

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 14, 2018



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.

Item 2.02 Results of Operations and Financial Condition.

On August 14, 2018, OptiNose, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2018. 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 14, 2018, 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 14, 2018.
99.2	OptiNose, Inc. Corporate Presentation, dated August 14, 2018.

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 14, 2018



**Optinose Reports Second Quarter 2018 Financial Results
and Recent Operational Highlights**

Company reports second quarter net product sales of \$1.3 million and that more than 2,600 physicians have prescribed XHANCE since launch

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

YARDLEY, Pa., Aug. 14, 2018 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, 2018, and provided recent operational highlights.

"We are making progress as a company and continue to believe that XHANCE is an importantly differentiated product that offers significant commercial opportunity," commented CEO Peter Miller. "We are pleased with the growing body of feedback we are receiving from physicians who have prescribed XHANCE and from patients who have used the product. Improving the lives of patients is at the heart of our mission, so we are particularly happy to report that approximately 80 percent of patients who responded to a survey as part of our innovative Xperience program reported symptom relief after their first prescription for XHANCE. In addition, we are preparing to start trials to develop XHANCE as a treatment for chronic sinusitis, an indication for which there are no FDA approved products. We continue to believe that all of our efforts will lead to XHANCE becoming an integral part of the treatment landscape for CRS patients."

Second Quarter and Recent Highlights

Commercial Update

Through July 27, 2018 more than 2,600 unique physicians have prescribed XHANCE[®] and approximately 12,000 prescriptions have been written by physicians for patients.

As planned, Optinose closed its early launch program, the XHANCE Xperience program, to new enrollments at the end of June 2018. The Company believes this program accelerated the ability of physicians to acquire positive patient treatment experiences and therefore has the potential to improve demand for XHANCE during the early phases of product launch. Following the end of the Xperience program Optinose introduced a new patient support program in order to encourage further patient trial and adoption of XHANCE.

Based on currently available third party data and our internal analyses, the Company estimates that approximately 76 percent of commercially insured lives are in a plan in which XHANCE is covered in a Tier 3 formulary position.

Publication of Pivotal Efficacy and Long-Term Safety Data for XHANCE

In June 2018, the Company announced that results of the Phase 3 NAVIGATE II trial and the EXHANCE-12 trial were published in peer-reviewed journals: the Journal of Allergy and Clinical Immunology¹ and the International Forum of Allergy & Rhinology², respectively.

NAVIGATE II and EXHANCE-12 were part of a comprehensive development program consisting of five clinical trials evaluating XHANCE in over 1,500 adult patients; including two randomized, double-blinded, placebo-controlled Phase 3 pivotal clinical trials in adults with nasal polyposis and two supportive open-label Phase 3 clinical trials of up to one-year duration in adults with symptoms of chronic sinusitis with or without nasal polyps. Based upon the results of this program, the U.S. Food & Drug Administration (FDA) approved XHANCE for the treatment of nasal polyps in patients 18 years of age and older in September 2017.

XHANCE Development Update

In addition to XHANCE's existing indication for nasal polyps, we plan to initiate a clinical program to seek a supplemental indication for the treatment of chronic sinusitis in the U.S. in order to broaden our market opportunity. In June 2018,

the Company met with the FDA to discuss key elements of its draft clinical trial protocols and expects to initiate the clinical program in the fourth quarter of 2018.

Public Offering

In June 2018, the Company completed an underwritten public offering of 5,750,000 of its common shares at a price to the public of \$22.25 per common share, including 750,000 common shares sold pursuant to the underwriters' exercise in full of their option to purchase additional common shares. The offering consisted of 2,875,000 shares sold by Optinose and 2,875,000 shares sold by certain selling stockholders, resulting in aggregate net proceeds of approximately \$59.9 million to Optinose after deducting discounts, commissions and offering expenses. Optinose did not receive any proceeds from the sale of shares by the selling stockholders.

Second Quarter 2018 Financial Results

Revenue

The Company generated \$1.3 million in net revenue through the sales of XHANCE in the three-month period ended June 30, 2018. Revenue for the three months ended June 30, 2018 was primarily generated through the Xperience program.

Operating expenses and net loss

For the three-month period ended June 30, 2018, research and development expenses were \$2.0 million and selling, general and administrative expenses totaled \$21.9 million. Net loss for the period was \$24.6 million, or \$0.64 per share.

Cash

The Company had cash and cash equivalents of \$245.0 million as of June 30, 2018.

