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

February 3, 2026

April 10, 2026 Target Action Date for RP1 in Advanced Melanoma

WOBURN, Mass., Feb. 03, 2026 (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 third quarter ended December 31, 2025 and provided a business update.

The Company's Biologics License Application (BLA) resubmission for RP1 (vusolimogene oderparepvec) in anti-PD-1 failed melanoma was accepted by the FDA in October 2025 with a Prescription Drug User Fee Act (PDUFA) target action date of April 10, 2026. Commercial readiness activities are well underway to support a potential launch, if approved.

The Company has amended its existing loan agreement with Hercules Capital, Inc. The amendment included the draw down of $35 million upon closing and the potential to draw another $120 million at post approval milestones. The amendment also delays the repayment of debt from 2026 to 2027. The Company has extended its cash runway late into to the first quarter of 2027.

"We have been engaged with the FDA in the review of the BLA resubmission for RP1," said Sushil Patel, Ph.D., CEO of Replimune. "Advanced melanoma patients can progress quickly and are in urgent need of safe and effective treatment options. Our team remains ready to launch RP1 with commercial supply produced and the commercial organization prepared to engage with our target accounts rapidly, assuming FDA approval."

Program Highlights & Milestones

RP1 (vusolimogene oderparepvec)

- **IGNYTE-3 Confirmatory Study:** The global Phase 3 trial will enroll approximately 400 patients and is assessing RP1 in combination with nivolumab versus 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:** Recent 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.
- **Advanced Non-melanoma Skin Cancer (NMSC) Studies:** 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, however, enrollment was stopped in Q4 2025.
- **ARTACUS Study:** 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. RP1 monotherapy showed robust anti-tumor activity in locally advanced CSCC with an ORR of 34.6% (CR rate was 23.1%) and 2-year duration of response of 61.0%. RP1 monotherapy was well tolerated, and the safety profile was similar to that observed in non-immunocompromised patients with advanced skin cancers.

RP2

- **REVEAL Study:** The registration-directed Phase 2/3 trial of RP2 in metastatic uveal melanoma is actively enrolling. The trial is evaluating RP2 in combination with nivolumab versus ipilimumab in combination with nivolumab in approximately 280 patients. 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. Phase 2/3 transition is expected in Q1 2027, with PFS analysis potentially supporting accelerated approval.
- **Liver-focused Studies:** 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 was 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 has enrolled its first patients in a cohort evaluating RP2 in patients with biliary tract cancer. This cohort will evaluate RP2 combined with durvalumab.

Financial Highlights

- **Cash Position:** As of December 31, 2025, cash, cash equivalents and short-term investments were $269.1 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 will enable us to fund operations late into the first quarter of calendar 2027. This 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 $53.1 million for the fiscal third quarter and $48.0 million for the fiscal third quarter ended December 31, 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 $3.6 million in stock-based compensation expenses for the fiscal third quarter ended December 31, 2025.
- **S,G&A Expenses:** Selling, general and administrative expenses were $18.7 million for the fiscal third quarter ended December 31, 2025, as compared to $18.0 million for the fiscal third quarter ended December 31, 2024. Selling, general and administrative expenses included $3.4 million in stock-based compensation expenses for the fiscal third quarter ended December 31, 2025.
- **Net Loss:** Net loss was $70.9 million for the fiscal third quarter ended December 31, 2025 and $66.3 million for the fiscal third quarter ended December 31, 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 of our BLA for RP1 or potential approval of such BLA, 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 the outcome of FDA's review process, 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 December 31,		Nine Months Ended December 31,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 53,140	$ 48,004	$ 168,860	$ 135,472
Selling, general and administrative	18,728	18,015	77,721	46,827
Total operating expenses	71,868	66,019	246,581	182,299
Loss from operations	(71,868)	(66,019)	(246,581)	(182,299)
Other income (expense):				
Research and development incentives	341	376	1,138	1,222
Investment income	2,846	5,137	11,256	15,243
Interest expense on finance lease liability	(514)	(528)	(1,553)	(1,594)
Interest expense on debt obligations	(1,466)	(1,450)	(4,429)	(4,314)
Other (expense) income, net	(580)	(3,281)	(865)	(850)
Total other income (expense), net	627	254	5,547	9,707
Loss before income taxes	$ (71,241)	$ (65,765)	$ (241,034)	$ (172,592)
Income tax (benefit) provision	$ (311)	$ 575	$ (311)	$ 575
Net loss	$ (70,930)	$ (66,340)	$ (240,723)	$ (173,167)
Net loss per common share, basic and diluted	$ (0.77)	$ (0.79)	$ (2.62)	$ (2.25)
Weighted average common shares outstanding, basic and diluted	92,187,581	83,498,892	91,874,481	77,113,695

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

	December 31, 2025	March 31, 2025
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 269,137	$ 483,804
Working capital	230,267	433,518
Total assets	333,590	551,328
Total stockholders' equity	210,539	415,843

Replimune, Inc.