# UNITED STATES

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Emerging growth company

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

Title of each class

Common stock, par value \$0.001 per share

		CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934				
	Dat	te of Report (Date of earliest event reported): August 11, 2021				
	 Delaware	42-1771610				
	(State or Other Jurisdiction of Incorporation or Organization)	<b>001-38241</b> (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 th	e 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 provision	ons (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	ne Exchange Act (17 CFR 240.14d-2(b))				
	Pre-commencement communications pursuant to Rule 13e-4(c) under th	e Exchange Act (17 CFR 240.13e-14(c))				
Indicate chapter).		efined 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			

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.

Name of each exchange on which registered

Nasdaq Global Select Market

Trading symbol(s)
OPTN

# Item 2.02 Results of Operations and Financial Condition.

On August 11, 2021, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2021. 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, 2021, the Company presented an updated Corporate Presentation during its financial results and corporate update 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
Press Release issued by OptiNose, Inc., dated August 11, 2021.
OptiNose, Inc. Corporate Presentation, dated August 11, 2021. 99.2

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: August 11, 2021



## Optinose Reports Second Quarter 2021 Financial Results and Recent Operational Highlights

Second quarter 2021 XHANCE net revenue of \$18.4 million increased 79% compared to second quarter 2020

Second quarter 2021 XHANCE prescriptions increased 33% from second quarter 2020

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

YARDLEY, Pa., August 11, 2021 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 guarter ended June 30, 2021, and provided operational updates.

"We are pleased with the progress we made in second quarter 2021 towards our objectives of growing XHANCE and successfully completing our chronic sinusitis program," stated CEO Peter Miller. "XHANCE net revenue increased 79% compared to second quarter 2020 and we recently completed enrollment in the first of our two pivotal chronic sinusitis clinical trials. We are focused on execution in the second half of 2021 in order to deliver at least \$80 million of XHANCE net revenue for the full year and to complete enrollment in the second chronic sinusitis pivotal clinical trial."

## Second Quarter 2021 and Recent Highlights

Total and New XHANCE Prescriptions
The number of total XHANCE® (fluticasone propionate) prescriptions increased by 33% from 62,500 in the second quarter 2020 to 82,900 in the second quarter 2021.

The number of new XHANCE prescriptions increased by 55% from 18,700 in the second quarter of 2020 to 29,000 in the second quarter of 2021.

# **Enrollment Complete in First Pivotal Chronic Sinusitis Trial**

In July, the Company completed patient recruitment in the first of two pivotal clinical trials to evaluate the safety and efficacy of XHANCE as a treatment for patients with chronic sinusitis (CS).

Expert Treatment Algorithm Highlights Role of XHANCE
In June, a new stepped-care treatment algorithm was published in the International Forum of Allergy & Rhinology, "Multidisciplinary consensus on a stepwise treatment algorithm for management of chronic rhinosinusitis with nasal polyps." It recommends Exhalation Delivery System-fluticasone (EDS-FLU; XHANCE) for the treatment of patients with nasal polyps as a step in between initial care with standard intranasal steroids and before escalation of care to surgery or biologic medicines.

The independent algorithm was informed by evidence-based, peer-reviewed data supporting the use of therapeutic and interventional treatments to arrive at the recommended stepwise care paradigm. The publication discusses considerations in a pathway for care that incorporates several new treatments approved in recent years into a logical stepwise escalation of medical care, including but not limited to standard nasal steroid sprays, EDS-FLU (XHANCE), surgery, implants and biologics.

European Inventor Award 2021 for Industry
In June, Dr. Per Djupesland, co-founder and Chief Scientific Officer of Optinose AS, received the European Inventor Award 2021 in the Industry category from the European Patent Office (EPO) for his invention of the technology that serves as a basis for Optinose Exhalation Delivery System (EDS<sup>TM</sup>) devices.

The European Inventor Award was launched by the EPO in 2006. The finalists and winners are selected by an independent body consisting of international authorities from the fields of business, politics,

and research who examine the proposals for their contribution towards technical progress, social development, economic prosperity and job creation in Europe. The Award is conferred in five categories (Industry, Research, Small and Medium-sized Enterprises, Non-EPO countries and Lifetime achievement). In addition, the public selects the winner of the Popular Prize from among the 15 finalists through online voting.

### OPN-019

In July 2021, the Company received approval from regulatory authorities in Mexico to conduct a randomized, proof-of-concept study in subjects who have tested positive for SARS-CoV-2 infection, are recently infected, and who have mild or no symptoms. The study is open for enrollment. This pilot study will evaluate both the magnitude and duration of viral load reduction after a single dose of OPN-019.

