Replimune Reports Fiscal Third Quarter 2025 Financial Results and Provides Corporate Update

February 12, 2025

- *U.S. Food and Drug Administration (FDA) recently accepted the Biologics License Application (BLA) for RP1 plus nivolumab in advanced melanoma for priority review with a PDUFA date of July 22, 2025*
- *IGNYTE-3 confirmatory trial of RP1(vusolimogene oderparepvec) plus nivolumab in advanced melanoma is enrolling*
- *Enrolled first patients in trials evaluating RP2 for the treatment of metastatic uveal melanoma and hepatocellular carcinoma*

WOBURN, Mass., Feb. 12, 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 third quarter ended December 31, 2024 and provided a business update.

“Over the past couple of months, we have achieved significant regulatory milestones for RP1 in anti-PD-1 failed melanoma,” said Sushil Patel, Ph.D., CEO of Replimune. “With Priority Review and a PDUFA date set for July 22, 2025, by the FDA, our efforts are focused on ensuring a successful commercial launch of RP1 upon approval. Our commercial strategy is built on a deep understanding of the patient population and prescriber landscape, coupled with a launch model designed to effectively deliver intratumoral therapy. With over $500 million in cash, we are well-capitalized to execute our plans and are excited to provide further updates as we transition to a commercial-stage company.”

Program Highlights & Milestones

RP1

- **RP1 combined with Opdivo® (nivolumab) in anti-PD1 failed melanoma**
  - In January, the FDA accepted the BLA for RP1 in combination with nivolumab for patients with advanced melanoma. The BLA was granted Priority Review by the FDA with a PDUFA action date of July 22, 2025.
  - The BLA is supported by the primary analysis data of the IGNYTE trial, evaluating RP1 combined with nivolumab in patients with anti-PD-1 failed melanoma.
  - Enrolling into the confirmatory Phase 3 trial, IGNYTE-3, with over 100 sites planned globally. This trial will assess 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.

RP2

- **RP2 in uveal melanoma**
  - Enrolled the first patient in a registration-directed study of RP2 in metastatic uveal melanoma in patients who are immune checkpoint inhibitor-naïve. The study will enroll approximately 280 patients and evaluate RP2 in combination with nivolumab versus ipilimumab in combination with nivolumab. The primary endpoints of the study are overall survival and progression free survival and key secondary endpoints are overall response rate and disease control rate.
- **RP2 in hepatocellular carcinoma (HCC)**
  - Enrolled the first patient in a Phase 2 clinical trial with RP2 combined with atezolizumab and bevacizumab in anti-PD1/PD-L1 progressed HCC. The trial is an open label trial that will enroll 30 patients and evaluate RP2 combined with the second-line therapy of atezolizumab and bevacizumab. The study is being conducted under a collaboration and supply agreement with Roche.

Financial Highlights

- **Financing:** Completed a public offering of shares of the Company’s common stock and pre-funded warrants, raising approximately $156.0 million net of issuance costs. Proceeds from the financing will be used to fund the continued development of our RPx platform, including expanding our ongoing studies within RP1 and broadening clinical development plans for RP2, as well as for working capital and general corporate purposes.
- **Cash Position:** As of December 31, 2024, cash, cash equivalents and short-term investments were $536.5 million, as compared to $420.7 million as of fiscal year ended March 31, 2024. The increase in cash balance was directly related to the public offering in November, 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 December 31, 2024 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 $48.0 million for the fiscal third quarter ended December 31, 2024, as compared to $42.8 million for the fiscal third quarter ended December 31, 2023. This increase was primarily due to an increase in personnel-related costs, as well as consulting and facility-related costs. Research and development expenses included $4.6 million in stock-based compensation expenses for the fiscal third quarter ended December 31, 2024.

- **S,G&A Expenses:** Selling, general and administrative expenses were $18.0 million for the fiscal third quarter ended December 31, 2024, as compared to $13.7 million for the fiscal third quarter ended December 31, 2023. Selling, general and administrative expenses included $4.1 million in stock-based compensation expenses for the fiscal third quarter ended December 31, 2024.

- **Net Loss:** Net loss was $66.3 million for the fiscal third quarter ended December 31, 2024, as compared to a net loss of $51.1 million for the fiscal third quarter ended December 31, 2023.

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 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.

Investor Inquiries

Chris Brinzey
ICR Healthcare
339.970.2843
chris.brinzey@icrhealthcare.com

Media Inquiries
Arleen Goldenberg
Replimune
917.548.1582
media@replimune.com

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,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 48,004	$ 42,847	$ 135,472	$ 132,384
General and administrative	18,015	13,693	$ 46,827	43,633
Total operating expenses	66,019	56,540	182,299	176,017
Loss from operations	(66,019)	(56,540)	(182,299)	(176,017)
Other income (expense):				
Research and development incentives	376	415	1,222	1,251
Investment income	5,137	5,686	15,243	17,922
Interest expense on finance lease liability	(528)	(540)	(1,594)	(1,626)
Interest expense on debt obligations	(1,450)	(1,012)	(4,314)	(3,083)
Other (expense) income	(3,281)	1,344	(850)	1,307
Total other income (expense), net	254	5,893	9,707	15,771
Loss before income taxes	$ (65,765)	$ (50,647)	$ (172,592)	$ (160,246)
Income tax provision	$ 575	$ 473	$ 575	$ 473
Net loss	$ (66,340)	$ (51,120)	$ (173,167)	$ (160,719)
Net loss per common share, basic and diluted	$ (0.79)	$ (0.77)	$ (2.25)	$ (2.42)
Weighted average common shares outstanding, basic and diluted	83,498,892	66,645,691	77,113,695	66,532,488

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

	December 31, 2024	March 31, 2024
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 536,539	$ 420,668
Working capital	499,687	393,229
Total assets	603,628	487,722
Total stockholders' equity	482,374	374,508

Replimune Group Inc