

Lantheus Holdings, Inc.
Form 8-K
April 25, 2017

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)

331 Treble Cove Road, North Billerica, MA 01862

35-2318913
(IRS Employer

Identification No.)

Edgar Filing: Lantheus Holdings, Inc. - Form 8-K

(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 Technel[®]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

Exhibit

No.	Description
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

Exhibit

No.	Description
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