Replimune Reports Financial Results for the Second Fiscal Quarter, Ended September 30, and Provides Development and Corporate Update

November 14, 2018

U.S. Clinical Sites for Phase 1/2 Trial of RP1 in Patients with Solid Tumors on Track to Initiate by End of Year

Additional Product Candidates RP2 and RP3 Continue to Advance Toward the Clinic

WOBURN, Mass., Nov. 14, 2018 (GLOBE NEWSWIRE) -- Replimune Group Inc. (NASDAQ: REPL), a biotechnology company developing oncolytic immunotherapies derived from its Immulytic™ platform, today announced financial results for its second fiscal quarter ended September 30, 2018, and provided an update on its business.

"All of our programs are progressing to track within the timelines outlined to investors during our July 2018 initial public offering" said Robert Coffin, Ph.D., co-founder and CEO of Replimune. "We were pleased to receive FDA acceptance of our IND for RP1 this past quarter which allows us to expand enrollment of our Phase 1/2 trial beyond the U.K. and into the U.S. by year-end 2018. In addition, we continue to make progress developing both RP2 and RP3 which will expand the potential utility of our platform beyond the current indications and into most solid tumors."

Recent Business Highlights and Upcoming Events

- **Investigational New Drug (IND) application for RP1 accepted by the U.S. Food and Drug Administration (FDA).** RP1 is Replimune's first Immulytic™ product candidate to enter the clinic and is based on a proprietary new strain of herpes simplex virus engineered to maximize tumor killing potency intended to result in highly immunogenic cell death and activation of a systemic anti-tumor immune response. The accepted IND allows Replimune to start enrolling patients in the Company's ongoing Phase 1/2 clinical trial in the U.S., which is expected to occur by year-end 2018.
- **Continued progress with the Phase 1/2 study of RP1 in multiple solid tumors.** Replimune's Phase 1/2 clinical trial with RP1 is currently ongoing in the U.K. In the first part of the clinical trial Replimune is initially testing RP1 alone and then in combination with nivolumab for safety and biological activity in patients with advanced, heavily pre-treated solid tumors. The combination phase of the first part of the clinical trial is expected to be underway in the U.S. and the U.K. by the year end. The second part of the Phase 1/2 clinical trial is on track to begin in the first half of 2019, and will study the safety and efficacy of RP1 in combination with nivolumab in approximately 120 patients with metastatic melanoma, metastatic bladder cancer, microsatellite instability high cancer, and non-melanoma skin cancers under Replimune's collaboration agreement with Bristol-Myers Squibb.
- **Phase 2 clinical trial of RP1 in combination with cemiplimab remains on track to initiate in the first half of 2019.** This Phase 2 trial is intended to be a randomized, controlled clinical trial of RP1 in combination with the anti-PD-1 antibody cemiplimab compared to cemiplimab alone, in approximately 240 patients with cutaneous squamous cell carcinoma (CSCC). CSCC is the highest mortality skin cancer after melanoma and accounts for 4,000 to 9,000 annual deaths in the U.S. The primary objective of the Phase 2 clinical trial is intended to assess the response rate of the combination therapy compared to treatment with anti-PD-1 therapy alone, with key secondary endpoints expected to include the rate of complete response and the duration of response. This clinical trial is the first to be conducted under our collaboration with Regeneron, and has been designed as a potentially registration-directed clinical trial.
- **Build out of Replimune's own manufacturing facility to support late-stage development and commercialization is on track and expected to be operational 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 facility is currently being built out and expected to be operational in the first half of 2020.
- **IND filing for RP2 remains on track for the first half of 2019.** The Company expects to file an IND during the first half of 2019 with the FDA in the U.S., and/or a Clinical Trial Authorisation (CTA) with the Medicine and Healthcare Products Regulatory Agency (MHRA) in the U.K., in order to initiate a Phase 1 trial of RP2 and RP2 in combination with anti-PD1 therapy in mixed solid tumors. RP2 is a version of RP1 that, in addition to expressing a fusogenic protein and GM-CSF, also expresses a genetically encoded anti-CTLA-4 antibody intended to block the inhibition of the immune response otherwise caused by CTLA-4.
- **RP3 product candidate to be finalized by year-end 2018.** RP3 is the Company's third oncolytic immunotherapy and includes the properties of both RP1 and RP2 while also expressing ligands for the various immune co-stimulatory

pathways responsible for T-cell proliferation and/or activation. The precise payload of immune-activating ligands for RP3 is expected to be finalized by the end of 2018, and initiation of the Phase 1 clinical trial with RP3 remains on track for the first half of 2020.

Financial Highlights

Replimune reported a net loss of $6.5 million for the quarter ended September 30, 2018 compared with $4.7 million for same period in the prior year. The increase in net loss for the year was due to increased research and development expenses as well as expenses related to Replimune's initial public offering (IPO).

Research and development expenses for the quarter ended September 30, 2018 were $5.0 million compared with $3.1 million for 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 28 on September 30, 2017 to 43 on September 30, 2018.

General and administrative expenses were $2.1 million for the quarter ended September 30, 2018 compared with $1.1 million for same period in the prior year. The increase in general and administrative expenses was primarily due to an increase in legal and accounting fees related to the Company's IPO, the increase in employee headcount and the impact of stock-based compensation in 2018.

Replimune ended the quarter with $147.9 million in cash, 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, 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 immunotherapies" 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, 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 second quarter ended September 30, 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 September 30,		Six Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Research and development	$ 4,962	$ 3,149	$ 8,898	$ 5,440
General and administrative	2,142	1,107	4,085	1,992
Total operating expenses	7,104	4,256	12,983	7,432
Loss from operations	(7,104)	(4,256)	(12,983)	(7,432)
Total other income (expense), net	643	(404)	(3,522)	(780)
Net loss	$ (6,461)	$ (4,660)	$ (16,505)	$ (8,212)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.26)	$ (0.94)	$ (1.11)	$ (1.65)
Weighted average common shares outstanding, basic and diluted	24,574,239	4,978,264	14,831,266	4,975,865

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

	September 30, 2018	March 31, 2018
Cash and cash equivalents	$ 23,282	$ 17,583
Short-term investments	124,612	43,968
Research and development incentives receivable	2,221	2,389
Prepaid expenses and other current assets	1,752	763
Property, plant and equipment, net	420	370
Research and development incentives receivable - long term	343	-
Restricted cash	1,186	78
Total assets	$ 153,816	$ 65,151
Accounts payable	$ 2,072	$ 1,993
Accrued expenses and other current liabilities	1,672	3,171
Deferred rent, net of current portion	36	52
Warrant liability	-	1,642
Total liabilities	3,780	6,858
Convertible preferred stock	-	86,361
Total stockholders' equity (deficit)	150,036	(28,068)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 153,816	$ 65,151

Source: Replimune Group Inc