# 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 6, 2021**

# 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 6, 2021, Replimune Group, Inc. issued a news release announcing its financial results for the first quarter ended June 30, 2021 and certain development and 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 6, 2021 |

**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 6, 2021

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

**Exhibit 99.1**

**Replimune Reports Fiscal First Quarter Financial Results and Provides Corporate Update**

*Updated complete and durable response data in RP1 (vusolimogene oderparepvec) skin cancer cohorts support the ongoing registration directed development programs in CSCC and anti-PD-1 failed melanoma, with full accrual for both programs expected in mid-2022*

*Initial data with RP2 as monotherapy and in combination with Opdivo® (nivolumab) in patients with difficult-to-treat and anti-PD-1 failed cancers supports expanding the Phase 1 clinical trial to focus on patients whose tumors have metastasized to the liver*

*A broad Phase 2 program with RP2 and/or RP3 with particular focus on patients with liver metastases from various prevalent cancer types is being designed with the detailed development plan expected to be presented in the first quarter of 2022*

*Cash at 30 June of $458m with runway into second half of 2024*

**Woburn, MA, August 6, 2021** – Replimune Group, Inc. (NASDAQ: REPL), a biotechnology company developing oncolytic immuno-gene therapies derived from its Immulytic® platform, today announced financial results for the fiscal first quarter ended June 30, 2021 and provided a business update.

"The data we presented in June continues to demonstrate the depth and durability of responses observed with RP1 and RP2, which we believe indicates the potential to provide new treatment options for a range of difficult-to-treat cancers with clear unmet need, including for patients with anti-PD-1 failed disease," said Philip Astley-Sparke, CEO of Replimune. "Beyond our evolving skin cancer franchise where we expect to complete accrual in our registration directed CERPASS study in CSCC and in our registration directed cohort of patients with anti-PD-1 failed melanoma mid next year, we are designing a comprehensive development plan with the goal of establishing our product candidates as a cornerstone of cancer treatment regimens, including in patients with liver metastases. The detail behind these plans will be made available early next year."

**Recent Events and Corporate Updates**

- **Presented data at June Virtual Investor Event that continues to indicate the durable efficacy of RP1 and RP2.** During the event, Replimune provided a data update from the Phase 2 cohorts of RP1 in combination with Opdivo in patients with melanoma and CSCC and other non-melanoma skin cancers and from the RP2 Phase 1 monotherapy cohort in patients with difficult-to-treat cancers. In addition to these updates, Replimune presented initial data with RP2 in combination with Opdivo. The RP1 data presented showed compelling depth and durability of response with RP1 that strongly supports the ongoing studies with registrational intent in CSCC and anti-PD-1 failed melanoma. The RP2 monotherapy and combination data presented also showed compelling activity in patients with immune insensitive tumors and with anti-PD-1 failed disease.

- **Announced intention to initiate a development program in patients with liver metastases from various cancer types.** In June, the Company announced its intention to initiate a development program for patients with liver metastases from various cancer types based on preliminary data in which durable clinical responses have been observed following treatment with RP1 in combination with Opdivo and RP2 alone and in combination with Opdivo. The Company also intends to further evaluate whether RP2 and/or RP3 will be used in this program and present the detailed development plan in the first quarter of 2022.

- **First RP1 batches produced and filled at state-of-the-art manufacturing facility.** Work to compare these batches to the contract manufactured material used in the Company's clinical studies is ongoing. RP1 batches produced and filled at the Company's 63,000-square-foot manufacturing facility in Framingham, MA, will be released once comparability work has been completed. Technology transfer and process development work for RP2 and RP3 are underway in readiness for bringing the facility on-line to support all of the Company's clinical development activities.

**Program Highlights***

**CERPASS – Registration directed Phase 2 clinical trial in CSCC**

- **RP1 in combination with Libtayo® (cemiplimab) in CSCC:** The Company continues to actively enroll patients in CERPASS, its registration directed, global, randomized Phase 2 study of RP1 in combination with Libtayo vs. Libtayo alone in patients with advanced CSCC. The Company recently submitted an amended protocol to the U.S. Food and Drug Administration (FDA) adding complete response (CR) rate as an independent primary endpoint, in addition to overall response rate (ORR), and with a reduction in sample size from 240 patients to 180 patients. The Company expects to complete enrollment in time for the primary data read-out to be triggered in late 2022.

