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): November 15, 2021

OPTINOSE, INC.
(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):

☐ 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-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.

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

Item 2.02 Results of Operations and Financial Condition.

On November 15, 2021, OptiNose, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2021. 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 Item 2.02 (including Exhibit 99.1) of this Form 8-K, 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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by OptiNose, Inc., dated November 15, 2021.

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 15, 2021

Optinose Reports Third Quarter 2021 Financial Results and Recent Operational Highlights

Third quarter 2021 XHANCE net revenue of $22 million increased 41% compared to third quarter 2020

Third quarter 2021 XHANCE prescriptions increased 25% from third quarter 2020

Conference call and webcast to be held tomorrow at 8:30 a.m. Eastern Time

YARDLEY, Pa., Nov. 15, 2021 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, 2021, and provided operational updates.

“We continued to make progress during third quarter 2021 towards our objectives of growing XHANCE and successfully completing our chronic sinusitis program,” stated CEO Peter Miller. “XHANCE net revenue increased 41% compared to third quarter 2020 and we completed enrollment in the second of our two pivotal chronic sinusitis clinical trials. I am pleased with the business that we have built promoting XHANCE as a treatment for the approximately 1 million patients diagnosed with nasal polyps. But what excites me is the significant new opportunities for growth if we are successful in developing XHANCE as a treatment for chronic sinusitis. A label expansion for chronic sinusitis will expand the target patient population for which our specialty-focused sales force can promote XHANCE as an appropriate treatment from approximately 1 million patients to approximately 3 million patients diagnosed and treated by the physicians that we target today. In addition, there is potential for a partner to leverage their deployed presence in primary care to expand promotion of XHANCE to a total of up to 30 million people in the U.S. who have chronic sinusitis.”

Third Quarter 2021 and Recent Highlights

Total and New XHANCE Prescriptions
The number of total XHANCE® (fluticasone propionate) prescriptions increased by 25% from 69,000 in the third quarter of 2020 to 86,300 in the third quarter of 2021.

The number of new XHANCE prescriptions increased by 22% from 23,000 in the third quarter of 2020 to 27,900 in the third quarter of 2021.

Enrollment Complete in Second Pivotal Chronic Sinusitis Trial
In October, the Company completed patient recruitment in the second of two pivotal clinical trials to evaluate the safety and efficacy of XHANCE as a treatment for patients with chronic sinusitis (CS). Enrollment in the first pivotal trial was completed in July 2021.

OPN-019
In October 2021, the Company completed enrollment of the first cohort of approximately 10 patients in a randomized, proof-of-concept study being conducted in Mexico. Up to three cohorts of 10 patients are planned.
This pilot study will evaluate both the magnitude and duration of viral load reduction after a single dose of OPN-019 in subjects who tested positive for SARS-CoV-2 infection. Further recruitment in this trial is currently paused while specimen-handling and laboratory procedures in Mexico undergo further evaluation.

Corporate Guidance

XHANCE Net Revenue and Average Net Revenue per Prescription

The Company expects XHANCE net revenue for the full year of 2021 to be in the range of $71 - $75 million. Previously the company expected XHANCE net revenue for the full year of 2021 to be at least $80 million.

In addition, the Company expects full year 2021 XHANCE net revenue per prescription to be greater than $210. Previously the company expected full year 2021 XHANCE net revenue per prescription to be greater than $200.

Operating Expenses

The Company expects total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2021 to be in the range of $132 - $137 million, of which the Company expects stock-based compensation to be approximately $10 million.

Previously the Company expected total GAAP operating expenses (selling, general & administrative expenses and research & development expenses) for 2021 to be in the range of $137 - $142 million, of which the Company expected stock-based compensation to be approximately $10 million.

Chronic Sinusitis Clinical Trials

The Company has completed enrollment in both of its clinical trials evaluating XHANCE as a potential treatment for chronic sinusitis and expects top-line results from the first trial, ReOpen1, in the first quarter of 2022 and from the second trial, ReOpen2, in the second quarter of 2022.

Third Quarter 2021 Financial Results

XHANCE Net Revenue

The Company generated $21.8 million and $51.1 million in net revenue from sales of XHANCE during the three and nine months ended September 30, 2021, respectively. Net revenue from sales of XHANCE increased 41% and 56% during the three and nine months ended September 30, 2021 compared to the three and nine months ended September 30, 2020, respectively.

