay Assistance Program is Suppressing Unprofitable High-Deductible NRx in 2022

XHANCE New Prescriptions Increased 1% from Q2 2021 to Q2 2022 and 5% on a Year-to-Date Basis



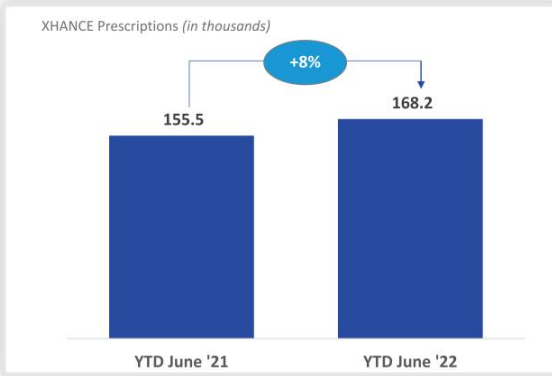
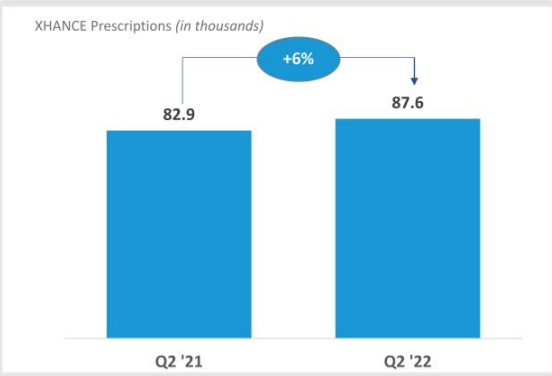
NRx for Intranasal Steroids Market increased 8% from Q2 2021 to Q2 2022 and increased 11% from YTD June 2021 to YTD June 2022

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.

XHANCE Total Prescriptions

Revised Co-Pay Assistance Program is Suppressing Unprofitable High-Deductible TRx in 2022

XHANCE Total Prescriptions Increased 6% from Q2 2021 to Q2 2022 and 8% on a Year-to-Date Basis

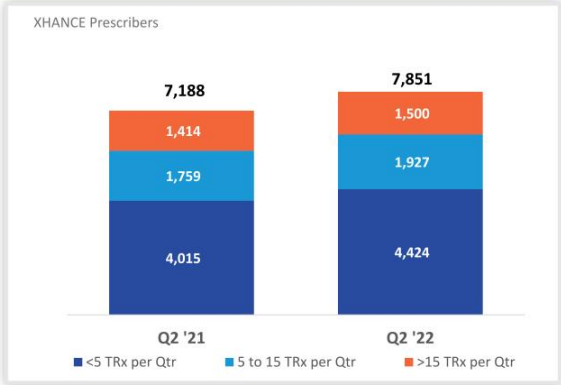
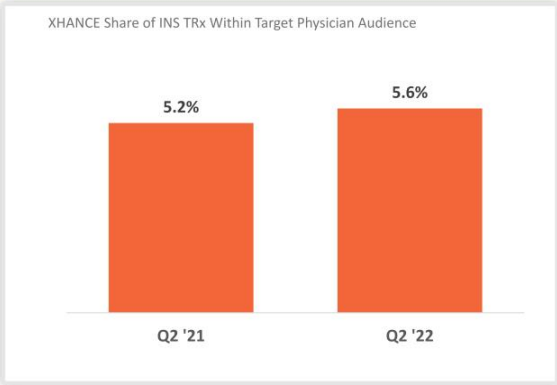


TRx for Intranasal Steroids Market increased 4% from Q2 2021 to Q2 2022 and increased 6% from YTD June 2021 to YTD June 2022

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.

XHANCE Market Share & Prescribers by Prescribing Frequency

XHANCE market share increased from 5.2% to 5.6% and HCPs who had more than 15 XHANCE prescriptions filled by their patients in a quarter increased by 6% (1,500 versus 1,414) from Q2 2021 to Q2 2022



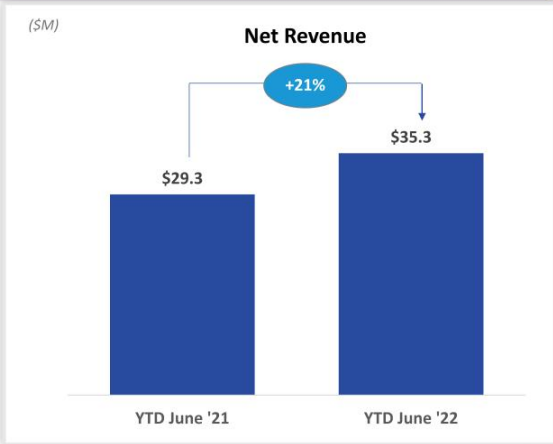
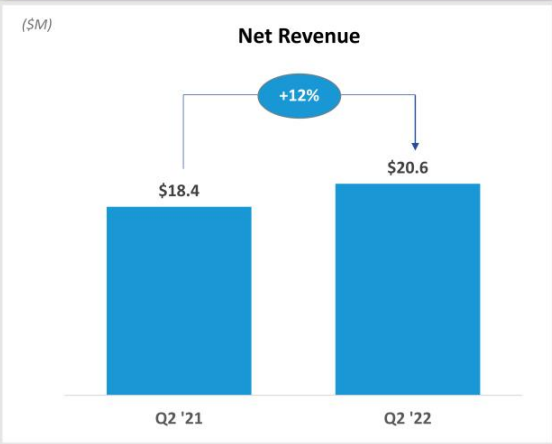
The Market on this slide is defined as the sum of all intranasal steroid prescriptions written by physicians in the XHANCE target physician audience of approximately 21,000 physicians. Estimated based on monthly prescription data from third parties and XHANCE preferred pharmacy network.



