# 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): **October 29, 2013**

# LANTHEUS MEDICAL IMAGING, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **333-169785** | **51-0396366** |
|---|---|---|
| (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))

**Item 8.01 Other Events**

A copy of Lantheus Medical Imaging, Inc.'s press release, dated October 29, 2013, announcing the preliminary results from the Phase 3 Clinical Trial of flurpiridaz F 18, is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information in this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Cautionary Note Regarding Forward-Looking Statements**

Some of the statements contained or incorporated by reference in this Current Report on Form 8-K are forward-looking statements. Such forward-looking statements are subject to risks and uncertainties, including, in particular, statements about our plans, strategies and prospects. Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements. They are neither statements of historical fact nor guarantees or assurances of future performance. The matters referred to in the forward-looking statements contained in this Current Report on Form 8-K may not in fact occur. We caution you therefore against relying on any of these forward-looking statements. Important factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national or global political, economic, business, competitive, market and regulatory conditions and other factors that are discussed in other documents we file with the Securities and Exchange Commission, such as those set forth in our Annual Report on Form 10-K for the year ended December 31, 2012 and any subsequent Quarterly Reports on Form 10-Q.

Any forward-looking statement made by us in this Current Report on Form 8-K speaks only as of the date on which it is made. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake 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.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

| Exhibit Number | Description of Exhibits |
|---|---|
| 99.1 | Press Release, dated October 29, 2013, announcing preliminary results from the Phase 3 Clinical Trial 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 MEDICAL IMAGING, INC.

By: /s/ Michael P. Duffy
Name: Michael P. Duffy
Title: Vice President and Secretary

Date: October 29, 2013

## EXHIBIT INDEX

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**Exhibit 99.1**

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**FOR IMMEDIATE RELEASE**

**Lantheus Releases Preliminary Results from Phase 3 Clinical Trial of Flurpiridaz F 18 for the Detection of Coronary Artery Disease**

**NO. BILLERICA, Mass. (October 29, 2013)** — Lantheus Medical Imaging, Inc., a global leader in developing, manufacturing and distributing innovative diagnostic imaging agents, today announced preliminary results from the first of two planned Phase 3 trials to assess the diagnostic efficacy of flurpiridaz F 18, an imaging agent used in Positron Emission Tomography (PET) myocardial perfusion imaging (MPI) for the detection of coronary artery disease (CAD). The trial compared PET MPI with flurpiridaz F18 to single photon emission computed tomography (SPECT) MPI, the current standard of care, using invasive coronary angiography as the truth standard. The open-label, multicenter study had two co-primary endpoints: superiority in sensitivity (identifying disease) and non-inferiority in specificity (ruling out disease). Flurpiridaz F 18 outperformed SPECT in a highly statistically significant manner in sensitivity and showed a statistical trend towards improved diagnostic accuracy. However, flurpiridaz F 18 did not meet the non-inferiority criterion for identifying subjects without disease.

“While preliminary results of this trial show that flurpiridaz F 18 missed one of the two co-primary endpoints, when looking at key secondary endpoints, such as image quality and diagnostic certainty, the image quality seen with flurpiridaz F 18 in the study is impressive, both absolutely and in comparison to SPECT, leading to a statistically significant improvement in diagnostic certainty,” stated Cesare Orlandi, M.D., F.A.C.C., Lantheus Chief Medical Officer. “Image quality is very important in nuclear cardiology, since it allows diagnosing presence or absence of disease with greater confidence, which may lead to a decreased need for patient re-testing.”

“We remain committed to our flurpiridaz F 18 clinical program. Next steps will include further image and data analysis, and meeting with our clinical advisors and the FDA,” stated Jeff Bailey, Lantheus President and Chief Executive Officer. “We will explore potential modifications to our clinical development plan and determine how we can use the results of this trial to advance the Phase 3 program for this exciting diagnostic candidate.”

