UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **August 4, 2022**

REPLIMUNE GROUP, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38596**	**82-2082553**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

500 Unicorn Park
Woburn, MA 01801
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: **(781) 222-9600**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	REPL	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02 Results of Operations and Financial Condition.

On August 4, 2022, Replimune Group, Inc. issued a news release announcing its financial results for the first quarter ended June 30, 2022 and certain corporate updates. A copy of the news release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly stated by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	News Release dated August 4, 2022
104	Cover page interactive data file (formatted as Inline XBRL)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REPLIMUNE GROUP, INC.

Date: August 4, 2022

By: /s/ Jean Franchi
Jean Franchi
Chief Financial Officer

Exhibit 99.1

Replimune Reports Fiscal First Quarter Financial Results and Provides Corporate Update

Target enrollment of 180 patients reached in the CERPASS randomized controlled registration-directed clinical trial evaluating RP1 in cutaneous squamous cell carcinoma (CSCC); primary analysis data expected to be released in H1 2023

First 75 patients enrolled in the IGNYTE clinical trial cohort of RP1 combined with Opdivo® (nivolumab) in anti-PD1 failed melanoma; data snapshot from these patients with six-month follow-up expected to be released in Q4 2022

RP2/3 update to be provided by year end, including detailed Phase 2 development plans

Woburn, MA, August 4, 2022 – 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 first quarter ended June 30, 2022 and provided a business update.

"Our ambition to establish a major skin cancer franchise, built off of our lead RP1 program, is progressing to plan. We are pleased to have reached target enrollment in the CERPASS registration-directed clinical trial in CSCC and expect to complete enrollment in the IGNYTE clinical trial cohort evaluating RP1 combined with Opdivo in anti-PD1 failed melanoma around the end of year. We look forward to sharing the primary analysis data from the CERPASS clinical trial in H1 2023 and a data snapshot from the first 75 patients enrolled in the IGNYTE anti-PD1 failed melanoma cohort in the fourth quarter of 2022. In addition to RP1, we remain excited about the previously reported data with RP2 and look forward to providing further updates from the RP2/3 program as we move towards initiation of our Phase 2 programs in head and neck cancer, hepatocellular carcinoma and colorectal cancer. Looking even further ahead, we are well financed as we continue to prepare for the potential commercialization of our oncolytic immunotherapies and remain on course to achieve our ultimate ambition of establishing our products as a cornerstone treatment for a variety of solid tumor indications."

Corporate Updates & Upcoming Milestones

RP1 Update

- **Reached target enrollment in the CERPASS registration-directed clinical trial evaluating RP1 combined with Libtayo® (cemiplimab-rwlc) in cutaneous squamous cell carcinoma (CSCC)**
    - Replimune has enrolled the pre-specified target of 180 patients in the CERPASS trial evaluating RP1 combined with Libtayo in patients with CSCC; additional patients screened this month will also be enrolled with the last patient expected to initiate dosing this quarter.
    - Topline primary analysis data from this clinical trial is expected to be released in H1 2023.

- **Recruited the first 75 patients treated with RP1 combined with Opdivo in the anti-PD1 failed melanoma cohort with registrational intent of the IGNYTE clinical trial with a data snapshot from the first 75 patients with 6 months follow-up expected in Q4 2022**

    - 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.

- **Other IGNYTE cohorts with RP1 combined with Opdivo:** Recruitment remains ongoing into the cohorts of patients with anti-PD1 failed non-melanoma skin cancers, including CSCC, anti-PD1 failed non-small cell lung cancer, and anti-PD1 failed MSI-high cancers, with a data update expected in H1 2023.

- **RP1 in solid organ transplant recipients with skin cancers (ARTACUS):** 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.

- **Development of RP1 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, with clinical trial initiation expected in H1 2023.

RP2 and RP3 Update

- **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 cohorts evaluating RP2 monotherapy (n=9) and RP2 in combination with Opdivo (n=30) (data presented in Nov 2020 and Nov 2021). Initial data from the RP2 expansion cohorts is expected around the end of this year.

- **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. Initial data for this RP3 combination cohort is expected around the end of this year. Additional monotherapy patients will also be enrolled.

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

Financial Highlights

- **Cash Position:** As of June 30, 2022, cash, cash equivalents and short-term investments were $395.1 million, as compared to $395.7 million as of March 31, 2022. Cash utilized in operating activities in advancing the Company's expanded clinical development plan was offset by $31.0 million in net proceeds generated from the sale of common stock under the Company's at-the-market facility.

  Based on the current operating plan, Replimune believes that existing cash, cash equivalents and short-term investments will fund operating expenses and capital expenditure requirements into the second half of 2024, excluding any confirmatory trial required by the FDA or other regulatory body.

- **R&D Expenses:** Research and development expenses were $29.5 million for the first quarter ended June 30, 2022, as compared to $18.6 million for the first quarter ended June 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 $2.6 million in stock-based compensation expenses for the first quarter ended June 30, 2022.

- **S,G&A Expenses:** Selling, general and administrative expenses were $11.4 million for the first quarter ended June 30, 2022, as compared to $8.8 million for the first quarter ended June 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 $4.6 million in stock-based compensation expenses for the first quarter ended June 30, 2022.

- **Net Loss:** Net loss was $42.3 million for the first quarter ended June 30, 2022, as compared to a net loss of $27.3 million for the first quarter ended June 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 comprises approximately 180 evaluable 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 in which the costs of the trial are shared 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 June 30,	
	2022	**2021**
Operating expenses:		
Research and development	$ 29,478	$ 18,554
Selling, general and administrative	11,398	8,827
Total operating expenses	40,876	27,381
Loss from operations	(40,876)	(27,381)
Other income (expense):		
Research and development incentives	851	788
Investment income	343	92
Interest expense on finance lease liability	(552)	(558)
Other (expense) income	(2,019)	(252)
Total other (expense) income, net	(1,377)	70
Net loss attributable to common stockholders	$ (42,253)	$ (27,311)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.78)	$ (0.53)
Weighted average common shares outstanding, basic and diluted	54,211,446	51,910,331

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

	June 30, 2022	**March 31, 2022**
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 395,082	$ 395,655
Working capital	381,633	383,221
Total assets	459,427	461,192
Total stockholders' equity	410,262	411,229