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 7, 2020**

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 Operation and Financial Condition.

On August 7, 2020, Replimune Group, Inc. issued a news release announcing its financial results for the quarter ended June 30, 2020 and certain corporate updates. A copy of the news release is furnished as Exhibit 99.1 herewith.

In accordance with General Instruction B.2 of Form 8-K, the information in 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 7, 2020

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 7, 2020

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

Exhibit 99.1

Replimune Reports Fiscal First Quarter Financial Results and Provides Corporate Update

Clinical proof of principle established with RP1 in combination with Opdivo® for the treatment of immune-responsive tumors supporting registration directed development in CSCC and anti-PD1 refractory melanoma

Pipeline progressing; initial single agent data with RP2 for less immune-responsive tumors expected to be presented in the fourth calendar quarter with RP3 expected to enter the clinic by the year end

Management team strengthened with the appointment of Andrea Pirzkall, M.D. as Chief Medical Officer

Raised gross proceeds of $115 million through a public offering; strengthened balance sheet allows for additional studies and extension of cash runway to mid-2023

Woburn, MA, August 7, 2020 – 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, 2020 and provided a business update.

"In the past few months, we have made important progress in demonstrating the power of our Immulytic platform to deliver meaningful new treatment options for a range of cancers," said Philip Astley-Sparke, CEO of Replimune. "In June, we provided an interim update from the Phase 2 portion of the Phase 1/2 clinical trial of RP1 in combination with Opdivo, establishing clinical proof of principle for RP1 in immune-responsive tumor types, including in patients with anti-PD1 refractory disease. In particular, we believe the data generated bode well for our registration directed programs already underway with RP1 in CSCC and anti-PD1 refractory melanoma. Following a successful follow-on offering, Replimune is now well-financed to advance and expand our pipeline with many exciting milestones ahead of us. We look forward to providing an initial data readout from RP2 later this year, as well as initiating clinical development with RP3 as we seek to establish our products more broadly, beyond immune-responsive tumor types, as a cornerstone of immuno-oncology."

Recent Events and Corporate Updates

- **Presented interim clinical data from the Phase 2 portion of the Phase 1/2 clinical trial of RP1 in combination with Opdivo in non-melanoma and melanoma skin cancers that continue to support the clinical programs in both cutaneous squamous cell carcinoma (CSCC) and anti-PD1 refractory melanoma.**
    - In CSCC, six of seven evaluable patients demonstrated ongoing response, with four of these six patients having ongoing complete responses (CRs).
    - Provided interim data evaluating treatment with RP1 in combination with Opdivo in 16 patients with anti-PD1 refractory cutaneous melanoma. Five of the 16 patients at the data cut-off had met the formal criteria for response, including four who had previously failed both anti-PD1 and anti-CTLA4 therapies, providing for a final response rate from this cohort of at least 31%.

- Announced promising data of RP1 in combination with Opdivo in patients with anti-PD1 naïve cutaneous melanoma, mucosal melanoma and uveal melanoma.

- Announced plans to enroll a new 30 patient cohort of anti-PD1 refractory NSCLC patients into the Phase 2 portion of the clinical trial of RP1 combined with Opdivo.

- A link to the data presented can be found here.

· **Strengthened management team with the appointment of Andrea Pirzkall, M.D. as Chief Medical Officer.** Dr. Pirzkall brings to Replimune a track record of drug development success in the biotechnology and pharmaceutical industry, particularly in immuno-oncology, together with multi-disciplinary clinical experience at the intersection of radiology and oncology. Dr. Pirzkall previously served as Executive Director of Clinical Development at BeiGene, Ltd., a publicly traded commercial-stage biotechnology company with responsibility for the development of tislelizumab (anti-PD1) and led successful pivotal trials in squamous and non-squamous cell lung cancer, prior to which Dr. Pirzkall spent 10 years at Genentech in roles of increasing responsibility.

· **Extended anticipated cash runway to mid-2023.** In June 2020, the Company raised gross proceeds of $115 million through a public offering of common stock and pre-funded warrants. The Company believes that the existing cash and cash equivalents and short-term investments, along with a limited use of debt, will enable the Company to fund additional studies and the overall operating plan to mid-2023.

· **COVID-19 potential impact on milestones:** Enrollment into our clinical trials, such as the Company's clinical trial of RP1 in solid organ transplant patients with CSCC, representing a highly immunocompromised patient population, has been slower than expected, which the Company attributes to the global pandemic. As the clinical sites continue to evaluate their capacity to treat patients, the Company could see additional impact in the second half of 2020 across its programs. The Company has not yet experienced delays that would require an update to previous guidance**.**

Program Highlights

Replimune is currently developing three oncolytic immuno-gene therapies derived from its Immulytic platform. The Company's first clinical product candidate, RP1, is a proprietary new strain of herpes simplex virus armed with a gene encoding a potent fusogenic protein (GALV-GP-R), intended to enhance tumor killing potency, immunogenic cell death and the activation of systemic anti-tumor immune responses and a gene encoding the cytokine GM-CSF. In addition to expressing GALV-GP-R and GM-CSF, the Company's second clinical candidate, RP2, also expresses a genetically encoded anti-CTLA-4 antibody-like molecule intended to block the inhibition of the initiation of immune response caused by CTLA-4. RP3 is a further armed oncolytic immuno-gene therapy which additionally expresses two immune co-stimulatory activating ligands – CD40L and 4-1BBL – together with anti-CTLA-4 and GALV-GP-R. CD40L activates CD40, with the goal of achieving broad activation of both innate and adaptive immunity, and 4-1BBL activates 4-1BB (CD137), intended to promote the expansion of cellular and memory immune responses.

