

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 5, 2020



**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 November 5, 2020, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2020. 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 5, 2020, 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release issued by OptiNose, Inc., dated November 5, 2020.</a>
99.2	<a href="#">OptiNose, Inc. Corporate Presentation, dated November 5, 2020.</a>

---

**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: November 5, 2020



**Optinose Reports Third Quarter 2020 Financial Results  
and Recent Operational Highlights**

*Company reports third quarter 2020 XHANCE net revenue of \$15.4 million*

*New prescriptions of XHANCE increased 23% from second quarter 2020*

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

**YARDELY, Pa., Nov. 5, 2020** 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 three and nine months ended September 30, 2020, and provided operational updates.

"New and total prescriptions for XHANCE reached an all-time quarterly high in the third quarter of 2020. We are pleased with this achievement after experiencing a challenging environment in the second quarter 2020 due to significant pandemic-related declines in patient volume in ENT and Allergy offices," stated CEO Peter Miller. "As a result of increased demand and improvement in net revenue per prescription, XHANCE net revenues were \$15.4 million. By exceeding the third quarter 2020 net revenue threshold specified in our debt facility, we open up the option to draw an additional \$20 million to add to our cash position, which would extend our cash runway and further enable us to focus on growth. Finally, we are excited by recent events that we believe meaningfully support XHANCE growth potential as we progress into 2021. These include both our co-promotion with kaléo, which first hit the field in October and grows our sales reach and frequency, and the new publication by Brent Senior, M.D., Professor of Otolaryngology and Vice Chair of Academics and Outreach at the University of North Carolina, and others that describes the value of XHANCE in the population of patients who are still symptomatic on conventional nasal steroids."

**Third Quarter 2020 and Recent Highlights**

**Total and New XHANCE Prescriptions**

The number of XHANCE® (fluticasone propionate) prescriptions increased by 61% from 43,000 in the third quarter of 2019 to 69,000 in the third quarter of 2020.

The number of new prescriptions for XHANCE increased by 23% from 18,700 in the second quarter of 2020 to 23,000 in the third quarter of 2020.

**Kaléo Co-Promotion Agreement**

In July the Company announced the signing of an agreement with kaléo, a pharmaceutical company dedicated to building innovative solutions for serious and life-threatening medical conditions, to co-promote XHANCE. Under the terms of the agreement, kaléo initiated promotion of XHANCE to an agreed-upon audience of office-based healthcare professionals on October 1st. The audience includes nearly 6,000 prescribers, about half of whom are outside of the current Optinose called-on universe of approximately 10,000 healthcare professionals.

**Peer-Reviewed Scientific Journal Publications**

In September the Company announced the publication of a peer-reviewed paper titled, "Efficacy of the exhalation delivery system with fluticasone (EDS-FLU) in patients who remain symptomatic on standard nasal steroid sprays"<sup>1</sup> in the *International Forum of Allergy & Rhinology*, the journal of the American Rhinologic Society. EDS-FLU is U.S. Food and Drug Administration (FDA) approved for the treatment of nasal polyps in patients 18 years of age or older and is marketed under the trade name XHANCE for the up to 1 in 3 patients whose chronic rhinosinusitis is complicated by nasal polyps.

**OPN-019**

In June, the Company announced the initiation of development of a new product candidate, OPN-019. OPN-019 will combine the Company's proprietary nasal Exhalation Delivery System (EDS) with an antiseptic that has been shown in third party *in vitro* studies to kill the virus that causes COVID-19.

The Company has performed *in vitro* testing against SARS-CoV-2 with a candidate antiseptic formulation in which a 4-log reduction (a 99.99% reduction) in virus count was produced. In addition, the Company is performing tests against other pathogens and expects results in November.

Because components of the drug-device combination product candidate, including both the active drug and delivery device, are currently commercially available in the U.S., the Company anticipates streamlined and accelerated development. Subsequent to a pre-Investigational New Drug (IND) submission the Company is engaged with FDA regarding an IND and clinical development pathway.

The Company is focused on supporting the initial stages of development within its current operating expense guidance and intends to seek grants, partnerships, and/or other sources of capital to fund future development.

**Third Quarter 2020 Financial Results****Net product revenues**

The Company generated \$15.4 million and \$32.8 million in net product revenues from sales of XHANCE during the three and nine months ended September 30, 2020, respectively.

