

**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): **November 11, 2019**

REPLIMUNE GROUP, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38596
(Commission
File Number)

82-2082553
(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 November 11, 2019, Replimune Group, Inc. (the “Company”) issued a news release announcing its financial results for the quarter ended September 30, 2019 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 Item 2.02 shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Company’s filings under the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	News Release dated November 11, 2019

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: November 12, 2019

By: /s/ Robert Coffin
Robert Coffin
President and Chief Executive Officer

Replimune Reports Second Fiscal Quarter Financial Results and Provides Corporate Update

RP1: Clinical data presented at the 34th Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2019) confirmed expected safety profile and mechanism of action: Efficacy data supports ongoing and expanded programs in cutaneous squamous cell carcinoma (CSCC) and melanoma

RP1: Announced additional studies of RP1 in anti-PD-1 refractory melanoma patients and organ transplant recipients with CSCC

RP1: Initiated registration-directed Phase 2 clinical trial of RP1 in combination with Libtayo® in CSCC

RP2: Initiated Phase 1 clinical trial of RP2 as single agent and in combination with Opdivo®

Woburn, MA, November 11, 2019 — Replimune Group Inc. (Nasdaq: REPL), a biotechnology company developing oncolytic immuno-gene therapies derived from its Immulytic™ platform, today announced financial results for its second fiscal quarter, ended September 30, 2019, and provided a corporate update.

“It has been a very productive and exciting period for Replimune,” said Robert Coffin, Ph.D., President and CEO of Replimune. “The highlight was the SITC 2019 presentation of RP1 clinical data which confirmed the expected mechanism of action, initial safety profile, and evidence of anti-tumor efficacy providing strong support for our ongoing and expanded programs in CSCC and melanoma. Based directly on this data, the decision was taken to conduct a new clinical trial in solid organ transplant patients with CSCC and in melanoma patients who are refractory to prior treatment with anti-PD1 directed therapy. We were also very pleased to have initiated the first clinical trial of our second clinical product candidate, RP2. Overall we are thrilled with Replimune’s progress in the quarter and excited for the future as we continue to execute upon our mission to make our oncolytic immuno-gene therapies a cornerstone of cancer treatment.”

Recent Business Highlights and Upcoming Events

- **RP1 — Presented initial data from the Phase 1/2 clinical trial of RP1 alone and in combination with Opdivo at SITC 2019.** The data presented demonstrated that RP1 used alone and in combination with Opdivo is well tolerated and showed clear anti-tumor efficacy in target tumor types that provides strong support for Replimune’s ongoing and planned development programs in melanoma and CSCC. This clinical trial is being conducted under a clinical trial collaboration and agreement with Bristol Myers Squibb (BMS) for the supply of Opdivo.
 - **RP1 — Initiated the registration-directed Phase 2 clinical trial of RP1 in combination with Libtayo in CSCC.** This multi-center, randomized, controlled clinical trial is intended to enroll approximately 240 patients with CSCC. The clinical trial’s primary objective is to compare the response rate following treatment with RP1 in
-

combination with Libtayo to the response rate achieved with Libtayo alone. Libtayo is an FDA-approved anti-PD-1 therapy developed by Regeneron and Sanofi for the treatment of patients with metastatic or locally-advanced CSCC who are not candidates for curative surgery or radiation. This clinical trial is being conducted under the Company's collaboration agreement with Regeneron, whereby the Company and Regeneron will split equally development and supply costs. Recruitment into this clinical trial is expected to take approximately 18 to 24 months.

- **RP1 — Recruitment ongoing in the Phase 2 part of the Phase 1/2 trial of RP1 in combination with Opdivo.** The Phase 2 part of the clinical trial is currently enrolling 30-patient cohorts of patients with melanoma, non-melanoma skin cancers, metastatic bladder cancer and microsatellite instability high (MSI-H) tumors.
- **RP1 - New clinical trial planned of RP1 as monotherapy in organ transplant recipients with CSCC.** CSCC represents a significant unmet medical need in organ transplant recipients where it is the most prevalent tumor type in a population at higher risk for malignancy in general, and where anti-PD-1 therapy provides a significant risk of rejection of the transplanted organ. The U.S. Food and Drug Administration (FDA) has accepted the protocol for this clinical trial under the Company's previously accepted Investigational New Drug Application for RP1. The clinical trial is intended to enroll approximately 30 patients and assess the safety and efficacy of RP1 in liver and kidney transplant recipients with recurrent CSCC. Replimune expects to initiate the clinical trial in the first quarter of 2020.
- **RP1 — Additional clinical trial intended of RP1 in combination with an anti-PD-1 therapy in anti-PD-1 refractory melanoma patients.** Based on the clinical efficacy data to date with RP1 in melanoma, the Company has decided to conduct a new clinical trial of RP1 in combination with an anti-PD-1 therapy in anti-PD-1 refractory melanoma patients. Discussions are underway to determine the particular anti-PD-1 therapy to be used. The trial is expected to begin enrollment in 2020.
- **RP2 — Initiation of the Phase 1 clinical trial of RP2 alone and in combination with Opdivo.** RP2 is based on RP1 but additionally expresses a genetically encoded anti-CTLA-4 antibody-like molecule. The addition of anti-CTLA-4 is intended to block the inhibition of the initiation of immune responses otherwise caused by CTLA-4. The clinical trial is designed to assess the safety, tolerability and to determine the optimal dose of RP2 alone and in combination with Opdivo and is being conducted under a clinical trial collaboration and agreement with BMS for the supply of Opdivo.
- **RP3 — The Phase 1 clinical trial of RP3 alone and in combination with an anti-PD1 therapy remains on track to initiate in 2020.** RP3 is a further armed oncolytic immuno-gene therapy which expresses two immune co-stimulatory activating ligands (CD40L and 4-1BBL) in addition to the GALV-GP R- fusogenic protein and anti-CTLA-4.
- **Build-out of Replimune's manufacturing facility to support late-stage development and commercialization remains on schedule.** The 63,000-square-foot facility in Framingham, MA is intended to provide multi-product manufacturing capabilities for Replimune's Immulytic product candidates. The capacity of this facility will be sufficient to support full commercialization of the Company's product candidates. An occupancy certificate for the facility has been obtained and technology transfer is underway.

