

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 4, 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 August 4, 2020, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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 August 4, 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	Press Release issued by OptiNose, Inc., dated August 4, 2020.
99.2	OptiNose, Inc. Corporate Presentation, dated August 4, 2020.

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 4, 2020



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

Company reports second quarter 2020 XHANCE net revenue of \$10.3 million

Second quarter 2020 XHANCE prescriptions increased 84% from second quarter 2019

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

YARDLEY, Pa., August 4, 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 quarter ended June 30, 2020, and provided operational updates.

"XHANCE prescription volume continued to grow in the second quarter, which was impressive given the major disruptions to patient volumes and care pathways within ENT and allergy physician practices," stated CEO Peter Miller. "XHANCE had exceptionally strong market share growth, demonstrating remarkable resilience, as we successfully adapted our business to the COVID-19 environment. We are excited by the potential for XHANCE to continue to grow and recently announced a co-promotion with kaléo that will amplify our effort. We look forward to a strong partnership that we believe can have meaningful impact."

Second Quarter 2020 and Recent Highlights

XHANCE Prescriptions

The number of XHANCE® (fluticasone propionate) prescriptions increased by 84% from second quarter 2019 to second quarter 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 will promote XHANCE to an agreed-upon audience of office-based healthcare professionals, which is expected to increase promotional reach and frequency starting by the fourth quarter of 2020. 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.

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) technology with an antiseptic that has been recently shown in third party *in vitro* studies to kill the virus that causes COVID-19. 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 expects to be able to rapidly progress to a meeting with FDA to discuss an IND and then onward to clinical trials. The Company is focused on supporting the initial stages of development within its current operating expense plan and intends to seek grants, partnerships, and/or other sources of capital to fund future development.

Peer-Reviewed Scientific Journal Publications

Pooled analysis of the Company's NAVIGATE I and II phase 3 clinical trials highlighting improvement in quality of life and health status measures were published in the International Forum of Allergy & Rhinology¹.

In addition, results from VIZUALIZE, a study using nasal endoscopy video to evaluate the efficacy and safety of XHANCE twice daily in adults with bilateral nasal polyps were published in Rhinology², the official journal of the International Rhinologic Society.

Second Quarter 2020 Financial Results

Net product revenues

The Company generated \$10.3 million and \$17.3 million in net product revenues from sales of XHANCE during 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, 2020, research and development expenses were \$5.5 million and \$10.4 million, respectively and selling, general and administrative expenses were \$25.7 million and \$52.8 million, respectively. The net loss for the three and six months ended June 30, 2020 was \$25.9 million, or \$0.56 per share (basic and diluted) and \$54.7 million, or \$1.19 per share (basic and diluted), respectively.

Cash

The Company had cash and cash equivalents of \$125.3 million as of June 30, 2020.

Corporate Guidance

XHANCE Net Revenue per Prescription

The Company expects XHANCE average net revenue per prescription to improve through the remainder of 2020.

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 \$131 - \$136 million, of which the Company expects stock-based compensation 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.

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 August 11, 2020 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID # 2298719. 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		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
Revenues:				
Net product revenues	\$ 10,272	\$ 6,677	\$ 17,334	\$ 10,653
Licensing revenues	—	—	—	500
Total revenues	<u>10,272</u>	<u>6,677</u>	<u>17,334</u>	<u>11,153</u>
Costs and expenses:				
Cost of product sales	1,700	1,089	3,056	1,827
Research and development	5,474	5,295	10,406	9,857
Selling, general and administrative	25,697	26,000	52,757	52,340
Total costs and expenses	<u>32,871</u>	<u>32,384</u>	<u>66,219</u>	<u>64,024</u>
Loss from operations	<u>(22,599)</u>	<u>(25,707)</u>	<u>(48,885)</u>	<u>(52,871)</u>
Other expense	3,253	1,670	5,823	3,380
Net loss	<u>\$ (25,852)</u>	<u>\$ (27,377)</u>	<u>\$ (54,708)</u>	<u>\$ (56,251)</u>
Net loss per share of common stock, basic and diluted	<u>\$ (0.56)</u>	<u>\$ (0.66)</u>	<u>\$ (1.19)</u>	<u>\$ (1.36)</u>
Weighted average common shares outstanding, basic and diluted	<u>45,908,104</u>	<u>41,310,068</u>	<u>45,907,133</u>	<u>41,283,478</u>

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

	June 30,	December 31,
	2020 (unaudited)	2019
Cash and cash equivalents	\$ 125,266	\$ 147,144
Other assets	27,782	25,506
Total assets	<u>\$ 153,048</u>	<u>\$ 172,650</u>
Total current liabilities	\$ 34,898	\$ 36,139
Long-term debt, net	104,947	74,531
Other liabilities	594	397
Total stockholders' equity	<u>12,609</u>	<u>61,583</u>
Total liabilities and stockholders' equity	<u>\$ 153,048</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., the U.K. and Norway. To learn more, please visit 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 expected commencement of promotional activities by kaléo by the fourth quarter of 2020 and the potential benefits of those activities; 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; the Company's 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 its chronic sinusitis trials in second half 2021; expectation that XHANCE average net revenue per prescription will improve through the remainder of 2020; 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 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.