- **RP1 in combination with Libtayo® in cutaneous squamous cell carcinoma (CSCC):** The Company is actively enrolling patients into the 240-patient registration-directed Phase 2, randomized, controlled clinical trial in the US and Australia, with clinical trial sites in Canada and Europe expected to open later in the year.

- **RP1 in combination with Opdivo in melanoma, non-melanoma skin cancers, and MSI-H/dMMR tumors:** The clinical trial remains on track with enrollment and accrual of the initial melanoma cohort completing in the first half of 2020 and patients expected to be fully accrued from the non-melanoma skin cancer (NMSC) cohort by the end of 2020. The Company is accumulating data from the MSI-H/dMMR cohort to inform a decision as to whether to pursue MSI-H/dMMR tumors into registration-directed development in 2021.

- **RP1 in combination with Opdivo in anti-PD-1 refractory melanoma:** The Company initiated recruitment into a new registration-directed 125-patient cohort in the Phase 2 clinical trial of RP1 in combination with Opdivo in February 2020 and is currently enrolling patients.

- **RP1 in anti-PD1 refractory patients with non-small cell lung cancer (NSCLC):** In June 2020, the Company announced its plans to add a 30 patient cohort of anti-PD1 refractory patients with NSCLC to the RP1 combined with Opdivo clinical trial. The Company plans to initiate enrollment into this cohort later this year.

- **RP1 as monotherapy in solid organ transplant recipients with CSCC:** The Company initiated enrollment into a 30 patient Phase 1b clinical trial to assess the safety and efficacy of RP1 in liver and kidney transplant recipients with recurrent CSCC in May 2020.

- **RP2 alone and in combination with Opdivo:** The Company plans to present initial safety and efficacy data from the ongoing Phase 1 clinical trial evaluating RP2 alone and in combination with Opdivo by the end of 2020.

- **RP3 alone and in combination with anti-PD-1 therapy:** The Phase 1 clinical trial of RP3 alone and in combination with anti-PD-1 therapy remains on track to initiate in 2020.

Financial Highlights

- **Cash Position:** As of June 30, 2020, cash, cash equivalents and short-term investments were $261.8 million, as compared to $168.6 million as of March 31, 2020. This increase was primarily related to $109.5 million in net proceeds from financing activities offset by cash utilized in fiscal quarter one operating activities largely associated with advancing our expanded clinical development plan.

  The Company believes that the existing cash and cash equivalents and short-term investments, along with a limited use of debt, will enable the Company to fund additional studies and the overall operating plan to mid-2023.

- **R&D Expenses:** Research and development expenses were $12.2 million for the first quarter ended June 30, 2020, as compared to $7.5 million for the first quarter ended June 30, 2019. 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 $1.0 million in stock-based compensation expenses for the first quarter ended June 30, 2020.

- **G&A Expenses:** General and administrative expenses were $5.7 million for the first quarter ended June 30, 2020, as compared to $3.5 million for the first quarter ended June 30, 2019. The increase was primarily driven by personnel-related costs, professional fees, and facility expansion. General and administrative expenses included $1.5 million in stock-based compensation expenses for the first quarter ended June 30, 2020.

- **Net Loss:** Net loss was $17.5 million for the first quarter ended June 30, 2020, as compared to a net loss of $9.5 million for the first quarter ended June 30, 2019.

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 a pair of optimized immune co-stimulatory pathway ligands. These therapeutics 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. 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 advancement of our clinical trials, our plans to initiate new clinical trials, 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.

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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,	
	2020	**2019**
Operating expenses:		
Research and development	$ 12,157	$ 7,457
General and administrative	5,676	3,450
Total operating expenses	17,833	10,907
Loss from operations	(17,833)	(10,907)
Other income (expense):		
Research and development incentives	686	621
Investment income	527	687
Interest expense on finance lease liability	(561)	-
Interest expense on debt obligations	(284)	-
Other income (expense)	(28)	91
Total other income (expense), net	340	1,399
Net loss attributable to common stockholders	$ (17,493)	$ (9,508)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.44)	$ (0.30)
Weighted average common shares outstanding - basic and diluted	39,862,319	31,661,430

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

	June 30, 2020	March 31, 2020
Consolidated Balance Sheet Data:		
Cash, cash equivalents and short-term investments	$ 261,759	$ 168,555
Working capital	255,863	162,377
Total assets	329,583	234,097
Total stockholders' equity	277,814	183,718