

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 30, 2020



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 30, 2020, the Company issued a press release announcing the initiation of the development of a new product candidate, OPN-019, intended to reduce illness and transmission of the COVID-19 virus. 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	Press release, dated June 30, 2020, issued by OptiNose, Inc.

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 30, 2020



Optinose Announces Anti-COVID-19 Product Candidate

Company initiates development program using its EDS technology to deliver a nasal "antiseptic" intended to reduce illness and transmission of the COVID-19 virus

YARDLEY, Pa., June 30, 2020— Optinose (NASDAQ:OPTN), a pharmaceutical company focused on patients treated by ear, nose and throat (ENT) and allergy specialists, today announced initiation of development of a new product candidate, OPN-019. OPN-019 will combine the Company's proprietary nasal Exhalation Delivery System (EDS) technology with an antiseptic that has been recently shown *in vitro* to kill the virus that causes COVID-19.

Because components of the drug-device combination product candidate, including both the active drug and delivery device, are currently commercially available in the U.S., the Company expects to be able to rapidly progress to a meeting with FDA to discuss an IND and then onward to clinical trials. The Company is focused on supporting the initial stages of development within its current operating expense plan and intends to seek grants, partnerships, and/or other sources of capital to fund future development.

"The medical community is still learning about COVID-19, but we think the virus frequently spreads from one person's upper airways - by coughing, sneezing, or talking for example - to another person's upper airways, especially the nose. That is why we wear masks and socially distance. Evidence suggests that the virus attaches to certain types of cells in the deep part of the nose, and can multiply for an extended period, often days, before symptoms appear - all the while risking spread to others," stated Ramy Mahmoud, M.D., MPH, President and Chief Operating Officer of Optinose. "Recently, this antiseptic has been shown to kill the COVID-19 virus, which leaves the problem of how to coat the deep lining of the nasal cavity with the drug, which is very difficult with standard approaches like nasal sprays. That is where our unique EDS technology comes in. We have demonstrated that an EDS can spread medicine thoroughly in the deep areas of the nasal cavity where the virus appears to be multiplying and shedding. With OPN-019, we want to offer people a safe antiseptic/antiviral combined with an EDS device that enables them to deliver it to surfaces deep in the nasal cavity."

"Today, someone with or without symptoms who tests positive is often sent home. Our intent is for OPN-019 to offer that person a way to reduce their own risk of disease progression and also help members of their household - or other at-risk people - avoid getting sick at all. It could help fill the gap between vaccines, which are for healthy people to prevent infection, and drugs that are used for very sick people who may have to be hospitalized," explained Dr. Mahmoud, adding, "We picked an antiseptic/antiviral that has been known for years to kill many viruses. With new third party research showing that it can kill the SARS-CoV-2 virus, we are excited

about the potential for OPN-019 to work against COVID-19. The bottom line is that we aim to give doctors a way to suppress virus multiplication and reduce viral load and the duration of shedding from the upper airways so that we can reduce progression of asymptomatic or mildly symptomatic disease, reduce transmission to others, and protect people by giving them post-exposure or high-risk prophylaxis.”

“We are very interested in the potential of this drug-device combination to help combat a public health crisis,” said David A. Gudis, M.D., Chief of the Division of Rhinology and Anterior Skull Base Surgery in the Department of Otolaryngology at Columbia University, who has no financial relationship with Optinose. “An intervention with potential to reduce virus load, limit replication, and decrease upper airway viral shedding could have enormous implications. I am excited about Optinose’s EDS, which may represent such a weapon in the fight against SARS-CoV-2. As the proposed antiseptic it delivers has been shown to kill not only coronaviruses and influenzae, but also many other viruses, bacteria and even fungi, this intervention may represent a treatment pathway for other upper airway infections in the future as well.”

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 Company’s development plans and objectives for OPN-019; the potential benefits of OPN-019 for the treatment and prevention of COVID-19 and other upper airway infections; the potential benefits of the Company’s EDS technology; the Company’s intention to fund initial development of OPN-019 within its current operating expense plan and to seek grants, partnerships and/or other sources of capital to fund future development; and other statements regarding the Company’s future operations, 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: unknowns relating to COVID-19 and the virus that causes COVID-19; risks, uncertainties and delays relating to product development, the enrollment, completion and results of clinical trials and the regulatory approval process; risks that results seen in preclinical studies may not be replicated in humans; unanticipated product development costs and expenses; intense competition for vaccines and other therapies for COVID-19; 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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