**Costs and expenses and net loss**

For the three and nine months ended September 30, 2020, research and development expenses were \$6.5 million and \$16.9 million, respectively and selling, general and administrative expenses were \$24.6 million and \$77.3 million, respectively. The net loss for the three and nine months ended September 30, 2020 was \$21.2 million, or \$0.43 per share (basic and diluted) and \$75.9 million, or \$1.62 per share (basic and diluted), respectively.

**Cash and cash equivalents**

The Company had cash and cash equivalents of \$143.1 million as of September 30, 2020.

**Corporate Guidance****Operating expenses**

The Company expects total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2020 to be in the range of \$127 - \$132 million, of which the Company expects stock-based compensation to be approximately \$10 million. Previously the Company expected total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2020 to be in the range of \$131 - \$136 million, of which stock-based compensation was expected to be approximately \$11 million.

**Chronic sinusitis clinical trials**

The Company expects top-line results from both of its clinical trials evaluating XHANCE as a potential treatment for Chronic Sinusitis in the second half of 2021.

**Cash and cash equivalents**

The Company expects to draw \$20 million of cash from its debt facility by early 2021, subject to continuing to meet eligibility requirements.

**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 November 12,

2020 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID #4167801. A simultaneous webcast of the call and presentation can be accessed by visiting the Investors section of Optinose's website at [www.optinose.com](http://www.optinose.com). In addition, a replay of the webcast will be available on the Company website for 60 days following the event.

#### Investor Conferences

Chief Executive Officer Peter Miller will present at the Jefferies Virtual London Healthcare Conference on November 18, 2020, at 9:05 a.m. ET. Additionally, Mr. Miller will present at the 32nd Annual Piper Sandler Healthcare Conference on November 23, 2020, at 10:00 a.m. ET.

A live webcast will be available for each conference in the Investors section of the Optinose website. A replay will be available for 60 days following the conclusion of each event.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenues:				
Net product revenues	\$ 15,436	\$ 8,667	\$ 32,770	\$ 19,320
Licensing revenues	—	3,730	—	4,230
Total revenues	<u>15,436</u>	<u>12,397</u>	<u>32,770</u>	<u>23,550</u>
Costs and expenses:				
Cost of product sales	2,221	1,389	5,276	3,216
Research and development	6,524	5,547	16,930	15,404
Selling, general and administrative	24,575	25,270	77,332	77,610
Total costs and expenses	<u>33,320</u>	<u>32,206</u>	<u>99,538</u>	<u>96,230</u>
Loss from operations	<u>(17,884)</u>	<u>(19,809)</u>	<u>(66,768)</u>	<u>(72,680)</u>
Other expense	3,330	8,999	9,154	12,378
Net loss	<u>\$ (21,214)</u>	<u>\$ (28,808)</u>	<u>\$ (75,922)</u>	<u>\$ (85,058)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.43)</u>	<u>\$ (0.69)</u>	<u>\$ (1.62)</u>	<u>\$ (2.06)</u>
Weighted average common shares outstanding, basic and diluted	<u>48,907,514</u>	<u>41,454,181</u>	<u>46,914,561</u>	<u>41,341,570</u>

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

	<u>September 30,</u> <u>2020</u> <small>(unaudited)</small>	<u>December 31,</u> <u>2019</u>
Cash and cash equivalents	\$ 143,134	\$ 147,144
Other assets	37,890	25,506
Total assets	<u>\$ 181,024</u>	<u>\$ 172,650</u>
Total current liabilities	\$ 43,350	\$ 36,139
Long-term debt, net	105,013	74,531
Other liabilities	4,978	397
Total stockholders' equity	<u>27,683</u>	<u>61,583</u>
Total liabilities and stockholders' equity	<u>\$ 181,024</u>	<u>\$ 172,650</u>

