

**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): February 3, 2020

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.)

331 Treble Cove Road, North Billerica, MA
(Address of principal executive offices)

01862
(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 8.01. Other Events.

On February 3, 2020, Lantheus Holdings, Inc. (the “Company”) issued a press release announcing topline results for its BENEFIT 1 LVEF Clinical Trial.

A copy of the press release is attached as Exhibit 99.1 and incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press release of Lantheus Holdings, Inc. and Lantheus Medical Imaging, Inc., dated February 3, 2020, announcing topline results for its BENEFIT 1 LVEF Clinical Trial.</u>

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/ Michael P. Duffy

Name: Michael P. Duffy

Title: Senior Vice President and General Counsel

Date: February 3, 2020



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Lantheus Announces Topline Results for BENEFIT 1 LVEF Clinical Trial

NORTH BILLERICA, MA, February 3, 2020 — Lantheus Holdings, Inc. (NASDAQ: LNTH) (“Lantheus” or the “Company”), parent company of Lantheus Medical Imaging, Inc. (“LMI”), a leader in the development, manufacture and commercialization of innovative diagnostic imaging agents and products, today announced topline results for the BENEFIT 1 Left Ventricular Ejection Fraction (“LVEF”) clinical trial.

Topline Results for the BENEFIT 1 LVEF Clinical Trial

The BENEFIT 1 LVEF clinical trial is one of two Phase 3, open-label, multicenter studies to evaluate LVEF measurement accuracy and reproducibility of DEFINITY® contrast-enhanced and unenhanced echocardiography as compared to non-contrast cardiac magnetic resonance imaging (“CMRI”) used as the truth standard. BENEFIT 1 enrolled 145 subjects. The primary objective of this study was to demonstrate improvement in accuracy in measuring LVEF using DEFINITY contrast-enhanced over unenhanced echocardiography as compared to LVEF measured using CMRI.

In BENEFIT 1, there was no statistically significant improvement in the accuracy of LVEF values for contrast-enhanced echocardiography versus unenhanced echocardiography as compared to CMRI. Analyses of the secondary endpoints revealed no improvement in inter-reader variability between the contrast-enhanced and unenhanced echocardiograms for LVEF assessments. A post-hoc analysis, however, did show statistically significant improvements in left ventricular diastolic, systolic and stroke volume measurements with contrast-enhanced versus unenhanced echocardiography when compared to CMRI.

“Although the endpoints for BENEFIT 1 were not met, we will continue to analyze the BENEFIT 1 data,” said Dr. Istvan Molnar, Chief Medical Officer of Lantheus. “When the data from BENEFIT 2 are available, we will compile the data sets to analyze the full results of the trials. We are grateful to the patients, investigators, and trial sites for participating in this trial.”

“DEFINITY is the worldwide leading product in the ultrasound contrast market and it remains a proven and preferred imaging agent serving the echocardiography community within its current indication,” said Mary Anne Heino, President and Chief Executive Officer of Lantheus. “DEFINITY’s consistent year-over-year double digit percentage revenue growth demonstrates the value it continues to provide physicians in diagnosing and managing patients. We are disappointed with the outcome of the BENEFIT 1 trial but we remain fully confident in DEFINITY and the long term growth potential of our microbubble franchise. We will continue to interact with the FDA to enhance the clinical utility for DEFINITY moving forward.”

About DEFINITY®

DEFINITY Vial for (Perflutren Lipid Microsphere) Injectable Suspension is an ultrasound contrast agent for use in patients with suboptimal echocardiograms (see Indications and Important Safety Information below and find full Prescribing Information at www.definityimaging.com).¹ DEFINITY is engineered to produce small and consistently sized durable microbubbles to fully evaluate the left ventricle.¹ DEFINITY® has extensive safety experience and a consistent safety profile.² Since its launch in 2001, more than 11 million echo studies have been performed with DEFINITY® and it is the most prescribed contrast agent in the U.S.³

INDICATIONS

Activated DEFINITY® (Perflutren Lipid Microsphere) Injectable Suspension is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.

CONTRAINDICATIONS

Do not administer DEFINITY® to patients with known or suspected hypersensitivity to perflutren.

IMPORTANT SAFETY INFORMATION

WARNING: Serious Cardiopulmonary Reactions

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following perflutren-containing microsphere administration [see *Warnings and Precautions (5.1)*]. Most serious reactions occur within 30 minutes of administration.

Assess all patients for the presence of any condition that precludes DEFINITY® administration [see *Contraindications (4)*].

Always have resuscitation equipment and trained personnel readily available.

In post marketing use, rare but serious cardiopulmonary or hypersensitivity reactions have been reported during or shortly following perflutren-containing microsphere administration [see *Adverse Reactions (6)*]. The risk for these reactions may be increased among patients with unstable cardiopulmonary conditions [see *Adverse Reactions (6.2)*]. It is not always possible to reliably establish a causal relationship to drug exposure due to the presence of underlying cardiopulmonary disease.

Please see full Prescribing Information, including boxed **WARNING** regarding serious cardiopulmonary reactions, on www.definityimaging.com.

About Lantheus Holdings, Inc. and Lantheus Medical Imaging, Inc.

Lantheus Holdings, Inc. is the parent company of LMI, a global leader in the development, manufacture and commercialization of innovative diagnostic imaging agents and products. LMI provides a broad portfolio of products, including the echocardiography contrast agent DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension and TechnoLite® (Technetium Tc99m Generator), a technetium-based generator that provides the essential medical isotope used in nuclear medicine procedures. The Company is headquartered in North Billerica, Massachusetts with offices in Puerto Rico and Canada. For more information, visit www.lantheus.com.

¹ DEFINITY® (Package Insert), North Billerica, MA, Lantheus Medical Imaging, Inc., 2017.

² Data on file, Lantheus Medical Imaging, Inc.

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Cautionary Statement Regarding Forward-Looking Statements

This document contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties and are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements are based upon current plans, estimates and expectations that are subject to various risks and uncertainties. The inclusion of forward-looking statements should not be regarded as a representation that such plans, estimates and expectations will be achieved. Words such as “anticipate,” “expect,” “project,” “intend,” “believe,” “may,” “will,” “should,” “plan,” “could,” “target,” “contemplate,” “estimate,” “predict,” “potential,” “opportunity,” “creates” and words and terms of similar substance used in connection with any discussion of future plans, actions or events identify forward-looking statements. All statements, other than historical facts, are forward-looking statements. Additional factors that may affect our future results are set forth in our filings with the SEC, including our most recently filed Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the SEC, which are available on the SEC’s website at www.sec.gov. Readers are urged to consider these factors carefully in evaluating these forward-looking statements, and not to place undue reliance on any forward-looking statements. Readers should also carefully review the risk factors described in other documents that we file from time to time with the SEC. The forward-looking statements in this document speak only as of the date of these materials. Except as required by law we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

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