Replimune Reports Fiscal Second Quarter Financial Results and Provides Corporate Update

November 4, 2021

RP1; Full patient accrual in CERPASS registration-directed clinical trial continues to be expected in mid-year 2022 with the primary data trigger expected in late 2022. Interim data in the IGNYTE anti-PD1 failed registration directed melanoma cohort continues to be expected in late 2022

RP2; Updated monotherapy and combination data with Opdivo (nivolumab) to be presented at SITC this month; Phase 1 protocol amendment expansion to add additional patients with liver metastases filed

RP2/3; Detailed Phase 2 clinical development program including patients with liver metastases to be presented in Q1 2022 along with initial RP3 Phase 1 monotherapy data

Cash at 30 September of ~$436m with runway into second half of 2024

WOBURN, Mass., Nov. 04, 2021 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a biotechnology company developing oncolytic immuno-gene therapies derived from its Immulytic® platform, today announced financial results for the fiscal second quarter ended September 30, 2021 and provided a business update.

"Replimune continues to build towards a data rich 2022 where we are expecting to reach multiple inflection points culminating in the primary data analysis trigger for our registration-directed randomized controlled clinical trial with RP1 in cutaneous squamous cell carcinoma (CSCC) and the presentation of interim data from our registration directed cohort in anti-PD1 failed melanoma from the IGNYTE clinical trial," said Philip Astley-Sparke, CEO of Replimune. "In the first quarter of 2022 we will be presenting initial data in anti-PD1 failed non-melanoma skin cancers (NMSC) and in NMSC transplant patients with single agent RP1, both including CSCC. Our objective is to establish a broad skin cancer franchise with RP1. In addition to an update on RP2 at SITC 2021, we look forward to presenting data during 2022 from the expansion of our Phase 1 studies with RP2 and RP3 with a focus on patients with liver metastases from prevalent tumor types. We also look forward to presenting a comprehensive Phase 2 development plan with RP2 and/or 3 in the first quarter of 2022, with study initiation intended around midyear, as we continue to make progress towards positioning our programs as a cornerstone of cancer treatment."

Recent Events and Corporate Updates

- **Replimune to present three 'Trial-In-Progress' posters and a poster including new data with RP2 at the 2021 Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting.** The Company is scheduled to present four posters at SITC being held November 10-14, 2021. Included in these posters will be a data update from its 30-patient Phase 1 clinical trial evaluating RP2 alone and combined with Opdivo in difficult-to-treat cancers.

Program Highlights*

CERPASS – Registration directed Phase 2 clinical trial in CSCC

- **RP1 in combination with Libtayo® (cemiplimab) in CSCC:** The Company is actively enrolling patients in CERPASS, its registration directed, global, randomized controlled Phase 2 clinical trial of RP1 in combination with Libtayo vs. Libtayo alone in 180 patients with advanced CSCC. The Company expects to complete enrollment such that the primary data analysis is expected to be triggered in late 2022.

IGNYTE – multi cohort Phase 2 clinical trial of RP1 combined with Opdivo

- **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 continues to expect to release interim data from this cohort in late 2022 but, as previously disclosed, in order to document sufficient durability of response, an important secondary endpoint of the study, the primary analysis is expected to be triggered in mid-year 2023.

- **Non-melanoma skin cancer (NMSC) cohort:** The Company has completed enrollment of 30-patients with anti-PD-1 naïve NMSC and continues to enroll patients with anti-PD-1 failed NMSC. The Company remains on track to provide updated data from the anti-PD1 naïve patients and initial data from the anti-PD-1 failed patients in the first quarter of 2022.

- **Anti-PD(L)-1 failed non-small cell lung cancer (NSCLC) cohort: Dosing is underway in a 30-patient cohort of RP1 in combination with Opdivo in anti-PD(L)-1 failed NSCLC.** A recently filed amendment to the IGNYTE protocol includes modifications to the patient eligibility criteria which are expected to enhance enrollment into this cohort of the clinical trial.

The Company had planned to provide initial data from this cohort in the first quarter of 2022. However, the changes made to facilitate enrollment are not expected to take effect in time to meet prior guidance and initial data is now expected to be released later in 2022.

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

- The Company continues to enroll patients in this 65-patient clinical trial, with potential registrational intent, assessing the safety and efficacy of RP1 in liver and kidney transplant recipients with skin cancers, including CSCC. The Company remains on track 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 remains on track to provide a data update from the Phase 1 clinical trial in patients treated as monotherapy with RP2 and RP2 combined with Opdivo at SITC in the fourth quarter of 2021. The Company has filed an amendment to expand this trial to, in particular, provide data in patients with liver metastases from various prevalent tumor types with a focus on patients with lung, breast and gastrointestinal cancers including colorectal cancer.

- **RP3 alone and in combination with anti-PD-1 therapy:** The Company is enrolling patients in its Phase 1 clinical trial with RP3, with initial monotherapy data expected to be presented in the first quarter of 2022. The Company expects to start enrolling patients to be treated with RP3 in combination with anti-PD-1 therapy early in the new year, including patients with liver metastases from various prevalent tumor types such as lung, breast, head and neck cancer and gastrointestinal cancers including colorectal cancer.

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

*****Program Highlight dates are on a calendar-year basis.

Financial Highlights

- **Cash Position:** As of September 30, 2021, cash, cash equivalents and short-term investments were $435.8 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 and 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 $19.9 million for the second quarter ended September 30, 2021, as compared to $14.1 million for the second quarter ended September 30, 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 $2.2 million in stock-based compensation expenses for the second quarter ended September 30, 2021.

- **G&A Expenses:** General and administrative expenses were $9.3 million for the second quarter ended September 30, 2021, as compared to $5.6 million for the second quarter ended September 30, 2020. The increase was primarily driven by personnel-related costs, professional fees, and facility expansion. General and administrative expenses included $4.1 million in stock-based compensation expenses for the second quarter ended September 30, 2021.

- **Net Loss:** Net loss was $29.4 million for the second quarter ended September 30, 2021, as compared to a net loss of $20.1 million for the second quarter ended September 30, 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-PD-1 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 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 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 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 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 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, the potential impact of the global coronavirus pandemic and the global economy 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)
(Unaudited)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 19,902	$ 14,050	$ 38,456	$ 26,207
General and administrative	9,345	5,613	18,172	11,289
Total operating expenses	29,247	19,663	56,628	37,496

Loss from operations	(29,247)	(19,663)	(56,628)	(37,496)
Other income (expense):				
Research and development incentives	725	755	1,513	1,441
Investment income	80	178	172	705
Interest expense on finance lease liability	(557)	(562)	(1,115)	(1,123)
Interest expense on debt obligations	-	(286)	-	(570)
Other (expense) income	(356)	(517)	(608)	(545)
Total other (expense) income, net	(108)	(432)	(38)	(92)
Net loss attributable to common stockholders	$ (29,355)	$ (20,095)	$ (56,666)	$ (37,588)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.56)	$ (0.46)	$ (1.09)	$ (0.90)
Weighted average common shares outstanding, basic and diluted	52,081,325	44,015,786	51,962,795	41,950,401

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

	September 30, 2021	March 31, 2021
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 435,771	$ 476,302
Working capital	427,748	469,200
Total assets	503,464	543,098
Total stockholders' equity	457,412	498,728

Replimune Group Inc