Replimune Reports Fiscal Second Quarter Financial Results and Provides Corporate Update

November 3, 2022

Completed enrollment in the CERPASS registration-directed clinical trial evaluating RP1 in cutaneous squamous cell carcinoma (CSCC); primary analysis data expected to be released in H1 2023

Six-month follow-up data from the first 75 patients enrolled in the IGNYTE clinical trial cohort of RP1 combined with Opdivo® (nivolumab) in anti-PD1 failed melanoma expected by year end

An update on the RP2/3 development program remains on track to be provided by year end

Completed $200 million term-loan that extended cash runway into 2025

WOBURN, Mass., Nov. 03, 2022 (GLOBE NEWSWIRE) -- Replimune Group, Inc. (NASDAQ: REPL), a clinical stage biotechnology company pioneering the development of a novel class of tumor-directed oncolytic immunotherapies, today announced financial results for the fiscal second quarter ended September 30, 2022 and provided a business update.

"We continue working towards establishing our oncolytic immunotherapies as the cornerstone treatment for a variety of solid tumor indications," said Philip Astley-Sparke CEO of Replimune. "We plan to establish a major skin cancer franchise with our lead program, RP1 and are on track to announce primary data from the CERPASS clinical trial in CSCC in the first half of 2023. Additionally, we look forward to announcing initial data from the IGNYTE clinical trial cohort evaluating RP1 combined with Opdivo in anti-PD1 failed melanoma later this year. As we continue advancing the rest of our pipeline, we are pleased to report that we also remain on track to provide an update on the RP2/3 program, targeted at treating a number of difficult-to-treat cancers, later this year. With a strong financial position enhanced by our recently announced term loan, we have extended our cash runway into 2025 to fund key value-driving catalysts, including the costs of funding commercial infrastructure and running a confirmatory clinical trial to support potentially filing for FDA approval in anti-PD1 failed melanoma under the accelerated approval pathway."

Corporate Updates

- **Extended cash runway into 2025.** The Company completed a $200 million non-dilutive debt financing with Hercules Capital, Inc. The financing extends the Company's cash runway into 2025 ahead of key catalysts from its registration-directed CERPASS and IGNYTE clinical trials in cutaneous squamous cell carcinoma (CSCC) and anti-PD1 failed melanoma, inclusive of the costs of funding commercial infrastructure and running a confirmatory clinical trial to support a potential filing for FDA approval in anti-PD1 failed melanoma under the accelerated approval pathway.

Program Highlights & Milestones:

RP1

- **RP1 combined with Libtayo® (cemiplimab-rwlc) in cutaneous squamous cell carcinoma (CSCC)**
  - Completed enrollment in the CERPASS registration-directed clinical trial.
  - Replimune has enrolled 211 patients in the CERPASS clinical trial evaluating RP1 combined with Libtayo in patients with CSCC.
  - Topline primary analysis data from this clinical trial is expected to be released in H1 2023.

- **RP1 combined with Opdivo in anti-PD1 failed melanoma**
  - Data evaluating the first 75 patients with 6 months follow up from the anti-PD1 failed melanoma cohort of the IGNYTE clinical trial remains on track to be presented by year end.
  - The anti-PD1 failed melanoma cohort of the IGNYTE clinical trial of RP1 combined with Opdivo is intended to ultimately enroll a total of approximately 125 patients, with enrollment expected to complete around the end of this year.
  - The data snapshot from the first 75 patients followed for 6 months will be investigator assessed as compared to the primary endpoint of ORR for all patients in the cohort which is to be assessed by central review.

- **RP1 combined with Opdivo in anti-PD1 failed non-melanoma skin cancers**
  - Recruitment remains ongoing into the cohorts of patients with anti-PD1 failed non-melanoma skin cancers, including CSCC with a data update expected in H1 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 in H1 2023.

- **RP1 alone and combined with anti-PD1 therapy for the neoadjuvant treatment of CSCC**
  - Protocol development is underway for the testing of RP1 alone and combined with anti-PD1 therapy for the neoadjuvant treatment of CSCC

RP2 and RP3

- **RP2 alone and in combination with Opdivo in difficult-to-treat cancers**
  - The Company continues to enroll patients in the expansion cohorts of the Phase 1 clinical trial evaluating RP2 in patients with tumor types of particular interest (gastro-intestinal [GI] cancers, breast cancer, lung cancer, head and neck cancer and uveal melanoma).
  - The Company had previously fully enrolled the prior cohorts of patients evaluating RP2 monotherapy (n=9) and RP2 in combination with Opdivo (n=30) (data presented in Nov 2020 and Nov 2021).

