Replimune Reports Fiscal Second Quarter Financial Results and Provides Corporate Update

November 5, 2020

RP1: Updated deep and durable response data with Opdivo® in CSCC and anti-PD1 failed melanoma continue to support ongoing registration-directed development

RP2: Single agent deep and durable responses in heavily pre-treated patients with immune insensitive tumor-types demonstrates the potential of the platform to become the second cornerstone of immune-based cancer treatments

RP3: Regulatory clearance to initiate Phase 1 clinical development obtained

Raised gross proceeds of approximately $287 million through October upsized public offering; strengthened balance sheet allows for additional clinical trials, initial build of commercial infrastructure

WOBURN, Mass., Nov. 05, 2020 (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 the fiscal second quarter ended September 30, 2020 and provided a business update.

“In October, we released clinical data with our second product candidate, RP2, demonstrating durable single agent responses in heavily pre-treated patients with immune insensitive tumor types that provides validation of our platform,” said Philip Astley-Sparke, CEO of Replimune. “We also presented updated data for RP1 in combination with Opdivo in melanoma and non-melanoma skin cancers that continues to improve upon our recent June update in terms of depth and durability of response, and supports our two registration-directed clinical programs in both cutaneous squamous cell carcinoma and anti-PD1 failed melanoma. Following a successful follow-on offering in October, we are well-financed to advance and expand our pipeline of product candidates and to fund the initial build of our commercial infrastructure with many exciting milestones ahead. In particular, we look forward to initiating clinical development with RP3 as we seek to establish our products more broadly beyond immune-responsive tumor types, as a cornerstone of immune-based cancer treatments.”

Recent Events and Corporate Updates

- **Presented updated clinical data with RP1 combined with Opdivo in melanoma and non-melanoma skin cancer (NMSC).** The updated data from the Phase 1 expansion of RP1 in combination with Opdivo and the Phase 2 cohorts in melanoma and NMSC showed eight of eleven patients with CSCC have achieved response (5 CR) with one patient currently assessed as stable disease at their first scan who remains on treatment. Five of 16 patients (87.5% with advanced visceral disease) with anti-PD-1 failed melanoma have achieved response, four of whom had also previously failed ipilimumab. A further patient is a surgical CR remaining tumor free currently more than 5 months from surgery and a further stable disease patient remains on treatment. Further responses have been observed in angiosarcoma and in anti-PD1 failed mucosal melanoma. All responses have been durable with only one patient with CSCC and one patient with any type of melanoma having progressed after response. Treatment has continued to be well tolerated and remains ongoing in many of the patients. RP1 is an enhanced potency oncolytic immunotherapy that expresses a GALV-GP R- fusogenic protein and GM-CSF.

  The Company has been selected to participate in the SITC 2020 Virtual Press Conference being held on Monday, November 9, 2020 at 7:45 AM ET where the principal investigator will discuss the Company’s poster titled “An Open-label, multicenter, Phase 1/2 clinical trial of RP1, an enhanced potency oncolytic HSV, combined with nivolumab: Updated results from the skin cancer cohorts”.

- **Presented single agent data from Phase 1 trial evaluating RP2 in heavily pre-treated patients.** The data presented demonstrated compelling monotherapy clinical activity in patients with immune insensitive tumor types. Nine patients were treated with single agent RP2. One patient (with mucoepidermoid carcinoma) has an ongoing complete response and two other patients (with uveal melanoma and esophageal cancer) have ongoing partial responses. All three of these responses are durable; ongoing at between eight and 11 months from the first dose. RP2 was observed to be well-tolerated with side effects consistent with RP1. Following from this single agent data, enrollment of patients being treated with RP2 combined with Opdivo is currently underway. RP2 is an enhanced potency oncolytic immunotherapy which expresses an anti-CTLA-4 molecule, intended to improve on the safety and efficacy profile of systemic antibody approaches to targeting CTLA-4.

