

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 20, 2022



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))

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 1.01 Entry into a Material Definitive Agreement

On September 20, 2022, OptiNose, Inc. ("Optinose") entered into Amendment No. 2 (the "Second Amendment") to that certain Manufacturing Services Agreement for Sub-Assembly with Advance Mold & Manufacturing, Inc. d/b/a Vision Technical Molding ("VTM"), dated December 21, 2018 (the "Original Agreement"), as amended by that certain Amendment No. 1 to Manufacturing Services Agreement for Sub-Assembly, dated September 15, 2020 (the "First Amendment" and together with the Second Amendment and the Original Agreement, the "Sub-Assembly Manufacturing Services Agreement"). The Sub-Assembly Manufacturing Services Agreement is for the assembly and supply of device subassembly units for use in the production of finished drug product for XHANCE. Pursuant to the Second Amendment, amongst other changes, the term of the Manufacturing Services Agreement has been extended to December 31, 2025, the requisite notice period for material changes in purchase order quantities was modified, the volume tiers and associated pricing for sub-assembly units were modified, and Optinose agreed to be responsible for the cost to install and qualify a third assembly line if necessary.

The foregoing description of the Second Amendment does not purport to be complete and is qualified in its entirety by reference to the full text of the Second Amendment, a copy of which is attached to this Current Report on Form 8-K as Exhibit 10.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
10.1	Amendment No.2, dated September 20, 2022, to the Manufacturing Services Agreement, dated December 21, 2018, by and among OptiNose US, Inc. and Advance Mold & Manufacturing, Inc. d/b/a Vision Technical Molding. †
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

† Portions of this exhibit (indicated by asterisks) have been omitted in compliance with Item 601 of Regulation S-K.

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

Date: September 23, 2022

Portions of this exhibit indicated by bracketed asterisks have been omitted because they are not material and would cause competitive harm to OptiNose, Inc. if publicly disclosed.

Amendment No. 2 to Manufacturing Services Agreement for Sub-Assembly

This Amendment (“Amendment”), dated as of September 6, 2022 (“Effective Date”), is among, on the one hand, OptiNose US, Inc., duly organized and existing under the laws of Delaware and having offices located at 1020 Stony Hill Road, Suite 300, Yardley, PA 19067 (referred to herein as “OptiNose US”) and OptiNose AS, duly organized and existing under the laws of Norway and having offices located at Gaustadalléen 21, 0349 Oslo, Norway (referred to herein as “OptiNose Norway” and collectively with OptiNose US, “OptiNose”), and, on the other hand, Advance Mold & Manufacturing, Inc. d/b/a Vision Technical Molding, a Connecticut corporation having offices located at 71 Utopia Road, Manchester, CT 06042 (“VTM”)

WHEREAS, the Parties entered into that certain Manufacturing Services Agreement for Sub-Assembly dated as of December 21, 2018 (“Agreement”); and

WHEREAS, the Parties desire to amend certain terms of the Agreement;

NOW, THEREFORE, in consideration of the mutual agreements contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. **Pricing.** A new Exhibit A-1 (attached hereto) shall be appended to the existing Exhibit A.
2. **Defined Terms.** Except as provided in this Amendment, all terms used in this Amendment that are not otherwise defined shall have the respective meanings ascribed to such terms in the Agreement.
3. **Section 2.01 Manufacture and Supply.** The last sentence of Section 2.01 shall be deleted. Section 2.01 now states: “During the Term and subject to the terms and conditions set forth herein, VTM shall procure Inventory and manufacture and assemble DSAs in compliance with the Specifications, Quality Agreement, applicable Laws and the other terms of this Agreement and deliver them to OptiNose or its designee. Delivery of the DSAs shall be EXW (“Ex-Works”) VTM’s manufacturing facility 71 Utopia Road, Manchester, CT 06042 (INCOTERMS 2000); VTM shall arrange for the DSAs to be picked up by a carrier identified and paid by OptiNose or its designee.
4. **Section 2.02 – Inputs for Supply of DSA’s.** Section 2.02(d) shall be deleted in its entirety and replaced with “Due to the nature of the assembly process and the uniquely dedicated staffing required to operate the line, purchase order quantities cannot be increased or decreased in consecutive months other than within the applicable tier’s volume ranges as set forth on Exhibit A unless agreed to by both parties. Additionally, volumes cannot be increased nor decreased in a manner that results in movement to a different tier as set forth in Exhibit A within 6 months of the last tier movement. Finally, VTM and OptiNose must agree to the timing required for monthly volume increases that would result in the movement of more than 1 volume tier (as defined in Exhibit A) to ensure that adequate time is given to install the necessary equipment or staffing needed to fulfill the requested volumes. VTM will use commercially reasonable efforts to ensure the timing to implement is no longer than 6 months.”

