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): **February 9, 2023**

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 February 9, 2023, Replimune Group, Inc. issued a news release announcing its financial results for the third quarter ended December 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 February 9, 2023
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: February 9, 2023

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

Exhibit 99.1

Replimune Reports Fiscal Third Quarter Financial Results and Provides Corporate Update

Strengthened balance sheet raising gross $259 million through an upsized public offering in December, extending cash runway into H2 2025 and increasing operational and strategic flexibility

Topline data from the CERPASS registration-directed clinical trial evaluating RP1 in cutaneous squamous cell carcinoma (CSCC) expected to be announced in Q3 2023 along with updates from ongoing RP1 skin cancer cohorts including anti-PD1 failed non-melanoma skin cancer (CSCC predominant) and the RP1 monotherapy clinical trial in organ transplant recipients with skin cancer

Achieved target enrollment of 125 patients in the IGNYTE clinical trial cohort of RP1 combined with Opdivo® (nivolumab) in anti-PD1 failed melanoma and in December presented positive data from the first 75 patients followed for at least 6 months

Announced collaboration with Roche for signal finding studies in RP2/3 in third-line (3L) colorectal cancer (CRC) and in first- and second-line (1L & 2L) hepatocellular carcinoma (HCC)

Woburn, MA, February 9, 2023 – 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 third quarter ended December 31, 2022 and provided a business update.

"We ended 2022 with a data update from our registration directed IGNYTE cohort of RP1 in anti-PD1 failed melanoma that demonstrated impressive and clinically meaningful activity in a patient population of major unmet need and with limited treatment options," said Philip Astley-Sparke CEO of Replimune. "As we turn the page to 2023, we believe this data has significantly de-risked our overall skin cancer franchise with RP1, and we look forward to providing additional updates on all of our skin cancer programs, including topline primary analysis data from our registration-directed CERPASS clinical trial evaluating RP1 in CSCC. As we prepare for a potential commercial launch we have made further key appointments to strengthen our commercial team and are well financed to build a commercial capability in the US. With RP2/3 we look forward to commencing our Phase 2 clinical trials and providing further updates from our Phase 1 program this year."

Corporate Updates

- **Entered into clinical collaboration and supply agreement with Roche for the initial development of RP2/3 in third-line (3L) colorectal cancer (CRC) and in first- and second-line (1L & 2L) hepatocellular carcinoma (HCC).** Under the terms of the agreement, the companies will share costs and Roche will supply its currently approved drugs, atezolizumab and bevacizumab in combination with RP3 in 1L & 2L HCC and 3L CRC and supply atezolizumab and bevacizumab for combination with RP2 in 3L CRC. Replimune will have responsibility for operationalizing these clinical trials.

- **Announced leadership appointments in preparation for potential 2024 commercial launch of RP1.** The Company appointed Christopher Sarchi, former Sanofi U.S. Commercial Oncology Head, as Chief Commercial Officer and Sushil Patel, Ph.D., previously Chief Commercial Officer, to a newly created position of Chief Strategy Officer. These appointments were made to prepare the Company as it begins to ramp up its commercial planning ahead of the potential 2024 commercial launch of RP1.

- **Increased operational and strategic flexibility and extended cash runway into H2 2025.** In December, the Company closed on an offering of common stock and pre-funded warrants raising approximately $259 million in gross proceeds and received aggregate net proceeds of approximately $243 million after deducting underwriting discounts, commissions, and other offering expenses. This includes the exercise in full by the underwriters of their option to purchase additional shares of common stock. In October, the Company secured a $200 million non-dilutive debt facility of which $30 million gross was funded at closing, the remaining $170 million can largely be drawn at the Company's option with satisfaction of certain milestones. Excluding any further debt draws the Company expects that its cash, cash equivalents and short-term investments of $616 million as of December 31, 2022 will fund its operating expenses and capital expenditure requirements into H2 2025.

Program Highlights & Milestones:

RP1

- **RP1 combined with Libtayo® (cemiplimab-rwlc) in cutaneous squamous cell carcinoma (CSCC)**
  - Completed enrollment of 211 patients in the CERPASS registration-directed clinical trial evaluating RP1 combined with Libtayo in patients with CSCC.
  - Topline primary analysis data from this clinical trial is expected to be announced in Q3 2023 updated from H1 2023. This is due to the time being taken and required for responses to be documented and confirmed, including per protocol response confirmation biopsies, and for central reviews to complete.

