

**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): January 26, 2024

LANTHEUS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36569
(Commission
File Number)

35-2318913
(IRS Employer
Identification No.)

201 Burlington Road, South Building
Bedford, Massachusetts 01730
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: (978) 671-8001

Not Applicable
(Former name or former address, if changed since 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 \$0.01 per share	LNTH	The Nasdaq Global 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 7.01. Regulation FD.

On January 26, 2024, Lantheus Holdings, Inc. (the “Company”) confirmed that the Company and its subsidiary, Lantheus Medical Imaging, Inc., were sued by Advanced Accelerator Applications USA, Inc. and Advanced Accelerator Applications SA, each a Novartis entity, for patent infringement in response to the Company’s filing of Abbreviated New Drug Application (“ANDA”) No. 217060 for Lutetium Lu 177 Dotatate (177Lu-PNT2003), a generic version of LUTATHERA® (lutetium Lu 177 dotatate). LUTATHERA® is indicated for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults.

Based on the most recent update to the FDA’s online paragraph IV database listings, the Company believes it is the “first applicant” to have filed a substantially complete ANDA for Lutetium Lu 177 Dotatate containing a Paragraph IV certification under the provisions of the Hatch-Waxman Act. As the “first applicant,” the Company believes it is eligible for 180 days of generic marketing exclusivity in the U.S. The plaintiff has filed a lawsuit for patent infringement against the Company in the United States District Court for the District of Delaware.

The information furnished pursuant to this Item 7.01 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act.

This Form 8-K contains “forward-looking statements” that are subject to risks and uncertainties. Forward-looking statements include, but are not limited to, statements relating to the potential FDA approval of and potential generic marketing exclusivity relating to 177Lu-PNT2003 and statements regarding the Company’s expectations, hopes, beliefs, intentions or strategies regarding the future. Forward-looking statements may be identified by their use of terms such as “should,” “believe” and other similar terms. Such forward-looking statements are based upon current plans, estimates and expectations that are subject to risks and uncertainties that could cause actual results to materially differ from those described in the forward-looking statements.

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.

LANTHEUS HOLDINGS, INC.

By: /s/ Daniel M. Niedzwiecki
Name: Daniel M. Niedzwiecki
Title: Chief Administrative Officer and General Counsel

Date: January 26, 2024