

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): July 7, 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 July 7, 2020, Optinose entered into an agreement with kaléo, Inc. to co-promote XHANCE® (fluticasone propionate) exhalation nasal spray 93 mcg, for the treatment of nasal polyps in patients 18 years or older in the United States. A copy of the press release announcing the co-promote is attached as Exhibit 99.1 to this report and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release, dated July 8, 2020, issued by OptiNose, Inc.</a>

**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: July 8, 2020



## Optinose Announces XHANCE Co-Promotion Agreement with Kaléo

**YARDLEY, Pa., July 8, 2020**— 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 with kaléo, a pharmaceutical company dedicated to building innovative solutions for serious and life-threatening medical conditions, to co-promote XHANCE® (fluticasone propionate) exhalation nasal spray 93 mcg, for the treatment of nasal polyps in patients 18 years or older in the United States.

"We are excited to partner with kaléo and leverage the strong relationships they have built with physicians in our target audience," said Vic Clavelli, Chief Commercial Officer of Optinose. "This co-promotion partnership will build upon that strength and help us grow our target audience's appreciation for all XHANCE has to offer by efficiently broadening and deepening our promotional reach. I am confident that the kaléo sales team will complement and amplify the efforts of the Optinose team starting in the fourth quarter of this year."

"Our team is pleased to collaborate with Optinose on the promotion of XHANCE," said Omar Khalil, kaléo's General Manager of Allergy and Pediatrics. "The deep relationships we have developed over the years with allergists makes kaléo a natural fit for this innovative product that serves the needs of patients with this condition."

Under the terms of the agreement, kaléo will promote XHANCE to an agreed-upon audience of office-based healthcare professionals, rapidly increasing promotional reach and frequency. The audience includes nearly 6,000 prescribers about half of whom are outside of the current Optinose called-on universe of approximately 10,000 healthcare professionals.

### 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](http://www.optinose.com) or follow us on Twitter and LinkedIn.

### Important Safety Information

**CONTRAINDICATIONS:** Hypersensitivity to any ingredient in XHANCE.

### WARNINGS AND PRECAUTIONS:

- Local Nasal Effects: epistaxis, erosion, ulceration, septal perforation, Candida albicans infection, and impaired wound healing. Monitor patients periodically for signs of

possible changes on the nasal mucosa. Avoid use in patients with recent nasal ulcerations, nasal surgery, or nasal trauma.

- Close monitoring for glaucoma and cataracts is warranted.
- Hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, contact dermatitis, rash, hypotension, and bronchospasm) have been reported after administration of fluticasone propionate. Discontinue XHANCE if such reactions occur.
- Immunosuppression: potential increased susceptibility to or worsening of infections (e.g., existing tuberculosis; fungal, bacterial, viral, or parasitic infection; ocular herpes simplex). Use with caution in patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients.
- Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue XHANCE slowly.
- Patients with major risk factors for decreased bone mineral content should be monitored and treated with established standards of care.

**ADVERSE REACTIONS:** The most common adverse reactions (incidence  $\geq 3\%$ ) are epistaxis, nasal septal ulceration, nasopharyngitis, nasal mucosal erythema, nasal mucosal ulcerations, nasal congestion, acute sinusitis, nasal septal erythema, headache, and pharyngitis.

**DRUG INTERACTIONS:** Strong cytochrome P450 3A4 inhibitors (e.g., ritonavir, ketoconazole): Use not recommended. May increase risk of systemic corticosteroid effects.

**USE IN SPECIFIC POPULATIONS:** Hepatic impairment. Monitor patients for signs of increased drug exposure.

**INDICATION AND USAGE:** XHANCE is a corticosteroid indicated for the treatment of nasal polyps in patients 18 years of age or older.

#### **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, the expected commencement of promotional activities by kaleo in the fourth quarter of 2020; the potential benefits of the agreement, including without limitation, increased reach and frequency and the potential to grow appreciation for XHANCE in the target audience; as well as 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: the COVID-19 environment restricting prescriber interactions and patient flow; the effectiveness of kaleo's sales representatives in promoting XHANCE; physician and patient acceptance of XHANCE in the segment of prescribers to be called on by kaleo; 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](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 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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