- **RP3 alone and in combination with Opdivo in difficult-to-treat cancers**
  - The Company completed enrollment in the initial part of its Phase 1 clinical trial with RP3 alone.
  - Following determination of the recommended Phase 2 dose (RP2D), the Company is enrolling patients in the cohort evaluating RP3 combined with Opdivo, with focus on patients with GI cancers, breast cancer, lung cancer and head and neck cancer.

- **RP2/3, including in combination with current standard of care, in squamous cell carcinoma of the head and neck (SCCHN), hepatocellular carcinoma (HCC), and colorectal cancer (CRC)**
  - The Company expects to initiate its Phase 2 development program with RP2/3 in the first half of 2023.
  - As previously announced, this program is intended to include Phase 2 clinical trials in SCCHN (locally advanced and recurrent/metastatic), HCC (first line and second line) and CRC (third line), combined with current standard of care where appropriate.

- The Company remains on track to provide an update on the RP2/3 program later this year.

Financial Highlights

- **Cash Position:** As of September 30, 2022, cash, cash equivalents and short-term investments were $371.8 million, as compared to $395.7 million as of fiscal year end March 31, 2022. Cash utilized in operating activities in advancing the Company's expanded clinical development plan was offset by $37.5 million year-to-date in net proceeds generated from the sale of common stock under the Company's at-the-market facility.

  Based on the current operating plan, the Company believes that existing cash, cash equivalents and short-term investments, as of September 30, 2022, together with unrestricted proceeds available to be drawn under the Hercules debt facility, will enable us to fund our operations into calendar 2025, inclusive of the costs of funding commercial infrastructure and running a confirmatory clinical trial to support a potential filing for FDA approval in anti-PD1 failed melanoma under the accelerated approval pathway.

- **R&D Expenses:** Research and development expenses were $28.8 million for the second quarter ended September 30, 2022, as compared to $19.9 million for the second quarter ended September 30, 2021. 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 $2.5 million in stock-based compensation expenses for the second quarter ended September 30, 2022.

- **S,G&A Expenses:** Selling, general and administrative expenses were $12.7 million for the second quarter ended September 30, 2022, as compared to $9.3 million for the second quarter ended September 30, 2021. 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 second quarter ended September 30, 2022.

- **Net Loss:** Net loss was $43.1 million for the second quarter ended September 30, 2022, as compared to a net loss of $29.4 million for the second quarter ended September 30, 2021.

About CERPASS

CERPASS is Replimune's registration-directed randomized, global Phase 2 clinical study 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 study is being conducted under a clinical trial collaboration agreement with Regeneron and full commercial rights retained by Replimune. Libtayo is being jointly developed by Regeneron and Sanofi. Libtayo is a registered trademark of Regeneron.

About IGNYTE

IGNYTE is Replimune's multi-cohort Phase 1/2 trial of RP1 plus Opdivo® (nivolumab). There are 4 tumor specific cohorts currently

enrolling in this clinical trial including a 125-patient cohort in anti-PD-1 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 cohorts are in non-melanoma skin cancers which includes both naïve and anti-PD-1 failed CSCC, in anti-PD1 failed microsatellite instability high, or MSI-H/dMMR tumors and anti-PD(L)-1 failed non-small cell lung cancer, or NSCLC. This trial is being conducted under a collaboration and supply agreement with Bristol-Myers Squibb Company. Opdivo is a registered trademark of Bristol-Myers Squibb Company.

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 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. 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)
(Unaudited)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 28,834	$ 19,902	$ 58,312	$ 38,456
General and administrative	12,745	9,345	24,143	18,172
Total operating expenses	41,579	29,247	82,455	56,628
Loss from operations	(41,579)	(29,247)	(82,455)	(56,628)
Other income (expense):				
Research and development incentives	574	725	1,425	1,513
Investment income	1,112	80	1,455	172
Interest expense on finance lease liability	(551)	(557)	(1,103)	(1,115)
Other (expense) income	(2,658)	(356)	(4,677)	(608)
Total other (expense) income, net	(1,523)	(108)	(2,900)	(38)
Net loss attributable to common stockholders	$ (43,102)	$ (29,355)	$ (85,355)	$ (56,666)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.79)	$ (0.56)	$ (1.57)	$ (1.09)
Weighted average common shares outstanding, basic and diluted	54,770,291	52,081,325	54,492,395	51,962,795

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

	September 30, 2022	March 31, 2022
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 371,820	$ 395,655
Working capital	355,853	383,221
Total assets	436,095	461,192
Total stockholders' equity	384,072	411,229

Replimune Group Inc