**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](http://www.optinose.com) or follow us on Twitter and LinkedIn.

**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 impact of, our plans regarding and the uncertainty caused by the COVID-19 pandemic; the potential for continued XHANCE growth; the potential benefits of kaléo promotional activities; the potential benefits of the publication of the peer-reviewed paper titled, "Efficacy of the exhalation delivery system with fluticasone (EDS-FLU) in patients who remain symptomatic on standard nasal steroid sprays" in the *International Forum of Allergy & Rhinology*; the potential benefits of our OPN-019 product candidate; our expectation to have additional OPN-019 *in vitro* testing data in November 2020; our development and funding plans and expectations for OPN-019; our expectation that we will draw an additional \$20.0 million under the Pharmakon Note Purchase Agreement before February 15, 2021, subject to continuing to meet the eligibility requirements at the time of the draw; our plans to seek approval for a follow-on indication for XHANCE for the treatment of chronic sinusitis and the expectation of top-line results from both of our chronic sinusitis trials in second half 2021; projected Company GAAP operating expenses and stock-based compensation for 2020; 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: the extent and duration of the COVID-19 pandemic and its impact on the Company's business, results of operations and financial condition; 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 effectiveness of kaléo's sales representatives in promoting XHANCE; risks, uncertainties and delays relating to product development, the initiation, enrollment, completion and results of clinical trials and the regulatory approval process; risks that results seen in preclinical studies may not be replicated in humans; intense competition for vaccines and other therapies for COVID-19; the Company's ability to grow XHANCE prescriptions and net revenues; unanticipated costs and expenses; the Company's ability to meet the continued eligibility requirements to draw the additional \$20 million under the Pharmakon Note Purchase Agreement and otherwise comply with the covenants and other terms of the 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](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 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.

#### References

1 - Senior BA, Schlosser RJ, Bosso J, Soler ZM. Efficacy of the exhalation delivery system with fluticasone in patients who remain symptomatic on standard nasal steroid sprays. *Int Forum Allergy Rhinol.* 2020 Sept 24. doi: 10.1002/alr.22693. [Epub ahead of print]

#### Optinose Investor Contact

Jonathan Neely  
jonathan.neely@optinose.com  
267.521.0531

###

# Building a Leading ENT / Allergy Specialty Company

## Corporate Presentation

November 5, 2020

# 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: impact of, our plans regarding and the uncertainties caused by, the COVID-19 pandemic; potential for continued XHANCE growth, potential growth drivers and market opportunity; prescription, refill, prescribing frequency and market share trends; potential effects of INS market seasonality on XHANCE prescriptions; projected operating expenses and stock-based compensation for 2020; the Company's plans to seek, and the potential benefits of, a follow-on indication for XHANCE for chronic sinusitis; the expectation of top line results from both CS trials in second half 2021; the expectation to draw additional \$20M from debt facility by end of 2021; the potential benefits of promotional activities by kaléo; the Company's development plans and objectives for OPN-019, the potential benefits of OPN-019 and the Company's intention to fund initial development of OPN-019 within its current operating expense plan and to seek grants, partnerships and/or other sources of capital to fund future development; 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: the extent and duration of the impact of the COVID-19 pandemic on the Company's business, results of operations and financial condition; 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, net revenues, market share and prescriber breadth and depth; market opportunities for XHANCE may be smaller than expected; the effectiveness of kaléo's sales representatives in promoting XHANCE; uncertainties and delays relating to product development, the initiation, enrollment, completion and results of clinical trials and regulatory approval process; unexpected costs and expenses; the ability to satisfy the conditions for additional funds under the Pharmakon note purchase agreement and ability to comply with the covenants and other terms of the 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.

