

---

---

**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): April 25, 2017**

---

**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 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 1.01 Entry into a Material Definitive Agreement.**

On April 25, 2017, Lantheus Medical Imaging, Inc. (“LMI”), the operating subsidiary of Lantheus Holdings, Inc. (the “Company”), entered into an exclusive Collaboration and License Agreement (the “License Agreement”) with GE Healthcare Limited (“GEHC”) for the continued Phase III development and worldwide commercialization of flurpiridaz F 18, an investigational positron emission tomography myocardial perfusion imaging agent that may improve the diagnosis of coronary artery disease.

Separately, LMI entered into an Amended and Restated Supply Agreement with GEHC, effective as of April 25, 2017 (the “Supply Agreement”), pursuant to which LMI will supply GEHC with TechnoLite® (Technetium Tc99m Generators), Xenon-133 (Xenon Xe 133 Gas) and Gallium-67 (Gallium Citrate Ga 67 Injection) through December 31, 2020.

*License Agreement*

Under the License Agreement, GEHC will complete the worldwide development of flurpiridaz F 18, pursue worldwide regulatory approvals and, if successful, lead a worldwide launch and commercialization of the agent, with LMI collaborating on both development and commercialization through a joint steering committee. LMI will maintain the option to co-promote the agent in the U.S. GEHC’s development plan will initially focus on obtaining regulatory approval for flurpiridaz F 18 in the U.S., Japan, Europe and Canada.

In connection with the transaction, GEHC will make a USD 5 million upfront cash payment to LMI.

In addition, if flurpiridaz F 18 receives regulatory approvals and is commercially successful, LMI will receive:

- up to USD 60 million in regulatory and sales milestones payments
- tiered double-digit royalties on U.S. sales
- mid-single-digit royalties on sales outside of the U.S.

LMI and the Company intend to use the proceeds of the upfront cash payment for general corporate purposes.

The License Agreement generally runs through December 31, 2036 and may be terminated (in whole or on a country-by-country basis, as specified in the License Agreement) by GEHC at will, by either party for the other party’s material breach or insolvency, by LMI for the cessation of development or commercialization activities or patent challenges brought by GEHC.

LMI retains rights to develop and commercialize flurpiridaz F 18 outside of cardiac imaging indications, subject to GEHC’s purchase option and rights of first offer.

The License Agreement contains customary covenants, representations and warranties, indemnities and limitations of liability.

*Supply Agreement*

The Supply Agreement specifies pricing levels and requires GEHC to purchase minimum percentage volumes of each of the specified products from LMI during the term of the agreement. The Supply Agreement will expire on December 31, 2020 and may be terminated upon the occurrence of specified events, including a material breach by the other party and certain force majeure events.

**Item 8.01 Other Events**

A copy of the joint press release of the Company and GEHC, dated April 25, 2017, announcing the signing of a definitive collaboration and license agreement for worldwide development and commercialization of flurpiridaz F 18 is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

---

**Item 9.01 Financial Statements and Exhibits****(d) Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Joint press release of Lantheus Holdings, Inc. and GE Healthcare Limited, dated April 25, 2017, entitled “Lantheus and GE Healthcare Announce the Signing of a Definitive License Agreement for Worldwide Development and Commercialization of Flurpiridaz F 18”

---

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: General Counsel, Secretary and Senior Vice President,  
Strategy and Business Development

Date: April 25, 2017

---

**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Joint press release of Lantheus Holdings, Inc. and GE Healthcare Limited, dated April 25, 2017, entitled “Lantheus and GE Healthcare Announce the Signing of a Definitive License Agreement for Worldwide Development and Commercialization of Flurpiridaz F 18”



**Lantheus and GE Healthcare Announce the Signing of a Definitive License Agreement for Worldwide Development and Commercialization of Flurpiridaz F 18**

*Companies also announce the extension and expansion of their existing commercial supply agreement for nuclear products through 2020*

**NORTH BILLERICA, Mass. (April 25, 2017)** – Lantheus Holdings, Inc. (NASDAQ: LNTH), parent company of Lantheus Medical Imaging, Inc. (collectively, “Lantheus”), and GE Healthcare (NYSE:GE), today announced the signing of a definitive license agreement (the “definitive agreement”) for the continued Phase III development and worldwide commercialization of flurpiridaz F 18, an investigational positron emission tomography (PET) myocardial perfusion imaging (MPI) agent that may improve the diagnosis of coronary artery disease (CAD), the most common form of heart disease. The definitive agreement follows the signing of a term sheet previously announced in late February 2017.