- **Clinical trials authorization (CTA) accepted by the MHRA for RP3.** The CTA for RP3, Replimune’s third product candidate, which in addition to the GALV-GP R- fusogenic protein and anti-CTLA-4 also expresses CD40L and 4-1BBL, has been accepted by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom allowing initiation of the Phase 1 clinical trial with RP3 alone and combined with anti-PD1 therapy, which is expected to initiate by

the end of 2020. RP3, in addition to maximizing so-called Signal 1 (antigen presentation), is intended to also maximize Signal 2 (immune co-stimulation) and Signal 3 (the production of inflammatory cytokines, stimulated by CD40L and 4-1BBL).

- **Extended cash runway into the second half of 2024.** In October 2020, the Company raised gross proceeds of approximately $287 million through a public offering of common stock and pre-funded warrants. The Company believes that the existing cash, cash equivalents and short-term investments at September 30, 2020, together with the proceeds raised in October, will enable the Company to conduct additional clinical trials including potentially registration-directed clinical development of RP2 and/or RP3, build initial commercial infrastructure, and to fund overall operations into the second half of 2024.

- **Announced new appointment to the Board of Directors.** In October, the Company announced the appointment of Tanya Lewis to the Board of Directors. The appointment adds deep strategic expertise in developing and executing regulatory strategies.

- **Completed manufacturing facility to support late-stage development and commercialization.** The 63,000-square-foot state-of-the-art facility in Framingham, MA provides multi-product manufacturing capabilities for the Company's product candidates with sufficient capacity to support full commercialization. The facility is now fully operational and technology transfer activities for RP1 complete. GMP batch production is underway with product expected to be released for use in 2021.

- **COVID-19 potential impact on milestones:** Enrollment into our clinical trials, such as the Company's clinical trial of RP1 in solid organ transplant patients with CSCC, representing a highly immunocompromised patient population, has been slower than expected, which the Company attributes to the global pandemic. As the clinical sites continue to evaluate their capacity to treat patients, the Company could see additional impact on the pace of enrollment in the final quarter of 2020 and the first half of 2021 across its clinical trial programs.

Program Highlights

- **RP1 in combination with Libtayo® in cutaneous squamous cell carcinoma (CSCC):** The Company is actively enrolling patients into its 240-patient, registration-directed Phase 2, randomized, controlled, global clinical trial.

- **RP1 in combination with Opdivo in melanoma, non-melanoma skin cancers, and MSI-H/dMMR tumors:** Enrollment and accrual of the initial melanoma cohort (including anti-PD1 naïve and failed patients) was completed in the first half of 2020. The Company continues to enroll into a cohort of patients with non-melanoma skin cancers which has been expanded from 30 patients to 45 to include anti-PD1 failed patients. The Company is accumulating data from the MSI-H/dMMR (anti-PD1 naïve) cohort to inform a decision as to whether to pursue MSI-H/dMMR tumors into registration-directed development in 2021.

- **RP1 in combination with Opdivo in anti-PD-1 failed melanoma:** The Company initiated recruitment into a new registration-directed 125-patient cohort in the Phase 2 clinical trial of RP1 in combination with Opdivo in the first half of 2020 and continues to enroll patients.

- **RP1 in anti-PD1 failed patients with non-small cell lung cancer (NSCLC):** The Company plans to initiate the 30 patient cohort of anti-PD1 refractory patients with NSCLC to the RP1 combined with Opdivo clinical trial later this year with the first patient expected to be dosed by the end of 2020 or in early 2021.

- **RP1 as monotherapy in solid organ transplant recipients with CSCC:** A 30 patient Phase 1b clinical trial assessing the safety and efficacy of RP1 in liver and kidney transplant recipients with recurrent CSCC is open for enrollment.

- **RP2 alone and in combination with Opdivo:** RP2 is being evaluated in a Phase 1 clinical trial evaluating the safety and efficacy of RP2 alone and combined with Opdivo. Following the monotherapy phase, enrollment is currently underway in a 30-patient expansion cohort in combination with Opdivo.