“I continue to believe this novel agent is likely to represent the next advance in nuclear cardiology,” said lead investigator Jamshid Maddahi, M.D., F.A.C.C., F.A.S.N.C., Professor of Molecular and Medical Pharmacology (Nuclear Medicine) and Medicine (Cardiology) at the David Geffen School of Medicine at UCLA. “Flurpiridaz F 18 has consistently demonstrated an ability to provide higher quality images and superior diagnostic performance than the current standard of care. In this study, the greater PET image resolution may have contributed to missing the non-inferiority specificity endpoint. More importantly, the SPECT results showed surprisingly low sensitivity and elevated specificity which is inconsistent with prior studies, including the flurpiridaz F 18 Phase 2 trial. These findings may have confounded the outcome of the trial. From a safety perspective, the agent appears to be well-tolerated and the prospect of unit dose availability would make this candidate an attractive alternative to currently available diagnostic agents.”

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

Flurpiridaz F 18 injection, a fluorine 18-labeled agent that binds to mitochondrial complex 1 (MC-1) [1], was designed to be a novel myocardial perfusion PET imaging agent that may better evaluate patients with known or suspected coronary artery disease (CAD). CAD is the most common form of heart disease, affecting approximately 16.8 million people in the United States [2]. CAD is the leading cause of death in the United States for both men and women. Each year more than half a million Americans die from CAD [3]. The flurpiridaz F 18 Phase 2 study results were published in the *Journal of the American College of Cardiology* (*JACC*) on January 29, 2013 [4].

**About PET and MPI**

Positron Emission Tomography, also called PET imaging or a PET scan, is a type of nuclear medicine imaging procedure [5] 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[6]. 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 (perfusion) 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 [7]. Although SPECT is most commonly used for MPI [8], 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, which results in higher image quality and improved diagnostic accuracy, accurate attenuation correction and risk stratification [9].

**About Lantheus Medical Imaging, Inc.**

Lantheus Medical Imaging, Inc., a global leader in developing, manufacturing and distributing innovative diagnostic imaging agents, is dedicated to creating and providing pioneering medical imaging solutions to improve the treatment of human disease. The Company's proven success in the field of diagnostic imaging provides a strong platform from which to bring forward breakthrough new tools for the diagnosis and management of disease. Lantheus imaging products include the echocardiography contrast agent DEFINITY ® Vial for (Perflutren Lipid Microsphere) Injectable Suspension, an ultrasound contrast agent for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border, TechneLite® (Technetium Tc 99m Generator), Cardiolite® (Kit for the Preparation of Technetium Tc 99m Sestamibi for Injection), and Thallium 201 (Thallous Chloride Tl 201 Injection). Lantheus has approximately 550 employees worldwide with headquarters in North Billerica, Massachusetts, and offices in Puerto Rico, Canada and Australia. 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. 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.

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[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] Cleveland Clinic. Coronary Artery Disease — Risk Factors. http://my.clevelandclinic.org/heart/prevention/riskfactors.aspx. Accessed October 2013.

[3] 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. Accessed October 2013.

[4] Berman, D.S., Maddahi,J., *et al*. Phase II Safety and Clinical Comparison with Single-Photon Emission Computed Tomography Myocardial Perfusion Imaging for Detection of Coronary Artery Disease: Flurpiridaz F 18 Positron Emission Tomography. *J AM Coll Cardiol*. 2013 Jan; 61(4):469-77.

[5] Radiology Info. What is Positron Emission Tomography — Computed Tomography (PET/CT) Scanning. http://www.radiologyinfo.org/en/info.cfm?pg=PET. Accessed October 2013.

[6] National Institutes of Health. NIH Clinical Center. Positron Emission Tomography Department Overview. http://clinicalcenter.nih.gov/pet/. Accessed October 2013.

[7] Society of Nuclear Medicine. Procedure Guidelines for Myocardial Perfusion Imaging. Version 3.0 June 2002. http://interactive.snm.org/docs/pg_ch02_0403.pdf.

[8] Salerno, M and Beller, GA, Noninvasive Assessment of Myocardial Perfusion. *Circ Cardiovasc Imaging.* 2009; 2:412-424.

[9] 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.