Corporate Guidance

Research and development

The Company expects to initiate a clinical program in pursuit of an additional indication for XHANCE for the "treatment of chronic sinusitis" in the fourth quarter of 2018.

Operating Expenses

The Company now believes that total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2018 will be in the range of \$117 - \$121 million (previous estimate of \$119 - \$125 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.

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 21, 2018 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID # 8192205. 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,	
	2018	2017	2018	2017
Net product revenues	\$ 1,274	\$ —	\$ 2,139	\$ —
Cost of product sales	351	—	551	—
Gross margin	923	—	1,588	—
Operating expenses:				
Research and development	2,046	4,749	3,747	8,979
Selling, general and administrative	21,860	3,588	49,871	6,661
Total operating expenses	23,906	8,337	53,618	15,640
Loss from operations	(22,983)	(8,337)	(52,030)	(15,640)
Other (income) expense:	1,598	(129)	3,124	643
Net loss	\$ (24,581)	\$ (8,208)	\$ (55,154)	\$ (16,283)
Deemed dividend	—	4,083	—	7,150
Accretion to redemption value	—	546	—	1,074
Net loss attributable to common stockholders	\$ (24,581)	\$ (12,837)	\$ (55,154)	\$ (24,507)
Net loss per share of common stock				
basic	\$ (0.64)	\$ (3.16)	\$ (1.44)	\$ (6.02)
diluted	\$ (0.64)	\$ (3.16)	\$ (1.44)	\$ (6.02)
Weighted average common shares outstanding				
basic	38,688,366	4,067,717	38,271,101	4,067,717
diluted	38,688,366	4,067,717	38,271,101	4,067,717

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

	June 30,	December 31,
	2018	2017
	(Unaudited)	
Cash and cash equivalents	\$ 244,990	\$ 234,854
Other assets	14,960	6,282
Total assets	\$ 259,950	\$ 241,136
Total current liabilities	\$ 23,213	\$ 14,777
Long-term debt, net	72,138	71,863
Other liabilities	267	—
Total stockholders' equity	164,332	154,496
Total liabilities and stockholders' equity	\$ 259,950	\$ 241,136

About Optinose

Optinose is a global 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 initiation and timing of a clinical program of XHANCE for chronic sinusitis; projected Company operating expenses for 2018; the potential benefits of XHANCE, the Xperience program and the Company's other patient support programs; 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 Company's ability to successfully commercialize XHANCE; physician and patient acceptance of XHANCE; the Company's ability to obtain adequate third-party reimbursement for XHANCE (market access); the Company's ability to successfully commercialize XHANCE without the support provided by the Xperience program and other patient support programs; market opportunities for XHANCE may be smaller than expected; uncertainties and delays relating to the initiation, enrollment and completion of clinical trials; unanticipated costs; and the risks, uncertainties and other factors discussed under the caption "Item 1A. Risk Factors" and elsewhere in our 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 we undertake no obligation to update such forward-looking statements, whether as a result of new information, future developments or otherwise.

References

1 - Leopold DA, Elkayam D, Messina JC, Kosik-Gonzalez C, Djupesland PG, Mahmoud RA. NAVIGATE II: randomized, double-blind trial of the exhalation delivery system with fluticasone (EDS-FLU) for nasal polyposis, *Journal of Allergy and Clinical Immunology* (2018), doi:10.1016/j.jaci.2018.06.010.

2 - Palmer JN, Jacobsen KW, Messina JC, Kosik-Gonzalez C, Djupesland PG, Mahmoud RA. EXHANCE-12: 1-Year Study of the exhalation delivery system with fluticasone (EDS-FLU) in chronic rhinosinusitis. *Int Forum Allergy Rhinol.* 2018;00:1-8.

Optinose Investor Contact

Jonathan Neely
jonathan.neely@optinose.com
267.521.0531

Optinose Media Contact

Kate Traynor, Sloane & Company
ktraynor@sloanepr.com
212.446.1871

A blue-tinted photograph showing the silhouette of a person's head and shoulders on the left, holding a string of several lightbulbs. The lightbulbs are of various sizes and are scattered across the frame, some appearing to float. The background is a solid blue color.

