Replimune Reports Third Fiscal Quarter Financial Results and Provides Corporate Update

February 13, 2020

RP1: Four of the first five cutaneous squamous cell carcinoma (CSCC) patients treated in combination with Opdivo® reported to be in response (all ongoing) including two complete responses; registration-directed randomized controlled Phase 2 clinical trial of RP1 in combination with cemiplimab-rwlc (Libtayo®) in CSCC underway

RP1: Study of RP1 as a monotherapy in solid organ transplant recipients with CSCC on track to initiate in H1 2020 with initial data expected by year-end

RP1: 30 patient cutaneous, uveal and mucosal melanoma phase 2 cohort evaluating RP1 combined with Opdivo (nivolumab) fully enrolled with initial data expected to be presented mid-year; recruitment initiated in additional 125 patient cohort in anti-PD-1 refractory cutaneous melanoma

RP2 & RP3: Programs on track with Phase 1 trial of RP2 in combination with Opdivo enrolling, and Phase 1 trial of RP3 alone and in combination with anti-PD1 therapy set to initiate in 2020

WOBURN, Mass., Feb. 13, 2020 (GLOBE NEWSWIRE) -- Replimune Group Inc. (Nasdaq: REPL), a biotechnology company developing oncolytic immuno-gene therapies derived from its Immulytic™ platform, today provided a corporate update, highlighting the progress of its key programs.

“Based on the early data in our lead indication of CSCC, we believe there is a high probability of success in our ongoing randomized registration-directed clinical trial of RP1 in combination with Libtayo compared to Libtayo alone, and we are also looking forward to starting an additional trial to test RP1 as a monotherapy in solid organ transplant recipients with CSCC. This is a patient population for whom immune checkpoint blockade is contraindicated due to the substantial risk of rejection of the transplanted organ and for whom the incidence of CSCC is particularly high,” said Philip Astley-Sparke, Chief Executive Officer of Replimune. “Deaths from CSCC in the US approach the levels of those from melanoma, suggesting a significant initial commercial opportunity. In addition to reporting further data from our lead indications and initial clinical data with RP2 during 2020, we look forward to announcing the expansion of the clinical development plan for RP1 into additional indications as we continue to execute upon our mission to make our oncolytic immuno-gene therapies a cornerstone of cancer treatment.”

Program Highlights

Replimune is currently developing three oncolytic immuno-gene therapies derived from its Immulytic platform. RP1 is Replimune’s first clinical product candidate and is based on a proprietary new strain of herpes simplex virus armed with a gene encoding a potent fusogenic protein (GALV-GP-R), 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. 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. RP3 is a further armed oncolytic immuno-gene therapy which expresses two immune co-stimulatory activating ligands – CD40L and 4-1BBL – together with anti-CTLA-4 and GALV-GP-R-. CD40L activates CD40, with the goal of achieving broad activation of both innate and adaptive immunity, and 4-1BBL activates 4-1BB (CD137), intended to promote the expansion of cellular and memory immune responses.

- **RP1 in combination with Libtayo in CSCC:** Enrollment in the 240-patient registration-directed Phase 2, randomized, controlled clinical trial is ongoing and is expected to take approximately 18 to 24 months with enrollment intended in the US, Australia, Canada, United Kingdom and European Union.
- **RP1 in combination with Opdivo in melanoma, non-melanoma skin cancers, metastatic bladder cancer, and MSI-H/dMMR tumors:** The Phase 2 part of the Phase 1/2 clinical trial of RP1 in combination with Opdivo remains on track with initial data from completely enrolled or ongoing skin cancer cohorts expected in mid-2020 with further data from all four cohorts expected to be available by year-end.
- **RP1 in combination with Opdivo in anti-PD-1 refractory melanoma patients:** The Company has initiated recruitment in a new registration-directed 125-patient cohort in the Phase 2 clinical trial of RP1 in combination with Opdivo in anti-PD-1 refractory melanoma patients.
- **RP1 as monotherapy in solid organ transplant recipients with CSCC:** The Company remains on track to initiate a 30 patient Phase 1/2 clinical trial to assess the safety and efficacy of RP1 in liver and kidney transplant recipients with recurrent CSCC in the first half of 2020.
- **RP2 alone and in combination with Opdivo:** The ongoing Phase 1 clinical trial evaluating the safety, tolerability, and optimal dose for further development of RP2 alone and in combination with Opdivo remains on track with initial data from

this all-comers clinical trial expected by the end of 2020.

