

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): June 4, 2019



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))

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

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 8.01 Other Events.

On June 4, 2019, the Company posted an updated Corporate Presentation on its website www.optinose.com. A copy of the presentation is furnished hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Optinose, Inc. Corporate Presentation dated June 4, 2019.

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: June 4, 2019

Building a Leading ENT / Allergy Specialty Company

Corporate Presentation

June 4, 2019

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® and our EDS technology; XHANCE market opportunities; potential drivers of future XHANCE growth; effects of XHANCE sales force expansion, 7-day samples and patient affordability programs; market access objectives; future business development; key priorities; potential effects of INS market seasonality on XHANCE prescriptions; the conduct and timing of clinical trials for chronic sinusitis; potential to obtain an indication for XHANCE for the treatment of chronic sinusitis; 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, maintain and increase insurance coverage for XHANCE (market access); our ability to grow XHANCE prescriptions and become profitable; uncertainties and delays relating to the initiation, enrollment, completion and results of clinical trials; market opportunities for XHANCE may be smaller than we believe; unexpected costs and expenses; 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.

Building a Leading ENT/Allergy Specialty Company



XHANCE[®] represents a significant opportunity in the ENT/Allergy market with the current indication



Potential for CS indication provides pipeline value



Future business development expected to focus on leveraging ENT/Allergy infrastructure and expertise



Recent license of EDS technology demonstrates ability to add value from applications outside ENT/Allergy



\$171 million of cash as of March 31, 2019

Chronic Rhinosinusitis (CRS) is an Attractive Market for XHANCE...with High Unmet Need

30 Million

US Adults suffer from CRS and up to 10 million of them have nasal polyps (NP)

9.75 Million

CRS patients seek physician care annually

3.5 Million

CRS patients treated by ENT/Allergy specialists

1.2 Million

NP patients treated by ENT/Allergy specialists

High Burden

- Disease persists for many years
- Significant quality of life impact (comparable to CHF, COPD, Angina)

Recognized Unmet Need

- **80% of patients** are frustrated with lack of symptom relief with standard inhaled steroids (INS)
- **75% of physicians** believe INS nasal sprays do not work well because they do not sufficiently reach site of inflammation

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.

Breakthrough Approach to Nasal Delivery

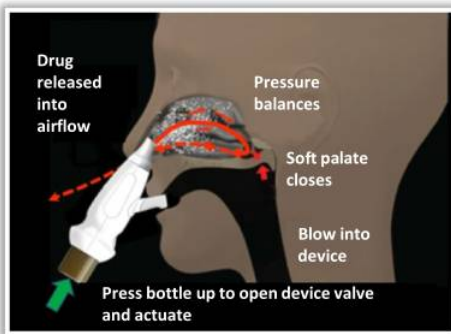
SOLVES A KNOWN MEDICAL PROBLEM WITH A UNIQUE APPROACH

Problem:

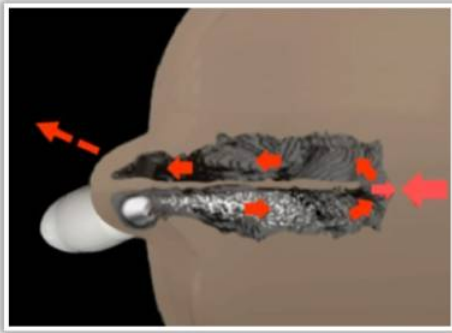
Nasal sprays and aerosols do not effectively place drug high and deep in the nasal passages

Solution:

Unique new concept for delivery gets medicine where needs to be to work



- Proprietary **exhalation delivery systems (EDS)** have a mouthpiece and sealing nosepiece
- Exhaled air passes through the EDS and drug is added
- Delivery takes advantage of natural behaviors of the upper airway
 - Exhaled breath naturally seals the soft palate then flows in one side and then out the opposite side of the nose

