Replimune Reports Fiscal Second Quarter 2024 Financial Results and Provides Corporate Update

November 7, 2023

The Company plans to hold a conference call in early December to provide a comprehensive RP1 skin cancer program update including:

- *Topline data from the CERPASS clinical trial of RP1 combined with Libtayo in cutaneous squamous cell carcinoma*
- *An initial data snapshot for all 140 patients in the IGNYTE clinical trial cohort of RP1 in anti-PD1 failed melanoma*
- *Initial data from the IGNYTE cohort of RP1 in anti-PD1 failed non-melanoma skin cancers*
- *A recap of interim data from the ARTACUS clinical trial of RP1 monotherapy in solid organ transplant recipients with skin cancer recently presented at SITC 2023*

WOBURN, Mass., Nov. 07, 2023 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of a novel portfolio of oncolytic immunotherapies, today announced financial results for the fiscal second quarter ended September 30, 2023 and provided a business update.

"We look forward to presenting the topline data from our registration-directed CERPASS clinical trial of RP1 in combination with Libtayo in cutaneous squamous cell carcinoma (CSCC) as well as sharing an initial snapshot from the full patient population in the IGNYTE clinical trial cohort of RP1 combined with Opdivo in anti-PD1 failed melanoma at an investor call in a few weeks time," said Philip Astley-Sparke, CEO of Replimune. "We are also excited to present the design of a confirmatory study agreed with the FDA to support a potential approval of RP1 in anti-PD1 failed melanoma via the accelerated approval pathway. For RP2 and RP3, we are continuing to see anti-tumor activity in our Phase 1 program and look forward to providing a full update in early 2024."

Program Highlights & Milestones

RP1

- **CERPASS clinical trial of RP1 combined with Libtayo® (cemiplimab-rwlc) in CSCC**
  - The trigger for the primary analysis from the registration-directed CERPASS clinical trial occurred in late June and data collection activities are now complete. The independent review process is expected to complete shortly, triggering a defined process timeline to disclosure in early December.
  - Assuming positive data demonstrating overall clinical benefit, the Company plans to submit a Biologics License Application (BLA) for RP1 in Q2 2024.
- **RP1 combined with Opdivo® (nivolumab) in anti-PD1 failed melanoma**
  - The Company will present initial snapshot data for all patients on its conference call in early December by which point all patients will have had at least 6 months follow up. The Company also plans to provide a regulatory update including the design of the intended confirmatory clinical trial to support a potential approval under the accelerated pathway. Planning for the confirmatory study is underway to ensure it has commenced ahead of any BLA submission. The per protocol primary analysis will take place 12 months post the last patient enrolled. Accordingly, the Company plans to submit the BLA in Q3 2024.

- **RP1 combined with Opdivo in anti-PD1 failed non-melanoma skin cancers (NMSC)**
  - Recruitment remains ongoing into the cohort of patients with anti-PD1 failed NMSC, including CSCC. The Company plans to provide a data update of the first 30 patients with at least 6 months follow up on its conference call in early December.

- **RP1 in solid organ transplant recipients with skin cancers**
  - Presented initial data from the ARTACUS clinical trial of RP1 monotherapy in solid organ transplant recipients with skin cancers at the Society for Immunotherapy of Cancer's (SITC) 38th Annual Meeting in November 2023. The data included 23 evaluable patients with CSCC (n=20) and Merkel cell carcinoma (n=3).
  - The data demonstrated an overall response rate (ORR) of 34.5% and a confirmed complete response (CR) rate of 21%.
  - RP1 monotherapy was well tolerated, and the safety profile was similar to non-immunocompromised patients with advanced skin cancers (i.e. from the IGNYTE study). No immune-mediated adverse events or evidence of allograft

rejection were observed.

RP2 and RP3

- **RP2 and RP3 Phase 1 program**
  - Accrual in the Phase 1 program is now substantially complete. Any additional Phase 2 development programs not already announced which are driven by data from the full Phase 1 data and other opportunistic considerations are expected to be announced in early 2024.
  - The Company will present updated data from a cohort of metastatic uveal melanoma patients enrolled in the open-label, multicenter Phase 1 study of RP2 as a single agent and in combination with nivolumab during a Plenary Session at the 20th Annual International Society for Melanoma Research Congress on November 8, 2023.
- **RP2 and RP3 Phase 2 program**
  - RP2 and RP3 in combination with atezolizumab and bevacizumab in third-line colorectal cancer (CRC)
    - Two signal finding cohorts of 30 patients each are being enrolled in collaboration with Roche. Patients in the first cohort will be treated with atezolizumab combined with bevacizumab and RP2 and the second cohort with atezolizumab and bevacizumab and RP3. This clinical trial is ongoing.
  - RP2 and RP3 in combination with atezolizumab and bevacizumab in second-line (2L) hepatocellular carcinoma (HCC)
    - Two signal finding cohorts of 15 patients each will be enrolled in collaboration with Roche. The first cohort will enroll 2L patients treated with standard of care atezolizumab combined with bevacizumab and RP3, and the second cohort will enroll 2L patients treated with atezolizumab combined with bevacizumab and RP2. This clinical trial has recently initiated.
  - RP3 in combination with standard of care therapy in squamous cell carcinoma of the head and neck (SCCHN)
    - Initiation has been delayed due to the global shortage of cisplatin and carboplatin.

Corporate Update

- Announced the appointment of Emily Hill as Chief Financial Officer (CFO). Ms. Hill was most recently CFO of the commercial stage biotech company PTC Therapeutics and has more than 15 years of experience in the biotechnology and life sciences industry having held senior financial management and investor relations roles at several leading public biotechnology and pharmaceutical companies.
- Due to the timing of expected data, the company will commence a quiet period on November 13, 2023 that will remain in effect until the planned conference call in early December.