# Key Takeaways and Q3 2020 Highlights



Largest Number of XHANCE New Prescriptions Since Launch

Successful Launch of kaléo Co-Promotion on October 1<sup>st</sup>

Lowering Full Year 2020 Operating Expense Guidance

Substantial Headroom for Future XHANCE Growth

XHANCE Revenue Exceeded Threshold for \$20 Million Draw

**+78%**

XHANCE Net Revenue  
Growth  
Q3 2020/Q3 2019

**\$224**

XHANCE Net Revenue  
per TRx  
in Q3 2020

**\$143M**

Cash and equiva  
as of  
September 30, 2020

**+61%**

XHANCE TRx  
Growth Q3 2020 / Q3  
2019

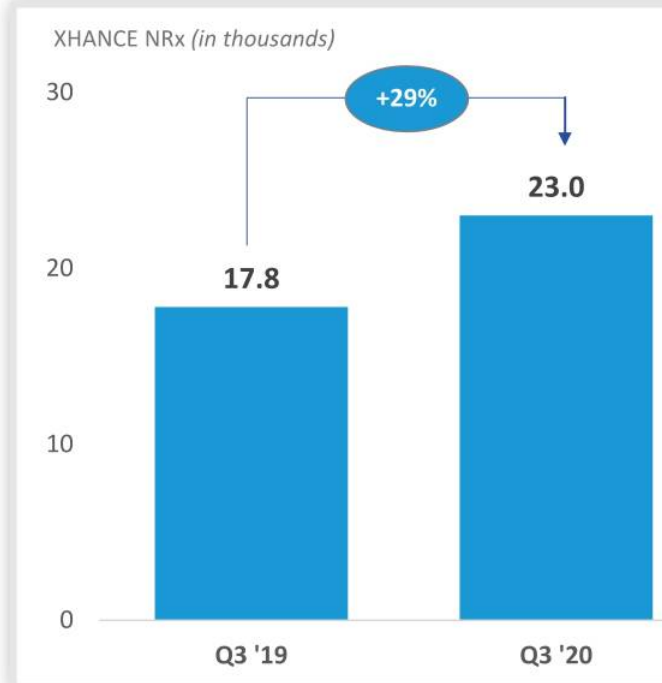
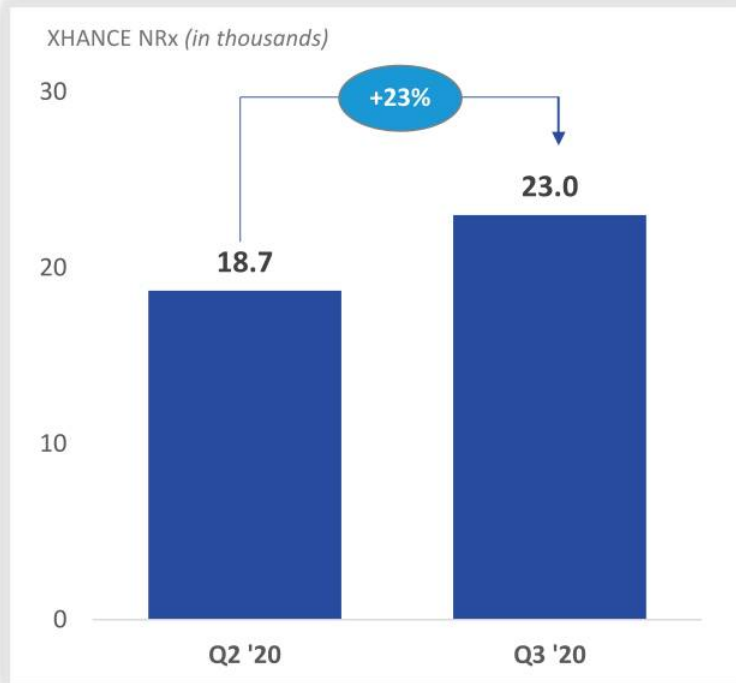
**5.7%**

Q3 2020 market share  
an increase of 2.7%  
compared to Q3 2019

# XHANCE Launch Update

# Q3 2020 XHANCE New Prescriptions

New prescriptions of XHANCE increased 23% in Q3 2020 compared to Q2 2020 and increased 29% in Q3 2020 compared to Q3 2019

