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

November 12, 2024

- *Completed Pre-Biologics License Application (BLA) meeting with the U.S. Food and Drug Administration (FDA) and remain on track to submit a BLA for RP1 plus nivolumab in anti-PD1 failed melanoma via the accelerated approval pathway before the end of the year*
- *IGNYTE-3 confirmatory trial of RP1(vusolimogene oderparepvec) in advanced melanoma underway with first patient enrolled in August*
- *Presented late-breaking abstracts at ESMO and SITC featuring the IGNYTE trial primary analysis showing clinical activity with RP1 plus nivolumab in anti-PD1 failed melanoma*

WOBURN, Mass., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (Nasdaq: REPL), a clinical stage biotechnology company pioneering the development of a novel class of oncolytic immunotherapies, today announced financial results for the fiscal second quarter ended September 30, 2024 and provided a business update.

"I am incredibly proud of our progress as we rapidly approach the submission of our BLA for RP1," said Sushil Patel, Ph.D., CEO of Replimune. "The IGNYTE data was presented at major medical meetings and was well received by the oncology community, who noted the importance of the systemic activity demonstrated and the continuing need for additional treatments for patients with advanced melanoma. As a team, we have been focused on our ongoing preparation for commercialization, including building our field teams, completing important market research and developing our market access teams, among many other activities to ensure we are well positioned to reach as many physicians and patients as possible."

Program Highlights & Milestones

RP1

- **RP1 combined with Opdivo® (nivolumab) in anti-PD1 failed melanoma**
  - In September, the Company completed a pre-BLA meeting with the FDA confirming plans to submit a BLA for RP1 for the treatment of anti-PD1 failed melanoma via the accelerated approval pathway before the end of the year.
  - The IGNYTE-3 confirmatory trial of RP1 in advanced melanoma is underway with first patient enrolled in August. This clinical trial is a 2-arm randomized Phase 3 trial with a defined list of physician's choice treatment options as the comparator arm in advanced melanoma patients who progressed on anti-PD1 and anti-CTLA-4 therapy or are ineligible for anti-CTLA-4 treatment.
  - Late-breaking abstracts presented at ESMO and SITC shared the primary analysis from the IGNYTE trial.
    - The primary analysis reiterated the positive top line results presented in June and confirmed the 12-month overall response rate was 33.6% by modified RECIST 1.1 criteria, the primary endpoint as defined in the protocol, and 32.9% by RECIST 1.1 criteria, an additional analysis requested by the FDA.
    - In addition, new data shared showed activity across all clinical subgroups, including patients who had prior anti-PD1 and anti-CTLA-4 (ORR 27.7%) and for those who had primary resistance to anti-PD1 (ORR 35.9%) by modified RECIST 1.1.
    - Median duration of response from response initiation was 21.6 months and median duration of response from treatment initiation was 27.6 months.
    - Initial biomarker data shows increased CD8+ T cell and PD-L1 expression post treatment in 50% of the tested biopsies. The increase in gene expression signature, associated CD8+ T cells and inflammatory cytokines further highlight the potential of RP1 plus nivolumab to generate a potent anti-tumor response.

RP2

- **RP2 in Uveal Melanoma**
  - Study start-up activities are underway for a registration-directed study of RP2 in metastatic uveal melanoma in patients who are immune checkpoints inhibitor-naïve. The study plans to enroll the first patient in a randomized trial of RP2 in combination with nivolumab vs. ipilimumab and nivolumab, or nivolumab for those ineligible for ipilimumab in the first quarter of 2025.

- **RP2 in hepatocellular carcinoma (HCC)**
  - A Phase 2 clinical trial with RP2 combined with atezolizumab and bevacizumab in anti-PD1/PD-L1 progressed HCC is actively screening patients.

Financial Highlights

- **Cash Position:** As of September 30, 2024, cash, cash equivalents and short-term investments were $432.1 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 PIPE financing in June, 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 September 30, 2024 will enable the Company to fund operations into the second half of 2026 which includes scale up for the commercialization of RP1 in skin cancers and for working capital and general corporate purposes.

- **R&D Expenses:** Research and development expenses were $43.4 million for the fiscal second quarter ended September 30, 2024, as compared to $49.1 million for the fiscal second quarter ended September 30, 2023. This decrease was primarily due to the wind down of the CERPASS and IGNYTE Phase II studies, as well as the deprioritization of development efforts on RP3. Research and development expenses included $4.1 million in stock-based compensation expenses for the fiscal second quarter ended September 30, 2024.

- **S,G&A Expenses:** Selling, general and administrative expenses were $15.5 million for the fiscal second quarter ended September 30, 2024, as compared to $14.7 million for the fiscal second quarter ended September 30, 2023. Selling, general and administrative expenses included $4.6 million in stock-based compensation expenses for the fiscal second quarter ended September 30, 2024.

- **Net Loss:** Net loss was $53.1 million for the fiscal second quarter ended September 30, 2024, as compared to a net loss of $60.0 million for the fiscal second quarter ended September 30, 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 a 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, 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
Westwicke, an ICR Company
339.970.2843
chris.brinzey@westwicke.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 September 30,		Six Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 43,448	$ 49,101	$ 86,420	$ 89,538
General and administrative	15,468	14,730	$ 29,863	29,941
Total operating expenses	58,916	63,831	116,283	119,479
Loss from operations	(58,916)	(63,831)	(116,283)	(119,479)
Other income (expense):				
Research and development incentives	408	443	846	836
Investment income	5,394	6,049	10,106	12,235
Interest expense on finance lease liability	(531)	(542)	(1,065)	(1,086)
Interest expense on debt obligations	(1,438)	(955)	(2,864)	(2,070)
Other income (expense)	2,028	(1,409)	2,433	(35)
Total other income (expense), net	5,861	3,586	9,456	9,880
Loss before income taxes	$ (53,055)	$ (60,245)	$ (106,827)	$ (109,599)
Income tax provision	$ —	$ (201)	$ —	$ —
Net loss	$ (53,055)	$ (60,044)	$ (106,827)	$ (109,599)
Net loss per common share, basic and diluted	$ (0.68)	$ (0.90)	$ (1.45)	$ (1.65)
Weighted average common shares outstanding, basic and diluted	78,570,135	66,582,280	73,903,650	66,475,577

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

	September 30, 2024	March 31, 2024
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 432,059	$ 420,668
Working capital	398,845	393,229
Total assets	498,202	487,722
Total stockholders' equity	381,459	374,508