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

February 8, 2024

- *Positive data update in December 2023 for all 140 patients in the IGNYTE clinical trial cohort of RP1 in anti-PD1 failed melanoma demonstrating durability of response*
- *Centrally reviewed 12-month primary analysis data from IGNYTE trial of RP1 in anti-PD1 failed melanoma and biologics license application (BLA) submission expected in 2H 2024*
- *Phase 3 confirmatory trial of RP1 in anti-PD1 failed melanoma skin cancers expected to initiate 2H 2024*
- *Cash runway extended to fund operations into 2H 2026*

WOBURN, Mass., Feb. 08, 2024 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (Nasdaq: REPL), a clinical stage biotechnology company pioneering the development of a novel class of oncolytic immunotherapies, today announced financial results for the fiscal third quarter ended December 31, 2023, and provided a business update.

“The collective data for RP1 shows that it has the potential to be a safe and effective treatment option for patients with a range of different skin cancers in various treatment settings. We plan to submit a BLA for the treatment of patients with anti-PD1 failed melanoma in 2H 2024. Subsequently, we will explore the potential for additional submissions based on the evolving data from our multiple non-melanoma skin cancer studies,” said Philip Astley-Sparke, CEO of Replimune. “We are excited about the data we have seen to-date with RP2 including as monotherapy in very difficult to treat tumors. Planning is underway for a clinical trial in advanced uveal melanoma as a foundational study for establishing a rare cancer franchise. Following the decision to reprioritize our pipeline, we have extended our cash runway to fund operations into 2H 2026, leaving us well positioned to bring our lead product to market.”

Program Highlights & Milestones

RP1

- **RP1 combined with Opdivo® (nivolumab) in anti-PD1 failed melanoma**
  - The Company presented initial data from the full population enrolled into the registration directed anti-PD1 failed melanoma cohort from the IGNYTE clinical trial in December 2023. In the full data set of 156 patients (140 patients from the registration-directed expansion cohort and 16 anti-PD1 failed cutaneous melanoma patients from the prior phase 2 cohort), had an overall response rate (ORR) of 31.4% with a complete response rate (CR) of 12% showing activity consistent with the prior snapshot of 91 patients. RP1 combined with nivolumab continues to be well-tolerated, with mainly Grade 1-2 “on target” side effects, observed.
  - Following a Type C meeting with the U.S. Food and Drug Administration (FDA), a confirmatory study design concept consisting of a 2-arm randomized trial with physician’s choice of treatment as a comparator arm in anti-PD1 failed melanoma patients was agreed. The FDA requested that the Phase 3 confirmatory trial be underway at the time of a BLA submission under the accelerated approval pathway. The FDA also indicated that all patients should be followed for at least 12 months and have undergone central review by RECIST v1.1. A BLA submission for RP1 in combination with nivolumab in anti-PD1 failed melanoma is planned for 2H 2024.

- **CERPASS clinical trial of RP1 combined with Libtayo® (cemiplimab-rwlc) in CSCC**
  - Following the initial report of the primary analysis data from the CERPASS clinical trial in December 2023, it is intended that a further analysis of the time-based endpoints of duration of response (DOR), progression free survival (PFS) and overall survival (OS) will be conducted when the data set has further matured.

- **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 MCC (n=3).
  - The data demonstrated an ORR of 34.8% and a CR 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.

- **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. The Company provided a data from the first 30 patients with at least 6 months of follow up including patients with CSCC, Merkel cell carcinoma (MCC), basal cell carcinoma, and angiosarcoma in December 2023.
  - The data showed that treatment with RP1 in combination with nivolumab led to an ORR of 30% which is consistent with data from the anti-PD1 failed melanoma cohort with approximately a third of patients responding and 60%

demonstrating clinical benefit. The combination of RP1 and nivolumab was well tolerated in this patient population with a safety profile consistent with the overall experience seen with this treatment regimen to date.

RP2

- **RP2 in second-line (2L) uveal melanoma**
  - The Company presented positive safety and efficacy 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 at the 20th Annual International Society for Melanoma Research Congress on November 8, 2023.
  - Based on the data in this population, planning is underway for a potentially registrational clinical trial of RP2 in advanced uveal melanoma as a foundational study for establishing a rare cancer franchise.

Financial Highlights

- **Cash Position:** As of December 31, 2023, cash, cash equivalents and short-term investments were $466.4 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 clinical development plans.

  Based on the current operating plan, the Company believes that existing cash, cash equivalents and short-term investments, as of December 31, 2023, will enable the Company to fund operations into the second half of 2026.

- **Debt:** As of December 31, 2023, the debt (net of discount) balance was $44.4 million, as compared to $28.6 million as of March 31, 2023. The increase was primarily related to the draw down of $15M in December 2023, at the time of the closing of the second amendment to the loan and security agreement with Hercules.
- **R&D Expenses:** Research and development expenses were $42.8 million for the third quarter ended December 31, 2023, as compared to $30.3 million for the third quarter ended December 31, 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 $3.8 million in stock-based compensation expenses for the third quarter ended December 31, 2023.
- **S,G&A Expenses:** Selling, general and administrative expenses were $13.7 million for the third quarter ended December 31, 2023, as compared to $11.4 million for the third quarter ended December 31, 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 $4.5 million in stock-based compensation expenses for the third quarter ended December 31, 2023.
- **Net Loss:** Net loss was $51.1 million for the third quarter ended December 31, 2023, as compared to a net loss of $39.7 million for the third quarter ended December 31, 2022.

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
RP2 is a derivative of RP1, Replimune's lead product candidate that 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 to maximize tumor killing potency, the immunogenicity of tumor cell death and the activation of a systemic anti-tumor immune response. RP2 additionally expresses an anti-CTLA-4 antibody-like molecule, as well as GALV-GP-R- and GM-CSF. RP2 is 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 activity 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. The RPx product candidates are 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 December 31,		Nine Months Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 42,847	$ 30,261	$ 132,384	$ 88,573
Selling, general and administrative	13,693	11,369	43,633	35,512
Total operating expenses	56,540	41,630	176,017	124,085
Loss from operations	(56,540)	(41,630)	(176,017)	(124,085)
Other income (expense):				
Research and development incentives	415	607	1,251	2,032
Investment income	5,686	2,675	17,922	4,130
Interest expense on finance lease liability	(540)	(548)	(1,626)	(1,650)
Interest expense on debt obligations	(1,012)	(941)	(3,083)	(941)
Other income (expense)	1,344	147	1,307	(4,531)
Total other income (expense), net	5,893	1,940	15,771	(960)
Loss before income taxes	$ (50,647)	$ (39,690)	$ (160,246)	$ (125,045)
Income tax provision	473	-	473	-
Net loss	$ (51,120)	$ (39,690)	$ (160,719)	$ (125,045)
Net loss per common share, basic and diluted	$ (0.77)	$ (0.69)	$ (2.42)	$ (2.25)
Weighted average common shares outstanding, basic and diluted	66,645,691	57,857,132	66,532,488	55,618,052

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

	December 31, 2023	March 31, 2023
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 466,351	$ 583,386
Working capital	440,514	558,778
Total assets	532,930	646,591
Total stockholders' equity	421,537	555,292