Under the definitive agreement, GE Healthcare will lead and fund the development program of flurpiridaz F18, including the second Phase III clinical study. GE Healthcare will also have exclusive worldwide rights for the commercialization of flurpiridaz F18. Lantheus will collaborate in both the development and commercialization process through a joint steering committee. Lantheus also maintains the option to co-promote the agent in the U.S.

Lantheus will receive a USD 5 million upfront cash payment and, if successful, up to USD 60 million in regulatory and sales milestones payments, plus double-digit royalties on U.S. sales and single-digit royalties on sales outside of the U.S.

Separately, the companies have also extended and expanded their current commercial agreement under which Lantheus will continue to supply GE Healthcare with TechneLite® (Technetium Tc99m Generators), Gallium-67 (Gallium Citrate Ga 67 Injection), and Xenon-133 (Xenon Xe 133 Gas) through December 31, 2020.

Mary Anne Heino, President and CEO of Lantheus commented, “With our definitive agreement for flurpiridaz F 18 in place, we look forward to collaborating with GE Healthcare to complete the development and commercialization efforts to bring this novel PET cardiac imaging agent to market. On the nuclear medicine products contracting strategy front, we are excited to extend and expand our longstanding commercial relationship with GE through a multi-year supply agreement.”

Emmanuel Ligner, General Manager of Core Imaging for GE Healthcare said, “We are committed to strengthening and expanding our nuclear portfolio through this strategic partnership with Lantheus and

---

potentially offer a new diagnostic option to clinicians and patients in CAD. I'm thrilled to bring GE Healthcare's proven track record of new product development and commercialization to this agreement as well as the quality and reliability that our customers expect globally."

#### **About Flurpiridaz F 18 and Coronary Artery Disease**

Flurpiridaz F 18, a fluorine 18-labeled agent that binds to mitochondrial complex 1 (MC-1)<sup>1</sup>, was designed to be a novel PET imaging agent that may better evaluate patients with known or suspected CAD, which is the most common form of heart disease<sup>2</sup>, affecting an estimated 15.5 million Americans 20 years of age or older<sup>3</sup>. CAD is the leading cause of death in the United States for both men and women<sup>2</sup>. Each year more than 400,000 Americans die from CAD<sup>2</sup>. In the first phase 3 study, flurpiridaz F 18 demonstrated improved CAD detection and reduced radiation exposure over standard single photon emission computed tomography (SPECT). In subgroup analyses, the risk-benefit profile of flurpiridaz F 18 PET imaging appeared to be favorable in women, obese patients and patients with multi-vessel disease. It is important to note that, with a 110 minute half-life, flurpiridaz F 18 can be used in conjunction with treadmill exercise, which is not feasible with other currently available PET tracers for MPI.

#### **About PET and MPI**

PET imaging or a PET scan is a type of nuclear medicine imaging procedure<sup>4</sup> that provides information about the function and metabolism of the body's organs, unlike computed tomography (CT) or magnetic resonance imaging (MRI), which primarily show anatomy and structure<sup>5</sup>. MPI is a non-invasive test that utilizes a small amount of radioactive material (radiopharmaceutical) injected into the body to depict the distribution of blood flow to the heart. MPI is used to identify areas of reduced blood flow to the heart muscle. The test is typically conducted under both rest and stress conditions, after which physicians examine and compare the two scans and predict whether the patient has significant coronary artery disease<sup>6</sup>. Although SPECT is most commonly used for MPI<sup>7</sup>, PET imaging has gained considerable support and use in the field of cardiovascular imaging, as it offers many advantages to SPECT, including higher spatial and contrast resolution, resulting in higher image quality and improved diagnostic accuracy, accurate attenuation correction and risk stratification<sup>8</sup>.