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

Financial Highlights

- **Cash Position:** As of September 30, 2020, cash, cash equivalents and short-term investments were $244.6 million, as compared to $168.6 million as of March 31, 2020. This increase was primarily related to $109.5 million in net proceeds from financing activities offset by cash utilized in operating activities largely associated with advancing our expanded clinical development plan.

In October the company closed on an offering of common stock and pre-funded warrants raising approximately $287 million in gross proceeds and received aggregate net proceeds of approximately $270 million after deducting underwriting discounts, commissions, and other offering expenses. This includes the exercise in full by the underwriters of their option to purchase additional shares of common stock.

- **R&D Expenses:** Research and development expenses were $14.0 million for the second quarter ended September 30, 2020, as compared to $8.2 million for the second quarter ended September 30, 2019. This increase was primarily due to increased clinical and manufacturing expenses driven by the Company's lead programs and increased personnel expenses. Research and development expenses included $1.3 million in stock-based compensation expenses for the second quarter ended September 30, 2020.

- **G&A Expenses:** General and administrative expenses were $5.6 million for the second quarter ended September 30, 2020, as compared to $4.1 million for the second quarter ended September 30, 2019. The increase was primarily driven by personnel-related costs, professional fees, and facility expansion. General and administrative expenses included $1.5 million in stock-based compensation expenses for the second quarter ended September 30, 2020.

- **Net Loss:** Net loss was $20.1 million for the second quarter ended September 30, 2020, as compared to a net loss of $11.1 million for the second quarter ended September 30, 2019.

About RP1

RP1 is Replimune's lead Immulytic™ product candidate and is based on a proprietary new strain of herpes simplex virus engineered to maximize tumor killing potency, the immunogenicity of tumor cell death and the activation of a systemic anti-tumor immune response through the expression of a GALV-GP R- fusogenic protein and GM-CSF.

About RP2 & RP3

RP2 and RP3 are derivatives of RP1 that express additional proteins. RP2 expresses an anti-CTLA-4 antibody-like molecule and RP3 additionally expresses the immune co-stimulatory pathway activating proteins CD40L and 4-1BBL. RP2 and RP3 are intended to provide targeted and potent delivery to the sites of immune response initiation in the tumor and draining lymph nodes, with the goal of focusing systemic immune-based efficacy on tumors and limiting off-target toxicity.

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. Replimune'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 across a broad range of cancers. 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, the advancement of our clinical trials, our plans to initiate new clinical trials, our goals to develop and commercialize our product candidates, patient enrollments in our existing and planned clinical trials and the timing thereof, the potential impact of COVID-19 on our operations and milestones, and our expectations about the appointment of a new director, our expectation about the timing of the release of product from our manufacturing facility 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 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, political and global macro factors including the impact of the coronavirus as a global pandemic and related public health issues, 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 SEC. 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,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 14,050	$ 8,168	$ 26,207	$ 15,625
General and administrative	5,613	4,074	11,289	7,524
Total operating expenses	19,663	12,242	37,496	23,149
Loss from operations	(19,663)	(12,242)	(37,496)	(23,149)
Other income:				
Research and development incentives	755	620	1,441	1,241
Investment income	178	567	705	1,254
Interest expense on finance lease liability	(562)	(195)	(1,123)	(195)
Interest expense on debt obligations	(286)	-	(570)	-
Other income	(517)	111	(545)	202
Total other income, net	(432)	1,103	(92)	2,502
Net loss attributable to common stockholders	$ (20,095)	$ (11,139)	$ (37,588)	$ (20,647)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.46)	$ (0.35)	$ (0.90)	$ (0.65)
Weighted average common shares outstanding, basic and diluted	44,015,786	31,675,323	41,950,401	31,668,414

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

	September 30, 2020	March 31, 2020
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 244,646	$ 168,555
Working capital	239,449	162,377
Total assets	314,244	234,097
Total stockholders' equity	261,390	183,718

Source: Replimune Group Inc