

**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): **November 21, 2024**

REPLIMUNE GROUP, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38596
(Commission
File Number)

82-2082553
(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 7.01 Regulation FD Disclosure.

On November 21, 2024, Replimune Group, Inc. (the “Company”) issued a news release announcing certain updates with respect to RP1, the Company’s lead product candidate. A copy of such news release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 7.01 and in the accompanying Exhibit 99.1 shall not be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference to such filing. The information in this Item 7.01 and the accompanying Exhibit 99.1 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended.

The Company undertakes no obligation to update, supplement or amend the materials furnished herewith.

Item 8.01 Other Events.

On November 21, 2024, the Company issued a news release announcing that it has submitted a biologics license application to the U.S. Food and Drug Administration (“FDA”) for RP1 (vusolimogene oderparepvec) in combination with nivolumab for the treatment of adult patients with advanced melanoma who have previously received an anti-PD1 containing regimen. The submission was made under the Accelerated Approval pathway. The Company also announced that FDA has granted Breakthrough Therapy designation to RP1 in combination with nivolumab in the same setting.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	News Release dated November 21, 2024
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: November 21, 2024

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

Replimune Receives Breakthrough Therapy Designation for RP1 and Submits RP1 Biologics License Application to the FDA under the Accelerated Approval Pathway

WOBURN, Mass., November 21, 2024 – Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced that it has submitted a biologics license application (BLA) to the FDA for RP1 (vusolimogene oderparepvec) in combination with nivolumab for the treatment of adult patients with advanced melanoma who have previously received an anti-PD1 containing regimen. The submission was made under the Accelerated Approval pathway. The Company also announced that the FDA has granted Breakthrough Therapy designation to RP1 in combination with nivolumab in the same setting.

Breakthrough Therapy designation is intended to expedite the development and review of therapies for serious diseases when preliminary clinical evidence indicates that the therapy may provide substantial improvement over existing available therapies on one or more clinically significant endpoints. This Breakthrough Therapy designation is based on the safety and clinical activity observed in the anti-PD1 failed melanoma cohort of the IGNYTE clinical trial.

“Today is an important milestone for Replimune and for the melanoma community as we are one step closer to having another potential treatment available for patients who have limited options after progressing on anti-PD1 containing regimens,” said Sushil Patel, Ph.D., CEO of Replimune.

The confirmatory Phase 3 IGNYTE-3 trial of RP1 in combination with nivolumab in advanced melanoma patients who have progressed on anti-PD1 and anti-CTLA-4 therapy, or who are not candidates for anti-CTLA-4 treatment is currently enrolling patients. For more information, visit <https://replimune.com/clinical-trials/ignyte-3/>.

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 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 our belief regarding the effect that the breakthrough designation will have on the timing and development of RPI 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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