Replimune Reports Fourth Fiscal Quarter and Year 2019 Financial Results and Provides Corporate Update

June 28, 2019

RP1: Initiated Phase 2 part of Phase 1/2 clinical trial of RP1 in combination with nivolumab in the U.S. and the U.K.

RP1: Initial Data from Phase 1 part of Phase 1/2 clinical trial expected to be presented in the fourth quarter of 2019

RP1: Randomized controlled Phase 2 clinical trial in combination with cemiplimab expected to initiate in the near term

RP2: Phase 1 clinical trial of RP2 as single agent and in combination with anti-PD1 expected to initiate in the third quarter of 2019

WOBURN, Mass., June 28, 2019 (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 its fourth fiscal quarter and year ended March 31, 2019, and provided an update on its business.

"This past fiscal year has been incredibly productive for Replimune, with the advancement of several important clinical programs and a successful IPO that provides us with a solid financial foundation to continue to develop our portfolio of therapies," said Robert Coffin, Ph.D., co-founder, President and CEO of Replimune. "We are continuing to make significant strides as we work towards delivering on the promise of our oncolytic immuno-gene therapies. Importantly, we expect to initiate our randomized controlled registration-directed Phase 2 clinical trial in cutaneous squamous cell carcinoma (CSCC) in the near term, and to advance our second product candidate into the clinic with the initiation of a Phase 1 trial of RP2 later this year. The Phase 2 part of our clinical trial of RP1 in combination with nivolumab in four solid tumor types has also initiated, and we expect to be sharing the first set of clinical data from the Phase 1 part of the clinical trial in the fourth quarter of 2019."

Recent Business Highlights and Upcoming Events

- **RP1 – Initiated the Phase 2 part of the Phase 1/2 clinical trial of RP1 in combination with nivolumab.** In the Phase 2 part of the clinical trial, RP1 in combination with nivolumab is being tested in four 30-patient cohorts of patients with melanoma, non-melanoma skin cancers (NMSC), metastatic bladder cancer and microsatellite instability-high (MSI-H) tumors. Enrollment in the United States and the United Kingdom is now open in the melanoma, NMSC and bladder cancer cohorts, and enrollment in the MSI-H cohort will open as soon as a protocol-required MSI-H patient is evaluable from Phase 1. The patients enrolled into the melanoma cohort will either be treatment naïve or have received one prior systemic therapy, including anti-PD1 and/or anti-CTLA-4 therapy, and the patients enrolled into the other three cohorts will all be naïve to anti-PD1 therapy. Efficacy and biomarker data will be evaluated within each tumor-type cohort.
- **RP1 – Data from the Phase 1 part of the Phase 1/2 clinical trial of RP1 alone and in combination with nivolumab is expected to be reported at a medical conference in the fourth quarter of 2019.** The Phase 1 part of this ongoing clinical trial tested single-agent RP1 by direct injection into a single superficial or nodal tumor and by imaging-guided injection into a single visceral tumor in patients with advanced heavily pre-treated cancers who have failed available therapy, with the goal of defining the recommended Phase 2 dose. Following determination of the recommended Phase 2 dose, an expansion group of advanced cancer patients, who have failed available therapy, then received RP1 at the recommended Phase 2 dose in combination with nivolumab at standard clinical doses. This clinical trial is being conducted under a clinical trial supply agreement with Bristol Myers Squibb (BMS) for the supply of nivolumab.
- **RP1 – Opening of the Phase 2 clinical trial of RP1 in combination with cemiplimab is expected in the near term.** The registration directed randomized controlled Phase 2 clinical trial will enroll approximately 240 patients with CSCC, comparing treatment with cemiplimab alone to treatment with cemiplimab in combination with RP1, under the Company's collaboration with Regeneron. Cemiplimab is Regeneron's anti-PD1 therapy that was approved by the U.S. Food and Drug Administration (FDA) for the treatment of locally recurrent and metastatic CSCC.
- **RP 2 – Phase 1 clinical trial of RP2 as a single agent and in combination with nivolumab anti-PD1 therapy anticipated to initiate in the third quarter of 2019.**RP2 is a further armed oncolytic immuno-gene therapy that, in addition to expressing GALV-GP-R- and GM-CSF, also expresses a genetically encoded anti-CTLA-4 antibody intended to block the inhibition of the initiation of immune response caused by CTLA-4. RP2 is intended to be used primarily in combination with anti-PD1 or anti-PD-L1 therapy. Because of the need to address questions from regulatory authorities regarding certain Chemistry, Manufacturing, and Controls aspects of RP2, this clinical trial is expected to initiate one quarter later than originally anticipated. As with the clinical trial with RP1 in combination with nivolumab, this clinical trial

will be conducted under a clinical trial supply agreement with BMS for the supply of nivolumab.

