

**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 25, 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 September 25, 2024, Lantheus Holdings, Inc. (the “Company”) announced it expects to release data in October 2024 for the SPLASH trial based on 75% of protocol-specified target overall survival events being reached.

About the SPLASH Trial

The Phase 3 SPLASH trial is a multicenter, randomized, open-label assessment of ¹⁷⁷Lu-PNT2002 (“PNT2002”) administered at 6.8 GBq for up to 4 cycles in patients with PSMA-expressing mCRPC who have progressed on ARPI therapy and refuse, or are not eligible for, chemotherapy. The randomization phase of the study randomized 412 patients across North America, Europe, and the United Kingdom. Patients were randomized 2:1 with those in arm A receiving PNT2002 and those in arm B receiving either abiraterone or enzalutamide. Patients in arm B who experience centrally assessed radiographic progression and meet protocol eligibility have the option to crossover and receive PNT2002. Patients will be followed for up to 5 years from their first PNT2002 dose. The primary endpoint of the study is radiographic progression-free survival. At the time of the primary analysis, 84.6% of patients who experienced progressive disease in the control arm subsequently crossed over to receive PNT2002. SPLASH was conducted across the United States, Canada, Europe, and the United Kingdom. Eighty percent of SPLASH patients resided in North America and approximately 10% of all participants were Black or African American. More information about the trial is accessible at www.ClinicalTrials.gov, identifier NCT04647526.

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.

Safe Harbor for Forward-Looking and Cautionary Statements

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 timing of the Company’s release of additional data for its SPLASH trial, potential of PNT2002 and statements regarding Lantheus’ expectations, hopes, beliefs, intentions or strategies regarding the future. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Forward-looking statements may be identified by their use of terms such as “expects,” “will,” 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. Risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements include (i) the outcome of the SPLASH trial after full data is available; (ii) a delay in obtaining, or failure to obtain, a positive regulatory outcome from the FDA and regulatory authorities for PNT2002; (iii) the additional costs and risks associated with Lantheus’ ability to successfully launch PNT2002 as a commercial product; (iv) the market and patient receptivity to PNT2002 as a radiopharmaceutical therapy; (v) the existence, availability and profile of competing products and therapies; (vi) Lantheus’ ability to obtain and maintain adequate coding, coverage and payment for PNT2002; (vii) the intellectual property protection of PNT2002; (viii) POINT Biopharma’s ability to successfully develop and scale the manufacturing capabilities to support the launch of PNT2002; and (ix) the risks and uncertainties discussed in Lantheus’ filings with the Securities and Exchange Commission (including those described in the Risk Factors section in its Annual Reports on Form 10-K and its Quarterly Reports on Form 10-Q). The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Readers are cautioned not to place undue reliance on the forward-looking statements contained herein, which speak only as of the date hereof. Lantheus undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

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: September 25, 2024