

**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): June 27, 2024

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.)

**201 Burlington Road, South Building
Bedford, Massachusetts 01730**
(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 7.01. Regulation FD.

On June 27, 2024, Lantheus Holdings, Inc. (the “Company”) issued a press release announcing the acquisition of the global rights of Life Molecular Imaging’s RM2, targeting the gastrin-releasing peptide receptor (GRPR), including the associated novel, clinical-stage radiotherapeutic and radiodiagnostic pair, referred to as 177Lu-DOTA-RM2 and 68Ga-DOTA-RM2. A copy of the press release is being furnished with this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

The information furnished pursuant to this Item 7.01 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	Press Release of Lantheus Holdings, Inc. dated June 27, 2024, entitled “Lantheus Acquires Global Rights to Life Molecular Imaging’s Novel Therapeutic and Diagnostic Pair Targeting GRPR for Prostate and Breast Cancers”.
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 M. Niedzwiecki
Name: Daniel M. Niedzwiecki
Title: Chief Administrative Officer and General Counsel

Date: June 27, 2024



Lantheus Acquires Global Rights to Life Molecular Imaging's Novel Therapeutic and Diagnostic Pair Targeting GRPR for Prostate and Breast Cancers

Deal Further Strengthens Lantheus' Prostate Cancer Portfolio and Expands Pipeline to Include Breast Cancer

BEDFORD, Mass., June 27, 2024 – Lantheus Holdings, Inc. (“Lantheus”) (NASDAQ: LNTH), the leading radiopharmaceutical-focused company committed to enabling clinicians to Find, Fight and Follow disease to deliver better patient outcomes, today announced its acquisition of the global rights of Life Molecular Imaging’s (“Life Molecular”) RM2, targeting the gastrin-releasing peptide receptor (GRPR), including the associated novel, clinical-stage radiotherapeutic and radiodiagnostic pair, referred to as ^{177}Lu -DOTA-RM2 and ^{68}Ga -DOTA-RM2. This acquisition strengthens Lantheus’ presence in prostate cancer and expands its pipeline to include breast and other cancers. The agreement includes global rights¹ to this radiotheranostic pair for an upfront payment of \$35 million and potential regulatory milestone payments plus royalties.

Lantheus’ acquisition of worldwide rights to ^{177}Lu -DOTA-RM2 and ^{68}Ga -DOTA-RM2 underscores its dedication to pioneering cancer care and marks a significant step towards addressing unmet medical needs in prostate and breast cancer treatment. RM2 was discovered at the Universities Bern and Basel and development was originally performed by Bayer Pharma AG. It was subsequently licensed to Life Molecular. ^{68}Ga -DOTA-RM2 targets cancers overexpressing GRPR, such as prostate, breast, lung, pancreatic, colorectal, gastric and ovarian cancers and has been extensively studied in various tumor types. First-in-human dosimetry showed a favorable safety and dosimetry profile and confirmed preclinical data demonstrating dose-dependent efficacy of ^{177}Lu -DOTA-RM2. Lantheus intends to begin a Phase 1/2a study with ^{177}Lu -DOTA-RM2 in prostate cancer patients in 2025. ^{68}Ga -DOTA-RM2 will be used as a companion diagnostic.

“While new PSMA-targeted diagnostics and therapeutics are transforming prostate cancer care, there are many patients for whom PSMA-targeted therapy may not be appropriate,” said Brian Markison, Lantheus CEO. “Targeting GRPR with ^{177}Lu -DOTA-RM2 and ^{68}Ga -DOTA-RM2 creates a potential new option to expand access to radiotheranostics for more prostate cancer patients. This expands our therapeutic offerings and opens avenues for commercial synergies.”

Life Molecular, a subsidiary of Life Healthcare Group, will complete the Phase 1/2a dose escalation study in collaboration with Lantheus.

“With Lantheus’ experience developing and providing access to radiotheranostics in cancer, we are confident in our decision to hand them the reins for this promising theranostic pair and are honored to work with them toward improving the future for people with prostate and breast cancer,” said Ludger Dinkelborg, CEO, Life Molecular Imaging.

