Replimune Reports Fiscal Fourth Quarter and Year End 2025 Financial Results and Provides Corporate Update

May 22, 2025

- *BLA priority review of RP1 plus nivolumab in advanced melanoma proceeding on schedule; manufacturing inspections and late cycle review meeting complete*

- *Full commercial infrastructure for launch in place ahead of July 22nd PDUFA date*

- *Conference call today at 8:00 AM ET*

WOBURN, Mass., May 22, 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 fourth quarter and year ended March 31, 2025 and provided a business update.

“As we near our PDUFA date, our commercial organization is now fully hired and ready to execute our first launch in advanced melanoma,” said Sushil Patel, Ph.D., CEO of Replimune. “We have a deep understanding of the market landscape, prescriber adoption and referral patterns, and a launch plan optimized for intra-tumoral delivery across all customer segments. We believe the opportunity for RP1 to help improve the lives of patients with advanced melanoma is significant. We estimate approximately 13,000 patients progress on or after PD-1 treatment annually in the U.S. with approximately 80% of these patients eligible for treatment with RP1. Importantly, these treatments will take place in the outpatient setting and not require hospitalization. We look forward to further discussing our commercial plans for RP1 and pipeline development for RP1 and RP2 at an investor day on June 24th.”

Program Highlights & Milestones

RP1 (vusolimogene oderparepvec)

- **RP1 combined with Opdivo® (nivolumab) in anti-PD1 failed melanoma**
  - The FDA recently completed their late-cycle review and manufacturing inspections for the biologics license application, which remains on schedule ahead of a July 22, 2025 PDUFA date.
  - The FDA has indicated no advisory committee is planned.
  - The Company completed the build out of its commercial infrastructure, including the hiring and training of customer-facing teams. Distribution channels have been established and are ready to receive product, pending approval, and key state licensing is in place.
  - Enrollment is ongoing in the confirmatory Phase 3 trial, IGNYTE-3, with over 100 sites planned globally. This trial is expected to enroll 400 patients 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.

RP2

- **RP2 in uveal melanoma**
  - The registration-directed 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. The clinical 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.

Upcoming Events

- American Society of Clinical Oncology (ASCO) 2025 Annual Meeting being held May 30-June 3, 2025:
  - **Poster**: Response analysis for injected and non-injected lesions and the safety and efficacy of superficial and deep/visceral RP1 injection in the registrational cohort of anti-PD-1 failed melanoma patients of the IGNYTE trial
  - **Poster**: Biosafety analysis from the skin cancer cohorts in the IGNYTE clinical trial of RP1
  - **Poster**: A randomized, controlled, multicenter, phase 3 study of vusolimogene oderparepvec combined with

nivolumab vs. treatment of physician's choice in patients with advanced melanoma that has progressed on anti-PD-1 and anti-CTLA-4 therapy (IGNYTE-3)
    - **Poster**: A randomized, phase 2/3 clinical trial investigating RP2 plus nivolumab vs. ipilimumab plus nivolumab in immune checkpoint inhibitor-naïve patients with metastatic uveal melanoma
    - **Additional poster from an investigator sponsored trial**: A phase 1/2 study of vusolimogene oderparepvec (RP1) in primary melanoma (mel) to reduce the risk of sentinel lymph node (SLN) metastasis.
- Fireside chat at the Jefferies Global Healthcare Conference on Thursday, June 5, 2025 at 4:20 PM ET
- Replimune to host an Investor Day on Tuesday, June 24, 2025 at 10:00 AM ET

Financial Highlights

- **Cash Position:** As of March 31, 2025, cash, cash equivalents and short-term investments were $483.8 million, as compared to $420.7 million as of fiscal year ended March 31, 2024. The increase in cash balance was a result of the public offering in November 2024, somewhat offset by cash utilized in 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 March 31, 2025 will enable the Company to fund operations into the fourth quarter of 2026 which includes scale up for 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 $54.0 million for the fiscal fourth quarter and $189.4 million for the fiscal year ended March 31, 2025, as compared to $42.6 million for the fiscal fourth quarter and $175.0 million for the fiscal year ended March 31, 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 consulting and facility-related costs. Research and development expenses included $4.5 million in stock-based compensation expenses for the fiscal fourth quarter and $18.4 million for the fiscal year ended March 31, 2025.
- **S,G&A Expenses:** Selling, general and administrative expenses were $25.4 million for the fiscal fourth quarter and $72.2 million for the fiscal year ended March 31, 2025, as compared to $16.2 million for the fiscal fourth quarter and $59.8 million for the fiscal year ended March 31, 2024. Selling, general and administrative expenses included $3.8 million in stock-based compensation expenses for the fiscal fourth quarter and $16.6 million for the fiscal year ended March 31, 2025.

Net Loss: Net loss was $74.1 million for the fiscal fourth quarter and $247.3 million for the fiscal year ended March 31, 2025, as compared to a net loss of $55.1 million for the fiscal fourth quarter and $215.8 million for the fiscal ended March 31, 2024.

Conference Call

In connection with this announcement, Replimune will host a conference call and webcast at 8:00 AM ET today. Listeners can register for the webcast via this link. Analysts wishing to participate in the question and answer session should use this link. A replay of the webcast will be available via the Company's investor website approximately two hours after the call's conclusion. Those who plan on participating are advised to join 15 minutes prior to the start time.

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 designed to have a unique dual local and systemic 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 ignite 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 in advance of our scheduled PDUFA date, 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 the coronavirus as a global pandemic and related public health issues and the Russian-Ukrainian and Israel-Hamas political and military 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)
(Audited)

	March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 189,447	$ 174,963
General and administrative	$ 72,180	$ 59,810
Total operating expenses	261,627	234,773
Loss from operations	(261,627)	(234,773)
Other income (expense):		
Research and development incentives	1,773	1,920
Investment income	21,120	23,356
Interest expense on finance lease liability	(2,118)	(2,163)
Interest expense on debt obligations	(5,775)	(4,497)
Other (expense) income	(202)	771
Total other income (expense), net	14,798	19,387
Loss before income taxes	$ (246,829)	$ (215,386)
Income tax provision	$ 468	$ 408
Net loss	$ (247,297)	$ (215,794)
Net loss per common share, basic and diluted	$ (3.07)	$ (3.24)
Weighted average common shares outstanding, basic and diluted	80,564,147	66,569,894

Replimune Group, Inc.
Condensed Consolidated Balance Sheets

(Amounts In thousands, except share and per share amounts)
(Audited)

	March 31, 2025	March 31, 2024
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 483,804	$ 420,668
Working capital	433,518	393,229
Total assets	551,328	487,722
Total stockholders' equity	415,843	374,508

Replimune Group Inc