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): **May 19, 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 May 19, 2022, Replimune Group, Inc. issued a news release announcing its financial results for the fourth quarter and year ended March 31, 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 May 19, 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: May 19, 2022

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

Exhibit 99.1

Replimune Reports Fiscal Fourth Quarter and Year-Ended 2022 Financial Results and Provides Corporate Update

Enrollment in the CERPASS clinical trial with RP1 in cutaneous squamous cell carcinoma (CSCC) expected to be completed in mid-year 2022; top line data expected Q1 2023

Directional data from the first 75 patents with 6 months follow up from the IGNYTE clinical trial with RP1 in anti-PD1 failed melanoma expected in late 2022

Phase 2 development plan for RP2/RP3 in HCC, CRC and SCCHN announced

Woburn, MA, May 19, 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 fourth quarter and year ended March 31, 2022 and provided a business update.

"We have ended the fiscal year in a very strong position from which to execute on our vision to establish our products as a cornerstone of immuno-oncology regimens and we look forward with these firm foundations in place to a potentially transformative 12-month period ahead," said Philip Astley-Sparke CEO of Replimune. "Updated data in anti-PD1 naïve cutaneous squamous cell carcinoma (CSCC) and anti-PD1 failed melanoma continue to support our two registration-directed clinical trials in these settings. We are maintaining guidance that we expect to complete enrollment into our registration directed CERPASS clinical trial in CSCC mid-year and to release top line data in early 2023. Further, we expect to release initial directional data from our registration directed IGNYTE clinical trial in anti-PD1 failed melanoma in late 2022. Launch scale manufacturing has been established and commercial planning to establish a major skin cancer franchise is advancing. With RP2/3 we have announced an exciting mid stage program in colorectal cancer (CRC), hepatocellular carcinoma (HCC) and head and neck cancer (SCCHN) where an expedited path to potential approval in some settings may be feasible. Finally, we have a strong cash position to drive value through multiple major data catalysts."

Corporate Updates

- **Provided data update for RP1 in its skin cancer programs at a virtual investor event in March 2022.**
    - IGNYTE anti-PD1 naïve NMSC cohort of patients treated with RP1 combined with Opdivo® (nivolumab) (n=32; recruitment complete): The overall response rate (ORR) in CSCC increased to 65%, compared to 60% at the June 2021 update with the complete response rate (CRR) unchanged at 47%. Updated response rates in BCC, MCC and angiosarcoma were 25%, 75% and 67% respectively with multiple complete responses documented, indicating the potential utility of RP1 in additional NMSCs beyond CSCC.

- IGNYTE anti-PD1 failed and anti-PD1 naïve melanoma cohort of patients treated with RP1 combined with Opdivo (n=36; recruitment complete): The ORR in anti-PD1 naïve cutaneous melanoma remained at 62.5%. The ORR in cutaneous melanoma patients who had previously failed anti-PD1 or both anti-PD1 and anti-CTLA-4 (n=16) was reported to have risen to 37.5%, an improvement from the 31% ORR reported in the June 2021 update, including two complete responses.

- IGNYTE anti-PD(L)-1 failed NMSC cohort of patients treated with RP1 combined with Opdivo (n=12; recruitment ongoing): The initial early ORR data in this group was 33.3% with responses having been observed in anti-PD(L)-1 failed CSCC, MCC and angiosarcoma, including one complete response as of the cutoff date. Other patients who remain on study with a shorter follow up also showed tumor shrinkage. The Company believes the clear activity of RP1 combined with Opdivo in anti-PD(L)-1 failed NMSC represents a new potential therapeutic option for these patients and supports the broader potential for RP1 in skin cancers, including those with anti-PD(L)-1 failed disease.

- Phase 1b/2 ARTACUS clinical trial of RP1 monotherapy in solid organ transplant recipients with skin cancer (n=6; recruitment ongoing): Initial data with RP1 monotherapy in solid organ transplant patients demonstrated a similar safety profile to that observed in patients who are not immune suppressed, with initial clinical activity having been seen. Two of the first six patients enrolled (33%) had so far achieved a response, with one complete response and one partial response.

- **Provided detailed strategy and clinical development plan for RP2/3 at a virtual investor event in March 2022.**

  - The Phase 2 development plan for RP2/3 is intended to target tumor types in large underserved markets, including where liver metastases are common, as well as patients with primary liver cancer, and patients with early disease where the objective of treatment would be to increase the rate of cure. This includes the development of RP2/3 in combination with current standards of care (SOC), including immunotherapy, chemotherapy and radiation, and in settings following the current SOC.

    The following indications for signal finding single arm Phase 2 clinical trials were identified which meet these criteria:

    - Locally advanced (LA) and 1L recurrent SCCHN in combination with chemoradiation, or SOC chemotherapy and anti-PD1 therapy, respectively. The Company's objective is to also expedite the initiation of a randomized controlled registration directed program in LA SCCHN.
    - 1L and 2L hepatocellular carcinoma (HCC) in combination with SOC immunotherapy and anti-PD1/L1 therapy respectively.
    - 3L micro-satellite stable colorectal cancer (CRC) in combination with anti-PD1 therapy.
    - Additional signal finding work is also intended in other indications.