Financial Highlights

- **Cash Position:** As of September 30, 2023, cash, cash equivalents and short-term investments were $496.8 million, as compared to $583.4 million as of March 31, 2023. The decrease was primarily related to cash utilized in operating activities in advancing the Company's expended clinical development plans.

  Based on the current operating plan, the Company believes that existing cash, cash equivalents and short-term investments, as of September 30, 2023, will enable the Company to fund operations into the second half of calendar year 2025.

- **R&D Expenses:** Research and development expenses were $49.1 million for the second quarter ended September 30, 2023, as compared to $28.8 million for the second quarter ended September 30, 2022. 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 $4.4 million in stock-based compensation expenses for the second quarter ended September 30, 2023.
- **S,G&A Expenses:** Selling, general and administrative expenses were $14.7 million for the second quarter ended September 30, 2023, as compared to $12.7 million for the second quarter ended September 30, 2022. The increase was primarily driven by personnel related costs, including sales and marketing personnel associated with pre-launch planning and build of the Company's commercial infrastructure. Selling, general and administrative expenses included $4.7 million in stock-based compensation expenses for the second quarter ended September 30, 2023.
- **Net Loss:** Net loss was $60.0 million for the second quarter ended September 30, 2023, as compared to a net loss of $43.1 million for the second quarter ended September 30, 2022.

About CERPASS

CERPASS is Replimune's registration-directed randomized, global Phase 2 clinical trial to compare the effects of Libtayo ® (cemiplimab-rwlc) alone versus a combination of Libtayo and Replimune's investigational oncolytic immunotherapy RP1. The clinical trial enrolled 211 patients with locally advanced or metastatic cutaneous squamous cell carcinoma who are naïve to anti-PD-1 therapy. The clinical trial will evaluate complete response rate and overall response rate as its two independent primary efficacy endpoints as assessed by independent review, as well as secondary endpoints including duration of response, progression-free survival, and overall survival. The clinical trial is being conducted under a clinical trial collaboration

agreement with Regeneron and full commercial rights retained by Replimune. Libtayo is a registered trademark of Regeneron.

About IGNYTE

IGNYTE is Replimune's multi-cohort Phase 1/2 clinical trial of RP1 in combination with Opdivo® (nivolumab). There are 3 tumor specific cohorts in this clinical trial including a cohort in anti-PD1 failed melanoma with registrational intent that has completed enrollment with 140 patients enrolled. This cohort was initiated after completing enrollment in a prior Phase 2 cohort in the same clinical trial of approximately 30 patients with melanoma. The additional cohorts currently enrolling and are in non-melanoma skin cancers which includes both naïve and anti-PD1 failed CSCC, and in anti-PD1 failed microsatellite instability high, or MSI-H/dMMR tumors. This trial is being conducted under a collaboration and supply agreement with Bristol-Myers Squibb. Opdivo is a registered trademark of Bristol-Myers Squibb.

About RP1

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

About RP2 & RP3

RP2 and RP3 are derivatives of RP1 that express additional immune-activating 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, but does not express GM-CSF. RP2 and RP3 are intended to provide targeted and potent delivery of these proteins 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 with the mission to transform cancer treatment by pioneering the development of a novel portfolio of oncolytic immunotherapies. Replimune's proprietary RPx platform is based on a potent HSV-1 backbone intended to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform is designed to have a unique dual local and systemic mechanism of action (MOA) consisting of direct selective virus-mediated killing of the tumor resulting in the release of tumor derived antigens and altering of the tumor microenvironment to ignite a strong and durable systemic response. This MOA is expected to be synergistic with most established and experimental cancer treatment modalities, leading to the versatility to be developed alone or combined with a variety of other treatment options. 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 design and advancement of our clinical trials, the timing and sufficiency of our clinical trial outcomes to support potential approval of any of our product candidates, our goals to develop and commercialize our product candidates, patient enrollments in our existing and planned clinical trials and the timing thereof, 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, the availability of combination therapies needed to conduct our clinical trials, 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 the Russian-Ukrainian and Israel-Hamas political and military conflicts, 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 September 30,		Six Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 49,101	$ 28,834	$ 89,538	$ 58,312

Selling, general and administrative	14,730	12,745	29,941	24,143
Total operating expenses	63,831	41,579	119,479	82,455
Loss from operations	(63,831)	(41,579)	(119,479)	(82,455)
Other income (expense):				
Research and development incentives	443	574	836	1,425
Investment income	6,049	1,112	12,235	1,455
Interest expense on finance lease liability	(542)	(550)	(1,086)	(1,102)
Interest expense on debt obligations	(955)	-	(2,070)	-
Other (expense) income	(1,409)	(2,659)	(35)	(4,678)
Total other income (expense), net	3,586	(1,523)	9,880	(2,900)
Loss before income taxes	$ (60,245)	$ (43,102)	$ (109,599)	$ (85,355)
Income tax (benefit)	(201)	-	-	-
Net loss	$ (60,044)	$ (43,102)	$ (109,599)	$ (85,355)
Net loss per common share, basic and diluted	$ (0.90)	$ (0.79)	$ (1.65)	$ (1.57)
Weighted average common shares outstanding, basic and diluted	66,582,280	54,770,291	66,475,577	54,492,395

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

	September 30, 2023	March 31, 2023
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 496,761	$ 583,386
Working capital	468,343	558,778
Total assets	562,398	646,591
Total stockholders' equity	465,172	555,292

Replimune Group Inc