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): **August 7, 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 2.02 Results of Operations and Financial Condition.

On August 7, 2025, Replimune Group, Inc. (the "Company") issued a news release announcing its financial results for the first fiscal quarter ended June 30, 2025 and certain corporate updates. A copy of the news release 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 2.02 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 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	News Release dated August 7, 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: August 7, 2025

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

Exhibit 99.1

Replimune Reports Fiscal First Quarter 2026 Financial Results and Provides Corporate Update

Woburn, MA, August 7, 2025 – Replimune Group, Inc. (Nasdaq: REPL), a clinical stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced financial results for the fiscal first quarter ended June 30, 2025 and provided a business update.

The Company announced on July 22, 2025 that the U.S. Food and Drug Administration (FDA) had issued a Complete Response Letter (CRL) for the RP1 BLA in advanced melanoma.

"Based on the compelling clinical data and safety profile generated to date with RP1 in the IGNYTE study, the melanoma community, including clinical experts and patients, strongly believe RP1 should be made available to patients that have few remaining treatment options as soon as possible. We are committed to finding an expeditious path forward with the FDA," said Sushil Patel, Ph.D., CEO of Replimune.

Program Highlights & Milestones

RP1 (vusolimogene oderparepvec)

- The global Phase 3 trial, IGNYTE-3 assessing RP1 in combination with nivolumab is ongoing. The trial is expected to enroll approximately 400 patients across 100 sites globally and 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. The primary endpoint of this trial is overall survival and key secondary endpoints are progression free survival and overall response rate. Following the CRL, the Company anticipates discussing the design of this trial with the FDA.

RP1 (vusolimogene oderparepvec)

- **RP1 + nivolumab in non-melanoma skin cancers**
  - The Company continues to evaluate the potential of RP1 in merkel cell carcinoma, basal cell carcinoma and angiosarcoma, and locally advanced cutaneous squamous cell carcinoma, including anti-PD1-failed patients, in the ongoing IGNYTE trial cohort.
- **RP1 in skin cancer organ transplant patients**
  - The Company continues to evaluate RP1 as monotherapy in cutaneous squamous cell carcinoma patients with organ transplants in its Phase 2 ARTACUS trial. Data to-date has shown RP1 to be well tolerated with no cases of RP1-related allograft rejection observed. The overall response rate was 34.6% with a duration of response of 24 months in 61% of patients in the intent-to-treat population. ARTACUS continues to enroll patients.

RP2

- **RP2 in uveal melanoma**
  - The registration-directed Phase 2/3 REVEAL trial of RP2 in metastatic uveal melanoma is currently enrolling. The clinical trial is expected to enroll approximately 280 patients with metastatic uveal melanoma who are immune checkpoint inhibitor-naïve and evaluate RP2 in combination with nivolumab versus ipilimumab in combination with nivolumab. The primary endpoints of the trial are overall survival and progression free survival, and key secondary endpoints are overall response rate and disease control rate.
- **RP2 in hepatocellular carcinoma (HCC)**
  - The Phase 2 clinical trial of RP2 combined with atezolizumab and bevacizumab in anti-PD1/PD-L1 progressed HCC is currently enrolling with data anticipated in the first half of 2026. This trial will evaluate RP2 combined with the second-line therapy of atezolizumab and bevacizumab and is expected to enroll 30 patients. The trial is being conducted under a collaboration and supply agreement with Roche.
- **RP2 in biliary tract cancer (BTC)**
  - As previously reported, the Company expects to dose its first patient in the second half of 2025 in a cohort evaluating RP2 in patients with biliary tract cancer. This trial will evaluate RP2 combined with durvalumab and is expected to enroll 30 patients.

Financial Highlights

- **Cash Position:** As of June 30, 2025, cash, cash equivalents and short-term investments were $403.3 million, as compared to $483.8 million as of fiscal year ended March 31, 2025. The decrease in cash balance was a result of cash burn related to operating activities in advancing the company's clinical development plans.

  Based on the current operating plan, the Company believes that existing cash, cash equivalents and short-term investments, as of June 30, 2025 will enable the Company to fund operations into the fourth quarter of 2026 which includes the potential commercialization of RP1 in skin cancers and for working capital and general corporate purposes and excludes any potential revenue.

- **R&D Expenses:** Research and development expenses were $57.8 million for the fiscal first quarter and $43.0 million for the fiscal first quarter ended June 30, 2024. This increase was primarily due to an increase in personnel-related costs as we scaled operations in preparation for commercial launch of RP1, as well as medical affairs and consulting costs. Research and development expenses included $4.7 million in stock-based compensation expenses for the fiscal first quarter ended June 30, 2025.

- **S,G&A Expenses:** Selling, general and administrative expenses were $32.6 million for the fiscal first quarter ended June 30, 2025, as compared to $14.4 million for the fiscal first quarter ended June 30, 2024. Selling, general and administrative expenses included $4.1 million in stock-based compensation expenses for the fiscal first quarter ended June 30, 2025.

- **Net Loss:** Net loss was $86.7 million for the fiscal first quarter ended June 30, 2025 and $53.8 million for the fiscal first quarter ended June 30, 2024.

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 RP2

RP2 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. RP2 additionally expresses an anti-CTLA-4 antibody-like molecule, as well as GALV-GP R- and GM-CSF. RP2 is intended to provide targeted and potent delivery of these proteins to the sites of immune response initiation in the tumor and draining lymph nodes, with the goal of focusing systemic-immune-based efficacy on tumors and limiting off-target toxicity.

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 status of the FDA review or interactions following the complete response letter, 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 regulatory review process and timing of potential product approval, 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 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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Replimune Group, Inc.
Condensed Consolidated Statements of Operations
(Amounts in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,	
	2025	**2024**
Operating expenses:		
Research and development	$ 57,843	$ 42,972
General and administrative	$ 32,579	14,395
Total operating expenses	90,422	57,367
Loss from operations	(90,422)	(57,367)
Other income (expense):		
Research and development incentives	420	438
Investment income	4,714	4,711
Interest expense on finance lease liability	(521)	(534)
Interest expense on debt obligations	(1,475)	(1,426)
Other (expense) income	591	406
Total other income (expense), net	3,729	3,595
Net loss	$ (86,693)	$ (53,772)
Net loss per common share, basic and diluted	$ (0.95)	$ (0.78)
Weighted average common shares outstanding, basic and diluted	91,516,199	69,185,885

Replimune Group, Inc.
Condensed Consolidated Balance Sheets
(Amounts In thousands, except share and per share amounts)
(Unaudited)

	June 30, 2025	March 31, 2025
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 403,340	$ 483,804
Working capital	353,807	433,518
Total assets	469,507	551,328
Total stockholders' equity	336,715	415,843