References

1 - Soler ZM, Colman S, Velez FF, Schlosser RJ. Exhalation delivery system with fluticasone improves quality of life and health status: pooled analysis of phase 3 trials NAVIGATE I and II, International Forum of Allergy & Rhinology, DOI: 10.1002/air.22573.

2 - Yao WC, Ramakrishnan VR, Luona AU, Citardi MJ. VISUALIZE: a 24-week, open-label study using nasal endoscopy video to evaluate the efficacy and safety of EDS-FLU 186 µg twice daily in adults with bilateral nasal polyps, Rhinology online, 3, Vol 3: 58-66.

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 4, 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; expectation that XHANCE net revenue per prescription will improve for the remainder of 2020; the Company's plans to seek, and the potential benefits of, a follow-on indication for XHANCE for chronic sinusitis (CS); the expectation of top line results from both CS trials in second half 2021; the expectation that existing cash plus funds that may be available under the Pharmakon note purchase agreement will be sufficient to fund operations until top line data from at least one CS trial; the commencement and potential benefits of promotional activities by kaleo; 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 kaleo'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

2 update such forward-looking statements, whether as a result of new information, future developments or otherwise.



Key Takeaways and Q2 2020 Highlights



Resilient XHANCE Performance in COVID-19 Environment

New Kaléo Co-Promotion to Strengthen Commercial Efforts

Substantial Headroom for Future XHANCE Growth

Maintaining Financial Guidance and Clinical Trial Timing

Strong Balance Sheet and Prudent Expense Management

5.6%

Q2 2020 market share
an increase of 1.8%
compared to Q1 2020

+54%

XHANCE Net
Revenue Growth
Q2 2020/Q2 2019

+84%

XHANCE TRx
Growth Q2 2020 /
Q2 2019

\$164

XHANCE Net
Revenue per TRx
in Q2 2020

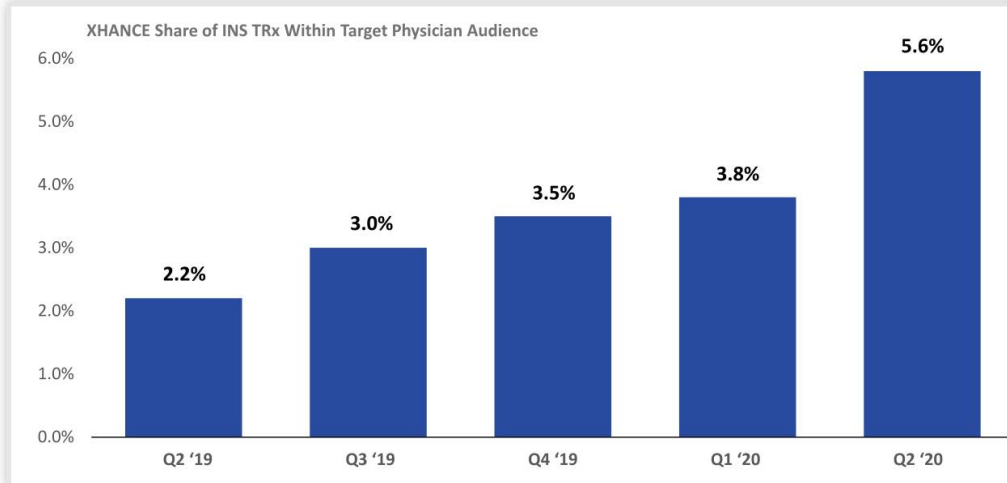
\$125M

Cash and equivalents
as of June 30, 2020

XHANCE Launch Update

XHANCE Share of INS Prescriptions Within the Target Physician Audience Increased Dramatically in Q2 2020 and a Large Opportunity Remains

Market share within the XHANCE target physician audience of 5.6% in Q2 2020 an increase of more than 2.5 times compared to Q2 2019 share of 2.2%