Q2 2022 Financial Update

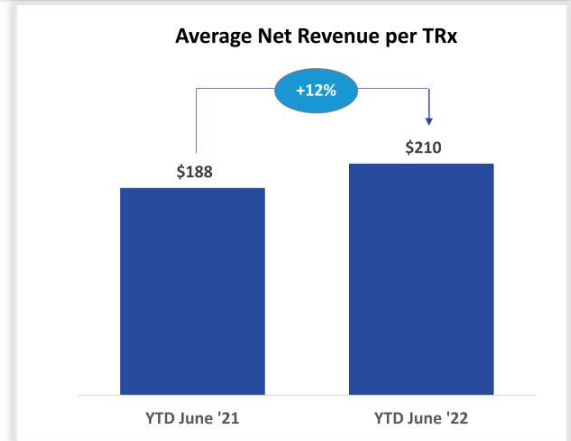
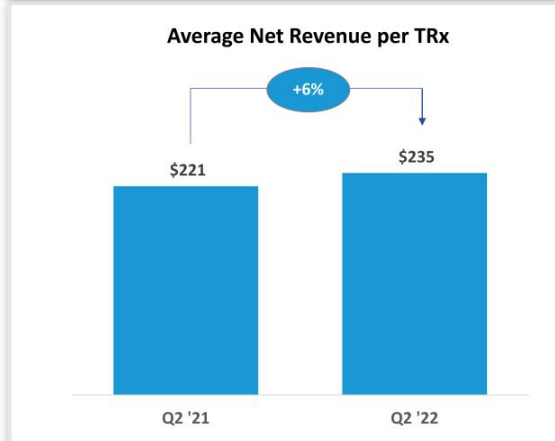
Financial Review – XHANCE Net Revenue

XHANCE Net Revenue Increased 12% from Q2 2021 to Q2 2022 and 21% on a Year-to-Date Basis



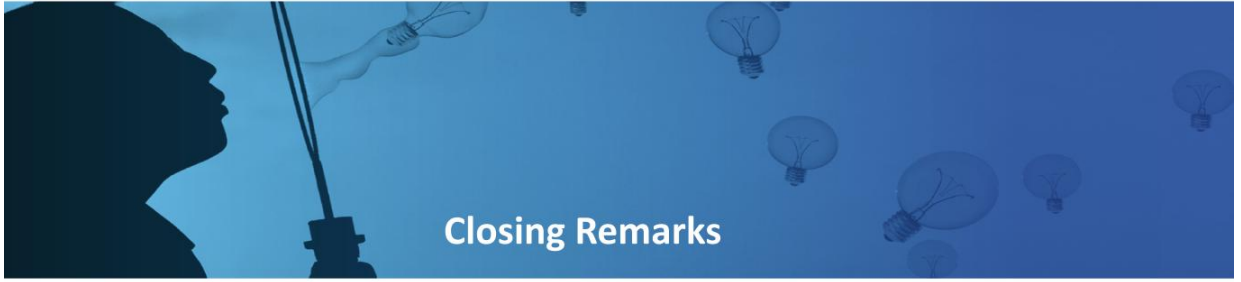
Financial Review – XHANCE Average Net Revenue per Prescription

XHANCE Average Net Revenue per TRx Increased from \$221 to \$235 from Q2 2021 to Q2 2022 and from \$188 to \$210 on a Year-to-Date Basis



Full Year 2022 Financial Guidance and Pharmakon Agreement

- **XHANCE Net Revenue**
 - Expected to be between \$85 - \$92 million; Previously expected to be at least \$90 million
- **XHANCE Average Net Revenue per Prescription**
 - FY 2022 expected to exceed \$220
- **Operating Expense (GAAP)**
 - Expected to be between \$129 – \$134 million; approximately \$9 million of which represents stock-based compensation;
 - Previously expected to be between \$135 – \$140 million; approximately \$10 million of which represents stock-based compensation
- **Pharmakon Amendment**
 - Entered into the Third Amendment to the Note Purchase Agreement with Pharmakon (the Third Amendment). The Third Amendment reduced the Company's December 31, 2022, trailing twelve-month net revenue covenant from \$90 million to \$85 million



Closing Remarks

Key Takeaways and Q2 2022 Highlights



Completed Landmark ReOpen Trials in Q2 2022

Plan to Submit sNDA by the end of 2022

Improved Profitability of XHANCE Prescriptions by 12% in H1 2022

Revised FY 2022 Net Revenue and Operating Expense Guidance

+21%

XHANCE Net
Revenue Growth
H1 2022/H1 2021

+12%

XHANCE Net
Revenue per TRx
Growth
H1 2022/H1 2021

1,500

Physicians in
15+ TRx Segment
in Q2 2022

5.6%

Q2 2022 market share
an increase of 0.4%
compared to Q2 2021

\$78M

Cash and equivalents
as of
June 30, 2022

Investor Relations – NASDAQ: OPTN

Analyst Coverage ¹
BMO: Gary Nachman
Cantor Fitzgerald: Brandon Folkes
Cowen: Ken Cacciatore
Piper Sandler: David Amsellem

As of June 30, 2022:

- \$78.3 million in cash
- Long-term debt: \$130 million
- 83.0 million common shares o/s
- 15.0 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.



**Building a Leading ENT / Allergy
Specialty Company**

**Corporate Presentation
August 11, 2022**