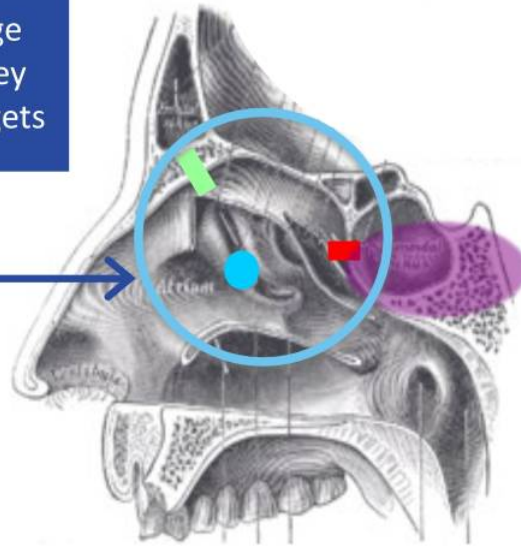


- **Simple, quick use** with limited coordination requirements
- “Positive pressure” delivery expands narrow passages
 - Helps “float” drug behind barriers to broadly fill one side of the nasal cavity
- Drug is **deposited high and deep** in the nasal passages

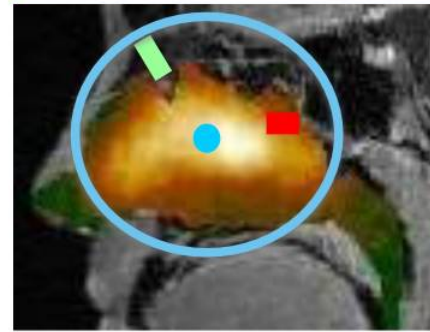
Optinose EDS Can Deliver Drug High & Deep in the Nose

KEY TO TREATING CRS (W OR W/OUT POLYPS)

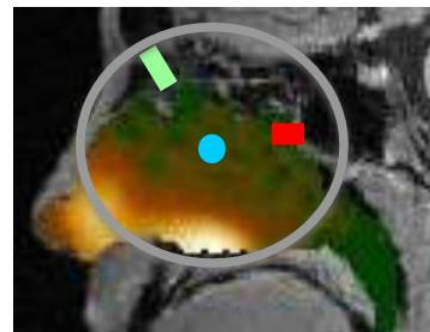
Sinus drainage regions are key treatment targets



Optinose EDS w/Exhalation



Nasal Spray w/o Exhalation



Intranasal steroids are **TOPICALLY ACTING** medications: Delivery to sites of chronic inflammation and nasal polyp origin is important

Differentiated Clinical Profile

Global Clinical Program

Trial	Type	N	Sites
NAVIGATE I	Phase 3 pivotal	323	54
NAVIGATE II	Phase 3 Pivotal	323	38
EXHANCE-3	Phase 3 open-label 3 month	700	38
EXHANCE-12	Phase 3 open-label 12 month	223	21
Study 1102	Phase 1 bioavailability	112	2

