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

August 8, 2024

- *Pre-Biologics License Application (BLA) meeting with the U.S. Food and Drug Administration (FDA) scheduled for September and BLA submission planned for 2H 2024*
- *Enrollment of first patient in Phase 3 confirmatory trial of RP1 in advanced melanoma expected in Q3 2024*
- *Protocol finalized for registration-directed study of RP2 in uveal melanoma with study initiation activities underway*

WOBURN, Mass., Aug. 08, 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 first quarter ended June 30, 2024 and provided a business update.

"We have had a highly productive quarter as we gear up for the upcoming pre-BLA meeting with the FDA and prepare to enroll the first patient in our confirmatory trial of RP1 in anti-PD1 failed melanoma," said Sushil Patel, Ph.D., CEO of Replimune. "Our confidence in the RP1 program is reinforced by the IGNYTE primary analysis data that we presented in June, which demonstrates the potential of RP1 to address unmet needs in anti-PD1 failed melanoma patients who have not responded to prior existing therapies. We remain committed to advancing the clinical programs in our pipeline, including RP2, where we are preparing to enroll patients in a registration-directed study in uveal melanoma."

Program Highlights & Milestones

RP1

- **RP1 combined with Opdivo® (nivolumab) in anti-PD1 failed melanoma**
  - In June, the Company announced positive topline primary analysis data by independent central review from the IGNYTE clinical trial of RP1 plus nivolumab in anti-PD1 failed melanoma. Topline results showed 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. Responses from baseline were highly durable, with all responses lasting more than 6 months and median duration of response exceeding 35 months.
  - The Company plans to present the full primary analysis data from the anti-PD1 failed melanoma cohort including key secondary endpoint data and subgroups for presentation at an upcoming medical congress.
  - The Company expects to enroll its first patient in the Phase 3 confirmatory IGNYTE-3 trial in Q3 2024, prior to submitting the RP1 BLA expected in 2H 2024. The Phase 3 trial design has been agreed to with the FDA and will be a 2-arm randomized 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.
  - A pre-BLA meeting with the FDA is scheduled for September and a BLA submission is planned for 2H 2024.

RP2

- **RP2 in Uveal Melanoma**
  - In June during ASCO 2024, the Company presented safety, efficacy, and biomarker results from an open-label, multicenter, Phase 1 study of RP2 alone or combined with nivolumab in a cohort of patients with uveal melanoma. RP2 administered as monotherapy or in combination with nivolumab demonstrated an ORR of 29.4%, with a disease control rate (DCR) of 58.8%.
  - Replimune has finalized the protocol based on FDA input and begun trial initiation activities for a registration-directed study of RP2 in metastatic uveal melanoma in patients who are immune checkpoints inhibitor-naïve. The study is a randomized trial of RP2 in combination with nivolumab vs. ipilimumab and nivolumab, or nivolumab for those ineligible for ipilimumab.

- **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 expected to dose its first patient in 2H 2024.

Financial Highlights

- **Financing:** Completed a securities purchase agreement for a private investment in public equity ("PIPE") raising $96.7 million net of issuance costs. Proceeds from the financing will be used to scale up for the commercialization of RP1 and for working capital and general corporate purposes.

- **Cash Position:** As of June 30, 2024, cash, cash equivalents and short-term investments were $469.1 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, 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 June 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 $43.0 million for the fiscal first quarter ended June 30, 2024, as compared to $40.4 million for the fiscal first quarter ended June 30, 2023. This increase was primarily due to increased personnel expenses, including a $2.8 million increase in payroll and fringe benefits, and a stock-based compensation increase of $0.9 million. Research and development expenses included $4.2 million in stock-based compensation expenses for the fiscal first quarter ended June 30, 2024.

- **S,G&A Expenses:** Selling, general and administrative expenses were $14.4 million for the fiscal first quarter ended June 30, 2024, as compared to $15.2 million for the fiscal first quarter ended June 30, 2023. Selling, general and administrative expenses included $5.2 million in stock-based compensation expenses for the fiscal first quarter ended June 30, 2024.

- **Net Loss:** Net loss was $53.8 million for the fiscal first quarter ended June 30, 2024, as compared to a net loss of $49.6 million for the fiscal first quarter ended June 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 portfolio of 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
ICR Westwicke
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 June 30,	
	2024	**2023**
Operating expenses:		
Research and development	$ 42,972	$ 40,437
Selling, general and administrative	14,395	15,211
Total operating expenses	57,367	55,648
Loss from operations	(57,367)	(55,648)
Other income (expense):		
Research and development incentives	438	393
Investment income	4,711	6,186
Interest expense on finance lease liability	(534)	(544)
Interest expense on debt obligations	(1,426)	(1,115)
Other income	406	1,374
Total other income (expense), net	3,595	6,294
Loss before income taxes	$ (53,772)	$ (49,354)
Income tax provision	-	201
Net loss	$ (53,772)	$ (49,555)
Net loss per common share, basic and diluted	$ (0.78)	$ (0.75)
Weighted average common shares outstanding, basic and diluted	69,185,885	66,367,702

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

	June 30, 2024	**March 31, 2024**
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 469,124	$ 420,668
Working capital	444,640	393,229
Total assets	534,965	487,722
Total stockholders' equity	426,451	374,508