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): May 27, 2021

LANTHEUS HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36569**	**35-2318913**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

331 Treble Cove Road, North Billerica, MA	**01862**
(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 8.01. Other Events.

On May 27, 2021, Lantheus Holdings, Inc. (the "*Company*") issued a press release announcing the approval by the U.S. Food and Drug Administration (FDA) of PYLARIFY®, the Company's F 18-labeled prostate-specific membrane antigen (PSMA) targeted positron emission tomography (PET) imaging agent to identify suspected metastases or recurrence of prostate cancer.

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

Exhibit No.	Description
99.1	Press release of Lantheus Holdings, Inc. entitled "Lantheus Receives U.S. FDA Approval of PYLARIFY® (piflufolastat F 18) Injection, the First and Only Commercially Available PSMA PET Imaging Agent for Prostate Cancer."
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 Niedzwiecki
Name: Daniel Niedzwiecki
Title: Senior Vice President and General Counsel

Date: May 27, 2021

Exhibit 99.1

331 Treble Cove Road
North Billerica, MA 01862
800.362.2668
www.lantheus.com

Lantheus Receives U.S. FDA Approval of PYLARIFY® (piflufolastat F 18) Injection, the First and Only Commercially Available PSMA PET Imaging Agent for Prostate Cancer

PYLARIFY will be available immediately to imaging centers in parts of the mid-Atlantic and southern regions and is expected to be broadly available throughout the U.S. by year end

NORTH BILLERICA, MA., May 27, 2021—Lantheus Holdings, Inc. (the "Company") (NASDAQ: LNTH), an established leader and fully integrated provider of innovative imaging diagnostics, targeted therapeutics and artificial intelligence solutions to find, fight and follow serious medical conditions, announced today that the U.S. Food and Drug Administration (FDA) has approved PYLARIFY, an F 18-labeled prostate-specific membrane antigen (PSMA) targeted positron emission tomography (PET) imaging agent to identify suspected metastasis or recurrence of prostate cancer. PYLARIFY is the first and only commercially available approved PSMA PET imaging agent for prostate cancer. The product will be immediately available in parts of the mid-Atlantic and southern regions and availability is expected to rapidly expand over the next six months with broad availability across the U.S. anticipated by year end.

"The FDA approval of PYLARIFY is a significant milestone for Lantheus and the prostate cancer community in the United States. We believe PYLARIFY represents a paradigm shift in the identification and management of patients with suspected metastasis or recurrent prostate cancer, providing more accurate and earlier detection of disease than conventional imaging so that doctors, along with patients and their families, can make more informed treatment decisions," said Mary Anne Heino, President and Chief Executive Officer of Lantheus. "I would like to thank the patients who participated in our clinical trials, the study investigators and our employees, whose efforts made this achievement possible."

Identification of suspected metastatic disease in men considering initial definitive therapy is important to optimize treatment planning and to avoid futile interventions. Of men with localized prostate cancer who undergo initial curative intent/management, up to 50% may experience recurrence of their disease within ten years of treatment.[1] Recurrent disease is often detected by a rise in serum prostate-specific antigen (PSA) levels; however, conventional imaging, especially at low PSA levels, is not able to identify the location and extent of the disease in the majority of cases.[2,3]

PYLARIFY was developed to target PSMA, a protein that is overexpressed on the surface of more than 90% of primary and metastatic prostate cancer cells.[4] PYLARIFY binds to the target, enabling the reader of the PET scan to detect and locate the disease. Cyclotron production of F 18 offers high batch capacity and high image resolution, and F 18's 110-minute half-life allows for wide geographic distribution.[5,6]

“Conventional imaging has significant limitations in detecting prostate cancer, both in initial staging and when the cancer has recurred or spread after initial primary treatment. Specifically, standard imaging poorly detects the early spread to distant organs, such as the lymph nodes, bones, and other organs,” said Michael J. Morris, M.D., Prostate Cancer Section Head, Genitourinary Medical Oncology, Memorial Sloan Kettering Cancer Center and the Lead Study Investigator in the CONDOR trial and Study Investigator in the OSPREY trial. “PYLARIFY can detect the spread of disease well before standard imaging and can be a transformative diagnostic tool that helps clinicians develop treatment plans based on a much more accurate understanding of a patient’s distribution of disease.”

