Replimune Reports Fiscal Fourth Quarter and Year-Ended 2021 Financial Results and Provides Corporate Update

May 20, 2021

Added complete response as an independent primary endpoint in registration-directed CERPASS study in CSCC and held Type B meeting with FDA to discuss the IGNYTE study in anti-PD1 failed melanoma

Dosed first patient with RP1 in the anti-PD1 failed NSCLC lung cancer cohort of the IGNYTE study

Data update on lead programs to be provided during virtual investor event on June 3, 2021

Strengthened management team to prepare for potential commercial launch and enable further later stage development

Ended fiscal year 2021 with approximately $476 million in Cash; Capitalized into second half of 2024

WOBURN, Mass., May 20, 2021 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a biotechnology company developing a series of oncolytic immuno-gene therapies derived from its Immulytic® platform, today announced financial results for the fiscal fourth quarter and year ended March 31, 2021 and provided a business update.

“We have made good progress advancing our programs over the quarter and look forward to providing a data update with RP1 and RP2 at our virtual investor event being held in June as we continue to enroll into our registration-directed clinical trials in CSCC and anti-PD1 failed melanoma, with expected readouts in 2022,” said Philip Astley-Sparke, CEO of Replimune. “Our vision extends well beyond our initial lead skin cancer indications, with the broader aim of becoming a cornerstone for immuno-oncology treatments across a wide spectrum of tumor types. With this in mind, and as we move closer to market, we recently expanded our senior management team with two key hires with a considerable track record of success in bringing multiple high profile programs to BLA approval and in overseeing the launch of new drugs in the immuno-oncology space.”

Corporate Updates

- **Expanded management team with key hires to prepare for the transition to a commercial company.** The Company hired Sushil Patel, Ph.D. as Chief Commercial Officer, arriving from Genentech where he was the head of their global oncology franchise for lung cancer, skin cancer and rare / agnostic tumor types, and previously the lifecycle leader in lung cancer for the multi-billion-dollar checkpoint blockade drug Tecentriq®. In addition to hiring Dr. Patel, the Company also appointed Tanya Lewis as Chief Development Operations Officer. Ms. Lewis’s past accomplishments include successful negotiations related to registration trial designs, approval, and/or commercialization of XPOVIO®, VELCADE®, VARUBI®, INTEGRILIN® and ZEJULA®.

- **Announced plans to amend the CERPASS clinical trial protocol to add complete response (CR) rate as an additional independent primary endpoint.** The amendment is based on the depth and durability of responses and the manageable safety profile seen in patients with non-melanoma skin cancers treated with RP1 in combination with Opdivo® to date. Under the modified clinical trial protocol for CERPASS, Replimune plans to add CR rate as an additional independent primary endpoint, in addition to overall response rate (ORR), and to reduce target enrollment from 240 patients to 180 patients. Secondary endpoints will continue to include duration of response, progression-free survival (PFS), and overall survival (OS). Replimune plans to submit the amended protocol to the FDA by the end of this quarter and is maintaining its guidance to expect primary data read out in 2022.

- **Held Type B meeting with the FDA to discuss the regulatory pathway for RP1 in combination with Opdivo® (nivolumab) in anti-PD1 failed melanoma.** Replimune recently held a Type B meeting with the FDA to discuss the design of the currently enrolling 125-patient registration-directed cohort of patients with anti-PD1 failed melanoma in the IGNYTE clinical trial. The FDA expressed that while a randomized controlled clinical trial would always be preferred for registration, if the clinical data is sufficiently compelling in this patient population with no clear standard of care, then the data could be submitted to the FDA for review under the accelerated approval pathway. The FDA also indicated that a randomized confirmatory trial would be needed as is required under the accelerated approval process.

- **Presented new biomarker and pre-clinical data for RP1 and RP2, at the 2021 American Association for Cancer Research (AACR) Annual Meeting.** The data presented continues to confirm potent anti-tumor activity and activation of robust systemic immune activation by RP1 and RP2.

- **Virtual Investor Event to be held on Thursday, June 3, 2021.** The Company will host a virtual investor event to present updated data from its Phase 2 skin cancer cohorts combining RP1 with Opdivo and data from its Phase 1 study of RP2 alone and in combination with Opdivo. The event will include presentations by the management team and Mark Middleton, Professor of Experimental Cancer Medicine in the Department of Oncology, consultant Medical Oncologist at the Oxford

Cancer and Hematology Centre and Head of the Department of Oncology at the University of Oxford.

