

**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): **October 20, 2025**

**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 8.01**      **Other Events.**

On October 20, 2025, Replimune Group, Inc. (the “Company”) issued a news release announcing that the U.S. Food and Drug Administration (the “FDA”) accepted the Company’s resubmission of the Biologics License Application for RP1 in combination with nivolumab for patients with advanced melanoma. The PDUFA date set by the FDA is April 10, 2026 based on a Class II resubmission timeline.

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.**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
<a href="#">99.1</a>	<a href="#">News Release dated October 20, 2025</a>
104	Cover page interactive data file (formatted as Inline XBRL)

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**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: October 20, 2025

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

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**Replimune Announces FDA Acceptance of BLA Resubmission of RP1 for the Treatment of Advanced Melanoma**

*Prescription Drug User Fee Act (PDUFA) target action date set for April 10, 2026*

WOBURN, Mass., October 20, 2025 - 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 resubmission of the Biologics License Application (BLA) for RP1 in combination with nivolumab for the treatment of advanced melanoma in patients who progress on an anti-PD-1 containing regimen. The PDUFA date set by the FDA is April 10, 2026 based on a Class II resubmission timeline.

“We are pleased the agency has accepted the resubmission of our BLA for RP1,” said Sushil Patel, Ph.D., CEO of Replimune. “RP1 plus nivolumab offers a strong risk benefit profile where there are few options for patients with advanced melanoma, who have progressed on PD-1 based therapy. We look forward to working closely with the agency to expedite this review as much as possible for patients’ benefit.”

During the past few months, Replimune has been working to address agency feedback. Additional information, data and analyses were included in the resubmission which will be part of the BLA review. The FDA indicated this resubmission is considered to be a complete response to the complete response letter received in July 2025.

**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<sup>-</sup>) 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 intended to ignite local 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 then activate 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](http://www.replimune.com).

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## **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 sufficiency of our clinical trials and outcomes, and regulatory filings with the FDA, the review and timing of our biologics license application by the FDA, the potential applicability of our product candidates to treat certain indications, and other statements identified by words such as “could,” “expects,” “intends,” “hope,” “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 sufficient continuous operation of our in-house manufacturing facility to produce the necessary quality and quantity of our product candidates for continuous clinical trial supply, the timing and scope of regulatory approvals, if any, our ability to resolve the issues identified in the CRL and the Type A meeting in a manner satisfactory to the FDA and to us and the timing thereof, 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 a global pandemic and related public health issues and the ongoing political and military conflicts, including trade 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.

### **Investor Inquiries**

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