- **RP1 combined with Opdivo in anti-PD1 failed melanoma**
  - Presented data evaluating the first 75 patients with at least six-months follow up in the anti-PD1 failed melanoma cohort of the IGNYTE clinical trial in December.
  - The data demonstrated an overall response rate (ORR) of 36% and complete response (CR) rate of 20%, with clinically meaningful activity across a broad range of anti-PD1 failed cutaneous melanoma settings observed, including in patients with high tumor burden and visceral disease.
  - Systemic activity was seen in both injected and in un-injected lesions responding, including in un-injected visceral disease, with most responses seen in patients who did not respond to prior anti-PD1 therapy.
  - Safety data with RP1 in combination with nivolumab assessed across all skin cancer patients treated with RP1 combined with nivolumab (all studies, N=187), including the 75 patients reported on in December, continues to demonstrate an attractive safety profile, with predominantly 'on target' Grade 1-2 side effects indicative of systemic immune activation.
  - Target enrollment of 125 patients was reached in January with patients in screening at that time continuing to be enrolled. Enrollment is expected to complete this month with a final total study size of approximately 140 patients. The primary analysis is expected in Q1 2024, 12 months after the enrollment of the last patient.

- **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 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 in Q3 2023.

- **RP1 in other skin cancer indications**
  - The Company is currently evaluating all strategic opportunities for RP1 in skin cancers, including the setting for the confirmatory clinical trial in melanoma which is expected to be required to support an accelerated approval of RP1 in anti-PD1 failed melanoma.

RP2 and RP3

- **RP2 alone and in combination with Opdivo in difficult-to-treat cancers**
  - Completed enrollment (N=17) in the uveal melanoma expansion cohort of the Phase 1 clinical trial evaluating RP2 monotherapy (N=4) and RP2 in combination with Opdivo (N=13) and presented updated data in December further demonstrating the potential to treat a range of intractable tumor types, including those which metastasize to the liver.
  - 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), with a data update expected in H2 2023.

- **RP3 alone and in combination with Opdivo in difficult-to-treat cancers**
  - The Company continues to enroll patients in its Phase 1 cohort evaluating RP3 combined with Opdivo with a focus on patients with GI cancers, breast cancer, lung cancer and head and neck cancer and expects to provide an update in H2 2023.
  - In December, the Company presented data from previously enrolled patients with multiple soft tissue sarcomas including in leiomyosarcoma, osteosarcoma, chondrosarcoma, and epithelioid sarcomas who had all failed standard of care.
  - At the data cut-off date, 3 of 5 patients had sufficient follow up for response assessment, and all three were responding to therapy in settings with no viable alternative treatment option, indicating the potential utility of RP3 in treating this difficult tumor type.

Phase 2 Program

- **RP3 in combination with standard of care therapy in squamous cell carcinoma of the head and neck (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 first- and second-line (1L & 2L) hepatocellular carcinoma (HCC)**
  - Two signal finding cohorts of 30 patients each will be conducted 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.

- **RP2/3 in combination with atezolizumab and bevacizumab in third-line (3L) colorectal cancer (CRC)**
  - Two signal finding cohorts of 30 patients each will be conducted in collaboration with Roche. The first cohort will enroll 3L 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.

These Phase 2 clinical trials are expected to initiate around mid-year.

Financial Highlights

- **Cash Position:** As of December 31, 2022, cash, cash equivalents and short-term investments were $616.4 million, as compared to $395.7 million as of fiscal year end March 31, 2022. The increase in cash as of December 31, 2022 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 December 31, 2022, will enable the Company to fund operations into the second half of calendar year 2025.

- **R&D Expenses:** Research and development expenses were $30.3 million for the third quarter ended December 31, 2022, as compared to $19.4 million for the third quarter ended December 31, 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 third quarter ended December 31, 2022.

- **S,G&A Expenses:** Selling, general and administrative expenses were $11.4 million for the third quarter ended December 31, 2022, as compared to $10.3 million for the third quarter ended December 31, 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 $4.4 million in stock-based compensation expenses for the third quarter ended December 31, 2022.

- **Net Loss:** Net loss was $39.7 million for the third quarter ended December 31, 2022, as compared to a net loss of $29.7 million for the third quarter ended December 31, 2021.

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)
(Unaudited)

	Three Months Ended December 31,		Nine Months Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 30,261	$ 19,353	$ 88,573	$ 57,809
General and administrative	11,369	10,345	35,512	28,517
Total operating expenses	41,630	29,698	124,085	86,326
Loss from operations	(41,630)	(29,698)	(124,085)	(86,326)
Other income (expense):				
Research and development incentives	607	733	2,032	2,246
Investment income	2,675	87	4,130	259
Interest expense on finance lease liability	(548)	(555)	(1,650)	(1,670)
Interest expense on debt obligations	(941)	-	(941)	-
Other income (expense)	147	(241)	(4,531)	(849)
Total other income (expense), net	1,940	24	(960)	(14)
Net loss attributable to common stockholders	$ (39,690)	$ (29,674)	$ (125,045)	$ (86,340)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.69)	$ (0.57)	$ (2.25)	$ (1.66)
Weighted average common shares outstanding, basic and diluted	57,857,132	52,319,877	55,618,052	52,104,548

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

	December 31, 2022	March 31, 2022
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 616,374	$ 395,655
Working capital	597,497	383,221
Total assets	678,550	461,192
Total stockholders' equity	595,345	411,229