- **First RP1 batches produced and filled at state-of-the-art manufacturing facility.** Release testing is underway for the first GMP RP1 batches produced at its 63,000-square-foot manufacturing facility in Framingham, MA, that was built to support the commercialization of all of its products. Technology transfer for RP2 has also commenced and is expected to complete in the next quarter.

Program Highlights and Upcoming Milestones

- **RP1 in combination with Libtayo® (cemiplimab) in CSCC:** CERPASS, the Company's Phase 2, global, randomized, controlled, registration-directed clinical trial continues to actively enroll patients and remains on track for a primary data read out in 2022.

- **RP1 in combination with Opdivo in anti-PD-1 failed melanoma:** The Company's 125-patient cohort in the IGNYTE Phase 2 clinical trial of RP1 in combination with Opdivo, continues to actively enroll patients and remains on track to report the primary data read out in 2022.

- **RP1 in combination with Opdivo in melanoma and non-melanoma skin cancers (NMSC):** Following a positive Phase 2 data update in October 2020 and enrollment of the initial melanoma cohort (including anti-PD1 naïve and anti-PD1 failed patients) being complete, the Company continues to enroll its 45-patient cohort evaluating RP1 in combination with Opdivo in NMSC. The Company plans to provide an update on these programs at its June 3rd investor event.

- **RP1 in anti-PD1 failed NSCLC:** The first patient in the cohort of 30 anti-PD1 failed NSCLC patients treated with RP1 combined with Opdivo has been dosed, and the Company expects to report initial data in the second half of 2021.

- **RP1 as monotherapy in solid organ transplant recipients with CSCC:** The Company is currently enrolling a 30 patient Phase 1b clinical trial (ARTACUS) assessing the safety and efficacy of RP1 in liver and kidney transplant recipients with CSCC. Enrollment in this immuno-compromised population has been hampered by COVID 19, but as the effects of the pandemic reduce the Company expects recruitment to increase. Early data from this clinical trial is intended to be presented in the second half of 2021.

- **RP1 in combination with Opdivo in MSI-H/dMMR tumors:** The Company continues to expect to be able to decide whether to pursue RP1 for MSI-H/dMMR tumors into registration-directed development by the end of 2021.

- **RP2 alone and in combination with Opdivo:** Following positive data with RP2 given as monotherapy that were presented in October 2020, the Company is actively enrolling a 30-patient cohort evaluating RP2 in combination with Opdivo. Updated data from this clinical trial, including an update on patients treated with RP2 monotherapy and initial data with RP2 in combination with Opdivo will be presented at the upcoming June 3rd investor event.

- **RP3 alone and in combination with anti-PD-1 therapy:** The Phase 1 clinical trial evaluating RP3 alone and in combination with anti-PD1 therapy in solid tumor patients is actively enrolling and the Company remains on track to report initial data in the second half of 2021.

- **Target evaluation for new indications is currently underway:** The Company remains on track to disclose part of its initial development plans for RP2 and/or RP3 in less immune responsive tumor types at the upcoming June 3rd investor event.

Financial Fiscal Quarter Four and Year End Highlights:

- **Cash Position:** As of March 31, 2021, cash, cash equivalents and short-term investments were $476.3 million, as compared to $168.6 million as of March 31, 2020. This increase was primarily related to $372.5 million in net proceeds from financing activities offset by an increase in cash utilized in operating activities in advancing our expanded clinical development plan.

  Based on the current operating plan, Replimune believes that existing cash and cash equivalents and short-term investments will fund operating expenses and capital expenditure requirements into the second half of 2024.

- **R&D Expenses:** Research and development expenses were $16.2 million for the fourth quarter and $56.8 million for the fiscal year ended March 31, 2021, as compared to $11.2 million for the fourth quarter and $38.8 million for the fiscal year ended March 31, 2020. This increase was primarily due to clinical expenses driven by the company's lead programs, expansion into additional studies, operating our dedicated manufacturing facility and related increased personnel costs. Research and development expenses included $2.0 million in stock-based compensation expenses for the fourth quarter and $5.7 million in stock-based compensation expenses for the fiscal year ended March 31, 2021.

- **G&A Expenses:** General and administrative expenses were $6.0 million for the fourth quarter and $23.2 million for the fiscal year ended March 31, 2021, as compared to $5.2 million for the fourth quarter and $17.4 million for the year ended March 31, 2020. The increase was primarily driven by personnel related costs, professional fees, and facility

expansion. General and administrative expenses included $1.5 million in stock-based compensation expenses for the fourth quarter and $6.0 million in stock-based compensation expenses for the fiscal year ended March 31, 2021.

