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): **January 21, 2025**

REPLIMUNE GROUP, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38596**	**82-2082553**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

500 Unicorn Park Drive
Suite 303
Woburn, MA 01801
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: **(781) 222-9600**

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:

☐ 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 $0.001 per share	REPL	The Nasdaq Stock Market LLC (Nasdaq Global Select 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 8.01 Other Events.

On January 21, 2025, Replimune Group, Inc. (the "Company") issued a new release announcing that the U.S. Food and Drug Administration (FDA) accepted the Company's Biologics License Application for RP1 in combination with nivolumab for patients with advanced melanoma.

A copy of the news release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein. The Company undertakes no obligation to update, supplement or amend the materials attached hereto.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	News Release dated January 21, 2025
104	Cover page interactive data file (formatted as Inline XBRL)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REPLIMUNE GROUP, INC.

Date: January 22, 2025

By: /s/ Sushil Patel
Sushil Patel
Chief Executive Officer

Exhibit 99.1

Replimune Announces Biologics License Application Acceptance and Priority Review for RP1 for the Treatment of Advanced Melanoma

January 21, 2025

PDUFA action date of July 22, 2025, with priority review

WOBURN, Mass., Jan. 21, 2025 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) for RP1 (vusolimogene oderparepvec) in combination with nivolumab for patients with advanced melanoma. The FDA granted the BLA Priority Review with a Prescription Drug User Fee Act (PDUFA) action date of July 22, 2025. The FDA also informed the Company that they are not currently planning to hold an advisory committee meeting in relation to this application, and at this time have not identified any potential review issues. The BLA is supported by the primary analysis data of the IGNYTE trial, evaluating RP1 combined with nivolumab in patients with anti-PD-1 failed melanoma. A confirmatory Phase 3 trial, IGNYTE-3, is currently underway with over 100 sites planned globally.

“There are limited treatment options and a significant unmet need for patients with advanced melanoma who previously received an anti-PD-1 containing regimen,” said Sushil Patel, Ph.D., Chief Executive Officer, Replimune. “The BLA acceptance is an important milestone for Replimune, and we look forward to working closely with the FDA on the review of our application.”

The FDA grants Priority Review to applications for medicines that, if approved, provide significant improvements in the safety or effectiveness of the treatment of a serious condition. Recently, Replimune received Breakthrough Therapy designation for RP1 in combination with nivolumab for the treatment of advanced melanoma, based on the safety and clinical activity observed in the anti-PD-1 failed melanoma cohort of the IGNYTE clinical trial.

The confirmatory IGNYTE-3 trial is assessing RP1 in combination with nivolumab in patients with advanced melanoma who have progressed on anti-PD-1 and anti-CTLA-4 therapies or are ineligible for anti-CTLA-4 treatment. For more information, please visit https://replimune.com/clinical-trials /ignyte-3/.

About Melanoma

Melanoma is the fifth most common cancer, with approximately 100,000 new cases and 8,000 deaths estimated in the U.S. in 2024.[i] Standard of care therapy includes treatment with immune checkpoint blockade, to which approximately half of patients will not respond or will progress after treatment. Options are limited after immune checkpoint blockade therapy, with no standard of care available to patients.

About RP1

RP1 (vusolimogene oderparepvec) is Replimune’s lead product candidate and is based on a proprietary strain of herpes simplex virus engineered and genetically armed with a fusogenic protein (GALV-GP R-) and GM-CSF, intended to maximize tumor killing potency, the immunogenicity of tumor cell death, and the activation of a systemic anti-tumor immune response.

About Replimune

Replimune Group, Inc., headquartered in Woburn, MA, was founded in 2015 with the mission to transform cancer treatment by pioneering the development of novel oncolytic immunotherapies. Replimune’s proprietary RPx platform is based on a potent HSV-1 backbone intended to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform is designed to have a unique dual local and systemic activity consisting of direct selective virus-mediated killing of the tumor resulting in the release of tumor derived antigens and altering of the tumor microenvironment to ignite a strong and durable systemic response. The RPx product candidates are expected to be synergistic with most established and experimental cancer treatment modalities, leading to the versatility to be developed alone or combined with a variety of other treatment options. For more information, please visit www.replimune.com.

Forward Looking Statements

This press release contains forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the design and advancement of our clinical trials, the timing and sufficiency of our clinical trial outcomes to support potential approval of any of our product candidates, the FDA review process, review timing and outcome of our BLA, our goals to develop and commercialize our product candidates, patient enrollments in our existing and planned clinical trials and the timing thereof, and other statements identified by words such as "could," "expects," "intends," "may," "plans," "potential," "should," "will," "would," or similar expressions and the negatives of those terms. Forward-looking statements are not promises or guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond our control, and which could cause actual results to differ materially from those contemplated in such forward-looking statements. These factors include risks related to our limited operating history, our ability to generate positive clinical trial results for our product candidates, the costs and timing of operating our in-house manufacturing facility, the timing and scope of regulatory approvals, the availability of combination therapies needed to conduct our clinical trials, changes in laws and regulations to which we are subject, competitive pressures, our ability to identify additional product candidates, political and global macro factors including the impact of the coronavirus as a global pandemic and related public health issues and the Russian-Ukrainian and Israel-Hamas political and military conflicts, and other risks as may be detailed from time to time in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q and other reports we file with the Securities and Exchange Commission. Our actual results could differ materially from the results described in or implied by such forward-looking statements. Forward-looking statements speak only as of the date hereof, and, except as required by law, we undertake no obligation to update or revise these forward-looking statements.

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[i] American Cancer Society. "Cancer Facts and Figures 2024". Atlanta: American Cancer Society; 2024.

Replimune Group Inc