# 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): January 31, 2019



## OPTINOSE, INC.

(Exact Name of Registrant as Specified in its Charter)

#### DELAWARE

001-38241

(State or Other Jurisdiction of Incorporation or Organization)

(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):

- 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 8.01 Other Events.

On January 31, 2019, OptiNose AS (the "Company"), a wholly owned subsidiary of OptiNose, Inc., entered into a License Agreement (the "License Agreement") with Inexia Limited ("Inexia").

Under the terms of the License Agreement, the Company has granted Inexia an exclusive, royalty-bearing, worldwide, non-transferable, sublicensable license to the Company's exhalation delivery system ("EDS") and other intellectual property for the use, sale, import and manufacture of products containing orexin receptor agonist and/or orexin receptor positive modulator molecule(s) as the sole active pharmaceutical ingredient(s) for the treatment, diagnosis or prevention of human diseases or conditions associated primarily with orexin receptor agonism and orexin receptor positive modulation. The license excludes the treatment of any disease or condition affecting the ear, nose or throat, or the treatment of any disease or condition associated primarily with another receptor, other than the Orexin 1 and Orexin 2 receptors. Inexia is solely responsible for all costs and activities related to its identification, development and commercialization of products under the License Agreement.

Under the terms of the License Agreement, Inexia is required to pay the Company a \$500,000 upfront payment (the "Upfront Payment"). For each product developed under the License Agreement, the Company is eligible to receive up to \$8 million of development milestone payments and up to \$37 million of sales milestone payments. In addition, the Company is eligible to receive tiered, low-to-mid single digit royalties based on net sales of any products successfully developed and commercialized under the License Agreement. Other than the Upfront Payment, the Company does not anticipate the receipt of any milestone or royalty payments from Inexia in the near term.

As a result of the License Agreement, the Company will discontinue its internal OPN-021 program, which combined the Company's EDS with orexin-A for the treatment of narcolepsy and symptoms of other diseases potentially amenable to the same pharmacologic activity, such as Parkinson's disease.

On February 4, 2019, OptiNose issued a press release announcing the License Agreement with Inexia. A copy of the press release is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

## Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. 99.1 Description Press Release dated February 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: February 4, 2019



# **Optinose Announces License Agreement**

**YARDLEY, Pa., Feb. 4, 2019**— <u>Optinose</u> (NASDAQ:OPTN), a pharmaceutical company focused on the development and commercialization of products for patients treated by ear, nose and throat (ENT) and allergy specialists, today announced that it has entered into a license agreement with Inexia whereby Inexia has obtained certain rights that will enable the use of Optinose's Exhalation Delivery Systems (EDS) and other intellectual property in their effort to discover and develop novel therapies based on positive modulators of Orexin OX1 and OX2 for neurological diseases.

Inexia was recently formed as part of a structured financing agreement between Japan-based Sosei Group Corporation (TSE code: 4565), a company focused on GPCR medicine design and development, and Medicxi, a venture fund dedicated to financing assetcentric companies.

In exchange for this license Optinose will receive an upfront payment and for each product developed under the license agreement, is eligible to receive up to \$8 million of development milestone payments and up to \$37 million of sales milestone payments. In addition, Optinose is eligible for tiered, low-to-mid single digit royalties based on net sales of any products successfully developed and commercialized under the license agreement. Inexia will be responsible for all costs and activities related to the identification, development and commercialization of potential products under this license.

"We are pleased to be delivering on our strategic objective of engaging in external partnerships to capture value from the potential for use of our Exhalation Delivery Systems for nose-to-brain applications, which is outside of our therapeutic focus area," said Peter Miller, CEO of Optinose. "We look forward to seeing our Inexia partnership produce novel products enabled by our technology, while we continue to concentrate our internal efforts on sustaining the success of our XHANCE launch and on the ENT and Allergy therapeutic space."

# **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. 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 benefits of Optinose Exhalation Delivery Systems and other intellectual property; the potential

discovery, development and commercialization of product candidates under the license agreement; the potential to receive future development and sales milestone payments and royalties under the license agreement; sustaining the success of the XHANCE® launch; and other statements regarding Optinose'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: risks and uncertainties relating to drug discovery, development and commercialization and the receipt of payments under the license agreement; Optinose's ability to successfully commercialize XHANCE; physician and patient acceptance of XHANCE; the ability to obtain adequate third-party reimbursement for XHANCE; the ability to grow XHANCE prescriptions and achieve profitability; 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.

#### **Optinose Investor Contact**

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