- **Net Loss:** Net loss was $21.5 million for the fourth quarter and $80.9 million for the fiscal year ended March 31, 2021, as compared to a net loss of $15.8 million for the fourth quarter and $52.6 million for the fiscal year ended March 31, 2020.

About CERPASS
CERPASS is Replimune's registration-directed randomized, global Phase 2 clinical study to compare the effects of Libtayo alone versus a combination of Libtayo and Replimune's investigational oncolytic immunotherapy RP1. The clinical trial will enroll 180 patients with locally advanced or metastatic cutaneous squamous cell carcinoma (CSCC) who are naïve to anti-PD1 therapy. The trial will evaluate complete response (CR) rate and overall response rate (ORR) as its two primary efficacy endpoints as assessed by independent review, as well as duration of response, progression-free survival (PFS), and overall survival (OS) as its secondary endpoints. The study is being run under a clinical trial collaboration agreement with Regeneron in which the costs of the trial are shared and full commercial rights retained by Replimune. Libtayo is being jointly developed by Regeneron and Sanofi.
Libtayo® is a registered trademark of Regeneron.

About IGNYTE
IGNYTE is Replimune's multi-cohort Phase 1/2 trial of RP1 plus Opdivo®. There are 4 tumor specific cohorts currently enrolling in this trial including a 125-patient extension cohort of RP1 combined with Opdivo in anti-PD-1 failed cutaneous melanoma. This cohort was initiated after completing enrollment in a prior Phase 2 cohort in the same trial of approximately 30 patients with melanoma. The additional thirty patient cohorts are studying RP1 in combination with Opdivo in non-melanoma skin cancers which includes both naïve and anti-PD-1 failed CSCC, in microsatellite instability high, or MSI-H/dMMR tumor types and anti-PD-1 failed non-small cell lung cancer, or NSCLC. This trial is being done under a collaboration and supply agreement with Bristol Myer Squibb.
Opdivo® is a registered trademark of Bristol-Myers Squibb Company.

About RP1
RP1 is Replimune's lead Immulytic® product candidate and is based on a proprietary new strain of herpes simplex virus engineered to maximize tumor killing potency, the immunogenicity of tumor cell death and the activation of a systemic anti-tumor immune response.

About RP2 & RP3
RP2 and RP3 are derivatives of RP1 that express additional proteins. RP2 expresses an anti-CTLA-4 antibody-like molecule and RP3 additionally expresses the immune co-stimulatory pathway activating proteins CD40L and 4-1BBL. RP2 and RP3 are intended to provide targeted and potent delivery 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 to develop the next generation of oncolytic immune-gene therapies for the treatment of cancer. Replimune is developing novel, proprietary therapeutics intended to improve the direct cancer-killing effects of selective virus replication and the potency of the immune response to the tumor antigens released. Replimune's Immulytic® platform is designed to maximize systemic immune activation, in particular to tumor neoantigens, through robust viral-mediated immunogenic tumor cell killing and the delivery of optimal combinations of immune-activating proteins to the tumor and draining lymph nodes. The approach is expected to be highly synergistic with immune checkpoint blockade and other approaches to cancer treatment across a broad range of cancers. Replimune intends to progress these therapies rapidly through clinical development in combination with other immuno-oncology products with complementary mechanisms of action as well as in standalone indications. 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 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, the potential impact of COVID-19 on our operations and milestones, 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, 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 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)

Statement of Operations	Year Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 56,754	$ 38,761
General and administrative	23,201	17,437
Total operating expenses	79,955	56,198
Loss from operations	(79,955)	(56,198)
Other income (expense):		
Research and development incentives	2,807	3,084
Investment income	916	2,424
Interest expense on finance lease liability	(2,242)	(1,185)
Interest expense on debt obligations	(818)	(734)
Loss on extinguishment of debt	(913)	-
Other (expense) income	(665)	(16)
Total other (expense) income, net	(915)	3,573
Net loss attributable to common stockholders	$ (80,870)	$ (52,625)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.75)	$ (1.54)
Weighted average common shares outstanding, basic and diluted	46,248,969	34,261,548

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

	March 31, 2021	**March 31, 2020**
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 476,302	$ 168,555
Working capital	469,200	162,377
Total assets	543,098	234,097
Total stockholders' equity	498,728	183,718