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): September 25, 2019



(Exact Name of Registrant as Specified in its Charter)

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)

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)
- 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))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-14(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 \boxtimes

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. \square

Item 8.01 Other Events.

On September 25, 2019, OptiNose AS ("Optinose"), a wholly owned subsidiary of OptiNose, Inc. (the "Company"), entered into a License Agreement (the "License Agreement") with Currax Pharmaceuticals LLC ("Currax").

Under the terms of the License Agreement, Optinose has granted Currax an exclusive license to certain OptiNose patents and a non-exclusive license to certain OptiNose know-how to use, sell, offer for sale, have sold and import ONZETRA® XSAIL® (sumatriptan nasal powder) in the U.S., Canada and Mexico. Currax is required to pay Optinose a \$4,480,000 upfront payment, of which \$750,000 shall be held in escrow for a limited period to cover certain indemnification obligations. Additionally, Optinose is eligible to receive a one-time 10% royalty on ONZETRA net sales in excess of \$3,000,000 solely for calendar year 2020, and an additional \$1,000,000 milestone payment subject to the achievement of a specified regulatory milestone.

On September 26, 2019, the Company issued a press release announcing the License Agreement with Currax. 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. Description

99.1 <u>Press Release dated September 26, 2019.</u>

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: September 26, 2019



OptiNose Announces License Agreement Related to ONZETRA XSAIL

YARDLEY, Pa., September 26, 2019- OptiNose, Inc. (Optinose) (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, today announced the signing of an agreement between its Norway-based subsidiary OptiNose AS and Currax Pharmaceuticals LLC (Currax) which grants Currax the exclusive rights to certain Optinose intellectual property for the purpose of marketing ONZETRA® XSAIL® (sumatriptan nasal powder) in the United States, Canada, and Mexico.

ONZETRA XSAIL provides a 22mg dose, dry powder formulation of sumatriptan, administered via an Optinose breath powered exhalation delivery system and is approved by the U.S. Food and Drug Administration (FDA) for the acute treatment of migraine in adults.

Under the terms of the License Agreement, Currax is required to pay a \$4.48 million upfront payment, of which \$750,000 shall be held in escrow for a limited period to cover certain indemnification obligations. Additionally, Optinose is eligible to receive a one-time 10% royalty on ONZETRA net sales in excess of \$3 million solely for calendar year 2020, and an additional \$1 million milestone payment subject to the achievement of a specified regulatory milestone.

"Currax is an ideal partner for ONZETRA XSAIL, with its deep experience in the migraine market and commercial focus on innovative treatments for pain and inflammation," said Peter Miller, CEO of OptiNose. "We are pleased to have a partner that will continue to make this important treatment option available for patients."

About ONZETRA XSAIL

ONZETRA® Xsail® is a prescription medication approved for the acute treatment of migraine, with or without aura in adults. ONZETRA Xsail is used for people who have been told by a healthcare provider that they have migraine headaches. ONZETRA Xsail is not for the prevention of migraines or for other types of headaches, including cluster headache.

Important Safety Information

ONZETRA Xsail may cause serious side effects, including:

- Heart attack and other heart problems, which may lead to death. Stop using ONZETRA Xsail and get emergency medical help right away if you have any symptoms of a heart attack like shortness of breath or tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw that is severe or does not go away
- Changes in color or sensation in your fingers and toes (Raynaud's syndrome)
- Stomach and intestinal problems (gastrointestinal and colonic ischemic events)
- Problems with blood circulation to your legs and feet (peripheral vascular ischemia)
- Serious allergic reactions (symptoms include hives; tongue, mouth, lip, or throat swelling; problems breathing)

- Medication overuse headaches. Some people who use ONZETRA Xsail too many times may have worse headaches. If your headaches get worse your doctor may decide to stop your treatment with ONZETRA Xsail
- Serotonin syndrome, a rare but serious problem that can happen in people using ONZETRA Xsail, especially if ONZETRA Xsail is used with antidepressant medicines called SSRIs, SNRIs, or TCAs. Call your doctor right away if you have any of the following symptoms of serotonin syndrome: mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; trouble walking; or nausea, vomiting, or diarrhea
- · Seizures. Seizures have happened in people taking sumatriptan who have never had seizures before

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 potential to receive funds to be held in escrow; the potential to receive the future regulatory milestone payment and royalty payments under the license agreement; 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 Currax's commercialization of ONZETRA XSAIL, the achievement of the regulatory milestone and the net sales threshold for the royalty payments; risks and uncertainties relating to indemnification obligations; 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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