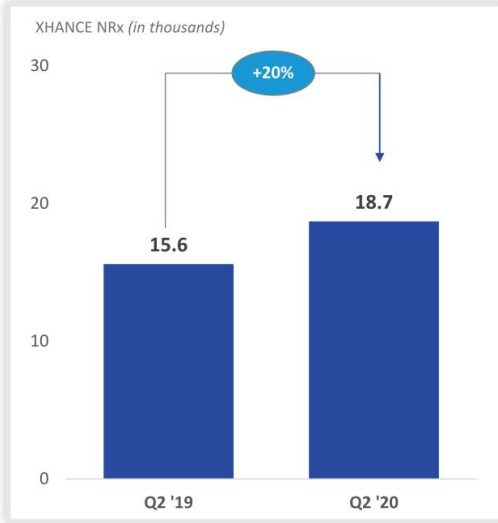


The Market on this slide is defined as the sum of all intranasal steroid prescriptions written by physicians in the XHANCE target physician audience of approximately 10,000 physicians.

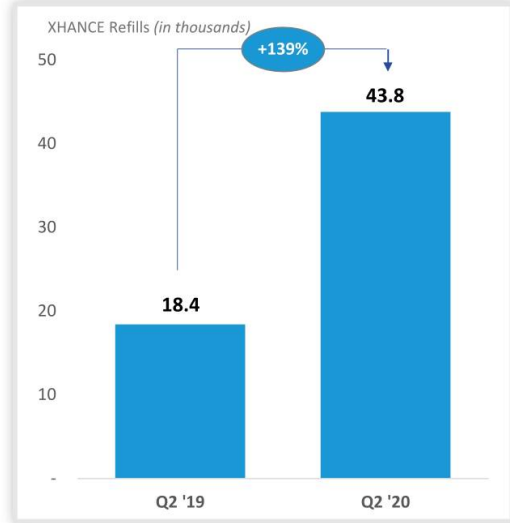
5 Estimated based on monthly prescription data from public source and XHANCE preferred pharmacy network.