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

Lantheus Holdings, Inc. is the parent company of Lantheus Medical Imaging, Inc., a global leader in the development, manufacture and commercialization of innovative diagnostic imaging agents and products. LMI provides a broad portfolio of products, which are primarily used for the diagnosis of cardiovascular diseases. LMI's key products include the echocardiography contrast agent DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension; TechnoLite® (Technetium Tc99m Generator), a technetium-based generator that provides the essential medical isotope used in nuclear medicine procedures; and Xenon (Xenon Xe 133 Gas), an inhaled radiopharmaceutical imaging agent used to evaluate pulmonary function and for imaging the lungs. LMI is headquartered in North Billerica, Massachusetts with offices in Puerto Rico and Canada. For more information, visit [www.lantheus.com](http://www.lantheus.com).

#### **About GE Healthcare**

GE Healthcare provides transformational medical technologies and services to meet the demand for increased access, enhanced quality and more affordable healthcare around the world. GE (NYSE: GE) works on things that matter - great people and technologies taking on tough challenges. From medical imaging, software & IT, patient monitoring and diagnostics to drug discovery, biopharmaceutical manufacturing technologies and performance improvement solutions, GE Healthcare helps medical professionals deliver great healthcare to their patients. For more information about GE Healthcare, visit [www.gehealthcare.com](http://www.gehealthcare.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, including with regard to the finalization and execution of a definitive agreement relating to completion of the development of, and expected value of, the flurpiridaz F 18 program. Such forward-looking statements are subject to risks and uncertainties that may be described from time to time in our filings with the Securities and Exchange Commission. 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.

###

- 1 Yalamanchili, P, Wexler, E, Hayes, M, Yu, M, MD, Bozek J, Radeke, H, Azure, M, Purohit, A, Casebier, DS, and Robinson, SP. Mechanism of uptake and retention of 18F BMS-747158-02 in cardiomyocytes: A novel PET myocardial imaging agent. *Journal Nuclear Cardiology* 2007 Nov-Dec;14(6):782-8.
- 2 National Institutes of Health, National Heart, Lung, and Blood Institute. Coronary Artery Disease: Who Is At Risk. [http://www.nhlbi.nih.gov/health/dci/Diseases/Cad/CAD\\_WhoIsAtRisk.html](http://www.nhlbi.nih.gov/health/dci/Diseases/Cad/CAD_WhoIsAtRisk.html). Accessed April 2017.
- 3 Heart Disease and Stroke Statistics. 2016 Update: A Report From the American Heart Association. *Circulation*. 2016;133:e38-e360.
- 4 Radiology Info. What is Positron Emission Tomography – Computed Tomography (PET/CT) Scanning. <http://www.radiologyinfo.org/en/info.cfm?pg=PET>. Accessed April 2017.
- 5 National Institutes of Health. NIH Clinical Center. Positron Emission Tomography Department Overview. <http://clinicalcenter.nih.gov/pet/>. Accessed April 2017.
- 6 Society of Nuclear Medicine. Procedure Guidelines for Myocardial Perfusion Imaging. Version 3.0 June 2002. [http://interactive.snm.org/docs/pg\\_ch02\\_0403.pdf](http://interactive.snm.org/docs/pg_ch02_0403.pdf).
- 7 Salerno, M and Beller, GA, Noninvasive Assessment of Myocardial Perfusion. *Circ Cardiovasc Imaging*. 2009; 2:412-424.
- 8 Heller, G, Calnon, D and Dorbala, S. Recent Advances in Cardiac PET and PET/CT Myocardial Perfusion Imaging. *J Nucl Cardiol* 2009; 16:962-9.

## CONTACTS:

Lantheus Holdings, Inc.  
Meara Murphy  
978-671-8508

Gary Santo  
978-671-8960