- **RP3 alone and in combination with anti-PD-1 therapy:** The Phase 1 clinical trial of RP3 alone and in combination with anti-PD-1 therapy remains on track to initiate in 2020.

Corporate Highlights

- **Organization transitioning into a late-stage clinical development company and preparing for commercialization.** Replimune continues to grow and evolve its leadership team as it transitions into a late-stage clinical development company with the recent appointment of Jean Franchi as Chief Financial Officer and the transition of Robert Coffin, Ph.D. from Chief Executive Officer into the newly created role of President and Chief Research & Development Officer. As previously announced, Philip Astley-Sparke has moved from part-time Executive Chairman to now full-time Chief Executive Officer, and together with Robert Coffin will co-lead the company going forward.

- **Completed building manufacturing facility to support late-stage development and commercialization.** The 63,000-square-foot facility in Framingham, MA is intended to provide multi-product manufacturing capabilities for Replimune's product candidates with sufficient capacity to support full commercialization. The facility is now fully operational and technology transfer activities are underway.

Financial Highlights

Replimune strengthened the balance sheet in the quarter closing with $180.9 million in cash, cash equivalents and short-term investments, compared with $134.8 million as of March 31, 2019, an increase of $46.1 million. Our increased cash operating expenses were offset by $99.7 million of net proceeds from financing activities.

Based on our current operating plan, we expect our current cash, cash equivalents, and short-term investments will be sufficient to fund operating expenses and capital expenditure requirements into the second half of calendar year 2022.

Research and development expenses for the quarter ended December 31, 2019 were $11.9 million compared with $7.9 million for the same period in the prior year. The increase was driven by increased headcount and services supporting advancement of our lead program RP1 into phase II trials, additional trials, and initiating work in RP2 and RP3.

General and administrative expenses were $4.7 million for the quarter ended December 31, 2019 compared with $2.3 million for the same period in the prior year. The increase was primarily driven by increased headcount and related expense, professional fees, and facility expansion.

Replimune reported a net loss of $16.2 million for the quarter ended December 31, 2019 compared with $7.7 million for the same period in the prior year.

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 cash runway, our advancement of our clinical trials, results of our clinical trials, our goals to develop and commercialize our product candidates, our plans to operate our own in-house manufacturing facility, our expectations with respect to 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 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, 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,	
	2019	**2018**	**2019**	**2018**
Research and development	$ 11,948	$ 7,857	$ 27,573	$ 16,760
General and administrative	4,716	2,280	12,240	6,360
Total operating expenses	16,664	10,137	39,813	23,120
Loss from operations	(16,664)	(10,137)	(39,813)	(23,120)
Other income (expense):				
Research and development incentives	951	1,577	2,192	1,937
Investment income	550	882	1,804	1,775
Interest expense	(834)	-	(1,029)	-
Change in fair value of warrant liability	-	-	-	(5,452)
Other income	(192)	5	10	682
Total other income (expense), net	475	2,464	2,977	(1,058)
Net loss	$ (16,189)	$ (7,673)	$ (36,836)	$ (24,178)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.46)	$ (0.24)	$ (1.13)	$ (1.18)
Weighted average common shares outstanding, basic and diluted	34,877,944	31,577,313	32,742,148	20,433,580

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

	December 31, 2019	March 31, 2019
Cash and cash equivalents	$ 63,002	$ 25,704
Short-term investments	117,877	109,107
Research and development incentives receivable	4,775	2,474
Prepaid expenses and other current assets	5,220	3,696
Property, plant and equipment, net	5,654	12,159
Deferred offering costs	-	-
Research and development incentives receivable - long term	-	-
Long term prepaid rent	-	-
Right od uae - operating lease	4,731	-
Right of use - financing lease	47,528	-
Restricted cash	1,636	1,186
Total assets	$ 250,423	$ 154,326
Accounts payable	$ 6,256	$ 7,084
Accrued expenses and other current liabilities	4,557	2,801
Deferred rent, net of current portion	-	24
Financing obligation	-	6,561
Operating lease liabilities - current	1,011	-
Financing lease liabilities - current	2,393	-

Long term debt, net of debt discount	9,739	-
Operating lease liabilities - non current	3,886	-
Financing lease liabilities - non current	25,016	-
Total liabilities	52,858	16,470
Total stockholders' equity (deficit)	197,565	137,856
Total liabilities, convertible preferred stock and stockholders’ equity (deficit)	$ 250,423	$ 154,326

Source: Replimune Group Inc