“We believe today’s approval is a game-changer for men facing prostate cancer,” said Jamie Bearse, Chief Executive Officer of ZERO—The End of Prostate Cancer, a Patient Advocacy Group. “Having a diagnostic tool that allows doctors to see suspected metastatic or recurrent prostate cancer earlier, anywhere in the body, is a significant step forward and will have a tremendous impact on patients’ lives.”

The approval of PYLARIFY is based on data from two Company-sponsored pivotal studies (OSPREY and CONDOR) designed to establish the safety and diagnostic performance of PYLARIFY across the prostate cancer disease continuum. Results from OSPREY (Cohort A) demonstrated improvement in specificity and positive predictive value (PPV) of PYLARIFY PET imaging over conventional imaging in men at risk for metastatic prostate cancer prior to initial therapy. CONDOR studied men with biochemical recurrent prostate cancer. In patients with biochemical recurrent prostate cancer and non-informative baseline imaging, PYLARIFY demonstrated high correct localization and detection rates, including in patients with low PSA values (median PSA 0.8 ng/mL).

In the clinical trials, PYLARIFY was well tolerated. In OSPREY and CONDOR, 593 patients with various states of prostate cancer were exposed to a single dose of PYLARIFY. Adverse reactions (headache, dysgeusia and fatigue) were reported in £ 2% of patients within the studies. In addition, a delayed hypersensitivity reaction was reported in one patient (0.2%) with a history of allergic reaction.

About PYLARIFY®

PYLARIFY® (piflufolastat F 18) injection (also known as ^{18}F-DCFPyL or PyL) is a fluorinated small molecule PSMA-targeted PET imaging agent that enables visualization of lymph nodes, bone and soft tissue metastases to determine the presence or absence of recurrent and/or metastatic prostate cancer. For men with prostate cancer, PYLARIFY PET combines the accuracy of PET imaging[2], the precision of PSMA targeting and the clarity of an F 18 radioisotope[5] for superior diagnostic performance. The recommended PYLARIFY dose is 333 MBq (9 mCi) with an acceptable range of 296 MBq to 370 MBq (8 mCi to 10 mCi), administered as a bolus intravenous injection.[1,5,7,8,9]

About Prostate Cancer

Prostate cancer is the second most common form of cancer affecting men in the United States — an estimated one in eight men will be diagnosed with prostate cancer in their lifetimes. The American Cancer Society estimates that in 2021, almost 250,000 new cases of prostate cancer will be diagnosed, and more than 30,000 men will die of the disease. Approximately 3.1 million men in the United States currently count themselves as prostate cancer survivors.[10]

PYLARIFY® (piflufolastat F 18) Injection

Indication

PYLARIFY® (piflufolastat F 18) Injection is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:

- with suspected metastasis who are candidates for initial definitive therapy.
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level.

Important Safety Information

Contraindications

None.

Warnings and Precautions

Risk of Image Misinterpretation

Imaging interpretation errors can occur with PYLARIFY imaging. A negative image does not rule out the presence of prostate cancer and a positive image does not confirm the presence of prostate cancer. The performance of PYLARIFY for imaging of patients with biochemical evidence of recurrence of prostate cancer seems to be affected by serum PSA levels. The performance of PYLARIFY for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by risk factors such as Gleason score and tumor stage. PYLARIFY uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes and in normal tissues. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended.

Hypersensitivity Reactions

Monitor patients for hypersensitivity reactions, particularly patients with a history of allergy to other drugs and foods. Reactions may be delayed. Always have trained staff and resuscitation equipment available.

Radiation Risks

Diagnostic radiopharmaceuticals, including PYLARIFY, expose patients to radiation. Radiation exposure is associated with a dose-dependent increased risk of cancer. Ensure safe handling and preparation procedures to protect patients and health care workers from unintentional radiation exposure. Advise patients to hydrate before and after administration and to void frequently after administration.

Adverse Reactions

The most frequently reported adverse reactions were headaches, dysgeusia and fatigue, occurring at rate of £2% during clinical studies with PYLARIFY. In addition, a delayed hypersensitivity reaction was reported in one patient (0.2%) with a history of allergic reactions.

Drug interactions

Androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, may result in changes in uptake of PYLARIFY in prostate cancer. The effect of these therapies on performance of PYLARIFY PET has not been established.