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

Corporate Presentation

August 14, 2018

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 benefits of XHANCE®, the Xperience program and other patient support programs; market access objectives; potential effects of INS market seasonality and XHANCE sampling on XHANCE prescriptions, market opportunities; commercial strategies; the initiation and timing of clinical trials for chronic sinusitis; projected operating expenses and other statements regarding our 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: physician and patient acceptance of XHANCE; our ability to obtain adequate third-party reimbursement for XHANCE (market access); our ability to successfully commercialize XHANCE without the support provided by the Xperience program; uncertainties and delays relating to the initiation, completion and results of clinical trials; market opportunities for XHANCE may be smaller than we believe; 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.

This presentation and our accompanying remarks also contain estimates, projections, market research and other data generated by independent third parties and by us concerning our industry, XHANCE, brand awareness, market access, the estimated size of markets, the prevalence of certain medical conditions and the perceptions and preferences of patients and physicians. Information that is based on estimates, projections, market research or similar methodologies is inherently subject to uncertainties and actual events and circumstances may differ materially from events and circumstances reflected in this information. You are cautioned not to give undue weight to such information.

Recent Key Accomplishments



Executed contracts with two of the largest PBMs in the US



Publication of NAVIGATE II and EXHANCE-12 studies in Peer-Reviewed Journals

Physician Adoption in ENT / Allergy



Completed successful \$60M public offering in June 2018



CS trial design reviewed in meeting with FDA

OPTINOSE® and XHANCE® are trademarks of OptiNose AS in the United States. All other trademarks appearing in this document are the property of their respective owners. OptiNose do not intend its use or display of other companies' trademarks to imply a relationship with, or endorsement or sponsorship of OptiNose by, any other companies.



High Awareness Generated Rapid Trials of XHANCE

	Pre-Launch (1Q 2018)			Early Launch (2Q 2018)		
	Jan	Feb	Mar	Apr	May	Jun
DIGITAL, SOCIAL AND NON-PERSONAL PROMOTION 	 Corporate Campaign					
CLINICAL NURSE EDUCATORS 						
OPTINOSE SALES FORCE 						

Encouraging Feedback From Xperience Patient Survey

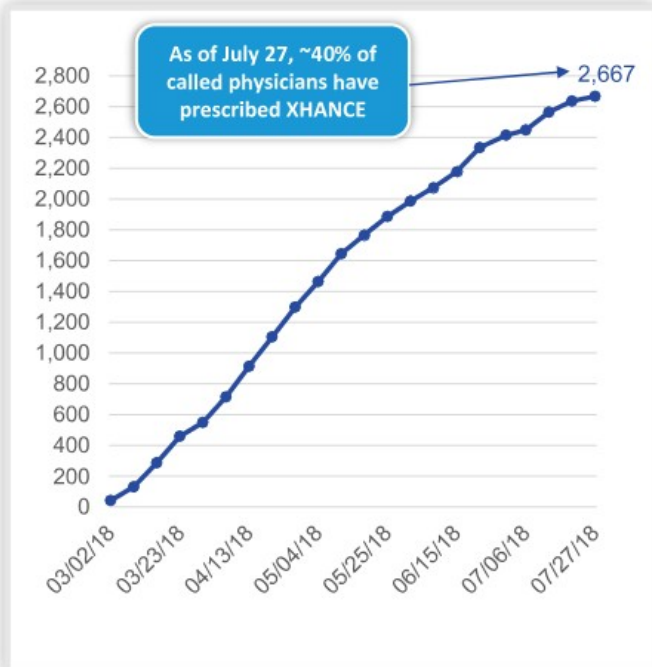
Patient Responses Prior to Month 2 Refill

	Total Respondents (N=2,733)	Prior User of Flonase / Nasonex (n=820)	Prior User Budesonide Rinse (N=175)
Patient Satisfaction	89%	90%	90%
Experience Symptom Improvement	80%	79%	68%
Prefer XHANCE	77%	82%	83%
Recommend XHANCE to a Friend	92%	91%	87%
Use without Difficulty	95%	95%	94%

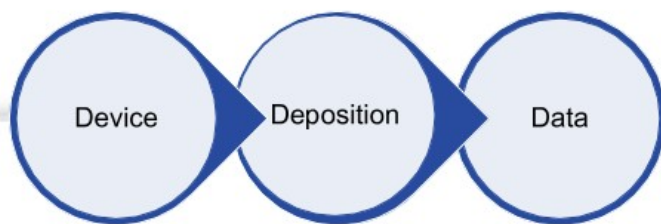
5 Note: in the same period that the 2,733 responses were received 402 patients declined the opportunity to respond to the survey to receive a second prescription for a \$0 co-pay.