**IGNYTE – multi cohort Phase 2 clinical trial of RP1 combined with Opdivo**

- **Anti-PD-1 failed melanoma cohort:** The Company's 125-patient cohort in the IGNYTE Phase 2 clinical trial of RP1 in combination with Opdivo continues to actively enroll patients. While the Company still expects to release data from this cohort in late 2022, in order to document sufficient durability of response, an important secondary endpoint of the study, the timing of the primary analysis upon which a filing is intended to be made is expected to be extended by approximately 6 months from year end 2022.

- **Non-melanoma skin cancer (NMSC) cohort:** The Company has enrolled 29 of the 30-patient PD-1 naïve cohort of RP1 in combination with Opdivo in non-melanoma skin cancers and continues to enroll patients with anti-PD-1 failed NMSC. The Company expects to provide initial data from the anti-PD-1 failed patients in the first quarter of 2022.

- **Anti-PD(L)-1 failed non-small cell lung cancer (NSCLC) cohort:** Dosing is underway in a 30-patient cohort of RP1 in combination with Opdivo in anti-PD(L)-1 failed NSCLC. A planned amendment to the IGNYTE protocol also includes modifications to the patient eligibility criteria which are expected to enhance enrollment into the trial. The Company now plans to provide initial data from this cohort in the first quarter of 2022.

- **MSI-H/dMMR tumor cohort:** Due to development challenges in the anti-PD-1 naïve setting, the Company has decided to not pursue RP1 with Opdivo for the treatment of anti-PD-1 naïve patients with MSI-H/dMMR tumors, but instead amend the clinical trial protocol to enroll patients with anti-PD-1 failed disease. This complements other cohorts in the clinical trial where patients with anti-PD-1 failed disease of other tumor types are being enrolled.

**ARTACUS – Phase 1b/2 clinical trial of RP1 as monotherapy in solid organ transplant recipients with skin cancers**

- The Company is currently enrolling its clinical trial assessing the safety and efficacy of RP1 in liver and kidney transplant recipients with CSCC. The protocol has recently been amended to now enroll up to 65 patients with potentially registrational intent. The Company now expects to present initial data from this clinical trial in the first quarter of 2022.

**RP2 and RP3**

- **RP2 alone and in combination with Opdivo in difficult-to-treat cancers:** The Company has fully enrolled the initial 30-patient cohort evaluating RP2 combined with Opdivo in difficult-to-treat cancers. The Company remains on track to provide updated data from this program in the second half of 2021. The Company intends to expand this clinical trial to provide further signal confirmation for the treatment of patients with liver metastases from various tumor types. A protocol amendment to facilitate the expansion is expected to be made in the third quarter of 2021.

- **RP3 alone and in combination with anti-PD-1 therapy:** The Phase 1 clinical trial evaluating RP3 alone in solid tumor patients is actively recruiting patients. Initial data from this cohort of the Phase 1 trial is now expected to be presented in the first quarter of 2022. In addition to this cohort, the Company expects to begin enrolling a cohort evaluating RP3 in combination with anti-PD-1 therapy in solid tumor patients by the end of 2021, with focus on patients with lung, breast and gastrointestinal cancers including colorectal cancer.

- **RP2 and/or RP3 in patients with liver metastases from a range of tumor types:** Based on the observation of the clinical responses in patients with liver metastases from a range of difficult-to-treat tumor types following treatment with RP1 in combination with Opdivo and RP2 alone and in combination with Opdivo, the Company plans to initiate a clinical development program with RP2 and/or RP3 with particular focus on patients with liver metastases from a range of prevalent cancer types. The Company expects to initiate a multi-tumor type Phase 2 clinical program with RP2 and/or RP3 in these patients around mid-year 2022. The details of this development program, including tumor types and setting, are intended to be disclosed in first quarter of 2022.

  *****Program Highlight dates are on a calendar-year basis.

**Financial Highlights**

- **Cash Position:** As of June 30, 2021, cash, cash equivalents and short-term investments were $458.3 million, as compared to $476.3 million as of March 31, 2021. This decrease was primarily related to cash utilized in operating activities in advancing our expanded clinical development plan.

  Based on the current operating plan, Replimune believes that existing cash and 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 $18.6 million for the first quarter ended June 30, 2021, as compared to $12.2 million for the first quarter ended June 30, 2020. 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 first quarter ended June 30, 2021.

