Replimune Reports Fiscal Fourth Quarter and Year Ended 2023 Financial Results and Provides Corporate Update

May 18, 2023

Topline data disclosure from the registration-directed CERPASS clinical trial of RP1 combined with Libtayo® (cemiplimab-rwlc) in cutaneous squamous cell carcinoma (CSCC) on track for Q3 2023 and Biologics License Application (BLA) submission on track for Q1 2024

Completed enrollment (n=141) of the IGNYTE registration directed cohort of RP1 in anti-PD1 failed melanoma; updated data for the first 75 patients to be presented at ASCO, with data snapshot for all 141 patients expected Q4 2023

RP2 and RP3 Phase 2 programs expected to initiate around mid-year 2023 in third-line (3L) colorectal cancer (CRC), first- and second-line (1L & 2L) hepatocellular carcinoma (HCC) and squamous cell carcinoma of the head and neck (SCCHN); Phase 1 study update expected at year end

Strong balance sheet with cash runway into H2 2025

WOBURN, Mass., May 18, 2023 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of a novel portfolio of tumor-directed oncolytic immunotherapies, today announced financial results for the fiscal fourth quarter and year ended March 31, 2023 and provided a business update.

“We have multiple value-driving catalysts across our pipeline ahead of us, with a focus on the topline data from our registration-directed CERPASS clinical trial of RP1 combined with Libtayo® in CSCC expected in the next quarter and plan to provide an initial data snapshot from the full IGNYTE anti-PD1 failed melanoma cohort by the year end, by which point all patients will have been followed for at least 6 months,” said Philip Astley-Sparke, CEO of Replimune. “As we prepare for the upcoming data readouts, and intended BLA submission, we continue to ramp up our commercial efforts for a potential launch in late 2024 as we seek to establish a major skin cancer franchise with RP1. We are also looking forward to launching our Phase 2 program with RP2 and RP3 in CRC, HCC and SCCHN in the next few months.”

Program Highlights & Milestones:

RP1

- **CERPASS clinical trial of RP1 combined with Libtayo® in cutaneous squamous cell carcinoma (CSCC)**
  - The Company remains on track to announce top line data from its registration-directed CERPASS clinical trial in Q3 2023, and assuming positive primary analysis data demonstrating overall clinical benefit, the Company plans to submit a BLA for RP1 in Q1 2024.
- **Completed enrollment in the IGNYTE anti-PD1 failed melanoma cohort**
  - The Company enrolled its last patient (n=141) in the registration directed cohort of patients evaluating RP1 combined with Opdivo® (nivolumab) in anti-PD1 failed melanoma in March 2023. In addition to presenting updated data from the first 75 patients at ASCO in June, the Company expects to announce snapshot data for all patients in Q4 2023 by which point all patients will have had at least 6 months follow up, prior to the per protocol primary analysis at 12 months post the last patient enrolled.
- **RP1 combined with Opdivo® in anti-PD1 failed non-melanoma skin cancers**
  - Recruitment remains ongoing into the cohort of patients with anti-PD1 failed non-melanoma skin cancers, including CSCC, with a data update expected in Q3 2023.
- **RP1 in solid organ transplant recipients with skin cancers**
  - The Company continues to enroll patients into its ARTACUS clinical trial of RP1 monotherapy in solid organ transplant recipients with skin cancers and expects to provide a data update at the American Transplant Congress in June.

RP2 and RP3

Phase 2 program

- **RP2 and RP3 in combination with atezolizumab and bevacizumab in 3L CRC**
  - Two signal finding cohorts of 30 patients each will be enrolled in collaboration with Roche. The first cohort will enroll patients to be treated with atezolizumab combined with bevacizumab and RP2 and the second cohort with atezolizumab and bevacizumab and RP3. The Company believes that data with both RP2 and RP3 in CRC will

allow the comparative efficacy of RP2 and RP3 to be evaluated in a particularly difficult to treat patient population.

- **RP3 in combination with standard of care therapy in SCCHN**
  - A two-cohort clinical trial will be conducted, with the first cohort of 100 patients with locally advanced disease being randomized to receive either standard of care (SOC) chemotherapy combined with radiation or RP3 combined with chemotherapy and radiation followed by adjuvant nivolumab therapy. The second, signal finding cohort, will enroll 30 patients with recurrent or metastatic SCCHN with low PDL1 levels (CPS<20) who will be treated with chemotherapy, nivolumab and RP3.

- **RP3 in combination with atezolizumab and bevacizumab in 1L & 2L HCC**
  - Two signal finding cohorts of 30 patients each will be enrolled in collaboration with Roche. The first cohort will enroll 1L patients treated with SOC atezolizumab combined with bevacizumab and RP3, and the second cohort will enroll patients who have progressed on 1L immunotherapy (including atezolizumab/bevacizumab), and will be treated with atezolizumab combined with bevacizumab and RP3.