Costs and Expenses and Net Loss

For the three and nine months ended September 30, 2021, research and development expenses were $6.7 million and $20.1 million, respectively and selling, general and administrative expenses were $25.8 million and $80.3 million, respectively. The net loss for the three and nine months ended September 30, 2021 was $(17.1) million, or $0.32 per share (basic and diluted) and $66.7 million, or $1.25 per share (basic and diluted), respectively.

Cash

The Company had cash and cash equivalents of $84.2 million as of September 30, 2021.

Company to Host Conference Call

Members of the Company's leadership team will host a conference call and presentation to discuss financial results and corporate updates on Tuesday, November 16, 2021, beginning at 8:30 a.m. Eastern Time .

To participate on the conference call, please dial (866) 916-4761 from the U.S. or +1 (409) 216-6496 from outside the U.S. In addition, following the completion of the call, a telephone replay will be accessible until Tuesday, November 23, 2021 by dialing (855) 859-2056 from the U.S. or +1 (404) 537-3406 from outside the U.S. and entering conference ID # 9477523. A simultaneous webcast of the call and presentation can be accessed by visiting the Investors section of Optinose's website at www.optinose.com. In addition, a replay of the webcast will be available on the Company website for 60 days following the event.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Net product revenues	$ 21,826	$ 15,436	$ 51,143	$ 32,770
Licensing revenues	—	$ —	$ 1,000	—
Total revenues	21,826	$ 15,436	52,143	32,770
Costs and expenses:				
Cost of product sales	2,411	2,221	6,576	5,276
Research and development	6,654	6,524	20,058	16,930
Selling, general and administrative	25,801	24,575	80,293	77,332
Total costs and expenses	34,866	33,320	106,927	99,538
Loss from operations	(13,040)	(17,884)	(54,784)	(66,768)
Other expense	4,077	3,330	11,888	9,154
Net loss	$ (17,117)	$ (21,214)	$ (66,672)	$ (75,922)
Net loss per share of common stock, basic and diluted	$ (0.32)	$ (0.43)	$ (1.25)	$ (1.62)
Weighted average common shares outstanding, basic and diluted	53,334,669	48,907,514	53,151,730	46,914,561

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

	September 30, 2021 (unaudited)	December 31, 2020
Cash and cash equivalents	$ 84,226	$ 144,156
Other assets	47,691	44,657
Total assets	$ 131,917	$ 188,813
Total current liabilities	$ 53,627	$ 52,172
Long-term debt, net	126,542	125,202
Other liabilities	3,217	4,651
Total stockholders' equity	(51,469)	6,788
Total liabilities and stockholders' equity	$ 131,917	$ 188,813

About Optinose
Optinose is a specialty pharmaceutical company focused on serving the needs of patients cared for by ear, nose and throat (ENT) and allergy specialists. Optinose has offices in the U.S. and Norway. To learn more, please visit www.optinose.com or follow us on Twitter and LinkedIn.

About XHANCE
XHANCE is a drug-device combination product that uses an Optinose Exhalation Delivery System (EDS™) device designed to deliver a topical anti-inflammatory corticosteroid to high and deep regions of the nasal cavity. XHANCE

was approved for the treatment of nasal polyps in patients 18 years of age or older by the U.S. Food and Drug Administration in September 2017 and is currently being studied for treatment of chronic sinusitis. If successful, XHANCE may be the first FDA-approved drug product for chronic sinusitis.

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 ≥ 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.

Please see full Prescribing Information.

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 for continued or increased XHANCE prescription and net revenue growth and potential growth drivers; the Company's plans to seek approval for a follow-on indication for XHANCE for the treatment of chronic sinusitis and the potential benefits of such indication; the expectation of top-line results from its first chronic sinusitis trial in the first quarter of 2022 and top line results from the second trial in the second quarter of 2022; projected average net revenue per prescription for full year 2021; projected XHANCE net revenue for full year 2021; projected Company GAAP operating expenses and stock-based compensation for 2021; development, funding plans for OPN-019 and the potential benefits of OPN-019; and other statements regarding the Company'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: impact of, and uncertainties caused by the COVID-19 pandemic; physician and patient acceptance of XHANCE; the Company's ability to maintain adequate third-party reimbursement for XHANCE (market access); market opportunities for XHANCE may be smaller than expected; the Company's ability to grow XHANCE prescriptions and net revenues; uncertainties and delays relating to the enrollment, completion, and results of clinical trials; unanticipated costs and expenses; the Company's ability to comply with the covenants and other terms of the Pharmakon note purchase agreement; the Company's ability to continue as a going concern; risks and uncertainties relating to intellectual property; 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.

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