Replimune Reports Fiscal Fourth Quarter and Year Ended 2024 Financial Results and Provides Corporate Update

May 16, 2024

- *Twelve-month primary analysis results by independent central review from the IGNYTE clinical trial of RP1 (vusolimogene oderparepvec) in anti-PD1 failed melanoma expected Q2 2024*
- *Recent Type C CMC meeting with the U.S. Food and Drug Administration (FDA) supports IGNYTE Biologics License Application (BLA) submission expected in 2H 2024*
- *Enrollment of first patients in Phase 3 confirmatory trial of RP1 in advanced melanoma expected in 2H 2024*
- *Cash runway to fund operations into 2H 2026*

WOBURN, Mass., May 16, 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 fourth quarter and year ended March 31, 2024 and provided a business update.

“We have exciting milestones in the coming months, including sharing the investigator-assessed 12-month IGNYTE data at ASCO and then the official primary analysis by independent central review later in the second quarter,” said Sushil Patel, Ph.D., CEO of Replimune. “Importantly, the design of our Phase 3 confirmatory IGNYTE-3 clinical trial has been agreed with the FDA, with patient enrollment planned to initiate in the second half of the year prior to the submission of our BLA for RP1. We also completed a successful Type C meeting with the FDA to align on our CMC plans ahead of the intended BLA. These are all critical steps as we plan for our next phase as a commercial stage company and, pending FDA approval, prepare to bring our first oncolytic immunotherapy to patients with advanced skin cancer.”

Corporate Updates

- **The following abstracts, including two oral presentations, will be presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting, May 31-June 4:**
  - Abstract #9517 (Rapid Oral Abstract Session): Efficacy and safety of RP1 combined with nivolumab in patients with anti-PD-1 failed melanoma from the IGNYTE clinical trial.
  - Abstract #9511 (Rapid Oral Abstract Session): Safety, efficacy, and biomarker results from an open-label, multicenter, phase 1 study of RP2 alone or combined with nivolumab in a cohort of patients with uveal melanoma.
  - Abstract #TPS9604 (Poster Session): A randomized, controlled, multicenter, phase 3 study of vusolimogene oderparepvec (VO) combined with nivolumab vs treatment of physician’s choice in patients with advanced melanoma that has progressed on anti–PD-1 and anti–CTLA-4 therapy (IGNYTE-3).
  - Abstract #TPS4191 (Poster Session): An open-label, multicenter study investigating RP2 oncolytic immunotherapy in combination with second-line systemic atezolizumab combined with bevacizumab in patients with locally advanced unresectable or metastatic hepatocellular carcinoma.
  - Abstract #TPS9614 (Poster Session): Trial in progress: A phase 1/2 study of Vusolimogene oderparepvec in primary melanoma (mel) to reduce the risk of sentinel lymph node (SLN) metastasis.
- **Manufacturing progress.** The Company completed a successful Type C meeting with the FDA that confirmed alignment on our Chemistry, Manufacturing and Controls (CMC) plans to support our IGNYTE anti-PD1 failed melanoma BLA submission in the 2H 2024.

Program Highlights & Milestones

RP1

- **RP1 combined with Opdivo® (nivolumab) in anti-PD1 failed melanoma**
  - The Company presented positive six-month follow up data by investigator assessment (N=140) from the anti-PD1 failed melanoma cohort of the IGNYTE clinical trial late last year. The Company is on track to present the 12-month primary analysis by independent central review in Q2 2024.
  - The Company plans to enroll its first patient in the Phase 3 confirmatory IGNYTE-3 trial prior to submitting the RP1 BLA. The Phase 3 trial design has been agreed to with the FDA and will be a 2-arm randomized trial with a defined list of physician’s choice treatment options as the comparator arm in advanced melanoma patients who progressed on anti-PD1 and anti-CTLA-4 therapy or are ineligible for anti-CTLA-4 treatment.
- **RP1 in solid organ transplant recipients with skin cancers**
  - The Company presented data from the ARTACUS clinical trial of RP1 monotherapy in solid organ transplant

recipients with skin cancers at the American Association of Cancer Research (AACR) 2024 Annual Meeting in April 2024. The data included 23 evaluable patients with CSCC (n=20) and MCC (n=3).
    - The data demonstrated an overall response rate (ORR) of 34.8% (8 of 23 evaluable patients, including 5 complete responses and 3 partial responses).
    - 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.
    - The ARTACUS clinical trial continues to enroll patients.

