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): March 9, 2024

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)
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

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.

Item 1.01 Entry into a Material Definitive Agreement

Hikma Manufacturing Agreement

OptiNose, Inc. ("Optinose") and Hikma Pharmaceuticals USA, Inc. ("Hikma") are parties to a Manufacturing and Supply Agreement, dated December 11, 2020 (the "Manufacturing Agreement") pursuant to which, following FDA approval of Hikma as an alternative manufacturing site (which occurred on March 9, 2024), Hikma will manufacture and supply finished XHANCE units. Optinose will provide rolling forecasts to Hikma for orders of XHANCE units, of which a certain portion of such forecasts are binding. Optinose is required to have purchased a specified minimum number of XHANCE units over an annual period or it will be required to pay a specified fee to Hikma based on the number of XHANCE units not purchased. The Manufacturing Agreement also contains representations, warranties, indemnification and other obligations of Optinose and Hikma.

The term of the Manufacturing Agreement expires on December 31, 2026 subject to earlier termination or extension in accordance with the terms of the agreement. Either Optinose or Hikma may terminate the Manufacturing Agreement prior to that date by mutual consent or for uncured material breach by or insolvency of the other party. Optinose may also terminate the Manufacturing Agreement if, among other things, any intellectual property of any third party is reasonably alleged by a third party to be infringed, misappropriated or otherwise violated by the manufacture, import, use, sale or distribution of XHANCE or if any regulatory authority requires us to cease production of the sale of XHANCE. Hikma may also terminate the Manufacturing Agreement if, among other things, Hikma is named in a third party claim which alleges Hikma's performance of its obligations under the agreement infringe, misappropriate, or otherwise violate the intellectual property of any third party.

Item 8.01 Other Events.

Approval of Hikma Pharmaceuticals as Additional Manufacturing Site for XHANCE

On March 9, 2024, the U.S. Food and Drug Administration ("FDA") approved Hikma Pharmaceuticals USA Inc.'s affiliate West-Ward Columbus Inc. ("Hikma"), as an additional manufacturing site for finished XHANCE units for commercial sale and sampling. As a result, there are now two sites approved by the FDA for the manufacturer of finished XHANCE units for commercial sale and sampling – Hikma and Contract Pharmaceuticals Limited Canada.

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/ Michael F. Marino
Michael F. Marino
Chief Legal Officer

March 14, 2024