- **RP3 – Phase 1 clinical trial of RP3 as a single agent and in combination with anti-PD1 therapy to initiate in 2020.**RP3 is a further armed oncolytic immuno-gene therapy which expresses two immune co-stimulatory activating ligands in addition to the GALV-GP R- fusogenic protein and anti-CTLA-4. Following the assessment of a number of co-stimulatory pathways, which, like anti-CTLA-4, are expected to be primarily active at the site and time of anti-tumor immune response initiation, the selected immune co-stimulatory pathway activating proteins are CD40L and 4-1BBL. CD40L activates CD40, resulting in the broad activation of both innate and adaptive immunity, and 4-1BBL activates 4-1BB (CD137) to promote the expansion of cellular and memory immune responses.
- **Presented posters at ASCO and AACR.** At the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting, Replimune presented a "trials in progress" poster on the Company's Phase 1/2 clinical trial of RP1 alone and in combination with nivolumab. A poster describing preclinical data relating to Replimune's Immulytic platform and entitled "Development & characterization of a new oncolytic immunotherapy platform based on herpes simplex virus type 1" was presented at the American Association of Cancer Research (AACR) annual meeting in March 2019. Both posters are available on the Company's website.
- **Build out of Replimune's manufacturing facility to support late-stage development and commercialization is on track and expected to be operational in the first half of 2020.** In July 2018, Replimune signed a lease for a 63,000-square-foot facility in Framingham, MA where the Company intends to establish world-class multi-product manufacturing capabilities for its Immulytic product candidates. The capacity of this facility is expected to be sufficient to support full commercialization of the Company's product candidates. The facility is expected to be operational in the first half of 2020.

Financial Highlights

Replimune reported a net loss of $6.6 million for the fiscal fourth quarter, ended March 31, 2019, and a net loss of $30.8 million for the fiscal year ended March 31, 2019, as compared to a net loss of $7.1 million and net loss of $19.7 million for the comparable periods in the prior fiscal year, respectively. The increase in net losses for both periods were primarily due to an increase in research and development expenses and administrative costs associated with our operations.

Research and development expenses were $5.4 million for the fiscal fourth quarter of 2019, and $22.2 million for the year ended March 31, 2019, as compared to $4.5 million and $13.5 million for the comparable periods in the prior fiscal year, respectively. The increase in research and development expenses was primarily driven by additional costs related to Replimune's preclinical and clinical development activities for its pipeline, as well as increased salary and related benefits costs due to the increase in employee headcount from 44 on March 31, 2018 to 67 on March 31, 2019.

General and administrative expenses were $2.4 million for the fiscal fourth quarter of 2019, and $8.8 million for the year ended March 31, 2019, as compared to $2.5 million and $5.7 million for the comparable periods in the prior fiscal year, respectively. The increase in general and administrative expenses was primarily due to the increase in employee headcount and the impact of stock-based compensation in 2019.

Replimune ended the fiscal year with $134.8 million in cash and cash equivalents and short-term investments, compared with $141.8 million as of December 31, 2018 and $61.6 million as of March 31, 2018. The year-on-year increase reflects net proceeds received of $103.3 million (net of deferred offering costs of $9.9 million) in connection with the Company's IPO in July 2018.

Based on its current operating plan, Replimune expects that its current cash and cash equivalents and short-term investments will enable it to fund its operating expenses and capital expenditure requirements into the second half of calendar 2021.

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. The Company'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. Replimune intends to progress these therapies rapidly through clinical development in combination with other immuno-oncology products with complementary mechanisms of action. 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 use of cash, our advancement of our clinical trials, our goals to develop and commercialize our product candidates, our plans to establish our own in-house manufacturing capabilities, our proposed scientific presentations, 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 establishing, equipping, and operating our planned 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, and other risks set forth under the heading "Risk Factors" of our Annual Report on Form 10-K for the year ended March 31, 2019. 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)

	Year Ended March 31,		
	2019	**2018**	**2017**
Operating expenses:			
Research and development	$ 22,173	$ 13,516	$ 6,936
General and administrative	8,773	5,713	2,711
Total operating expenses	30,946	19,229	9,647
Loss from operations	(30,946)	(19,229)	(9,647)
Other income (expense):			
Research and development incentives	2,528	2,267	1,442
Interest income	2,585	288	25
Change in fair value of warrant liability	(5,452)	(972)	(150)
Other income (expense), net	451	(2,056)	626
Total other income (expense), net	112	(473)	1,943
Net loss	(30,834)	(19,702)	(7,704)
Net loss attributable to common shareholders	$ (30,834)	$ (19,702)	$ (7,704)
Net loss per share attributable to common shareholders, basic and diluted	$ (1.33)	$ (3.96)	$ (1.55)
Weighted average common shares outstanding—basic and diluted	23,198,400	4,978,539	4,973,439

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

	March 31,	
	2019	**2018**
Cash and cash equivalents	$ 25,704	$ 17,583
Short-term investments	109,107	43,968

Research and development incentives receivable	2,474	2,389
Prepaid expenses and other current assets	3,696	763
Property, plant and equipment, net	12,159	370
Restricted cash	1,186	78
Total assets	$ 154,326	$ 65,151
Accounts payable	$ 7,084	$ 1,993
Accrued expenses and other current liabilities	2,801	3,171
Deferred rent, net of current portion	24	52
Warrant liability	-	1,642
Lease liability	6,561	-
Total liabilities	16,470	6,858
Convertible preferred stock	-	86,361
Total stockholders' equity (deficit)	137,856	(28,068)
Total liabilities, convertible preferred stock and stockholders’ equity (deficit)	$ 154,326	$ 65,151

Source: Replimune Group Inc