  - The RP2/3 Phase 2 program is expected to initiate around the calendar year end.

  - The decision as to whether RP2 or RP3 will be used in these clinical trials will be made later in the calendar year, following generation and analysis of further clinical data with RP2 and RP3 in their respective ongoing Phase 1 clinical trials.

Upcoming Milestones

CERPASS – Registration-directed Phase 2 clinical trial in CSCC

- **RP1 in combination with Libtayo® (cemiplimab-rwlc) in CSCC:** The Company is actively enrolling patients in a registration-directed, global, randomized, controlled, 180-patient Phase 2 clinical trial (CERPASS) evaluating RP1 in combination with Libtayo vs. Libtayo alone in patients with advanced CSCC. The Company expects to complete enrollment in mid-year 2022 with top line data expected to be available in Q1 2023.

IGNYTE – Multi-cohort Phase 2 clinical trial of RP1 combined with Opdivo

- **Anti-PD1 failed melanoma cohort:** The Company continues to enroll patients in the 125-patient cohort of the IGNYTE Phase 2 clinical trial in patients with anti-PD1 failed melanoma. The Company continues to expect to report initial directional data from the first 75 patient with six months follow up in late 2022.

RP2 and RP3

- **RP2 alone and in combination with Opdivo in difficult-to-treat cancers:** After fully enrolling patients in the RP2 monotherapy (n=9) and combination with Opdivo (n=30) cohorts in the Phase 1 clinical trial with RP2 (data presented in Nov 2020 and Nov 2021), a further cohort of Phase 1 patients with tumor types of particular interest (gastro-intestinal [GI] cancers, breast cancer, lung cancer, head and neck cancer and uveal melanoma) was opened, with the first patients having been enrolled and from which initial data is expected towards the end of the 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), enrollment into the cohort of patients dosed with RP3 combined with Opdivo has recently commenced. This cohort will focus on enrolling patients with GI cancers, breast cancer, lung cancer and head and neck cancer. Initial data for this combination cohort is expected towards the end of the year. Additional patients will also be dosed as monotherapy.

Financial Highlights

- **Cash Position:** As of March 31, 2022, cash, cash equivalents and short-term investments were $395.7 million, as compared to $476.3 million as of March 31, 2021. The decrease was primarily related to cash utilized in operating activities in advancing the Company's 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 $21.7 million for the fourth quarter and $79.5 million for the fiscal year ended March 31, 2022, as compared to $16.2 million for the fourth quarter and $56.8 million for the fiscal year ended March 31, 2021. This increase was primarily due to clinical expenses driven by the Company's lead programs, expansion into additional studies, operating our dedicated manufacturing facility and related increased personnel costs. Research and development expenses included $2.1 million in stock-based compensation expenses for the fourth quarter and $8.6 million in stock-based compensation expenses for the fiscal year ended March 31, 2022.

- **S,G&A Expenses:** Selling, general and administrative expenses were $10.3 million for the fourth quarter and $38.8 million for the fiscal year ended March 31, 2022, as compared to $6.0 million for the fourth quarter and $23.2 million for the year ended March 31, 2021. The increase was primarily driven by personnel related costs, including sales and marketing personnel associated with pre-launch planning and the initial build of the Company's commercial infrastructure. Selling, general and administrative expenses included $3.7 million in stock-based compensation expenses for the fourth quarter and $15.7 million in stock-based compensation expenses for the fiscal year ended March 31, 2022.

- **Net Loss:** Net loss was $31.7 million for the fourth quarter and $118.0 million for the fiscal year ended March 31, 2022, as compared to a net loss of $21.5 million for the fourth quarter and $80.9 million for the fiscal year ended March 31, 2021.

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 is enrolling 180 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 primary efficacy endpoints as assessed by independent review, as well as duration of response, progression-free survival (PFS), and overall survival (OS) as 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 clinical trial including a 125-patient cohort in anti-PD-1 failed cutaneous melanoma. 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)
(Audited)

	Year Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 79,545	$ 56,754
Selling, general and administrative	38,769	23,201
Total operating expenses	118,314	79,955
Loss from operations	(118,314)	(79,955)
Other income (expense):		
Research and development incentives	3,170	2,807
Investment income	390	916
Interest expense on finance lease liability	(2,223)	(2,242)
Interest expense on debt obligations	-	(818)
Loss on extinguishment of debt	-	(913)
Other (expense) income	(1,059)	(665)
Total other income (expense), net	278	(915)
Net loss attributable to common stockholders	$ (118,036)	$ (80,870)
Net loss per common share, basic and diluted	$ (2.26)	$ (1.75)
Weighted average common shares outstanding, basic and diluted	52,212,269	46,248,969

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

	March 31, 2022	**March 31, 2021**
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 395,655	$ 476,302
Working capital	383,221	469,200
Total assets	461,192	543,098
Total stockholders' equity	411,229	498,728