
**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 30, 2018**

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)

Replimune Group, Inc.
18 Commerce Way, Woburn, MA 01801
(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: **(781) 995-2443**

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))

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 30, 2018, Replimune Group, Inc. issued a news release announcing its financial results for the period ended June 30, 2018 and certain development and 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	News Release dated August 30, 2018

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 30, 2018

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

Replimune Reports Financial Results for the First Fiscal Quarter, Ended June 30, and Provides Development and Corporate Update

Completed initial public offering raising \$111 million in total gross proceeds

Entered into strategic collaboration with Regeneron Pharmaceuticals

Signed lease for 63,000 sq. ft. manufacturing facility

Woburn, MA, August 30, 2018 — Replimune Group Inc. (NASDAQ: REPL), a biotechnology company developing oncolytic immunotherapies derived from its Immulytic™ platform, today announced financial results for its first fiscal quarter ended June 30, 2018, and provided an update on its business.

“With the completion of our successful initial public offering, Replimune is well funded to advance our new generation of oncolytic immunotherapy product candidates derived from our Immulytic platform through clinical trials in multiple tumor types and to establish in-house manufacturing capabilities,” said Robert Coffin, Ph.D., co-founder and CEO of Replimune. “We are pleased with the preparations underway to initiate clinical studies under our collaboration agreements with Bristol-Myers Squibb, entered in February, for the development of RPI in combination with the anti-PD-1 antibody nivolumab, and with Regeneron, entered in May, for the development of RPI in combination with the anti-PD1 antibody cemiplimab. We were also pleased to enter an agreement for the lease of a manufacturing site in Framingham, MA where we intend to produce supplies for later-stage clinical development and ultimate commercialization of our product candidates.”

Recent Business Highlights

- **The investigational new drug (IND) application for RP1 submitted with the U.S. Food and Drug Administration (FDA) is progressing on track.** Replimune submitted an amendment to the IND in early August to include the longer-term toxicology data previously requested by the FDA and expects to receive acceptance of the IND in the U.S. in the coming months. Replimune’s Phase 1/2 clinical trial with RP1 is currently ongoing in the United Kingdom, and Replimune plans to open the clinical trial in the U.S. later in the year. The first part of the clinical trial is testing RP1 initially alone and then in combination with nivolumab for safety and biological activity in patients with advanced, heavily pre-treated solid tumors, and the second part of the clinical trial will test RP1 in combination with nivolumab in approximately 120 patients with metastatic melanoma, metastatic bladder cancer, microsatellite instability high cancer, and non-melanoma skin cancers, under Replimune’s collaboration agreement with Bristol-Myers Squibb (BMS).
 - **Entered into a strategic collaboration with Regeneron Pharmaceuticals.** In May, Replimune entered into an open-ended agreement with Regeneron that allows for clinical development of Replimune’s Immulytic product candidates in combination with Regeneron’s cemiplimab (REGN2810), an investigational PD-1 antibody, on a 50/50 cost sharing basis. The first clinical trial under this agreement is intended to be a randomized, controlled Phase
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2 clinical trial of RP1 combined with cemiplimab compared to cemiplimab alone in cutaneous squamous cell carcinoma (CSCC). CSCC is the highest mortality skin cancer after melanoma, and while no drugs are currently FDA-approved for its treatment, cemiplimab has been filed with the FDA for approval based on encouraging data with cemiplimab in this disease.

- **Entered into a collaboration with BMS.** In February, Replimune entered into a collaboration agreement with Bristol-Myers Squibb under which BMS will provide to Replimune, at no cost, nivolumab, its anti-PD-1 therapy, for use in combination with RP1 in the ongoing Phase 1/2 clinical trial.
- **Signed an agreement for the lease of a manufacturing facility to support late-stage development and commercialization.** Replimune signed an agreement in June for the lease of a 63,000-square-foot facility in Framingham, MA where the Company intends to establish world-class, multi-product manufacturing capabilities for its Immulytic product candidates. The facility is expected to be operational in the first half of 2020.
- **Continued to build a strong leadership team.** In June, Replimune appointed Dieter Weinand and Hyam Levitsky to the Board of Directors. Mr. Weinand is the current President of Bayer Pharmaceuticals and serves on the board of Bayer AG. Dr. Levitsky is a pioneer in immuno-oncology research with expertise in multiple areas including adoptive T cell therapies, cancer vaccines, and immunomodulatory therapies for the treatment of hematologic malignancies and solid tumors, and most recently served as Chief Scientific Officer of Juno Therapeutics prior to its acquisition by Celgene Inc.
- **Successfully completed an Initial Public Offering (IPO).** In July, the Company completed its IPO, raising approximately \$111 million in gross proceeds, before underwriting discounts and commissions and other offering expenses. Replimune intends to use the net proceeds to fund the development of multiple product candidates derived from its Immulytic platform into and through clinical trials, fund the fit-out and commissioning of its manufacturing facility, and general corporate expenses.