Early XHANCE Launch Accelerated by CNEs/Xperience (Week ending July 27, 2018)

Cumulative Physician Trialists



Source: cumulative physician trialists based on mail order pharmacy data under Xperience program and available retail data.



- 94% brand / device awareness among ENT and Allergists
- Market research suggests that ENTs and Allergists now believe that XHANCE performs better than other inhaled nasal steroid sprays in producing high and deep deposition of medication in the nose
- Publication and distribution of clinical trials (NAVIGATE-2 and EXHANCE-12) coupled with growing clinical experience is beginning to positively differentiate the XHANCE efficacy profile

Examples of Positive XHANCE Physician Feedback *



"I have a patient who has been advised for years that he had to have surgery. After treatment with XHANCE, he went to see his ENT and he was told he did not need surgery anymore." - Allergist

"I had a severe patient and my goal was for the patient's polyps and symptoms to not get any worse. Not only are they not getting worse, he is improving. This patient could be the 'face' of Xhance!" - ENT

"I prescribed XHANCE for a patient three weeks prior to their scheduled surgery. Due to the patient's vacation, I pushed the surgery out another two weeks. When I went in to do the surgery, the polyps were 80% gone. I could not believe it." - ENT

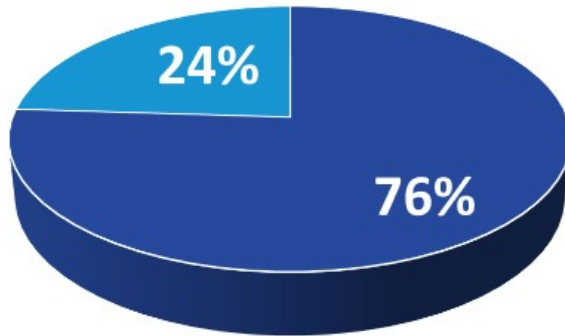
*Testimonials are individual experiences, reflecting real life experience of those who have reported using XHANCE. However, they are individual results and results do vary. We do not claim that they are typical results that users will generally achieve.

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optinose

XHANCE Commercial Market Access

XHANCE Overall Access: July 2018



Access Key

-  NDC Blocked / Not Covered
-  Covered (Single step edit, double step edit, PA or better)

- Nationally, we believe **76% of commercial lives** are currently in a plan where XHANCE is covered.
- We continue to focus on access with **minimized hassle** for prescribers and patients.
- We are working towards achieving “limited hassle” access to XHANCE for **75% of commercial lives** by year end 2018.

Source: Third party syndicated data and internal analyses as of July 2018. Coverage is subject to change.

Key Observations From the Initial Months of Launch

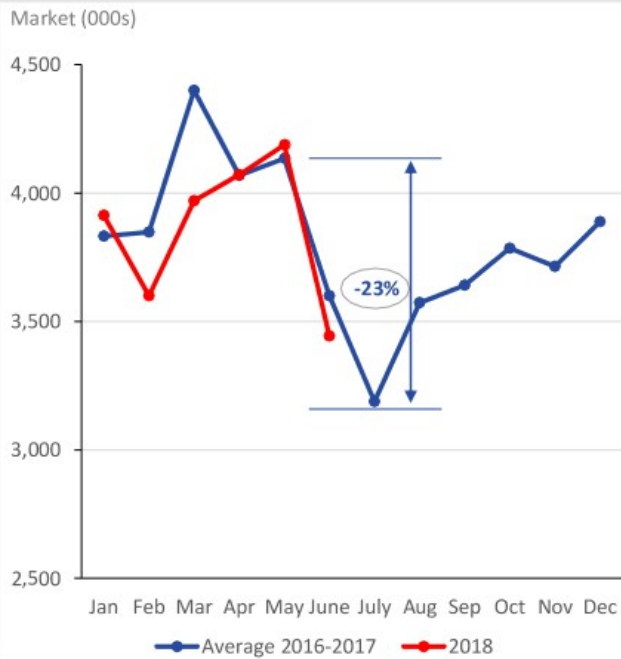


- Our Clinical Nurse Educator initiative helped drive high awareness levels and created “pent up demand” prior to launch
- The Xperience program was effective at lowering barriers to pull-through of “pent up demand” and in helping drive initial trial of XHANCE
- After Xperience ended, traditional launch sampling greatly increased: physicians continue to want a vehicle for trial that is low/no cost to patient
- The XHANCE market, particularly during launch, appears to be subject to some seasonality, which may or may not be as much as the overall INS market
- Recent market research indicates that the target audience now perceives XHANCE as differentiated from inhaled nasal steroids on “Device” and “Deposition” – can now shift communication emphasis to appreciation for “Efficacy”
- Physicians may initially perceive market access as worse than it really is: negative prior perceptions of market access for the category must be overcome.