Wolf, Greenfield & Sacks, P.C. acted as legal advisor to Lantheus in connection with the transaction.

About GRPR

Gastrin-releasing peptide receptor (GRPR) is a member of the bombesin G protein-coupled receptor family. It has been found to be overexpressed in multiple cancers, including prostate, breast, lung and others.²

About Lantheus

Lantheus is the leading radiopharmaceutical-focused company, delivering life-changing science to enable clinicians to Find, Fight and Follow disease to deliver better patient outcomes. Headquartered in Massachusetts with offices in Canada and Sweden, Lantheus has been providing radiopharmaceutical solutions for more than 65 years. For more information, visit www.lantheus.com.

About Life Molecular Imaging (Life Molecular)

Life Molecular Imaging (Life Molecular) is a global radiopharmaceutical company dedicated to developing and offering novel cutting-edge radiopharmaceuticals that improve early detection and characterization of chronic and life-threatening diseases, leading to better therapeutic outcomes and improved quality of life. Life Molecular is an affiliate of Life Healthcare Group – an international people-centered, diversified healthcare organization with four decades of experience in the South African private healthcare sector. To learn more, please visit <https://life-mi.com>.

About Life Healthcare Group

Life Healthcare is a global people-centered, diversified healthcare organization listed on the Johannesburg Stock Exchange. Life Healthcare has over 40 years' experience in the South African private healthcare sector, and currently operates 64 healthcare facilities in southern Africa. Services include acute hospital care, acute physical rehabilitation, acute mental healthcare, renal dialysis, oncology, diagnostic and molecular imaging and health risk management services which include occupational health and wellness services. The Group also owns Life Molecular Imaging, a radiopharmaceutical business dedicated to developing and globally commercializing innovative radiopharmaceuticals. Visit: <https://www.lifehealthcare.co.za/> | <https://life-mi.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 “intends,” “may,” “potential,” “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) the timing and potential outcomes of clinical studies using ¹⁷⁷Lu-DOTA-RM2 and ⁶⁸Ga-DOTA-RM2, including the Phase 1/2a study; (ii) a delay in obtaining, or failure to obtain, a positive regulatory outcome from the FDA and other regulatory authorities for ¹⁷⁷Lu-DOTA-RM2 or ⁶⁸Ga-DOTA-RM2; (iii) our ability to launch ¹⁷⁷Lu-DOTA-RM2 or ⁶⁸Ga-

DOTA-RM2 as commercial products; (iv) the market receptivity to ¹⁷⁷Lu-DOTA-RM2 and ⁶⁸Ga-DOTA-RM2 as radiotheranostics; (v) the existence, availability and profile of competing products; (vi) our ability to obtain and maintain adequate coding, coverage and payment for ¹⁷⁷Lu-DOTA-RM2 and ⁶⁸Ga-DOTA-RM2; (vii) the safety and efficacy of ¹⁷⁷Lu-DOTA-RM2 and ⁶⁸Ga-DOTA-RM2; (viii) the intellectual property protection of ¹⁷⁷Lu-DOTA-RM2 and ⁶⁸Ga-DOTA-RM2; (ix) our ability to successfully develop and scale the manufacturing capabilities to support the launch of ¹⁷⁷Lu-DOTA-RM2 and ⁶⁸Ga-DOTA-RM2; and (x) the risks and uncertainties discussed in our filings with the Securities and Exchange Commission (including those described in the Risk Factors section in our most recently filed Annual Report on Form 10-K and Quarterly Reports on Form 10-Q).

¹ Lantheus' global rights are exclusive for therapeutic fields in all countries and diagnostic fields in the Americas and co-exclusive with Life Molecular for diagnostic fields outside of the Americas.

² Ma, Y., Gao, F. Advances of radiolabeled GRPR ligands for PET/CT imaging of cancers. *Cancer Imaging* 24, 19 (2024).
<https://doi.org/10.1186/s40644-024-00658-y>

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