# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

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# FORM 8-K

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**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 27, 2017**

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## OPTINOSE, INC.
(Exact Name of Registrant as Specified in its Charter)

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| **DELAWARE** | **001-38241** | **42-1771610** |
|---|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (Commission File No.) | (I.R.S. Employer Identification No.) |

**1020 Stony Hill Road, Suite 300**
**Yardley, Pennsylvania 19067**
(Address of principal executive offices and zip code)

**(267) 364-3500**
(Registrant's telephone number, including area code)
(Former name or former address, if changed from last report)

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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):

q Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

q Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

q Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

q Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-14(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 November 27, 2017, OptiNose, Inc. (the “Company”) issued a press release announcing its financial results for its third quarter ended September 30, 2017. 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 this Item 2.02, including Exhibit 99.1, is being "furnished" pursuant to Item 2.02 and 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 of 1933, as amended (the “Securities Act”), or the Exchange Act (regardless of any general incorporation language in such filing) unless expressly incorporated into such filing by specific reference to the "furnished" information contained herein.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press Release dated November 27, 2017, announcing financial results for the third quarter ended September 30, 2017 |

**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 27, 2017

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
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# Optinose Reports Third Quarter 2017 Financial Results and Recent Operating Highlights

## *FDA Approval of XHANCE™, Successful IPO, Leadership Team Expanded to Drive Commercialization*

**YARDLEY, PA, November 27, 2017**— 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 September 30, 2017, and provided recent operational highlights.

"Following our successful initial public offering in October, we are well-positioned to launch XHANCE in the second quarter of 2018," said Optinose chief executive officer Peter Miller. "With an outstanding leadership team in place, we expect an exciting and productive year ahead as we work to deliver XHANCE to patients in need. We believe XHANCE has the potential to improve the lives of millions of patients who are searching for new treatment options and lays a strong foundation for Optinose to become a leading ENT/allergy company."

**Third Quarter 2017 and Recent Highlights**

**FDA Approval of XHANCE:** The U.S. Food & Drug Administration approved the Company's New Drug Application for XHANCE (fluticasone propionate) nasal spray, 93mcg (previously referred to by the development name OPN-375) for the treatment of nasal polyps in patients 18 years of age and older, as announced on September 18, 2017. XHANCE is designed to deliver medicine to targeted areas high and deep in the nose using one of Optinose's patented Exhalation Delivery Systems (EDS) for the up to 10 million Americans who suffer from nasal polyps and the symptoms that accompany them.

**Successful IPO:** Optinose completed its initial public offering (IPO) of 8,625,000 shares of common stock at a public offering price of $16.00 per share, which included an additional 1,125,000 shares of common stock issued upon the exercise in full by the underwriters of their option to purchase additional shares, on October 17, 2017. The aggregate gross proceeds to Optinose from the offering were approximately $138 million before deducting underwriting discounts and commissions and estimated offering expenses payable by Optinose. All of the shares were offered and sold by Optinose.

**Leadership Team Expanded to Drive XHANCE Commercialization**: On October 30, 2017, Optinose announced the addition of five new members to the leadership team to drive the commercialization of XHANCE:

> **Ricci Whitlow, Vice President, Technical Operations**. With over 20 years of manufacturing, supply chain and product development related experience, Ms. Whitlow will drive all activities associated with the commercial supply chain; clinical supplies; chemistry, manufacturing and controls; and device development of the product portfolio. She was most recently responsible for the management of nine pharmaceutical manufacturing sites as part of Catalent, a large contract

pharmaceutical manufacturer, and has extensive prior technical operations experience at companies including Johnson & Johnson and LifeCell.

**Harry Sacks, MD, Vice President, Medical Affairs and Corporate Medical Officer**. Bringing more than 20 years of experience in pharmaceutical clinical development and medical affairs and deep expertise in the respiratory therapeutic category, Dr. Sacks was recently Vice President and Head of Respiratory, U.S. Clinical Development and Medical Affairs at Novartis. Dr. Sacks also held leadership roles in medical and scientific affairs and clinical development with a strong focus on respiratory at companies including Forest Research Institute, Meda Pharmaceuticals and Schering-Plough Corporation.

**John Peterkins, Vice President, Market Access**. Mr. Peterkins assumes leadership of all components of market access including pricing strategy, contracting, patient access and health plan coverage. He has more than 20 years of relevant experience in the pharmaceutical industry, having recently established a market access team for the launch of the branded business unit and helping lead Sun Pharmaceuticals through three launches in two years. Prior to Sun, Mr. Peterkins spent more than 18 years at Johnson & Johnson in various leadership roles in the pharma/biologics business including leading the managed markets team for Immunology, Oncology and Virology for the Janssen Biotech and Janssen Therapeutics businesses.

**David Fabbri, Vice President, Sales**. A seasoned business leader with more than 20 years of pharmaceutical commercial experience in sales, marketing and commercial operations roles, Mr. Fabbri is responsible for building, training and leading a performance-driven sales team and supporting sale force infrastructure at Optinose. Mr. Fabbri's prior commercial experience includes leadership roles at Johnson & Johnson and at Sun Pharmaceuticals where he led numerous marketing and field sales teams and executed multiple product launches.