Q2 2020 XHANCE New and Refill Prescriptions

New prescriptions of XHANCE increased 20% in Q2 2020 compared to Q2 2019

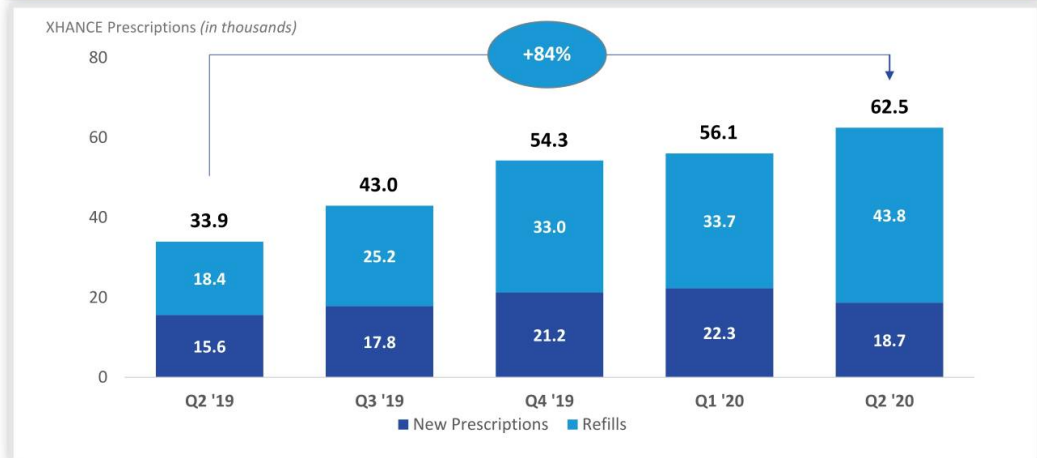


Refill prescriptions of XHANCE increased 139% in Q2 2020 compared to Q2 2019



XHANCE Prescription Trends

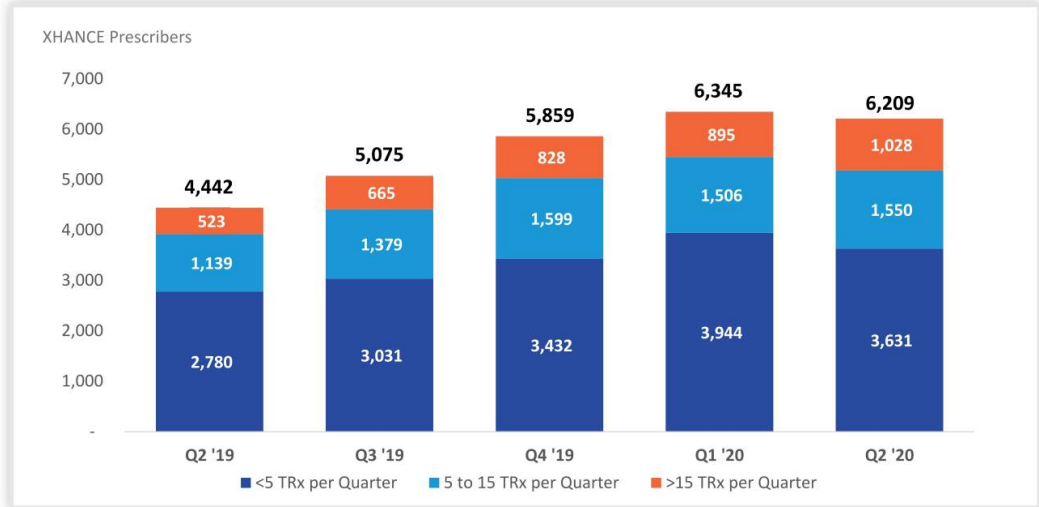
Prescriptions of XHANCE increased 84% in Q2 2020 compared to Q2 2019



TRx for Intranasal Steroids Market decreased 12% from Q2 2019 to Q2 2020, and decreased 16% from Q1 2020 to Q2 2020
NRx for Intranasal Steroids Market decreased 25% from Q2 2019 to Q2 2020, and decreased 30% from Q1 2020 to Q2 2020

Number of XHANCE Prescribers by Prescribing Frequency

Physicians who had more than 15 XHANCE prescriptions filled by their patients in a quarter increased by 97% from Q2 2019 to Q2 2020 (1,028 versus 523)

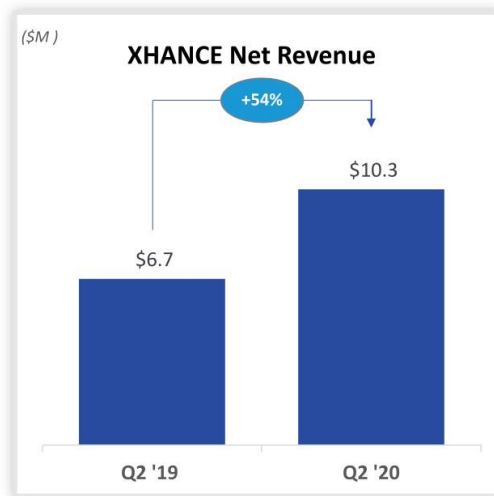


Estimated based on monthly prescription data from public source and XHANCE preferred pharmacy network.

Q2 2020 Financial Update

Financial Review – Second Quarter 2020

Q2 2020 XHANCE Net Revenue Increased 54% Compared to Q2 2019



XHANCE Average Net Revenue per TRx

- \$164 in Q2 2020
 - Increase compared to \$126 in Q1 2020

Corporate Guidance

- **XHANCE Average Net Revenue per TRx**
 - XHANCE Average Net Revenue per Prescription expected to improve for the remainder of 2020
- **Operating Expense (GAAP) expected to be between \$131 – \$136 million**
 - Approximately \$11 million of which represents 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

Closing Remarks

Key Takeaways and Q2 2020 Highlights



Resilient XHANCE Performance in COVID-19 Environment

New Kaléo Co-Promotion to Strengthen Commercial Efforts

Substantial Headroom for Future XHANCE Growth

Maintaining Financial Guidance and Clinical Trial Timing

Strong Balance Sheet and Prudent Expense Management

5.6%

Q2 2020 market share
an increase of 1.8%
compared to Q1 2020

+54%

XHANCE Net
Revenue Growth
Q2 2020/Q2 2019

+84%

XHANCE TRx
Growth Q2 2020 /
Q2 2019

\$164

XHANCE Net
Revenue per TRx
in Q2 2020

\$125M

Cash and equivalents
as of June 30, 2020

Investor Relations – NASDAQ: OPTN

Analyst Coverage ¹

BMO: Gary Nachman

Cantor Fitzgerald: Brandon Folkes

Cowen: Ken Cacciatore

Jefferies: David Steinberg

Piper Sandler: David Amsellem

RBC: Randall Stanicky

At 30 June 2020:

- **\$125 million** in cash
- Long-term debt: **\$110 million**
- **45.9 million** common shares o/s
- **12.3 million** options, RSUs & warrants o/s

Optinose Investor Contact

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



investors@optinose.com



www.optinose.com



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

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 4, 2020

The logo for Optinose, featuring the word "optinose" in a blue, lowercase, sans-serif font with a thin blue swoosh underneath.