- **RP1 in combination with Libtayo® (cemiplimab-rwlc) in CSCC**
    - The CERPASS trial continues as planned to assess the time-based endpoints of duration of response, progression free survival and overall survival with greater maturity.

RP2

- **RP2 in Uveal Melanoma**
    - The protocol for the registration-directed clinical trial of RP2 combined with nivolumab in advanced uveal melanoma is near final following input from the FDA.

- **RP2 in Hepatocellular Carcinoma (HCC)**
    - The Phase 2 clinical trial with RP2 in anti-PD1/PD-L1 progressed HCC of RP2 combined with atezolizumab and bevacizumab is expected to initiate in 2H 2024.

Financial Highlights

- **Cash Position:** As of March 31, 2024, cash, cash equivalents and short-term investments were $420.7 million, as compared to $583.4 million as of fiscal year 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 March 31, 2024 will enable the Company to fund operations into the second half of 2026.

- **Debt:** As of March 31, 2024, the debt (net of discount) balance was $44.8 million, as compared to $28.6 million as of March 31, 2023. The increase was primarily related to the draw down of $15 million 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 $42.6 million for the fourth quarter and $175.0 million for the fiscal year ended March 31, 2024, as compared to $37.9 million for the fourth quarter and $126.5 million for the fiscal year ended March 31, 2023. 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 $3.2 million in stock-based compensation expenses for the fourth quarter and $14.7 million in stock-based compensation expenses for the fiscal year ended March 31, 2024.

- **S,G&A Expenses:** Selling, general and administrative expenses were $16.2 million for the fourth quarter and $59.8 million for the fiscal year ended March 31, 2024, as compared to $15.0 million for the fourth quarter and $50.6 million for the year ended March 31, 2023. 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 fourth quarter and $19.4 million in stock-based compensation expenses for the fiscal year ended March 31, 2024.

- **Net Loss:** Net loss was $55.1 million for the fourth quarter and $215.8 million for the fiscal year ended March 31, 2024, as compared to a net loss of $49.2 million for the fourth quarter and $174.3 million for the fiscal year ended March 31, 2023.

About RP1
RP1 (vusolimogene oderparepvec) is Replimune's lead product candidate and is based on a proprietary 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 based on a proprietary 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)
(Audited)

	Year Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 174,963	$ 126,527
Selling, general and administrative	59,810	50,553
Total operating expenses	234,773	177,080
Loss from operations	(234,773)	(177,080)
Other income (expense):		
Research and development incentives	1,920	2,914
Investment income	23,356	10,006
Interest expense on finance lease liability	(2,163)	(2,197)
Interest expense on debt obligations	(4,497)	(1,963)
Other income (expense)	771	(5,676)
Total other income (expense), net	19,387	3,084
Loss before income taxes	$ (215,386)	$ (173,996)

Income tax provision		408		288
Net loss	$	(215,794)	$	(174,284)
Net loss per common share, basic and diluted	$	(3.24)	$	(2.99)
Weighted average common shares outstanding, basic and diluted		66,569,894		58,213,010

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

		March 31, 2024		March 31, 2023
Consolidated Balance Sheet Data:				
Cash, cash equivalents and short-term investments	$	420,668	$	583,386
Working capital		393,229		558,778
Total assets		487,722		646,591
Total stockholders' equity		374,508		555,292

Replimune Group Inc