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

November 6, 2025

WOBURN, Mass., Nov. 06, 2025 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (Nasdaq: REPL), a clinical stage biotechnology company pioneering the development of novel oncolytic immunotherapies, today announced financial results for the fiscal second quarter ended September 30, 2025 and provided a business update.

The Company announced on October 20, 2025, that the U.S. Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) resubmission of RP1 for the treatment of advanced melanoma with a Prescription Drug User Fee Act (PDUFA) target action date set for April 10, 2026. The resubmission is considered by the FDA to be a complete response to the complete response letter received on July 21, 2025. In the Type A meeting minutes, the FDA indicated that the IGNYTE-3 trial could potentially support approval.

“After a collaborative dialogue and productive engagement with the FDA we are encouraged by the acceptance of our BLA resubmission for RP1 in combination with nivolumab,” said Sushil Patel, Ph.D., CEO of Replimune. "We are currently partnering with the agency on the ongoing review to bring this important therapy to patients.”

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 globally and is evaluating RP1 in combination with nivolumab versus a control arm of physician’s choice 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.
- Acral melanoma data for RP1 plus nivolumab was recently presented at the ESMO Congress 2025. The analysis of acral melanoma data from the IGNYTE anti-PD-1 failed melanoma cohort showed treatment with RP1 combined with nivolumab resulted in an objective response rate (ORR) of 44% (8/18) with a median duration of response of 11.9 months. The safety profile was favorable with generally transient grade 1 and 2 treatment related adverse events.
- Additionally, a poster from ESMO featuring data from the IGNYTE clinical trial showed that RP1 plus nivolumab provided responses across multiple advanced non-melanoma skin cancer (NMSC) tumor types, including anti–PD-1 naïve and failed disease, as well as both in locally advanced and metastatic disease. The ORR was 100.0%, 33.3%, 66.7%, and 56.3% in patients with anti–PD-1 naïve MCC, BCC, angiosarcoma, and CSCC, respectively. The ORR was 26.3%, 30.0%, 37.5%, and 15.2% in patients with anti–PD-1 failed MCC, BCC, angiosarcoma, and CSCC, respectively. The IGNYTE clinical trial cohort in NMSC is ongoing.
- Data from the ongoing ARTACUS Phase 2 trial evaluating the potential of RP1 as monotherapy in cutaneous squamous cell carcinoma patients following organ transplant were recently presented during an oral session at the Society for Melanoma Research 22nd International Congress. A publication for ARTACUS is planned for 2026.

RP2

- 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.
- The Phase 2 clinical trial of RP2 combined with atezolizumab and bevacizumab in anti-PD-1/PD-L1 progressed hepatocellular carcinoma is currently enrolling. The protocol is being amended to include RP2 as monotherapy with data planned by the end of 2026. The trial is being conducted under a collaboration and supply agreement with Roche. The Company also expects to enroll its first patient in the fourth quarter of 2025 in a cohort evaluating RP2 in patients with biliary tract cancer. This cohort will evaluate RP2 combined with durvalumab.

Upcoming Events

- Society for Immunotherapy of Cancer (SITC) 2025 40th Annual Meeting being held November 5th to 9th, 2025:
  - Late-Breaking Oral Presentation: Biomarker and updated clinical data for RP1 plus nivolumab in anti-PD-1 failed melanoma from the IGNYTE trial demonstrate reversal of mechanisms of resistance to immune checkpoint blockade (Abstract 1327, November 7th, 4:45 pm ET)

- Poster: RP1 plus nivolumab in patients with and without prior BRAF-directed therapy: A subgroup analysis of patients with anti–PD-1 failed BRAF-mutant melanoma from the IGNYTE clinical trial (Poster 611, November 7, 5:35-7:00 pm ET)
- Poster: Retreatment with RP1 in combination with nivolumab in patients with advanced anti–PD-1 failed melanoma (Poster 600, November 8, 5:10-6:35 pm ET)

Financial Highlights

- **Cash Position:** As of September 30, 2025, cash, cash equivalents and short-term investments were $323.6 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 September 30, 2025 will enable the Company to fund operations late 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 $57.9 million for the fiscal second quarter and $43.4 million for the fiscal second quarter ended September 30, 2024. This increase was primarily due to an increase in RP1 direct research costs related to the IGNYTE-3 confirmatory study and other study costs including lab and operating supplies, as well as increased RP2 study costs. In addition, personnel-related costs increased as we continued to prepare for a potential commercial launch of RP1. Research and development expenses included $4.4 million in stock-based compensation expenses for the fiscal second quarter ended September 30, 2025.

- **S,G&A Expenses:** Selling, general and administrative expenses were $26.4 million for the fiscal second quarter ended September 30, 2025, as compared to $15.5 million for the fiscal second quarter ended September 30, 2024. Selling, general and administrative expenses included $4.0 million in stock-based compensation expenses for the fiscal second quarter ended September 30, 2025.

- **Net Loss:** Net loss was $83.1 million for the fiscal second quarter ended September 30, 2025 and $53.1 million for the fiscal second quarter ended September 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 September 30,		Six Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 57,877	$ 43,448	$ 115,721	$ 86,420
General and administrative	26,414	15,468	58,994	29,863
Total operating expenses	84,291	58,916	174,715	116,283
Loss from operations	(84,291)	(58,916)	(174,715)	(116,283)
Other income (expense):				
Research and development incentives	377	408	797	846
Investment income	3,696	5,394	8,411	10,106
Interest expense on finance lease liability	(518)	(531)	(1,039)	(1,065)
Interest expense on debt obligations	(1,488)	(1,438)	(2,963)	(2,864)
Other (expense) income, net	(876)	2,028	(284)	2,433
Total other income (expense), net	1,191	5,861	4,922	9,456
Net loss	$ (83,100)	$ (53,055)	$ (169,793)	$ (106,827)
Net loss per common share, basic and diluted	$ (0.90)	$ (0.68)	$ (1.85)	$ (1.45)
Weighted average common shares outstanding, basic and diluted	91,915,769	78,570,135	91,717,076	73,903,650

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

	September 30, 2025	March 31, 2025
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 323,644	$ 483,804
Working capital	280,849	433,518
Total assets	389,450	551,328
Total stockholders' equity	263,336	415,843