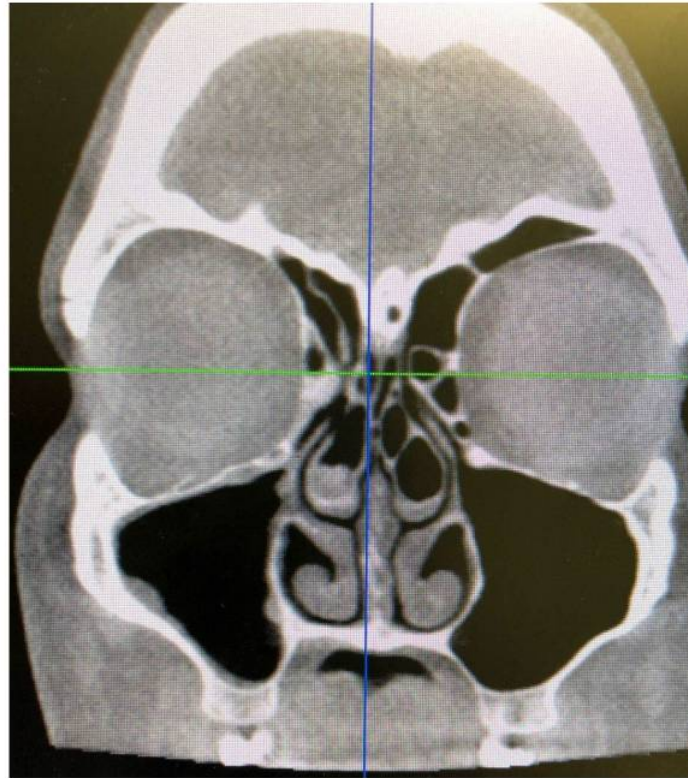
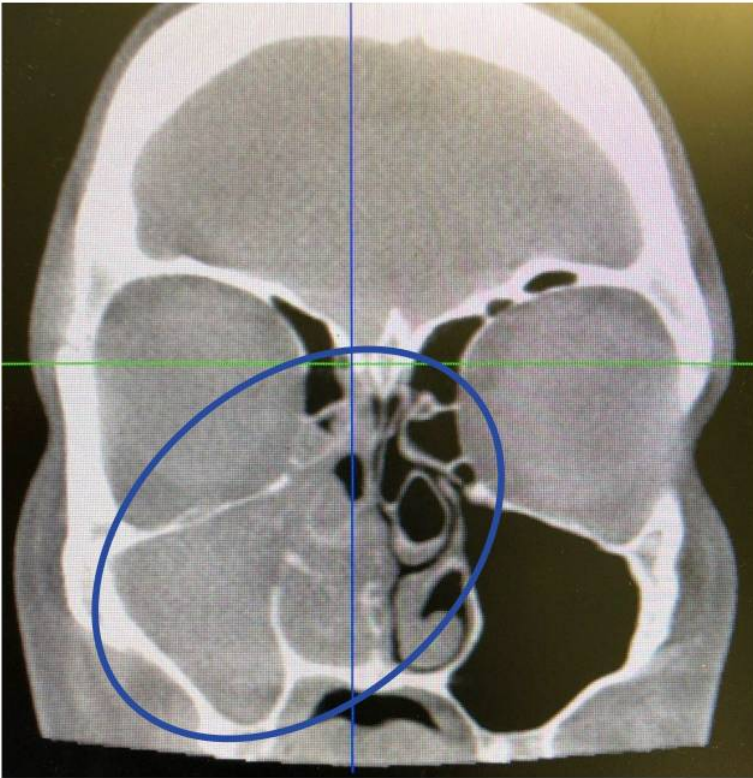
1,500+ Patients
792 CS w/o polyps
780 CS w/ polyps

Key Highlights

- Significant benefit on all four defining symptoms of CS
- Similar improvements in patients with and without nasal polyps
- “Medical” polyp elimination in some patients
- Magnitude of relief comparable to surgery
- Reduction in eligibility for surgery
- Approximately 70% of patients reported being “much” or “very much” improved

XHANCE Launch Update

Examples of Positive XHANCE Physician Feedback*



*Testimonials and images reflect 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.

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 Rins (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%

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.

Key Levers to Continue to Drive XHANCE Growth

Continued Execution of Strategy

(Defined Appropriate Patient Type, Enhanced Efficacy Message & Affordability Program)

Sales Force Expansion

7-Day Samples

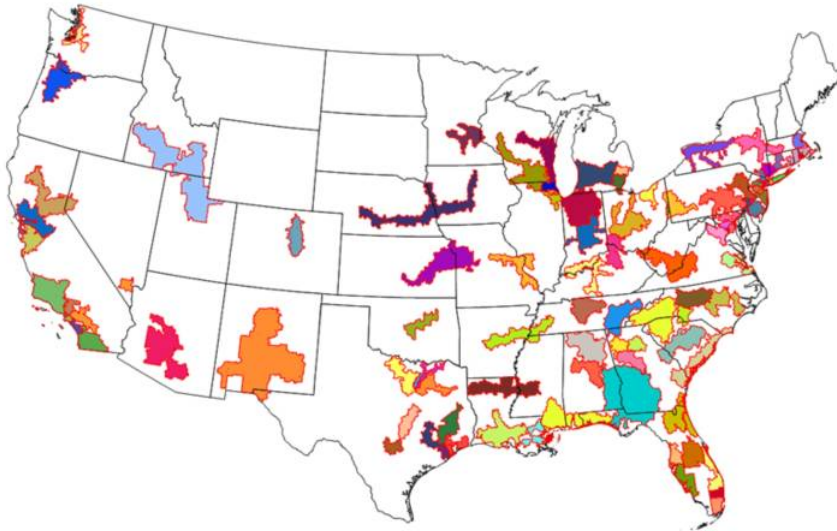
Increase Payer Coverage

Direct to Consumer Pilot



Deployed Territory Managers to New Territories in April and no Promote XHANCE in 100 Territories Total

