
**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): **September 16, 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 7.01 **Regulation FD Disclosure.**

On September 18, 2025, Replimune Group, Inc. (the “Company”) issued a news release announcing that it completed a Type A meeting with the U.S. Food and Drug Administration (the “FDA”) on September 16, 2025 regarding the Company’s Biologics License Application (“BLA”) for RP1 in combination with nivolumab for the treatment of advanced melanoma. The Company is evaluating the feedback from the FDA provided during the meeting to determine next steps. A copy of such news release regarding this meeting is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly stated by specific reference in such filing.

Item 8.01 **Other Events.**

On September 16, 2025, the Company completed a Type A meeting with the FDA regarding the Company’s BLA for RP1 in combination with nivolumab for the treatment of advanced melanoma.

Item 9.01 **Financial Statements and Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	News Release dated September 18, 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: September 18, 2025

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

Replimune Provides Update Following Type A Meeting with FDA

WOBURN, Mass., Sept 18, 2025 – Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced that the company completed a Type A meeting with the U.S. Food and Drug Administration (FDA) on September 16th to discuss the complete response letter (CRL) for the Company’s Biologics License Application (BLA) for RP1 in combination with nivolumab for the treatment of advanced melanoma.

The company is evaluating the feedback from the FDA provided during the meeting to determine next steps. At this time, a path forward under the accelerated approval pathway has not been determined.

“The feedback from the melanoma community, including patients and physicians, clearly highlights the unmet need in advanced melanoma and the compelling risk-benefit profile of RP1 observed in the IGNYTE trial,” said Sushil Patel, Ph.D., CEO of Replimune. “We remain committed to working with the FDA to determine an expeditious path forward for RP1.”

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 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.

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 expectations about our cash runway, the content of our interactions with the FDA at our Type A Meeting, the outcome and timing of any resolutions following such meeting, the viability of the continuation of our confirmatory trial in advanced melanoma, 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 timing of operating our in-house manufacturing facility, 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.

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