Proof-of-concept clinical data is expected to support the Company's pursuit of grants, partnerships, and/or other sources of capital that will be necessary to fund future development.

## Corporate Guidance

## XHANCE Net Revenue and Average Net Revenue per Prescription

The Company expects XHANCE net revenue for the full year of 2021 to be at least \$80 million. In addition, the Company expects full year 2021 XHANCE net revenue per prescription to be greater than \$200.

## Operating Expenses

The Company expects total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2021 to be in the range of \$137 - \$142 million, of which the Company expects stock-based compensation to be approximately \$10 million.

## **Chronic Sinusitis Clinical Trials**

The Company has completed enrollment in the first of its two clinical trials evaluating XHANCE as a potential treatment for chronic sinusitis and expects top-line results in the first quarter of 2022. The Company expects to complete patient enrollment in its second clinical trial in the fourth quarter of 2021 and to have top-line results in the second quarter of 2022.

## Second Quarter 2021 Financial Results

## XHANCE net revenue

The Company generated \$18.4 million and \$29.3 million in net revenue from sales of XHANCE during the three and six months ended June 30, 2021, respectively. Net revenue from sales of XHANCE increased 79% and 69% during the three and six months ended June 30, 2021 compared to the three and six months ended June 30, 2020, respectively.

## Costs and expenses and net loss

For the three and six months ended June 30, 2021, research and development expenses were \$27.3 million and \$13.4 million, respectively and selling, general and administrative expenses were \$27.3 million and \$54.5 million, respectively. The net loss for the three and six months ended June 30, 2021 was \$23.5 million, or \$0.44 per share (basic and diluted) and \$49.6 million, or \$0.93 per share (basic and diluted), respectively.

## Cash

The Company had cash and cash equivalents of \$93.9 million as of June 30, 2021.

## 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 Wednesday, August 18, 2021 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID # 2867629. 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 June 30,			Six Months Ended June 30,		
		2021	2020	2021		2020	
Revenues:							
Net product revenues	\$	18,357 \$	10,272	\$	29,317 \$	17,334	
Licensing revenues		\$		\$	1,000		
Total revenues		18,357 \$	10,272		30,317	17,334	
Costs and expenses:	<u></u>						
Cost of product sales		2,425	1,700		4,165	3,056	
Research and development		8,179	5,474		13,404	10,406	
Selling, general and administrative		27,308	25,697		54,493	52,757	
Total costs and expenses		37,912	32,871		72,062	66,219	
Loss from operations		(19,555)	(22,599)		(41,745)	(48,885)	
Other expense	·	3,947	3,253		7,810	5,823	
Net loss	\$	(23,502) \$	(25,852)	\$	(49,555) \$	(54,708)	
Net loss per share of common stock, basic and diluted	\$	(0.44) \$	(0.56)	\$	(0.93) \$	(1.19)	
Weighted average common shares outstanding, basic and diluted		53,120,574	45,908,104	53	,059,492	45,907,133	

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

	June 30, 2021		December 31, 2020	
	(unaudited)			
Cash and cash equivalents	\$	93,916	\$	144,156
Other assets		45,599		44,657
Total assets	\$	139,515	\$	188,813
Total current liabilities Long-term debt, net Other liabilities Total stockholders' equity	\$	46,798 126,043 3,747 (37,073) 139,515	\$	52,172 125,202 4,651 6,788 188,813
Total liabilities and stockholders' equity	<b>3</b>	139,515	\$	188,813

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 an Optinose Exhalation Delivery System (EDS™) device 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. looking statements for this purpose and include, among others, statements relating to the potential for continued or increased XHANCE prescription and net revenue growth and potential growth drivers; the Company's plans to seek approval for a follow-on indication for XHANCE for the treatment of chronic sinusitis and the potential benefits of such indication; the expectation of top-line results from its first chronic sinusitis trial in the first quarter of 2022 and top line results from the second trial in the second quarter of 2022; projected Average net revenue per prescription for full year 2021; projected Company GAAP operating expenses and stock-based compensation for 2021; development, funding plans for OPN-019 and the potential benefits of OPN-019; 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 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; the Company's ability to maintain adequate third-party reimbursement for XHANCE (market access); market opportunities for XHANCE may be smaller than expected; the Company's ability to grow XHANCE prescriptions and net revenues; uncertainties and delays relating to the enrollment, completion, and results of clinical trials; unanticipated costs and expenses; 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 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 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 performance of XHANCE and the risks and control of the performance of XHANCE and the respectation of the performance of XHANCE and the respectation of respectations. result of new information, future developments or otherwise

