Replimune Reports Third Fiscal Quarter Financial Results and Provides Corporate Update

February 3, 2022

Data expected to be presented at an investor event in March 2022:

Data updates from the completed RP1 IGNYTE cohorts in anti-PD1 naïve non-melanoma skin cancer (NMSC) and anti-PD1 naïve and failed melanoma

Initial data from the ongoing study in anti-PD1 failed NMSC and from the ARTACUS trial, a Phase 1b/2 trial of RP1 as monotherapy in solid organ transplant recipients with cutaneous squamous cell carcinoma (CSCC)

RP3 initial data and the Phase 2 development plan for RP2/3

WOBURN, Mass., Feb. 03, 2022 (GLOBE NEWSWIRE) -- Replimune Group Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of a novel class of tumor-directed oncolytic immunotherapies, today announced financial results for the fiscal third quarter ended December 31, 2021 and provided a business update.

"We are looking forward to hosting an investor event next month to present on commercial strategy and RP2/3 development plans as well as provide anticipated data updates," said Philip Astley-Sparke, Chief Executive Officer of Replimune. "At the event we intend to present our plans to establish a broad, high value skin cancer franchise with RP1 and provide a thorough overview of our mid-stage development plans for the RP2/3. We will also review other key milestones that we expect to achieve over the next year, including the release of data from registrational studies that we believe will highlight our platform's potential to become a cornerstone of cancer treatment."

Corporate Updates

- **Replimune to host an investor event in March 2022.** The event will review updated data from completed IGNYTE cohorts in non-melanoma skin cancer (NMSC) and melanoma. In addition, the Company intends to present initial data from the ongoing study in anti-PD1 failed NMSC and from its ARTACUS trial, a Phase 1b/2 trial of RP1 as monotherapy in solid organ transplant recipients with skin cancer. The Company will also provide a detailed overview of its RP2/3 program including the Phase 2 development plan.

- **Presented updated RP2 data at the 2021 Society for Immunotherapy of Cancer's (SITC) 36 th Annual Meeting.** In November, the Company presented updated interim data from its ongoing Phase 1 trial of RP2 alone and in combination with Opdivo® (nivolumab) that demonstrated the potential clinical utility of RP2 in patients with hard-to-treat, anti-PD1 failed cancers, including durability of response, together with biomarker data demonstrating the ability of RP2 to turn immunologically 'cold' tumors 'hot.'

Upcoming Milestones

CERPASS – Registration-directed Phase 2 clinical trial in cutaneous squamous cell carcinoma (CSCC)

- **RP1 in combination with Libtayo® (cemiplimab-rwlc) in CSCC:** The Company is actively enrolling patients in a registration-directed, global, randomized, controlled, 180-patient Phase 2 clinical trial (CERPASS) evaluating RP1 in combination with Libtayo vs. Libtayo alone in patients with advanced CSCC. The Company expects to complete enrollment in mid-year 2022 and the trigger for the primary data analysis to be six months thereafter.

IGNYTE – Multi-cohort Phase 2 clinical trial of RP1 combined with Opdivo® (nivolumab)

- **Anti-PD-1 failed melanoma cohort:** The Company continues to enroll patients in the 125-patient cohort of the IGNYTE Phase 2 clinical trial in patients with anti-PD1 failed melanoma. The Company expects to release initial directional data from this cohort in late 2022.

- **Non-melanoma skin cancer (NMSC) cohort:** The Company continues to enroll patients with anti-PD-1 failed NMSC. The Company expects to provide initial data from this cohort in the first quarter of 2022.

- **Anti-PD(L)-1 failed non-small cell lung cancer (NSCLC) cohort:** Enrollment is open in a 30-patient cohort of RP1 in combination with Opdivo in anti-PD(L)-1 failed NSCLC patients, with initial data expected to be released in late 2022.

ARTACUS – Phase 1b/2 clinical trial of RP1 as monotherapy in solid organ transplant recipients with skin cancer

- Enrollment continues in this 65-patient clinical trial with potential registrational intent, assessing the safety and efficacy of RP1 in organ transplant recipients with skin cancer. The Company expects to present initial data from this clinical trial in the first quarter of 2022.

RP2 and RP3

- **RP2 alone and in combination with Opdivo in difficult-to-treat cancers:** The Company has initiated the expansion of the Phase 1 clinical trial of RP2 in combination with Opdivo, with a focus on patients with liver metastases from various prevalent tumor types including patients with lung, breast and gastrointestinal cancers. The Company expects to release initial expansion patient data in late 2022.

- **RP3 alone and in combination with Opdivo:** The Company is enrolling patients in a Phase 1 clinical trial for RP3, with initial data expected to be released in the first quarter of 2022. The Company expects to start enrolling patients to be treated with RP3 in combination with Opdivo this quarter, including patients with various prevalent tumor types such as lung, breast, head and neck cancer and gastrointestinal cancers. The Company expects to release initial expansion patient data in late 2022.

