Replimune Reports Third Fiscal Quarter Financial Results and Provides Corporate Update

February 4, 2021

RP1: Initial data in new indications expected in 2021 in anti-PD1 failed NSCLC, anti-PD1 failed CSCC and CSCC solid organ transplant recipient patients; further updates expected to be provided across all studies

RP2: Initial data to be reported in 2021 in combination with Opdivo in Phase 1 all comers study

RP3: First patient dosed; initial single agent data expected to be reported in 2021

Commercial-scale facility operational; GMP manufacturing underway

WOBURN, Mass., Feb. 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 third quarter ended December 31, 2020 and provided a business update.

“It has been a productive start to 2021,” said Philip Astley-Sparke, Chief Executive Officer of Replimune. “We started the current quarter with the news that dosing has commenced with our third product candidate, RP3, which like RP2 is intended to treat tumor types that are not traditionally thought of as ‘immune-responsive’. The later stage clinical development pathway for these programs is currently being defined. We continue to enroll into our two registration-directed clinical trials with RP1 in cutaneous squamous cell carcinoma (CSCC), the “CERPASS” study, and anti-PD1 failed melanoma, the “IGNYTE” study, and commercial planning activities are underway. We also expect to start dosing RP1 combined with Opdivo® in anti-PD1 failed non-small cell lung cancer (NSCLC) patients and anti-PD1 failed CSCC patients at approximately the quarter end and look forward to releasing data on all our product candidates during the course of 2021.”

Corporate Updates

- **Commenced GMP Manufacturing in completed state of the art facility.** The Company has completed buildout of its 63,000-square-foot state-of-the-art manufacturing facility in Framingham, MA, which will support late-stage development and full commercialization of all of its products. GMP production is underway with the first RP1 batch having been filled. RP2 tech-transfer is scheduled to commence this quarter.

- **Extended cash runway into the second half of 2024.** In October, the company closed on an offering of common stock and pre-funded warrants raising approximately $287 million in gross proceeds and received aggregate net proceeds of approximately $270 million after deducting underwriting discounts, commissions, and other offering expenses. This includes the exercise in full by the underwriters of their option to purchase additional shares of common stock. Based on its current operating plan, Replimune expects that its cash, cash equivalents and short-term investments of $493.3 million as of December 31, 2020 will fund its operating expenses and capital expenditure requirements into the second half of 2024.

- **Potential impact of COVID-19 on milestones:** Enrollment into the Company’s clinical trials, in particular the clinical trial of RP1 in solid organ transplant patients with CSCC, which represents a highly immune-compromised patient population, has been slower than expected, which the Company attributes to the global pandemic. While mitigation plans have been and are being implemented, as the clinical trial sites continue to evaluate their capacity to enroll patients into clinical trials, the Company could see additional impact on the pace of enrollment across its clinical trial programs.

Program Highlights and Upcoming Milestones

- **RP1 in combination with Libtayo® in CSCC:** The Company is actively enrolling patients into its global registration-directed Phase 2, randomized, controlled, clinical trial. The Company remains on track to report the primary data read out in 2022.

- **RP1 in combination with Opdivo in anti-PD-1 failed melanoma:** The Company initiated recruitment into a new registration-directed 125-patient cohort Phase 2 clinical trial of RP1 in combination with Opdivo in the first half of 2020 and continues to enroll patients. The Company remains on track to report the primary data readout in 2022.

- **RP1 in combination with Opdivo in melanoma and non-melanoma skin cancers (NMSC):** In October 2020, Replimune provided positive Phase 2 data updates in melanoma and NMSC which demonstrated deep and durable responses to RP1 combined with Opdivo, including in anti-PD1 failed melanoma that continues to support the Company’s ongoing registration-directed development in this setting and in CSCC. Enrollment of the initial melanoma cohort (including anti-PD1 naïve and anti-PD1 failed patients) was completed in the first half of 2020 with the NMSC cohort now being expanded from 30 to 45 patients to also include 15 patients with anti-PD1 failed disease.