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





Corporate Presentation August 11, 2021

# **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; early year effects on net revenue and prescriptions related to patient insurance; projected Company GAAP operating expenses and stock-based compensation for 2021; projected XHANCE net revenues for full year 2021; projected XHANCE net revenue per prescription for the remainder of 2021; the Company's plans to seek approval for a follow-on indication for XHANCE for the treatment of chronic sinusitis and the potential benefits of such indication; the expectation of having top-line results from one chronic sinusitis trial in the first quarter of 2022 and results from the second trial in the second quarter of 2022; our development, timing of data, and funding plans for OPN-019 and the potential benefits of OPN-019; 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; 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; market opportunities for XHANCE may be smaller than expected; uncertainties and delays relating to the initiation, enrollment, completion and results of clinical trials; unexpected costs and expenses; 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 <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 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.

optinose<sup>\*</sup>

# Key Takeaways and Q2 2021 Highlights

Cash and equivalents as

of June 30, 2021



**Q2 2021 Performance Aligned with Company Guidance** 

**Multiple Factors Support Continued Revenue Growth in 2021** 

**Enrollment Complete in First CS Trial with Data Expected in Q1 2022** 

Market Opportunity in CS is Significantly Larger than NP

+79%

XHANCE Net Revenue Growth Q2 2021/Q2 2020 +33%

XHANCE TRx Growth Q2 2021/Q2 2020 +55%

XHANCE NRx Growth Q2 2021/Q2 2020

21/Q2 2020 \$22

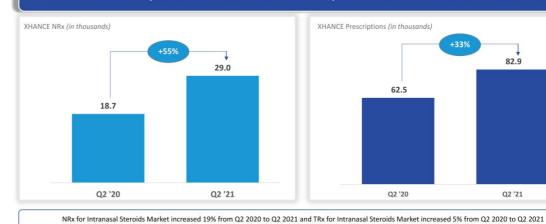
XHANCE Net Revenue per TRx in Q2 2021

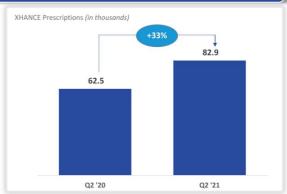
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# **XHANCE New and Total Prescriptions**

# XHANCE New Prescriptions increased 55% and Total Prescriptions increased 33% from Q2 2020 to Q2 2021

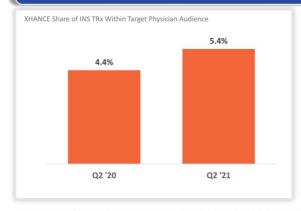


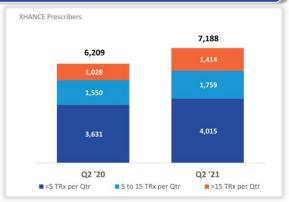




# **XHANCE Market Share & Prescribers by Prescribing Frequency**

XHANCE market share increased from 4.4% to 5.4% and HCPs who had more than 15 XHANCE prescriptions filled by their patients in a quarter increased by 38% (1,414 versus 1,028) from Q2 2020 to Q2 2021





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 18,000 physicians. Estimated based on monthly prescription data from third parties and XHANCE preferred pharmacy network.

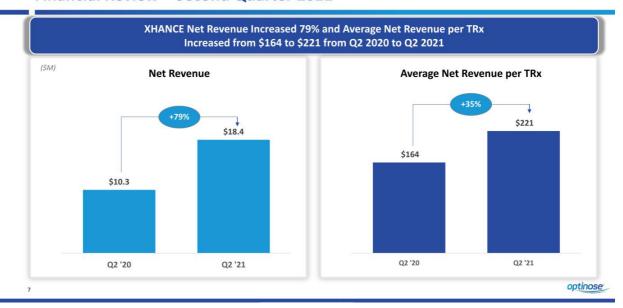
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# Financial Review - Second Quarter 2021



# **Full Year 2021 Financial Guidance**

- XHANCE Net Revenue and Average Net Revenue per Prescription
  - FY 2021 expected to be at least \$80 million
  - **FY 2021** average net revenue per prescription expected to exceed \$200
- Operating Expense (GAAP) expected to be between \$137 \$142 million
  - Approximately \$10 million of which is expected to represent stock-based compensation