- **G&A Expenses:** General and administrative expenses were $8.8 million for the first quarter ended June 30, 2021, as compared to $5.7 million for the first quarter ended June 30, 2020. The increase was primarily driven by personnel-related costs, professional fees, and facility expansion. General and administrative expenses included $3.8 million in stock-based compensation expenses for the first quarter ended June 30, 2021.

- **Net Loss:** Net loss was $27.3 million for the first quarter ended June 30, 2021, as compared to a net loss of $17.5 million for the first quarter ended June 30, 2020.

**About CERPASS**
CERPASS is Replimune's registration-directed randomized, global Phase 2 clinical study to compare the effects of Libtayo alone versus a combination of Libtayo and Replimune's investigational oncolytic immunotherapy RP1. The clinical trial will enroll 180 patients with locally advanced or metastatic cutaneous squamous cell carcinoma (CSCC) who are naïve to anti-PD-1 therapy. The trial will evaluate complete response (CR) rate and overall response rate (ORR) as its two primary efficacy endpoints as assessed by independent review, as well as duration of response, progression-free survival (PFS), and overall survival (OS) as its secondary endpoints. 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®. There are 4 tumor specific cohorts currently enrolling in this trial including a 125-patient extension cohort of RP1 combined with Opdivo in anti-PD-1 failed cutaneous melanoma. This cohort was initiated after completing enrollment in a prior Phase 2 cohort in the same trial of approximately 30 patients with melanoma. The additional cohorts are studying RP1 in combination with Opdivo in non-melanoma skin cancers which includes both naïve and anti-PD-1 failed CSCC, in 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 Immulytic® product candidate and is based on a proprietary new strain of herpes simplex virus engineered 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 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 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 to develop the next generation of oncolytic immune-gene therapies for the treatment of cancer. Replimune is developing novel, proprietary therapeutics intended to improve the direct cancer-killing effects of selective virus replication and the potency of the immune response to the tumor antigens released. Replimune's Immulytic® platform is designed to maximize systemic immune activation, in particular to tumor neoantigens, through robust viral-mediated immunogenic tumor cell killing and the delivery of optimal combinations of immune-activating proteins to the tumor and draining lymph nodes. The approach is expected to be highly synergistic with immune checkpoint blockade and other approaches to cancer treatment across a broad range of cancers. Replimune intends to progress these therapies rapidly through clinical development in combination with other immuno-oncology products with complementary mechanisms of action as well as in standalone indications. 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, the potential impact of COVID-19 on our operations and milestones, 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.

**Investor Inquiries**
Chris Brinzey
Westwicke, an ICR Company
339.970.2843
chris.brinzey@westwicke.com

**Media Inquiries**
Arleen Goldenberg
Verge Scientific Communications
917.548.1582
agoldenberg@vergescientific.com

**Replimune Group, Inc.**
**Condensed Consolidated Statements of Operations**
**(Amounts in thousands, except share and per share amounts)**
**(Unaudited)**

| | Three Months Ended June 30, | |
|---|---|---|
| | **2021** | **2020** |
| Operating expenses: | | |
| Research and development | $ 18,554 | $ 12,157 |
| General and administrative | 8,827 | 5,676 |
| Total operating expenses | 27,381 | 17,833 |
| Loss from operations | (27,381) | (17,833) |
| Other income (expense): | | |
| Research and development incentives | 788 | 686 |
| Investment income | 92 | 527 |
| Interest expense on finance lease liability | (558) | (561) |
| Interest expense on debt obligations | - | (284) |
| Other (expense) income | (252) | (28) |
| Total other (expense) income, net | 70 | 340 |
| Net loss attributable to common stockholders | $ (27,311) | $ (17,493) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.53) | $ (0.44) |
| Weighted average common shares outstanding, basic and diluted | 51,910,331 | 39,862,319 |

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

| | **June 30, 2021** | **March 31, 2021** |
|---|---|---|
| **Consolidated Balance Sheet Data:** | | |
| Cash, cash equivalents and short-term investments | $ 458,331 | $ 476,302 |
| Working capital | 449,514 | 469,200 |
| Total assets | 523,724 | 543,098 |
| Total stockholders' equity | 479,024 | 498,728 |