**Andrew Muzsi Vice President, Marketing**. Mr. Muzsi will lead the development and implementation of marketing strategy. Mr. Muzsi brings 20 years of broad marketing experience to Optinose including U.S. marketing, global marketing and payer marketing. Mr. Muzsi has prior experience at Johnson & Johnson and Bayer and most recently worked at Bristol-Myers Squibb where he held several marketing roles within the U.S. and global organizations including key leadership positions launching market-leading products including Eliquis.

**Launched Clinical Nurse Educator Team calling on approximately 10,000 ENT and Allergy Specialists:** Within six weeks of FDA approval of XHANCE, Optinose recruited, trained and deployed approximately 85 Clinical Nurse Educators (CNEs) targeting approximately 10,000 ENT and allergy specialists. The objectives of the CNE team are to introduce Optinose as a company, raise awareness of the significant unmet need that exists within nasal polyps, explain how the Optinose EDS enables delivery of medication to targeted areas deep in the nose and familiarize healthcare practitioners with proper use of XHANCE. The CNE team initiated customer engagement activities on November 13, 2017.

**Third Quarter 2017 Financial Results**

Research and development expenses for the three-month period ended September 30, 2017, were $6.6 million. General and administrative expenses totaled $6.6 million for the three-month period ending September 30, 2017. Net loss for the period was $13.1 million, or $4.23 per share (basic and diluted, after giving effect to the 1-for-2.8879 stock split that occurred on October 10, 2017). As of September 30, 2017, Optinose had cash and cash equivalents of $49.4 million. In addition, the Company raised $125.5 million in net cash proceeds from the closing of its IPO on October 17, 2017. Following the closing of the IPO, the Company had 37,761,273 shares of common stock outstanding.

**About Optinose®**

Optinose is a specialty pharmaceutical company on a mission to improve lives with a focus on patients cared for by ear, nose and throat (ENT) and allergy specialists. The Company's first two products rely on its patented Exhalation Delivery Systems (EDS), which are capable of deep intranasal deposition of medication. The exhalation delivery systems enable the creation of products with potential for meaningful new clinical benefits. Optinose developed its first product, Onzetra® Xsail® (sumatriptan nasal powder), through the completion of Phase 3 and subsequently out-licensed the product to Otsuka Pharmaceutical Co., Ltd. Onzetra Xsail received FDA approval and was launched in the U.S. in 2016. The Company's second product, XHANCE (fluticasone propionate) nasal spray, is approved for the treatment of nasal polyps in patients 18 years of age and older and is in development for the treatment of chronic sinusitis. Subsequent Optinose pipeline products will aim to serve the needs of patients treated by ENT and allergy specialists and are expected to include products using EDS as well as other technologies. The Company is also currently engaged in the early development of products for neurologic orphan diseases for which the "nose-to-brain" application of an EDS may enable improved treatment. This includes OPN-300 (autism and others) and OPN-21 (narcolepsy and others). Optinose has corporate offices in the U.S., the U.K. and Norway. To learn more, please visit www.optinose.com.

**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 planned launch of XHANCE in the second quarter of 2018; development plans and potential advantages of XHANCE and our product candidates; 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: our ability to establish supply chain and commercial infrastructure and capabilities to launch XHANCE; physician and patient acceptance of XHANCE; our ability to obtain adequate third-party reimbursement for XHANCE; varying interpretation of clinical data; and the risks, uncertainties and other factors discussed in the "Risk Factors" section and elsewhere in our 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.

**Optinose Media Contact**

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Licensing revenues | $ - | $ - | $ - | $ 47,500 |
| Operating expenses: | | | | |
| Research and development | 6,641 | 3,868 | 15,620 | 12,241 |
| Selling, general and administrative | 6,553 | 1,761 | 13,214 | 5,057 |
| Total operating expenses | 13,194 | 5,629 | 28,834 | 17,298 |
| (Loss) income from operations | (13,194) | (5,629) | (28,834) | 30,202 |
| Other (income) expense, net | (126) | 477 | 517 | 2,001 |
| Net (loss) income | $ (13,068) | $ (6,106) | $ (29,351) | $ 28,201 |
| Deemed dividend | 4,105 | 2,752 | 11,255 | 8,254 |
| Accretion to redemption value | 19 | 527 | 1,093 | 1,582 |
| Net (loss) income attributable to common stockholders | $ (17,192) | $ (9,385) | $ (41,699) | $ 18,365 |
| Net (loss) income per share of common stock | | | | |
| basic | $ (4.23) | $ (2.32) | $ (10.25) | $ 0.77 |
| diluted | $ (4.23) | $ (2.32) | $ (10.25) | $ 0.63 |
| Weighted average common shares outstanding | | | | |
| basic | 4,067,717 | 4,050,065 | 4,067,717 | 4,049,800 |
| diluted | 4,067,717 | 4,050,065 | 4,067,717 | 4,975,012 |

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

| | September 30, 2017 (unaudited) | December 31, 2016 |
|---|---|---|
| Cash and cash equivalents | $ 49,410 | $ 36,797 |
| Other assets | 5,725 | 4,754 |
| Total assets | $ 55,135 | $ 41,551 |
| | | |
| Total other liabilities | $ 9,699 | $ 9,319 |
| Convertible notes payable, net | - | 15,256 |
| Redeemable convertible preferred stock | 236,542 | 168,173 |
| Total stockholders' deficit | (191,106) | (151,197) |
| Total liabilities and stockholders' deficit | $ 55,135 | $ 41,551 |