# 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 29, 2011

## LANTHEUS MEDICAL IMAGING, INC.

(Exact name of registrant as specified in its charter)

**Delaware** (State or other jurisdiction of incorporation)

333-169785

(Commission File Number)

51-0396366

(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.

Update on BVL

As previously disclosed, the Company relies on Ben Venue Laboratories, Inc. ("BVL") for sole source manufacturing of DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension, Neurolite® (Kit for the Preparation of Technetium Tc99m Bicisate Injection), and certain TechneLite® (Technetium Tc99m Generator) accessories. The Company also relies on BVL for a majority of its Cardiolite® (Kit for Preparation of Technetium Tc99m Sestamibi for Injection) supply. In July 2010, BVL temporarily shut down the facility where it manufactures products for a number of customers, including the Company, in order to upgrade the facility to meet certain regulatory requirements. In anticipation of the shutdown, BVL manufactured additional inventory of the Company's products to meet the Company's expected needs during the shutdown period. Although the shutdown period ran longer than either BVL or the Company had anticipated, on September 29, 2011 BVL resumed manufacturing of Cardiolite®, and BVL has informed the Company that it anticipates resuming manufacturing of Neurolite®, DEFINITY®, and TechneLite® accessories in the fourth quarter of 2011. Before the Company can distribute to its customers products that BVL has manufactured following the shutdown, BVL must submit an additional regulatory filing with the U.S. Food and Drug Administration (the "FDA") reporting the changes in manufacturing process implemented following the shutdown. BVL has informed the Company that it anticipates making this regulatory filing — a "changes-being-effected in 30 days" or "CBE-30" filing — in the first half of October 2011, and the FDA has 30 days to respond as to whether the reported changes are appropriate without further information, documentation or regulatory consideration. If BVL does not hear from the FDA by the end of the 30-day period, it can assume that the implementation of the changes reported in the CBE-30 is permissible. The Company can give no assurances that the FDA will not respond to BVL's CBE-30 filing or request addi

The Company is currently evaluating any financial impact associated with the shutdown of BVL.

Update on Recall

As previously disclosed, as a result of recent FDA inspections of BVL and of the Company's own facilities in North Billerica, MA, the Company filed a field alert and initiated a recall of six lots of Cardiolite® and Neurolite® manufactured for the Company by BVL prior to the shutdown described above. In connection with the field alert, the Company conducted a 100% visual inspection for the presence of foreign matter for all unexpired lots of Cardiolite® within the Company's control, including retained vials, stability samples, and any remaining inventory. The Company has completed the visual inspections and has concluded that the probability of patient exposure to foreign matter is very low, and the overall patient risk associated with Cardiolite product in the field is very low. Accordingly, the Company has concluded that Cardiolite lots in the field are suitable for use. Additionally, all inspected material has been returned to active inventory status.

The Company believes that any financial impact associated with the six recalled lots is minimal.

## 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 General Counsel

Date: September 30, 2011