Guidance on Upcoming Events

- RP1 — In the second half of calendar 2018, define the dose of RP1 intended for future use and initiate dosing of RP1 combined with nivolumab in a cohort of 12 advanced cancer patients with a range of solid tumors, in the second part of the Phase 1 stage of the ongoing Phase 1/2 study.
- RP1 — In the first half of 2019, initiate dosing of approximately 120 patients with RP1 in combination with nivolumab, in four defined indications: metastatic melanoma, metastatic bladder cancer, microsatellite instability high cancer, and non-melanoma skin cancers.
- RP1 — In the first half of 2019, initiate a randomized, controlled Phase 2 clinical trial of RP1 in combination with cemiplimab, compared to cemiplimab alone, in approximately 240 patients with CSCC.
- RP2 — In the first half of 2019, file an IND with the FDA and/or a CTA with the MHRA in the United Kingdom. RP2 is a version of RP1 that, in addition to expressing a fusogenic protein and GM-CSF, also expresses a genetically encoded anti-CTLA-4 antibody.
- In the second half of calendar 2018, finalize the RP3 product candidate to be progressed into clinical trials. RP3 is intended to additionally express immune co-stimulatory pathway

activating ligands, with the goal of activating immune co-stimulatory pathways, in addition to blocking immune co-inhibition through CTLA-4.

Financial Highlights

Replimune reported a net loss of \$10.0 million for the quarter ended June 30, 2018 compared with \$3.6 million for same period in the prior year. The increase in net loss for the year was due to increased research and development expenses, change in fair value of warrant liability, as well as expenses related to Replimune's IPO.

Research and development expenses for the quarter ended June 30, 2018 were \$3.9 million compared with \$2.3 million for 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, as well as increased salary and related benefits costs due to the increase in employee headcount from 28 on June 30, 2017 to 36 on June 30, 2018.

General and administrative expenses were \$1.9 million for the quarter ended June 30, 2018 compared with \$0.9 million for same period in the prior year. The increase in general and administrative expenses was primarily due to an increase in legal and accounting fees related to the Company's IPO, the increase in employee headcount and the impact of stock-based compensation in 2018.

Replimune ended the quarter with \$52.0 million in cash, cash equivalents and short-term investments, compared with \$61.6 million as of March 31, 2018. The decrease reflected continuing expenses in the ordinary course, along with a transfer of \$1.8 million to restricted cash in connection with the signing of a lease for our manufacturing facility in Framingham, MA. Following the end of the first quarter, the Company received net proceeds of \$103.3 million in connection with its IPO.

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 2021.

About Replimune

Replimune Group Inc., headquartered in Woburn, MA, was founded in 2015 to develop the next generation of "oncolytic immunotherapies" 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, our goals to develop and commercialize our product candidates, our plans to establish our own in-house manufacturing capabilities, 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 obtain necessary funding, 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 set forth under the heading “Risk Factors” of our Quarterly Report on Form 10-Q for the first quarter ended June 30, 2018. 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,	
	2018	2017
Operating expenses:		
Research and development	\$ 3,936	\$ 2,291
General and administrative	1,943	885
Total operating expenses	5,879	3,176
Loss from operations	(5,879)	(3,176)
Total other income (expense), net	(4,165)	(376)
Net loss	\$ (10,044)	\$ (3,552)
Net loss per share attributable to common stockholders, basic and diluted	\$ (2.02)	\$ (0.71)
Weighted average common shares outstanding, basic and diluted	4,981,227	4,973,439

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

	<u>June 30, 2018</u>	<u>March 31, 2018</u>
Cash and cash equivalents	\$ 12,910	\$ 17,583
Short-term investments	39,119	43,968
Research and development incentives receivable	2,251	2,389
Prepaid expenses and other current assets	944	763
Property, plant and equipment, net	443	370
Deferred offering costs	1,344	—
Research and development incentives receivable - long term	426	—
Restricted cash	1,856	78
Total assets	<u>\$ 59,293</u>	<u>\$ 65,151</u>
Accounts payable	\$ 2,854	\$ 1,993
Accrued expenses and other current liabilities	1,642	3,171
Deferred rent, net of current portion	43	52
Warrant liability	7,092	1,642
Total liabilities	<u>11,631</u>	<u>6,858</u>
Convertible preferred stock	86,361	86,361
Total stockholders' deficit	<u>(38,699)</u>	<u>(28,068)</u>
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 59,293</u>	<u>\$ 65,151</u>