XHANCE Impacted by Seasonality Observed in INS Market

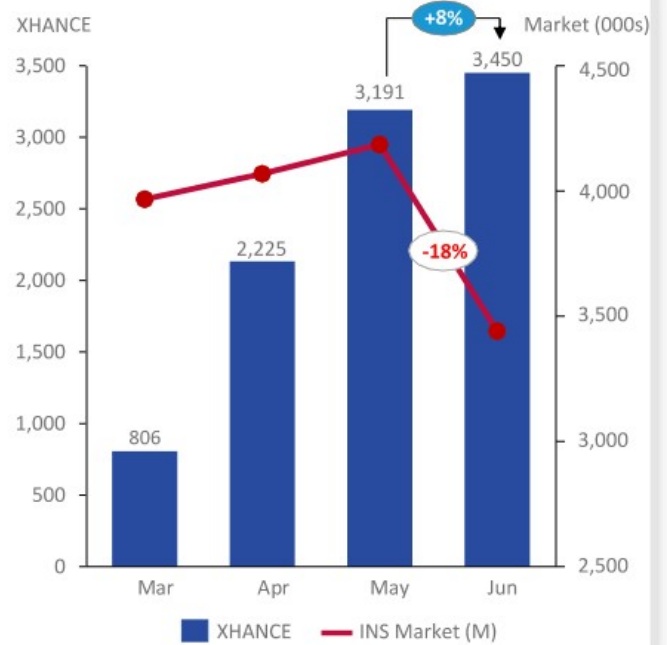
Continued growth during strong seasonal decline

Monthly TRxs for Intra-nasal Steroids (INS) for 2016-2018



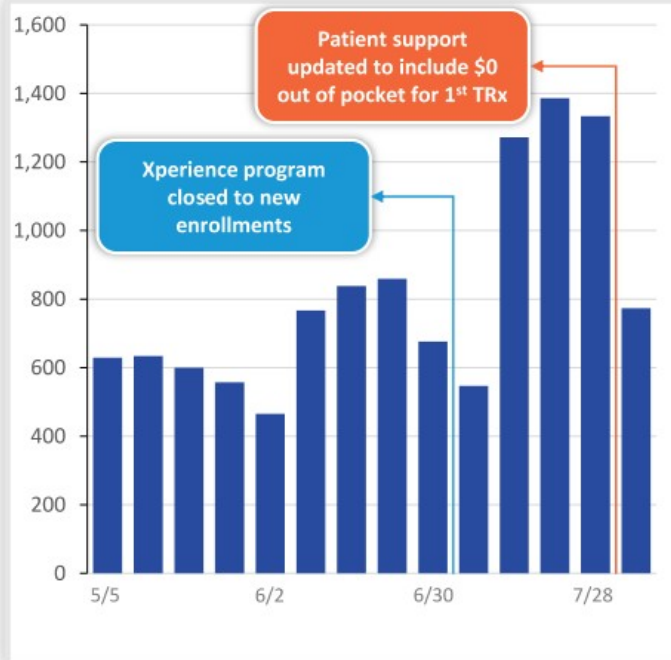
Source Monthly prescription data from public sources and mail order pharmacy

Monthly XHANCE and INS Market TRxs (Through June 2018)