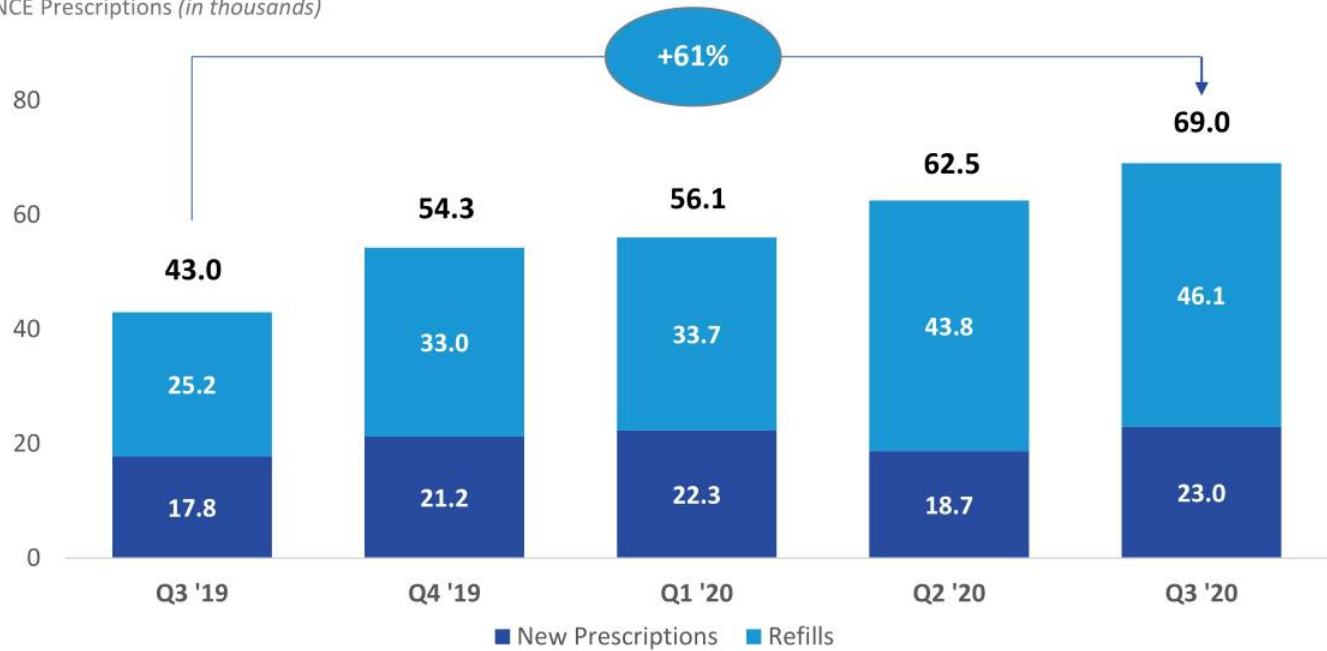


NRx for Intranasal Steroids Market decreased 5% from Q2 2020 to Q3 2020, and decreased 12% from Q3 2019 to Q3 2020

# XHANCE Prescription Trends

Prescriptions of XHANCE increased 61% in Q3 2020 compared to Q3 2019

XHANCE Prescriptions (in thousands)

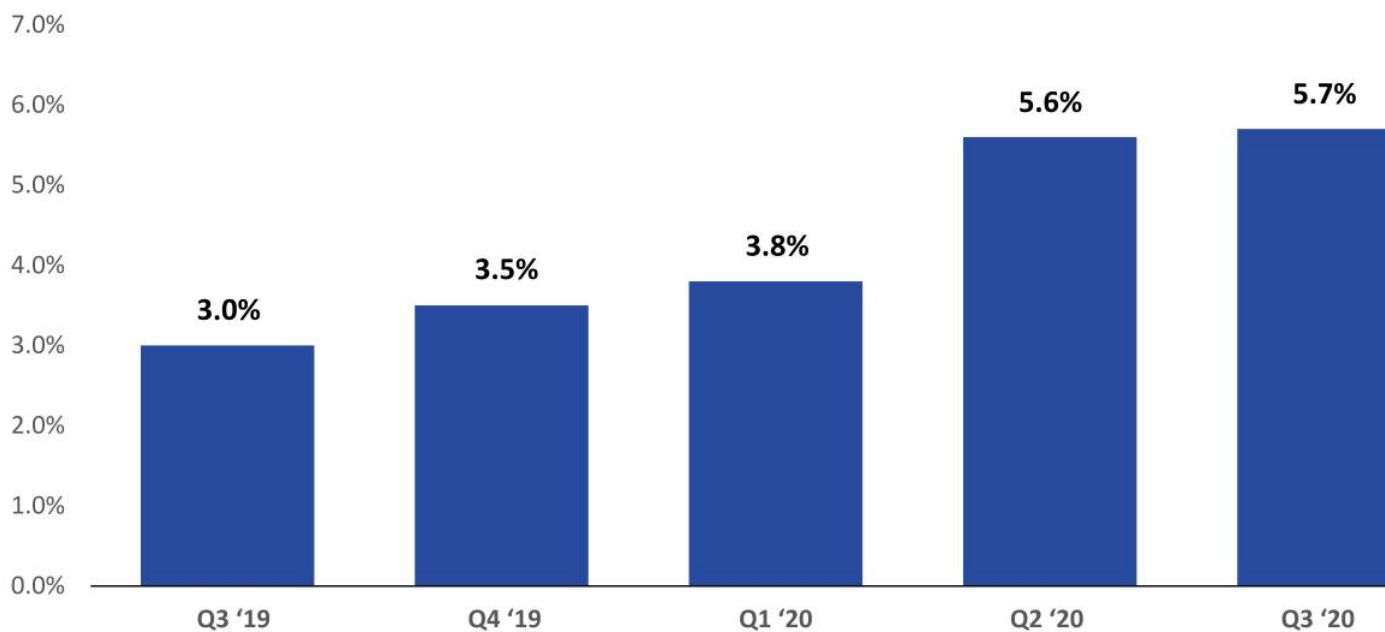


TRx for Intranasal Steroids Market decreased 6% from Q2 2020 to Q3 2020, and decreased 7% from Q3 2019 to Q3 2020