XHANCE® Sales Territories

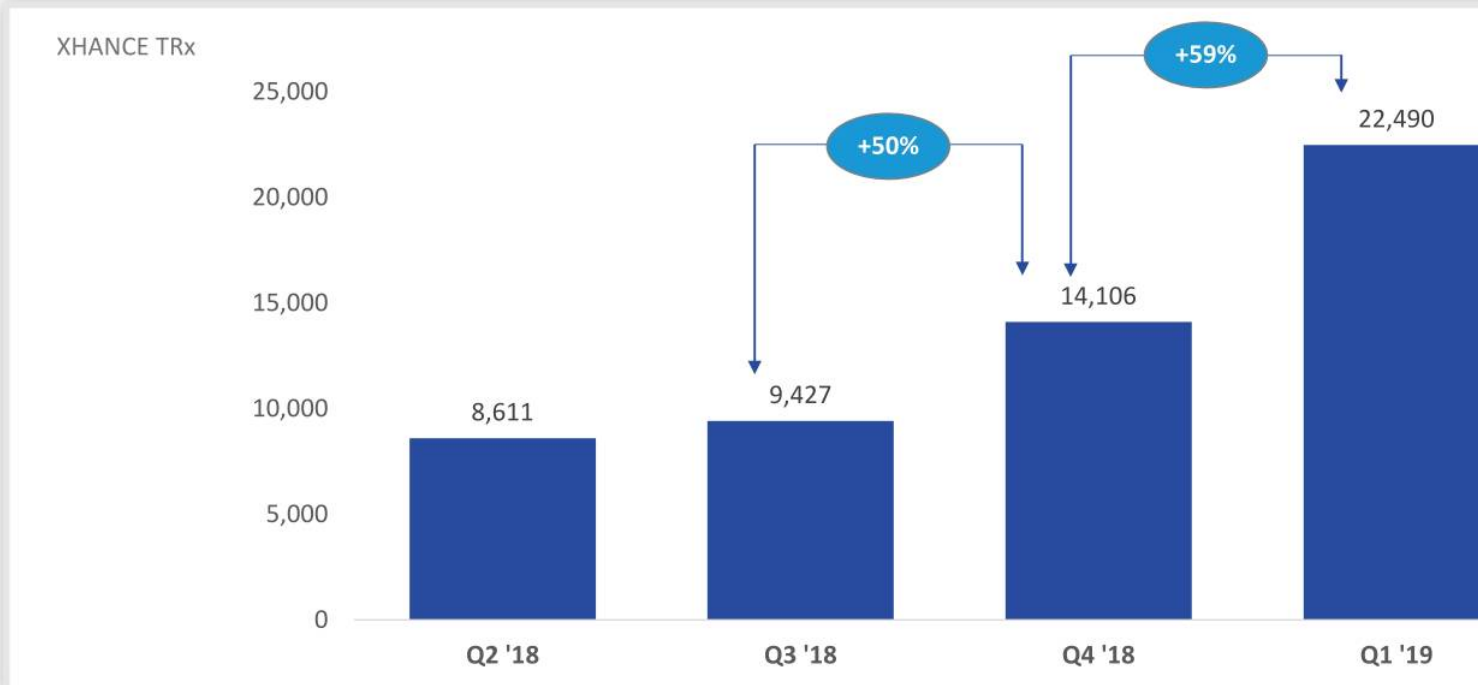


- Albany, NY
- Albuquerque, NM
- Baltimore, MD
- Boston, MA
- Charleston, SC
- Columbia, SC
- Detroit (South), MI
- Dothan, AL
- Fort Wayne, IN
- Grand Rapids, MI
- Greenville, SC
- Huntington, WV
- Jackson, MS
- Knoxville, TN
- Memphis, TN
- Nashville, TN
- Pittsburgh, PA
- Portland, OR
- Providence, RI
- Stamford, CT
- Suffolk County, NY