The Company expects to initiate the Phase 2 program with RP2 and RP3 around mid-year.

Phase 1 program

- Accrual in the Phase 1 program is expected to materially complete in Q3 2023. 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 disclosed by year end.

Corporate Update

Replimune has entered into a transition and separation agreement with Jean Franchi, who has informed the company of her intention to leave effective June 2, 2023. Jean will continue to work with the Company as an advisor until December 31, 2023. Andrew Schwendenman, Vice President of Finance, will assume the role of Chief Accounting Officer. Philip Astley-Sparke will serve as interim CFO while the search for a replacement is conducted.

"I would like to express my deep gratitude to Jean for all her contributions in leading and strengthening our finance, and general and administrative functions over the last three and a half years," said Philip Astley-Sparke. "I look forward to continuing to work with her during her transition and we wish her best of luck in her future endeavors."

Financial Highlights

- **Cash Position:** As of March 31, 2023, cash, cash equivalents and short-term investments were $583.4 million, as compared to $395.7 million as of fiscal year end March 31, 2022. The increase in cash as of March 31, 2023 reflects net proceeds from equity offerings and the initial debt tranche resulting in approximately $311.4 million of year-to-date financing inflows partially offset by 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, 2023, will enable the Company to fund operations into the second half of calendar year 2025.

- **R&D Expenses:** Research and development expenses were $37.9 million for the fourth quarter and $126.5 million for the fiscal year ended March 31, 2023, as compared to $21.7 million for the fourth quarter and $79.5 million for the fiscal year ended March 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 $2.3 million in stock-based compensation expenses for the fourth quarter and $10.1 million in stock-based compensation expenses for the fiscal year ended March 31, 2023.

- **S,G&A Expenses:** Selling, general and administrative expenses were $15.0 million for the fourth quarter and $50.6 million for the fiscal year ended March 31, 2023, as compared to $10.3 million for the fourth quarter and $38.8 million for the year ended March 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 $4.6 million in stock-based compensation expenses for the fourth quarter and $18.1 million in stock-based compensation expenses for the fiscal year ended March 31, 2023.

- **Net Loss:** Net loss was $49.2 million for the fourth quarter and $174.3 million for the fiscal year ended March 31, 2023, as compared to a net loss of $31.7 million for the fourth quarter and $118.0 million for the fiscal year ended March 31, 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 recently completed enrollment and enrolled 211 patients with locally advanced or metastatic cutaneous squamous cell carcinoma (CSCC) who are naïve to anti-PD-1 therapy. The clinical trial will evaluate complete response (CR) rate and overall response rate (ORR) as its two independent primary efficacy endpoints as assessed by independent review, as well as secondary

endpoints including duration of response, progression-free survival (PFS), and overall survival (OS). 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 trial of RP1 plus nivolumab. The leading IGNYTE cohort is a 125-patient cohort in anti-PD1 failed cutaneous melanoma with registrational intent. 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 cohort is enrolling in non-melanoma skin cancers which includes both naïve and anti-PD1 failed CSCC. This trial is being conducted under a collaboration and supply agreement with 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 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 novel tumor-directed oncolytic immunotherapies. Replimune's proprietary RPx platform is based on a potent HSV-1 backbone with payloads added to maximize immunogenic cell death and the induction of a systemic anti-tumor immune response. The RPx platform has 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 (TME) to ignite a strong and durable systemic response. This MOA is expected to be synergistic with most established and experimental cancer treatment modalities, and, with an attractive safety profile the RPx platform has 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, 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 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,	
	2023	**2022**
Operating expenses:		
Research and development	$ 126,527	$ 79,545
Selling, general and administrative	50,553	38,769
Total operating expenses	177,080	118,314
Loss from operations	(177,080)	(118,314)
Other income (expense):		
Research and development incentives	2,914	3,170
Investment income	10,006	390
Interest expense on finance lease liability	(2,197)	(2,223)
Interest expense on debt obligations	(1,963)	-
Other (expense) income	(5,676)	(1,059)
Total other income, net	3,084	278
Loss before income taxes	(173,996)	(118,036)
Income tax provision	288	-
Net loss	$ (174,284)	$ (118,036)
Net loss per common share, basic and diluted	$ (2.99)	$ (2.26)
Weighted average common shares outstanding, basic and diluted	58,213,010	52,212,269

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

	March 31, 2023	**March 31, 2022**
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 583,386	$ 395,655
Working capital	558,778	383,221
Total assets	646,591	461,192
Total stockholders' equity	555,292	411,229

Replimune Group Inc