- **RP1 in anti-PD1 failed NSCLC:** The Company has opened for recruitment a new cohort of 30 anti-PD1 failed NSCLC patients treated with RP1 combined with Opdivo and expects to report initial data from this cohort 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 assessing the safety and efficacy of RP1 in liver and kidney transplant recipients. Although the company recently dosed the initial patient, the study continues to be particularly impacted by COVID-19 due to the immune suppression that solid organ transplant patients receive and mitigation steps are therefore being taken to aid enrollment. Initial 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 is accumulating data from the MSI-H/dMMR (anti-PD1 naïve) cohort. Based on the data, the Company expects to be able to decide whether to pursue MSI-H/dMMR tumors into registration-directed development by the end of 2021.

- **RP2 alone and in combination with Opdivo:** RP2 is being evaluated in a Phase 1 clinical trial alone and combined with Opdivo in advanced solid tumor patients. In October 2020, Replimune presented positive data from the single agent RP2 portion of the clinical trial that showed deep and durable responses, including in patients with immune insensitive tumor types. Following the monotherapy phase, enrollment is currently underway in a 30-patient cohort in combination with Opdivo. Updated data from this clinical trial, including initial data with RP2 in combination with Opdivo, is expected to be presented mid-year.

- **RP3 alone and in combination with anti-PD-1 therapy:** Replimune initiated dosing in its Phase 1 clinical trial of RP3 in December 2020. The Phase 1 clinical trial is designed to evaluate RP3 alone and combined with anti-PD1 therapy in advanced solid tumor patients. Initial data is expected to be presented in the second half of 2021.

- **Targeted evaluation for new indications is currently underway:** An analysis of the solid tumor space is currently underway to define the later stage clinical development pathway initially intended for RP2 and/or RP3. This is from the perspective that RP2 and RP3 are intended to target less immune responsive tumor types, and follows from initial promising data having been generated with single agent RP2, including in immune non-responsive tumor types. The details of this initial development plan are intended to be announced mid-year.

Financial Highlights

- **Cash Position:** As of December 31, 2020, cash, cash equivalents and short-term investments were $493.3 million, as compared to $168.6 million as of March 31, 2020. This increase was primarily related to $371.7 million in net proceeds from financing activities offset by cash utilized in operating activities largely associated with advancing our expanded clinical development plan.

- **R&D Expenses:** Research and development expenses were $14.3 million for the third quarter ended December 31, 2020, as compared to $11.9 million for the third quarter ended December 31, 2019. 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 $1.5 million in stock-based compensation expenses for the third quarter ended December 31, 2020.

- **G&A Expenses:** General and administrative expenses were $6.0 million for the third quarter ended December 31, 2020, as compared to $4.7 million for the third quarter ended December 31, 2019. The increase was primarily driven by personnel-related costs, professional fees, and facility expansion. General and administrative expenses included $1.6 million in stock-based compensation expenses for the third quarter ended December 31, 2020.

- **Net Loss:** Net loss was $21.8 million for the third quarter ended December 31, 2020, as compared to a net loss of $16.2 million for the third quarter ended December 31, 2019.

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 through the expression of a GALV-GP R- fusogenic protein and GM-CSF.

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 advancement of our clinical trials, our plans to initiate new clinical trials, 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)
(Unaudited)

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 14,322	$ 11,948	$ 40,529	$ 27,573
General and administrative	5,953	4,716	17,242	12,240
Total operating expenses	20,275	16,664	57,771	39,813
Loss from operations	(20,275)	(16,664)	(57,771)	(39,813)
Other income (expense):				
Research and development incentives	550	951	1,991	2,192
Investment income	116	550	821	1,804
Interest expense on finance lease liability	(560)	(834)	(1,683)	(1,029)

Interest expense on debt obligations	(247)	-	(817)	-
Loss on extinguishment of debt	(913)	-	(913)	-
Other income (expense)	(454)	(192)	(999)	10
Total other income (expense), net	(1,508)	475	(1,600)	2,977
Net loss attributable to common stockholders	$ (21,783)	$ (16,189)	$ (59,371)	$ (36,836)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.44)	$ (0.46)	$ (1.34)	$ (1.13)
Weighted average common shares outstanding, basic and diluted	49,382,213	34,877,944	44,436,680	32,742,148

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

	December 31, 2020	March 31, 2020
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 493,272	$ 168,555
Working capital	486,410	162,377
Total assets	559,198	234,097
Total stockholders' equity	516,195	183,718

Replimune Group Inc