NEW

XHANCE Prescription Volume Grew 59% in Q1 2019 versus Q4 2018

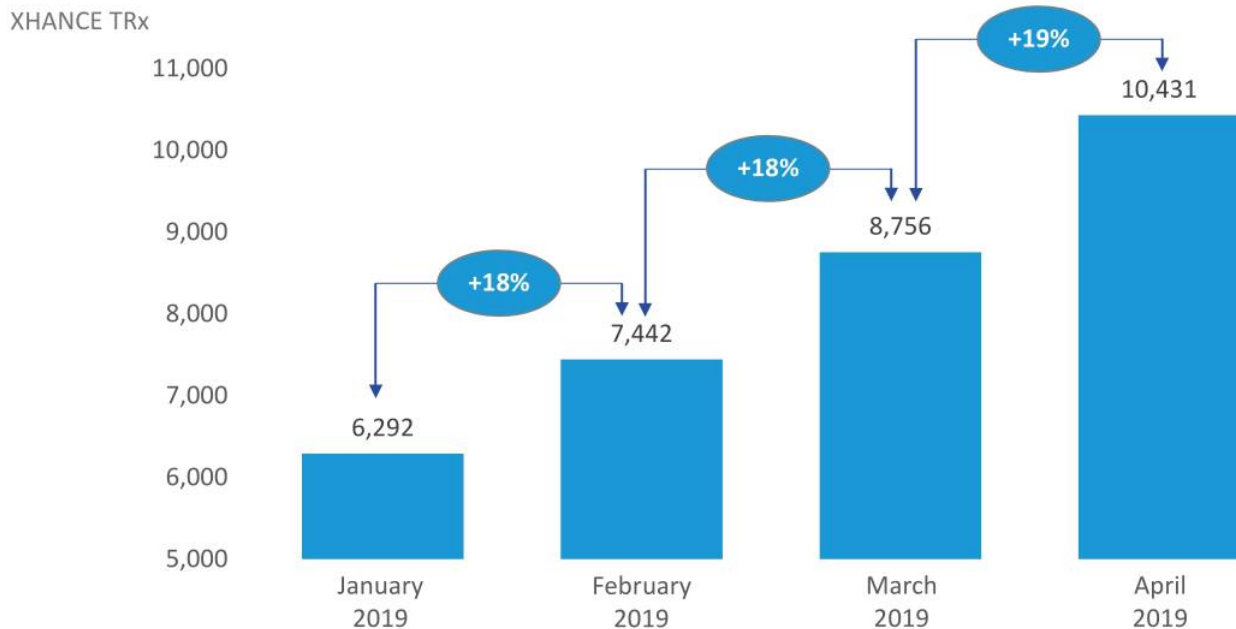
Continued growth in Q1 2019 driven by promotional materials and patient affordability program rolled out in August/September 2018



TRx for Intranasal Steroids Market increased 11% from Q3 2018 to Q4 2018 and increased 3% from Q4 2018 to Q1 2019

XHANCE Prescription Volume Grew 19% in April 2019 versus March 2019

April Prescription Trends Aligned with Q4 2018 and Q1 2019 Growth Rates



TRx for Intranasal Steroids market decreased 9% from January 2019 to February 2019, increased 13% from February 2019 to March 2019 and increased 5% from March 2019 to April 2019

Chronic Sinusitis Trials Update

XHANCE Chronic Sinusitis Indication (sNDA)

Study 3205 - ClinicalTrials.gov Identifier: NCT03781804

- 24-week randomized, double-blind, placebo-controlled, parallel-group, multicenter study
- First patient enrolled in Q4 2018
- Estimated enrollment: 378 patients
- Focused on successful execution of site initiation plan in Q2 2019

Study 3206 - ClinicalTrials.gov Identifier: NCT03960580

- 24-week randomized, double-blind, placebo-controlled, parallel-group, multicenter study
- Trial started in May 2019
- Estimated enrollment: 399 patients
- Focused on successful execution of site initiation plan in Q2 2019

Co-primary endpoints for each trial include an objective measure of inflammation and a subjective measure of symptom relief

Closing Remarks

Optinose Key Priorities



Continue to drive XHANCE[®] prescription growth



Advance our XHANCE clinical program for a follow-on indication for the treatment of Chronic Sinusitis



Support our commercial and development objectives through efficient use of capital

- \$171 Million of cash as of March 31, 2019

Investor Relations – NASDAQ: OPTN

Analyst Coverage¹

BMO: Gary Nachman

Jefferies: David Steinberg

Cantor Fitzgerald: Brandon Folkes

Piper Jaffray: David Amsellem

RBC: Randall Stanicky

At 31 March 2019:

- \$171 million in cash
- Long-term debt: \$75 million
- 41.3 million common shares o/s
- 9.6 million options & warrants 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 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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