Replimune Reports Financial Results for the Third Fiscal Quarter, Ended December 31, and Provides Development and Corporate Update

February 14, 2019

RP1: Completed Single Agent Enrollment in Part 1 Portion of Phase 1/2 Clinical Trial in the UK;
Part 1 Enrollment Opened for Combination with Nivolumab in Patients with Solid Tumors in the US

RP1: Opening of Part 2 in Defined Tumor Cohorts On Track for First Half 2019

RP1: Randomized Controlled Phase 2 Clinical Trial in Combination with Cemiplimab
Versus Cemiplimab Alone On Track to Initiate in First Half 2019

RP2: Phase 1 Clinical Trial of RP2 as Single Agent and in Combination with Anti-PD1
Therapy On Track to Initiate in First Half 2019

WOBURN, Mass., Feb. 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 third fiscal quarter ended December 31, 2018, and provided an update on its business.

"Replimune continues to make significant progress with all of our development programs," said Robert Coffin, Ph.D., co-founder, President and CEO of Replimune. "We anticipate a number of key events in the first half of 2019, including the initiation of the Phase 2 portion of the Phase 1/2 clinical trial of RP1 in combination with nivolumab in four solid tumor types, initiation of a Phase 1 clinical trial of RP2 alone and in combination with anti-PD1 therapy and, of particular note, the initiation of enrollment of our potentially pivotal randomized controlled Phase 2 clinical trial of RP1 in combination with cemiplimab in cutaneous squamous cell carcinoma."

Recent Business Highlights and Upcoming Events

- **RP1 - Completed enrollment of RP1 as single agent and opened enrollment of patients to be treated with RP1 in combination with nivolumab in the Phase 1 portion of the Phase 1/2 clinical trial.** RP1 is Replimune's first product candidate to enter the clinic and is based on a proprietary strain of herpes simplex virus armed with a gene encoding a potent fusogenic protein, intended to enhance tumor killing potency, immunogenic cell death and the activation of systemic anti-tumor immune responses, and with a gene encoding the cytokine GM-CSF. Replimune is currently testing RP1 in a two-part Phase 1/2 clinical trial of RP1 alone and in combination with nivolumab in approximately 150 patients. In the Phase 1 portion of the Phase 1/2 clinical trial, Replimune is assessing the safety and tolerability of RP1 administered alone in patients with advanced solid tumors followed by dosing in combination with nivolumab anti-PD1 therapy. In part 2 of the Phase 1/2 clinical trial, Replimune intends to study the safety and efficacy of RP1 in combination with nivolumab in four cohorts of patients with melanoma, bladder cancer, microsatellite instability high cancers, and non-melanoma skin cancers. The Phase 2 portion of the clinical trial is on track to initiate in the first half of 2019. Data from the Phase 1 portion of the clinical trial (RP1 alone and RP1 combined with nivolumab) is expected to be presented at a medical conference in the second half of 2019.

- **RP1 - Phase 2 clinical trial of RP1 in combination with cemiplimab remains on-track to initiate in the first half of 2019.** The registration directed randomized controlled Phase 2 clinical trial is intended to enroll approximately 240 patients with cutaneous squamous cell carcinoma (CSCC) comparing treatment with cemiplimab alone to treatment in combination with RP1, under the Company's collaboration with Regeneron. Cemiplimab is Regeneron's anti-PD1 drug which was approved by the U.S. Food and Drug Administration (FDA) for the treatment of locally recurrent and metastatic CSCC in 2018.

- **RP 2 - Phase 1 clinical trial of RP2 as a single agent and in combination with anti-PD1 therapy remains on-track to initiate in first half of 2019.**RP2 is a version of RP1 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.

- **RP3 - Phase 1 clinical trial of RP3 as a single agent and in combination with anti-PD1 therapy remains on-track to initiate in the first half of 2020.**RP3 is a further armed oncolytic immuno-gene therapy which expresses two immune

co-stimulatory activating ligands. 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 RP3 product candidate expresses CD40L and 4-1BBL together with anti-CTLA-4 and GALV-GP-R-. 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.

- **Poster to be presented at AACR.** A poster describing pre-clinical data relating to Replimune's Immulytic™ platform and entitled "Development & characterization of a new oncolytic immunotherapy platform based on herpes simplex virus type 1" is to be presented at the American Association of Cancer Research (AACR) annual meeting in Atlanta, Georgia, March 29th-April 1st, 2019 (Abstract # 3136). The poster will be made available on the Company's website at the time of presentation.

- **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 $7.7 million for the quarter ended December 31, 2018 compared with $4.4 million for the same period in the prior year. The increase in the net loss was primarily due to an increase in research and development expenses and administrative costs associated with our operations.

Research and development expenses for the quarter ended December 31, 2018 were $7.9 million compared with $3.6 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 increased salary and related benefits costs due to the increase in employee headcount from 33 on December 31, 2017 to 48 on December 31, 2018.

General and administrative expenses were $2.3 million for the quarter ended December 31, 2018 compared with $1.2 million for the same period in the prior year. The increase in general and administrative expenses was primarily due to the increase in employee headcount and the impact of stock-based compensation in 2018.

Replimune ended the quarter with $141.8 million in cash and cash equivalents and short-term investments, compared with $61.6 million as of March 31, 2018. The increase reflects net proceeds received of $103.3 million in connection with its IPO.

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 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 Quarterly Report on Form 10-Q for the third quarter ended December 31, 2018. 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,	
	2018	**2017**	**2018**	**2017**
Research and development	$ 7,857	$ 3,573	$ 16,760	$ 9,013
General and administrative	2,280	1,159	6,360	3,151
Total operating expenses	10,137	4,732	23,120	12,164
Loss from operations	(10,137)	(4,732)	(23,120)	(12,164)
Total other income (expense), net	2,464	378	(1,058)	(690)
Net loss	$ (7,673)	$ (4,354)	$ (24,178)	$ (12,854)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.24)	$ (0.87)	$ (1.18)	$ (2.58)
Weighted average common shares outstanding, basic and diluted	31,577,313	4,981,227	20,433,580	4,977,659

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

	December 31, 2018	**March 31, 2018**
Cash and cash equivalents	$ 21,052	$ 17,583
Short-term investments	120,751	43,968
Research and development incentives receivable	1,843	2,389
Prepaid expenses and other current assets	1,300	763
Property, plant and equipment, net	6,055	370
Deferred offering costs	-	-
Restricted cash	1,186	78
Total assets	$ 152,187	$ 65,151
Accounts payable	$ 1,501	$ 1,993
Accrued expenses and other current liabilities	2,307	3,171
Deferred rent, net of current portion	168	52
Warrant liability	-	1,642
Lease liability	4,972	-
Total liabilities	8,948	6,858
Convertible preferred stock	-	86,361
Total stockholders' equity (deficit)	143,239	(28,068)
Total liabilities, convertible preferred stock and stockholders’ equity (deficit)	$ 152,187	$ 65,151

Source: Replimune Group Inc