## XHANCE Share of INS Prescriptions Within the Target Physician Audience Increased in Q3 2020 and a Large Opportunity Remains

Market share within the XHANCE target physician audience of 5.7% in Q3 2020  
an increase of 2.7% compared to 3.0% share in Q3 2019

XHANCE Share of INS TRx Within Target Physician Audience



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 10,000 physicians.

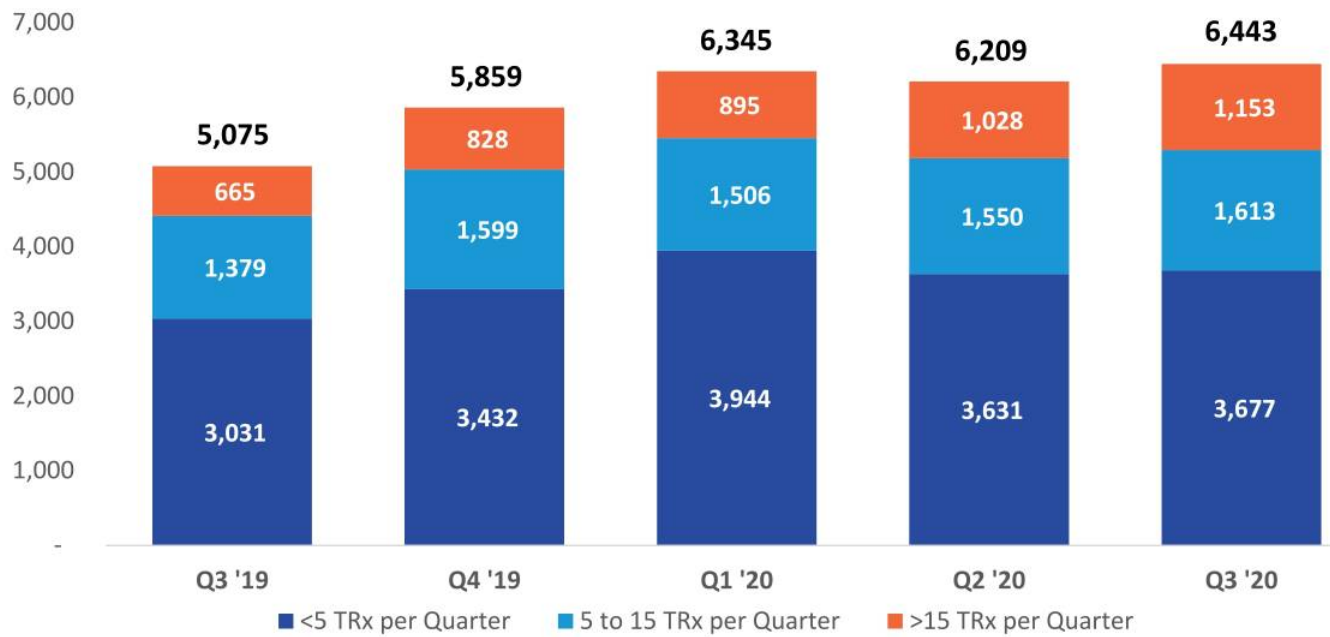
7 Estimated based on monthly prescription data from public source and XHANCE preferred pharmacy network.



