Replimune Reports First Fiscal Quarter Financial Results and Provides Corporate Update

August 14, 2019

RP1: Initial data from Phase 1 part of Phase 1/2 clinical trial alone and in combination with nivolumab expected to be presented in the fourth calendar quarter of 2019

RP1: Enrollment is ongoing in the Phase 2 part of the Phase 1/2 trial of RP1 in combination with nivolumab

RP1: Randomized controlled Phase 2 clinical trial in combination with cemiplimab expected to open this month

RP2: Phase 1 clinical trial of RP2 as single agent and in combination with nivolumab expected to open this quarter

WOBURN, Mass., Aug. 14, 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 first fiscal quarter, ended June 30, 2019, and provided an update on its business.

“All programs are on track and progressing as expected,” said Robert Coffin, Ph.D., co-founder, President and CEO of Replimune. “The second half of this year will be important for Replimune, with the release of the initial Phase 1 data from our ongoing Phase 1/2 clinical trial of RP1 alone and in combination with nivolumab in the fourth quarter, the initiation of a registration-directed randomized controlled Phase 2 clinical trial in cutaneous squamous carcinoma (CSCC), and the initiation of clinical development with our second product candidate, RP2. In particular, we look forward to sharing the initial Phase 1 results with RP1 in patients with advanced solid tumors later in the year.”

Recent Business Highlights and Upcoming Events

- **RP1 – Data from the Phase 1 part of the Phase 1/2 clinical trial of RP1 alone and in combination with nivolumab expected to be reported at a medical conference in the fourth quarter of 2019.** The Phase 1 part of the clinical trial enrolled patients with advanced heavily pre-treated cancers, who have failed available therapy. Initially, single-agent RP1 was administered into a single tumor up to five times at a range of dose levels by direct injection into superficial tumors or by imaging-guided injection into deeper, including visceral, tumors. Following determination of the recommended Phase 2 dose, an expansion group of advanced cancer patients then received RP1 in combination with nivolumab. The main goals of the Phase 1 part of the clinical trial were to assess safety, to determine the optimal dose to administer in combination with nivolumab in the Phase 2 portion of the study, and to gather evidence of clinical activity in line with the expected profile of RP1. This clinical trial is being conducted under a clinical trial collaboration and supply agreement with Bristol Myers Squibb (BMS) for the supply of nivolumab.

- **RP1 – Enrollment is ongoing in the Phase 2 part of the Phase 1/2 trial of RP1 in combination with nivolumab**. The Phase 2 part of the clinical trial is currently enrolling 30-patient cohorts of patients with melanoma, non-melanoma skin cancers and metastatic bladder cancer. Enrollment in a fourth, microsatellite instability high (MSI-H) tumor cohort, is expected to open once a protocol-required MSI-H patient is evaluable for safety from Phase 1 (expected in September). The patients enrolled into the melanoma cohort will either be treatment naïve or have received 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 – Phase 2 clinical trial of RP1 in combination with cemiplimab remains on track to open in August 2019.** This registration-directed randomized controlled Phase 2 clinical trial is planned to 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 which was approved by the U.S. Food and Drug Administration (FDA) for the treatment of locally recurrent or metastatic CSCC in 2018.

- **RP2 – Phase 1 clinical trial of RP2 as a single agent and in combination with nivolumab remains on track to initiate in the current quarter.**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. As with the clinical trial with RP1 in combination with nivolumab, this clinical trial will be conducted under a clinical trial collaboration and 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 (CD40L and 4-1BBL) in addition to the GALV-GP R- fusogenic protein and anti-CTLA-4. The Phase 1 trial of RP3 as a single agent and in combination with anti-PD1 therapy remains on track to be initiated in 2020.

- **Paper describing the development of Replimune's Imlytic platform published in the Journal for Immunotherapy of Cancer (JITC).** A paper describing the design, underlying characteristics and pre-clinical data for the Company's enhanced potency oncolytic immuno-gene therapy product platform and entitled "Development of a new fusion-enhanced oncolytic immunotherapy platform based on herpes simplex virus type 1" was recently published in JITC.

- **Build-out of Replimune's manufacturing facility to support late-stage development and commercialization is on track.** The 63,000-square-foot facility in Framingham, MA is intended to provide multi-product manufacturing capabilities for Replimune's Immulytic product candidates. The capacity of this facility will be sufficient to support full commercialization of the Company's product candidates and is expected to be operational in the first half of 2020.

Financial Highlights

Replimune reported a net loss of $9.5 million for the quarter ended June 30, 2019 compared with $10.0 million for the same period in the prior year.

Research and development expenses for the quarter ended June 30, 2019 were $7.5 million compared with $3.9 million for the same period in the prior year. 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 an increase in employee headcount.

General and administrative expenses were $3.5 million for the quarter ended June 30, 2019 compared with $1.9 million for the same period in the prior year. The increase in general and administrative expenses was primarily due to an increase in employee headcount and the impact of stock-based compensation in 2019.

Replimune ended the quarter with $120.8 million in cash and cash equivalents and short-term investments, compared with $134.8 million as of March 31, 2019.

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)

	Three Months Ended June 30,	
	2019	**2018**
Research and development	$ 7,457	$ 3,936
General and administrative	3,450	1,943
Total operating expenses	10,907	5,879
Loss from operations	(10,907)	(5,879)
Total other income (expense), net	1,399	(4,165)
	$ (9,508)	$ (10,044)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.30)	$ (2.02)
Weighted average common shares outstanding, basic and diluted	31,661,430	4,981,227

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

	June 30, 2019	March 31, 2019
Cash and cash equivalents	$ 38,364	$ 25,704
Short-term investments	82,435	109,107
Research and development incentives receivable	2,410	2,474
Prepaid expenses and other current assets	4,529	3,696
Property, plant and equipment, net	963	12,159
Research and development incentives receivable - long term	613	-
Right-to-use asset	690	-
Long-term prepaid rent	11,901	-
Restricted cash	1,636	1,186
Total assets	$ 143,541	$ 154,326
Accounts payable	$ 10,830	$ 7,084
Accrued expenses and other current liabilities	1,829	2,801
Lease liabilities, current	394	-
Total current liabilities	13,053	9,885
Deferred rent, net of current portion	-	24

Financing obligation	-	6,561
Lease liabilities, non-current	336	-
Total stockholders' equity (deficit)	130,152	137,856
Total liabilities, convertible preferred stock and stockholders’ equity (deficit)	$ 143,541	$ 154,326

Source: Replimune Group Inc