To report suspected adverse reactions for PYLARIFY, call 1-800-362-2668 or contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For important risk and use information about PYLARIFY Injection, please see Full Prescribing information.

About Lantheus Holdings, Inc.

Lantheus Holdings, Inc. is the parent company of Lantheus Medical Imaging, Inc., Progenics Pharmaceuticals, Inc. and EXINI Diagnostics AB and an established leader and fully integrated provider of innovative imaging diagnostics, targeted therapeutics and artificial intelligence solutions to Find Fight and Follow® serious medical conditions. Lantheus provides a broad portfolio of products, including the echocardiography agent DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension; PYLARIFY®, a PSMA PET imaging agent for the detection of suspected recurrent or metastatic prostate cancer; TechneLite® (Technetium Tc99m Generator), a technetium-based generator that provides the essential medical isotope used in nuclear medicine procedures; AZEDRA® for the treatment of certain rare neuroendocrine tumors; and RELISTOR® for the treatment of opioid-induced constipation, which is partnered with Bausch Health Companies, Inc. The Company is headquartered in North Billerica, Massachusetts with offices in New York, New Jersey, Canada and Sweden. For more information, visit www.lantheus.com.

Safe Harbor for Forward-Looking and Cautionary Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, 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. Forward-looking statements may be identified by their use of terms such as “anticipate,” “believe,” “confident,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “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. 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. The Company 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. Risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements include (i) a delay in obtaining, or failure to obtain, FDA approval for additional PET manufacturing facilities that will manufacture PYLARIFY; (ii) the Company’s ability to successfully launch PYLARIFY as a commercial product; (iii) the ability of the Company’s third party PET manufacturing facilities and radiopharmacies to supply PYLARIFY to the market; (iv) the market

receptivity to PYLARIFY as a new diagnostic agent; (v) the safety and efficacy of PYLARIFY; (vi) the intellectual property protection of PYLARIFY; and (vii) the risk and uncertainties discussed in our filings with the Securities and Exchange Commission (including those described in the Risk Factors section in our Annual Reports on Form 10-K and our Quarterly Reports on Form 10-Q).

[1]Mena et al. 18 F-DCFPyL PET/CT Imaging in Patients with Biochemically Recurrent Prostate Cancer After Primary Local Therapy J Nucl Med 2020 Jun;61(6):881-889. doi: 10.2967/jnumed.119.234799. Epub 2019 Nov 1.
[2]Alipour et al. Guiding management of therapy in prostate cancer: time to switch from conventional imaging to PSMA PET? Ther Adv Med Oncol. 2019; 11: 1758835919876828.
[3]Taneja Imaging in the Diagnosis and Management of Prostate Cancer Rev Urol. 2004 Summer; 6(3): 101–113.
[4]Ceci & Fanti. PSMA-PET/CT imaging in prostate cancer: why and when. Clinical and Translational Imaging volume 7, pages377–379 (2019).
[5]Werner et al 18F-Labeled, PSMA-Targeted Radiotracers: Leveraging the Advantages of Radiofluorination for Prostate Cancer Molecular Imaging Theranostics 2020; 10(1):1-16. doi:10.7150/thno.37894.
[6]Martiniova et al. Gallium-68 in Medical Imaging Curr Radiopharm 2016;9(3):187-207. doi: 10.2174/1874471009666161028150654.
[7]Petersen LJ, Zacho HD. PSMA PET for primary lymph node staging of intermediate and high-risk prostate cancer: an expedited systematic review. Cancer Imaging. 2020;20(1):1-8. doi:10.1186/s40644-020-0290-
[8]Tan N, Oyoyo U, Bavadian N, et al. PSMA-targeted radiotracers versus 18F fluciclovine for the detection of prostate cancer biochemical recurrence after definitive therapy: a systematic review and meta-analysis. Radiology. 2020;296:44-55. doi:10.1148/radiol.2020191689
[9]PYLARIFY® [package insert]. North Billerica, MA: Progenics Pharmaceuticals, Inc., a Lantheus company
[10]American Cancer Society. Facts & Figures 2021. American Cancer Society. Atlanta, GA. 2021.

Contacts:

Mark Kinarney
Senior Director, Investor Relations
978-671-8842
ir@lantheus.com

Melissa Downs
Director, Corporate Communications
646-975-2533
media@lantheus.com