## Number of XHANCE Prescribers by Prescribing Frequency

Physicians who had more than 15 XHANCE prescriptions filled by their patients in a quarter increased by 73% from Q3 2019 to Q3 2020 (1,153 versus 665)

XHANCE Prescribers

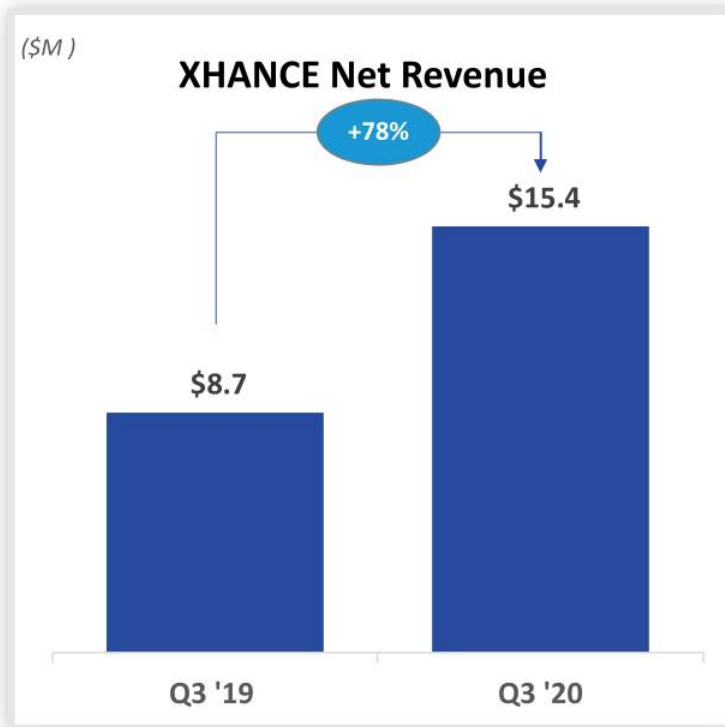


Estimated based on monthly prescription data from public source and XHANCE preferred pharmacy network.

# Q3 2020 Financial Update

# Financial Review – Third Quarter 2020

Q3 2020 XHANCE Net Revenue Increased 78% Compared to Q3 2019



## XHANCE Average Net Revenue per TRx

- \$224 in third quarter 2020
  - Increase compared to \$164 in Q2 2020
- \$175 for the nine months end September 30, 2020

# Updated Corporate Guidance

---

- **Operating Expense (GAAP)**
  - Expected to be between \$127 – \$132 million; approximately \$10 million of which represents stock-based compensation
  - Prior guidance range of \$131 - \$136 million; approximately \$11 million of which was stock-based compensation
  
- **Chronic Sinusitis Clinical Trials**
  - Expect top-line results from both trials evaluating XHANCE as a potential treatment for Chronic Sinusitis in the second half of 2021
  
- **Cash and Cash Equivalents**
  - Company qualified to draw \$20 million of cash from debt facility as a result of Q3 2020 XHANCE net revenues > \$14.5M
    - Company expects to draw the \$20 million by early 2021 (subject to meeting continued eligibility requirements)
  - A final \$20 million from the debt facility is available subject to achieving XHANCE net revenues of at least \$26.0 million in Q2 2021

# Closing Remarks

# Key Takeaways and Q3 2020 Highlights



Largest Number of XHANCE New Prescriptions Since Launch

Successful Launch of kaléo Co-Promotion on October 1<sup>st</sup>

Lowering Full Year 2020 Operating Expense Guidance

Substantial Headroom for Future XHANCE Growth

XHANCE Revenue Exceeded Threshold for \$20 Million Draw

**+78%**

XHANCE Net Revenue  
Growth  
Q3 2020/Q3 2019

**\$224**

XHANCE Net Revenue  
per TRx  
in Q3 2020

**\$143M**

Cash and equiva  
as of  
September 30, 2020

**+61%**

XHANCE TRx  
Growth Q3 2020 / Q3  
2019

**5.7%**

Q3 2020 market share  
an increase of 2.7%  
compared to Q3 2019

# 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: Randall Stanicky

### At 30 September 2020:

- \$143 million in cash
- Long-term debt: \$110 million
- 52.1 million common shares o/s

### At 5 November 2020:

- 10.5 million options, RSUs & warrants c

### Optinose Investor Contact

Jonathan Neely, VP, Investor Relations and  
Business Operations  
267-521-0531



[investors@optinose.com](mailto:investors@optinose.com)



[www.optinose.com](http://www.optinose.com)



[@optinose](https://twitter.com/optinose)

<sup>1</sup> - Optinose is followed by the analysts listed above. Please note that any opinions, estimates or forecasts regarding the Company's performance made by the 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 of this information imply its endorsement of or concurrence with such information, conclusions or recommendations.

# Building a Leading ENT / Allergy Specialty Company

## Corporate Presentation

November 5, 2020