- **RP2 and/or RP3 next stage development including in patients with liver metastases from a range of tumor types:** The Company remains on track to initiate a broad Phase 2 clinical development program with RP2 and/or RP3, intended to include a range of prevalent tumor types, including in patients with liver metastases, around mid-year 2022. Details of this plan remain on track to be presented in the first quarter of 2022.

Financial Highlights

- **Cash Position:** As of December 31, 2021, cash, cash equivalents and short-term investments were $420.2 million, as compared to $476.3 million as of March 31, 2021. This decrease was primarily related to cash utilized in operating activities in advancing the Company's expanded clinical development plan.

  Based on the current operating plan, Replimune believes that existing cash, cash equivalents and short-term investments will fund operating expenses and capital expenditure requirements into the second half of 2024, excluding any confirmatory trial required by the FDA or other regulatory body.

- **R&D Expenses:** Research and development expenses were $19.4 million for the third quarter ended December 31, 2021, as compared to $14.3 million for the third quarter ended December 31, 2020. This increase was primarily due to increased clinical and manufacturing expenses driven by the Company's lead programs and increased personnel expenses. Research and development expenses included $1.8 million in stock-based compensation expenses for the third quarter ended December 31, 2021.

- **G&A Expenses:** General and administrative expenses were $10.3 million for the third quarter ended December 31, 2021, as compared to $6.0 million for the third quarter ended December 31, 2020. The increase was primarily driven by personnel-related costs, including sales and marketing personnel associated with pre-launch planning and initial build of the Company's commercial infrastructure. General and administrative expenses included $4.1 million in stock-based compensation expenses for the third quarter ended December 31, 2021.

- **Net Loss:** Net loss was $29.7 million for the third quarter ended December 31, 2021, as compared to a net loss of $21.8 million for the third quarter ended December 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 is enrolling 180 patients with locally advanced or metastatic cutaneous squamous cell carcinoma (CSCC) who are naïve to anti-PD-1 therapy. The clinical 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 secondary endpoints. The study is being conducted 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 clinical trial including a 125-patient cohort in anti-PD-1 failed cutaneous melanoma. This cohort was initiated after completing enrollment in a prior Phase 2 cohort in the same clinical trial of approximately 30 patients with melanoma. The additional cohorts are in non-melanoma skin cancers which includes both naïve and anti-PD-1 failed CSCC, in anti-PD1 failed microsatellite instability high, or MSI-H/dMMR tumors and anti-PD(L)-1 failed non-small cell lung cancer, or NSCLC. This trial is being conducted under a collaboration and supply agreement with Bristol-Myers Squibb Company. Opdivo is a registered trademark of Bristol-Myers Squibb Company.

About RP1

RP1 is Replimune's lead product candidate and is based on a proprietary new strain of herpes simplex virus engineered and genetically armed 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 immune-activating 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 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 tumor-directed oncolytic immunotherapies. Replimune's proprietary RPx platform is based on a potent HSV-1 backbone with payloads added to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform has a unique dual local and systemic mechanism of action (MOA) consisting of direct selective virus-mediated killing of the tumor resulting in the release of tumor derived antigens and altering of the tumor microenvironment (TME) to ignite a strong and durable systemic response. This MOA is expected to be synergistic with most established and experimental cancer treatment modalities, and, with an attractive safety profile the RPx platform has 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, our upcoming investor event, 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)
(Unaudited)

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 19,353	$ 14,322	$ 57,809	$ 40,529
General and administrative	10,345	5,953	28,517	17,242

Total operating expenses	29,698	20,275	86,326	57,771
Loss from operations	(29,698)	(20,275)	(86,326)	(57,771)
Other income (expense):				
Research and development incentives	733	550	2,246	1,991
Investment income	87	116	259	821
Interest expense on finance lease liability	(555)	(560)	(1,670)	(1,683)
Interest expense on debt obligations	-	(247)	-	(817)
Loss on extinguishment of debt	-	(913)	-	(913)
Other (expense) income	(241)	(454)	(849)	(999)
Total other (expense) income, net	24	(1,508)	(14)	(1,600)
Net loss	$ (29,674)	$ (21,783)	$ (86,340)	$ (59,371)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.57)	$ (0.44)	$ (1.66)	$ (1.34)
Weighted average common shares outstanding, basic and diluted	52,319,877	49,382,213	52,104,548	44,436,680

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

	December 31, 2021	March 31, 2021
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 420,172	$ 476,302
Working capital	409,504	469,200
Total assets	485,282	543,098
Total stockholders' equity	437,509	498,728

Replimune Group Inc