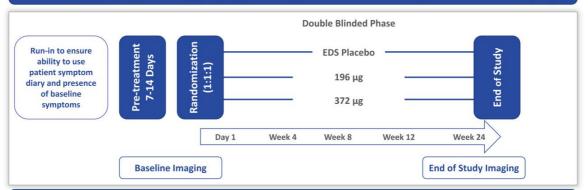
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# **Chronic Sinusitis Pivotal Study Design Summary**

Randomized, double-blind, placebo-controlled, parallel-group, multicenter studies to evaluate efficacy and safety of OPN-375 186  $\mu$ g (1 spray) and 372  $\mu$ g (2 sprays) BID in subjects with chronic sinusitis (with or without nasal polyps)



Treatment duration of 24 weeks allows characterization of objective changes that may occur more gradually with continued treatment in this chronic condition

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# **XHANCE Chronic Sinusitis Program**

- Enrollment in trial -3205 is complete
- In June we conducted a planned, blinded, interim analysis (IA) to assess variance in APOV (the CT scan co-primary endpoint) in trial -3205
  - The observed variance in the IA is less than the variance assumed for the purpose of sample size estimation during the initial design of the study
  - Given this result, and the previously reported similar result for variance in the symptom co-primary endpoint, we reduced sample size while maintaining statistical power for the final analysis
  - Final enrollment of ~330 compared to original target enrollment of 378
- We have planned to allow a similar blinded IA for trial -3206 when sufficient data, including 6-month follow up CT scan data, is available

Top-line results expected from the first trial in Q1 2022 and the second trial in Q2 2022

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# **OPN-019 Pilot Study**

- In early July we received approval from regulatory authorities in Mexico to proceed with conduct of a randomized, adaptive proof of concept single-dose study to evaluate change in viral load after use of OPN-019 by adults with COVID-19
  - Study drug was made available in Mexico before the end of July and the study is open for enrollment
  - Up to three cohorts of 10 patients are planned
  - Assessments will include reduction in viral load by qRT-PCR and in number of infectious viral particles by culture
  - Recent news concerning variants and breakthrough infections in vaccinated people suggests value for a product like OPN-019 in the evolving pandemic

Proof-of-concept clinical data is expected to support pursuit of grants, partnerships, and/or other sources of capital that will be necessary to fund future development

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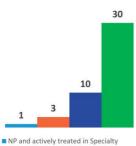
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# Successful CS Development and a Primary Care Partner Could Enable **Promotion of XHANCE to up to 30 Million Patients**





- NP+CS and actively treated in Specialty
- NP+CS and actively treated by Specialty or Primary Care
- All NP+CS Patients

- Approximately 1 Million patients with nasal polyps (NP) are treated by specialty physicians who are the current focus of our sales call plans
  - Specialty physician preference share for XHANCE is strong for these patients
- Approximately 3 Million patients with NP+CS are treated by specialty physicians who are the current focus of our sales call plans
  - Successful development in CS enables Optinose build physician preference share in a larger set of patients
- Approximately 10 Million patients with NP+CS are treated by a physician
  - Successful development in CS can enable a significant physician audience expansion for a primary care partner, allowing access to a greatly expanded pool of patients
- Approximately 30 Million patients have NP+CS, of which approximately 20 million are believed to be suffering from symptoms of CS but have stopped seeking regular care from a physician for nasal symptoms
  - Successful CS development can enable 'lapsed patient' activation by a partner (e.g., by DTC promotion of CS indication)

Source: Palmer J et al. A cross-sectional population-based survey of the prevalence, disease burden, and characteristics of the US adult population with symptoms of chronic rhinosinusitis (CRS). Poster session presented at: 62nd Annual Meeting of the American Rhinologic Society; September 16-17, 2016; San Diego, CA. Optinose Market Research. Data on file.







# Key Takeaways and Q2 2021 Highlights



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XHANCE TRx Growth Q2 2021/Q2 2020 +55%

XHANCE NRx Growth Q2 2021/Q2 2020

\$94M

Cash and equivalents as of June 30, 2021

XHANCE Net Revenue per TRx in Q2 2021

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# Investor Relations - NASDAQ: OPTN

# Analyst Coverage <sup>1</sup> BMO: Gary Nachman Cantor Fitzgerald: Brandon Folkes Cowen: Ken Cacciatore Jefferies: David Steinberg Piper Sandler: David Amsellem RBC: Daniel Busby

At 30 June 2021:

- \$94 million in cash
- Long-term debt: \$130 million
- 53.1 million common shares o/s
- 11.4 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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Corporate Presentation August 11, 2021