5. **Section 2.06 – Pricing.** Section 2.06(a) (annual reconciliation of purchase volumes) shall be deleted in its entirety.

6. **Section 3.01—OptiNose Equipment.**

The last sentence of Section 3.01(a) shall be deleted. Section 3.01(a) shall now state: “VTM acknowledges that the OptiNose Equipment has been paid for by OptiNose, is owned by OptiNose and that OptiNose may place identifying tags on the OptiNose Equipment confirming and providing notice of OptiNose’s ownership. VTM shall not permit any lien, claim, encumbrance or other security interest to be placed on the OptiNose Equipment relating in any way to any liability or VTM or of any party other than OptiNose and shall only use the OptiNose Equipment for the manufacture of DSAs hereunder or other activities for OptiNose. VTM hereby disclaims any interest, to the extent that it has any, in the OptiNose Equipment and agrees to execute and deliver any agreements or other documents evidencing OptiNose’s ownership of such OptiNose Equipment.”

A new Section 3.01(d) shall be added: “In the event that any OptiNose Equipment is to be shipped to, or from, VTM, OptiNose shall be responsible for all reasonable packing, temporary storage and shipping costs related thereto. OptiNose shall be responsible for cost to install and qualify a third assembly line, costs not to exceed \$[***] USD. With exception to the initial installation of a third assembly line, VTM shall be responsible for the installation, qualification and decommissioning of the OptiNose Equipment and any reasonable costs related thereto.”

8. **Section 4.01 – Notification of Defective Product.** Section 4.01 shall be deleted in its entirety and replaced with: “OptiNose or its designee shall notify VTM within:

- Thirty (30) days after receiving a shipment of DSAs if it determines that such shipment contains a Quantitative Defect,
- Thirty (30) days after receiving a shipment of DSAs if it determines that such shipment contains a Patent Defect, and
- Thirty (30) days after OptiNose becomes aware of a Latent Defect.

OptiNose or its designee shall provide VTM a sample of what it alleges contains a Latent or Patent Defect, subject to Compliance with the foregoing notice requirements and the provisions of Section 4.02, below.”

9. **Section 14.01 – Term.** Section 14.01 of the Agreement shall be deleted and replaced with: The Agreement shall commence as of the Effective Date and shall expire at 11:59pm on December 31st, 2025, unless sooner terminated pursuant to Article XV. After the expiration of the initial term hereunder, this Agreement shall be automatically renewed for separate but successive three (3) year terms unless: (a) OptiNose provides written notice to VTM that OptiNose does not intend to renew this Agreement ninety (90) days or more prior to the end of any term; or, (b) VTM provides written notice to OptiNose that VTM does not intend to renew this Agreement 180 days or more prior to the end of any term to allow OptiNose sufficient time to qualify a substitute supplier.

9. **No Other Modifications.** Except as specifically modified and amended herein, all of the terms, provisions, requirements and specifications contained in the Agreement remain in full force and effect.

10. **Counterparts.** This Amendment may be signed by facsimile or electronic means (including .PDF) and in one or more counterparts, each of which shall be an original, but which together shall constitute one binding instrument.

11. **Authority.** Each party hereby represents and warrants that is it has full power and authority to enter into this Amendment. Further, OptiNose US hereby represents and warrants that it has full power and authority to enter into this Amendment on behalf of OptiNose Norway.

IN WITNESS WHEREOF, the duly authorized representatives of the parties have executed and delivered this Amendment effective as of the Effective Date.

ADVANCE MOLD & MANUFACTURING, INC.

OPTINOSE US, INC.

By: /s/ Timothy Miller

By: /s/ Peter Miller

Print Name: Timothy Stewart

Print Name: Peter Miller

Title: VP, Secretary

Title: CEO

Date: September 12, 2022

Date: September 20, 2022

EXHIBIT A-1

Revised Pricing as of Effective Date of this Amendment

DSA Sub-assembly	TIER 1	TIER 2	TIER 3	TIER 4	TIER 5	TIER 6
Monthly Volume	[***]	[***]	[***]	[***]	[***]	[***]
Price	\$ [***]	\$ [***]	\$ [***]	\$ [***]	\$ [***]	\$ [***]
Direct Material	\$ [***]	\$ [***]	\$ [***]	\$ [***]	\$ [***]	\$ [***]
VAM (Labor & MOH)	\$ [***]	\$ [***]	\$ [***]	\$ [***]	\$ [***]	\$ [***]

The pricing set forth herein shall be effective for new Purchase Orders issued as of the Effective Date and for the unfulfilled quantities of existing Purchase Orders that remain open as of the Effective Date. Notwithstanding the requirements of a Binding Forecast, OptiNose shall have right to adjust its purchase volumes in such existing Purchase Orders and VTM shall adjust the price in accordance with this Exhibit A-1.