Sample Distribution Increased in June and July

XHANCE Sample Distribution for Weeks ended May 5 through July 28

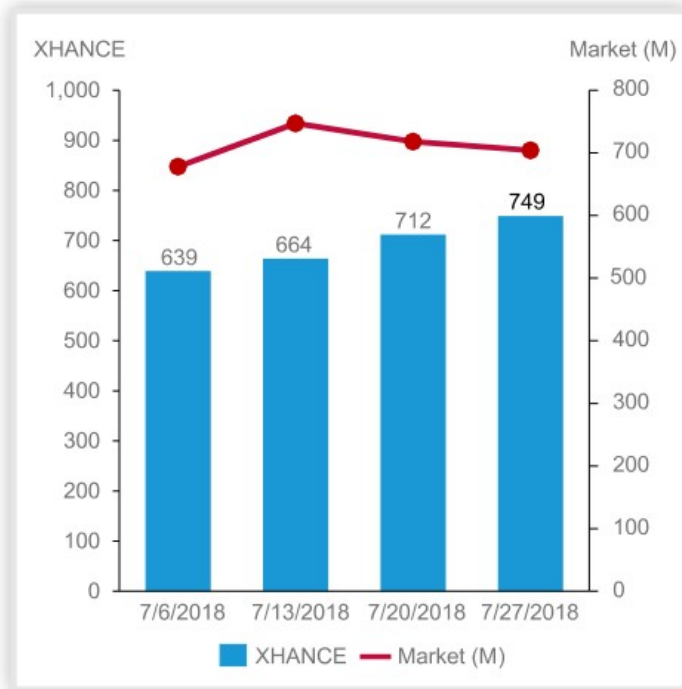


Source Company data on file. Not all samples distributed to a physician office are immediately utilized.

- XHANCE samples contain 120 sprays – the same as the bottle available by prescription
- Sampling volume increased in June and sharply accelerated in July (after Xperience closed)
- We believe this data indicates continued strong demand for trial of XHANCE
- Based upon customer feedback and more favorable economics, we have revised the post-Xperience strategy to de-emphasize sampling and towards \$0 out-of-pocket patient co-pay support

XHANCE and INS Market Weekly TRx Demand in July Includes Xperience Program and Retail Data

XHANCE July Weekly TRx Demand
(Through July 27, 2018)



- Total samples distributed in the last 3 weeks of July increased by ~2,000 relative to an average 3 weeks from May and June
- Average weekly XHANCE TRx reported in July decreased slightly more than the average weekly INS market TRx.
 - XHANCE samples do not appear as TRx
- Following the 1st week of July XHANCE resumed week over week growth

Second Half 2018 Business Priorities



- Continue to leverage rich data sets to maintain balance of discipline and flexibility in commercial execution
- Shift communication emphasis toward Xhance efficacy during calls with physicians and their staff
 - Promote additional registration data (eg, SNOT-22, PGIC)
 - Distribute NAVIGATE-2 and XHANCE-12 publications
- To accelerate clinical experience that creates differentiation and preference, we will reduce and communicate to physicians the low barriers to trial and ongoing usage
 - \$0 patient co-pay for first prescription; low co-pays for refills
 - Expanded specialty pharmacy network
- Continue to work to increase coverage and to reduce hassles that create barriers to adoption in physician offices
- Prepare for start of the Chronic Sinusitis clinical program

Financial Review – Second Quarter 2018

Q2 2018 Revenues and Average Selling Price (ASP)

(\$ 000's)



- As planned, most units of XHANCE were sold through the Xperience program in Q2
 - As a reminder, Q1 revenues were primarily the result of building wholesale inventory for the April 2018 retail launch of XHANCE
- We estimate higher gross to net deductions for sales of XHANCE through Xperience than through retail
- We believe the Xperience program has helped to accelerate demand in the early phase of launch
- As a result of this program, ASP in Q2 was significantly less than in Q1

Financial Review – Third Quarter and Full Year 2018

Q3 and Full Year 2018 Perspectives

- Operating Expenses now expected in the range from \$117M to \$121M for the full year of 2018
 - Prior range was \$119M to \$125M
- We expect Q3 ASP to be similar to Q2 ASP due to the following factors:
 - A substantial number of patients remain eligible for a second prescription through the Xperience program
 - We expect our revised patient assistance program, in which eligible patients can receive a first prescription with \$0 out-of-pocket and low subsequent co-pays, to apply to a large number of new XHANCE patients
- Retail volumes have been sufficient to drive consistent reordering by all of our Wholesale customers
- We have observed an average refill cycle of approaching 6 weeks for patients in the Xperience program

Chronic Sinusitis Supplemental Indication (sNDA)

Met with FDA
regarding CS
study design

Selection of CRO
and study
locations

First patients
expected to
enroll in 4Q 2018

Chronic Sinusitis trial design expected to include co-primary endpoints: both an objective measure of inflammation and a subjective measure of symptom relief



Investor Relations – NASDAQ: OPTN

Analyst Coverage¹

BMO: Gary Nachman

Jefferies: David Steinberg

Cantor Fitzgerald: William Tanner

Piper Jaffray: David Amsellem

RBC: Randall Stanicky

At 30 June 2018:

- \$245 million in cash
- Long-term debt: \$75 million
- 41.1 million common shares o/s
- 8.0 million options & 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.