Financial Highlights

Replimune reported a net loss of \$11.1 million for the quarter ended September 30, 2019 compared with \$6.5 million for the same period in the prior year.

Research and development expenses for the quarter ended September 30, 2019 were \$8.2 million compared with \$5.0 million for the same period in the prior year. The increase in research and development expenses was primarily driven by additional costs related to Replimune's preclinical and clinical development activities for its pipeline.

General and administrative expenses for the quarter ended September 30, 2019 were \$4.1 million compared with \$2.1 million for the same period in the prior year. The increase in general and administrative expenses was primarily due to an increase in employee headcount, professional fees and facility costs.

Replimune ended the quarter with \$109.9 million in cash, cash equivalents, and short-term investments, compared with \$134.8 million as of March 31, 2019.

Based on its current operating plan, Replimune expects that its current cash, cash equivalents, and short-term investments will enable it to fund its operating expenses and capital expenditure requirements into the second half of calendar year 2021.

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. The Company'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. Replimune intends to progress these therapies rapidly through clinical development in combination with other immunology 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 use of cash, our advancement of our clinical trials, results of our clinical trials, our goals to develop and commercialize our product candidates, our plans to establish our own in-house manufacturing capabilities, our proposed scientific presentations, 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 establishing, equipping, and operating our planned 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, 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.

Replimune Contact

Pamela Esposito, Ph.D.
Replimune Group Inc.
617.233.6988
pamela@replimune.com

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 September 30,		Six Months Ended September 30,	
	2019	2018	2019	2018
Research and development	\$ 8,168	\$ 4,962	\$ 15,625	\$ 8,898
General and administrative	4,074	2,142	7,524	4,085
Total operating expenses	12,242	7,104	23,149	12,983
Loss from operations	(12,242)	(7,104)	(23,149)	(12,983)
Other income (expense):				
Research and development incentives	620	(77)	1,241	361
Investment income	567	664	1,254	891
Interest expense	(195)	—	(195)	—
Change in fair value of warrant liability	—	(2)	—	(5,452)
Other income	111	58	202	678
Total other income (expense), net	1,103	643	2,502	(3,522)
Net loss	\$ (11,139)	\$ (6,461)	\$ (20,647)	\$ (16,505)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.35)	\$ (0.26)	\$ (0.65)	\$ (1.11)
Weighted average common shares outstanding, basic and diluted	31,675,323	24,574,239	31,668,414	14,831,266

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

	<u>September 30,</u> <u>2019</u>	<u>March 31,</u> <u>2019</u>
Cash and cash equivalents	\$ 53,298	\$ 25,704
Short-term investments	56,581	109,107
Research and development incentives receivable	2,337	2,474
Prepaid expenses and other current assets	5,796	3,696
Property, plant and equipment, net	3,528	12,159
Deferred offering costs	—	—
Research and development incentives receivable - long term	1,212	—
Long term prepaid rent	15,072	—
Right of use - operating lease	4,873	—
Right of use - financing lease	7,105	—
Restricted cash	1,636	1,186
Total assets	\$ 151,438	\$ 154,326
Accounts payable	\$ 7,965	\$ 7,084
Accrued expenses and other current liabilities	3,352	2,801
Deferred rent, net of current portion	—	24
Financing obligation	—	6,561
Operating lease liabilities - current	631	—
Financing lease liabilities - current	34	—
Long term debt, net of debt discount	9,659	—
Operating lease liabilities - non current	4,384	—
Financing lease liabilities - non current	4,772	—
Total liabilities	30,797	16,470
Total stockholders' equity (deficit)	120,641	137,856
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 151,438	\$ 154,326