

**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 11, 2020

RUBIUS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of Incorporation)

001-38586
(Commission
File Number)

46-2688109
(IRS Employer
Identification Number)

399 Binney Street, Suite 300
Cambridge, MA
(Address of registrant's principal executive office)

02139
(Zip code)

(617) 679-9600
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

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 203.425)
- 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	RUBY	The 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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 11, 2020, Rubius Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2020. A copy of the press release issued in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is intended to be furnished and shall not be deemed “filed” for 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 set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by Rubius Therapeutics, Inc. on May 11, 2020, furnished herewith.

EXHIBIT INDEX

Exhibit No.	Description
<u>99.1</u>	<u>Press Release issued by Rubius Therapeutics, Inc. on May 11, 2020, furnished herewith.</u>

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 11, 2020

RUBIUS THERAPEUTICS, INC.

By: /s/ Andrew M. Oh

Andrew M. Oh

Chief Financial Officer



Rubius Therapeutics Reports First Quarter 2020 Financial Results and Provides Operational Update

Completed Strategic Reprioritization of Pipeline to Focus on Oncology and Autoimmunity

Dosed First Patient in Phase 1/2 Clinical Trial of RTX-240 for Advanced Solid Tumors

Successfully Produced cGMP Clinical Supply of RTX-240 from Fully Owned Manufacturing Facility

Strong Cash Position

Cambridge, Mass., May 11, 2020 (GLOBE NEWSWIRE) -- Rubius Therapeutics, Inc. (Nasdaq:RUBY), a clinical-stage biopharmaceutical company that is genetically engineering red blood cells to create an entirely new class of cellular medicines, today reported first quarter 2020 financial results and provided an overview of operational progress.

“During the first quarter, we made significant progress in advancing our business by reprioritizing our therapeutic areas of focus and progressing our oncology pipeline of Red Cell Therapeutics™, including the dosing of our first patient in the RTX-240 clinical trial. RTX-240 is an allogeneic cellular therapy product candidate that is designed to mimic and amplify the functions of the innate and adaptive immune systems by activating and expanding NK cells and T cells to generate a potent anti-tumor response, potentially providing patients with a dual-mechanistic approach to fight their cancer,” said Pablo J. Cagnoni, chief executive officer of Rubius Therapeutics. “With the advances in our oncology pipeline, a fully owned and operational manufacturing facility and cash runway that takes us into 2022, we believe we are well positioned to execute our objectives and bring potentially life-saving therapies to patients.”

First Quarter and Recent Highlights

- Completed strategic reprioritization of the pipeline to focus on the development of oncology and autoimmune Red Cell Therapeutic programs.
 - o Development in these therapeutic areas is enabled by the investment in internal manufacturing at the Rubius Smithfield, RI facility.
 - Dosed the first patient in the Phase 1/2 clinical trial of RTX-240 for the treatment of patients with relapsed/refractory or locally advanced solid tumors.
 - o The cGMP cells used to dose the first patient were produced at the fully owned Rubius manufacturing facility. All subsequent clinical supply for the Company’s oncology programs is expected to be produced from this facility.
-

- On track to file an Investigational New Drug application for lead artificial antigen-presenting cell program, RTX-321, for the treatment of HPV 16-positive cancers by year-end 2020.
- Unveiled abstracts for the American Society of Gene and Cell Therapy (ASGCT) 23rd Annual Meeting, highlighting preclinical data from its oncology pipeline of Red Cell Therapeutics™, including data supporting RTX-321.
 - o The posters will be made available at the beginning of the virtual meeting tomorrow, Tuesday, May 12, 2020, at 6:00 a.m. ET.
- Implemented multiple measures in response to the COVID-19 pandemic to safeguard the health and well-being of employees, their families, business partners and healthcare providers, while continuing to operate its Smithfield, RI manufacturing facility and conduct research and development activities. The extent to which the COVID-19 pandemic may impact Rubius will depend on future developments.

First Quarter 2020 Financial Results

Net loss for the first quarter of 2020 was \$48.5 million or \$0.60 per common share, compared to \$32.6 million or \$0.42 per common share in the first quarter of 2019.

In the first quarter of 2020, Rubius invested \$36.2 million in research and development (R&D) related to its novel RED PLATFORM® and towards expanding and advancing its product pipeline, compared to \$20.9 million in the first quarter of 2019. The year-over-year increase was driven by \$9.9 million of incremental costs incurred in advancing our cancer programs, including preparation for the Phase 1/2 clinical trial for RTX-240 and preclinical and IND-enabling activities for RTX-321. There was also a \$1.6 million increase in costs incurred for our rare disease pipeline prior to the deprioritization of these programs in March 2020. In addition, costs not allocated to programs increased by \$3.8 million, resulting from increases in personnel-related costs, stock-based compensation, contract research and development and facility related and other costs. These higher costs were driven by R&D headcount growth and expanded platform development and drug discovery activities.

G&A expenses were \$12.7 million during the first quarter of 2020, compared to \$13.5 million for the first quarter of 2019. The lower costs were primarily driven by a reduction in stock-based compensation expense.

Cash Position

As of March 31, 2020, cash, cash equivalents and investments were \$241.4 million, compared to \$283.3 million as of December 31, 2019, providing Rubius with a cash runway into 2022.

During the quarter, the Company used \$40.0 million of cash to fund operations and \$2.9 million to fund capital expenditures, consisting mostly of payments for assets purchased in 2019.

About Rubius Therapeutics

Rubius Therapeutics is a clinical-stage biopharmaceutical company developing a new class of medicines called Red Cell Therapeutics™. The Company's proprietary RED PLATFORM® was designed to genetically engineer and culture Red Cell Therapeutics™ that are selective, potent and off-the-shelf allogeneic cellular therapies for the potential treatment of several diseases across multiple therapeutic areas. Rubius' initial focus is to advance RCT™ product candidates for the treatment of cancer and autoimmune diseases by leveraging two distinct therapeutic modalities —potent cell-cell interaction and tolerance induction. For more information, visit www.rubiustx.com, follow us on [Twitter](#) or [LinkedIn](#) or like us on [Facebook](#).

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the planned timing, enrollment and results for our preclinical and clinical activities, including the Phase 1/2 clinical trial for RTX-240, our expectations regarding the impact of COVID-19 pandemic on our operations and business, including the Phase 1/2 clinical trial for RTX-240, our expectations regarding the therapeutic potential of our Red Cell Therapeutics, including RTX-240 for the treatment of cancer, our expectations and planned timing for filing an Investigational New Drug application for RTX-321 and our strategy, objectives, business plans and focus, including the benefits we expect from our recent strategic shift to focus on the development of our oncology and autoimmunity pipeline. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “target” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those risks and uncertainties related to the development of our Red Cell Therapeutic product candidates and their therapeutic potential and other risks identified in our SEC filings, including our Annual Report on Form 10-K for the year ended December 31, 2019, and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

Rubius Therapeutics, Inc.
Condensed Consolidated Statement of Operations
(in thousands, except share and per share data)
(unaudited)

	For the three months ended March 31,	
	2020	2019
Revenue	\$ -	\$ -
Operating expenses:		
Research and development	36,186	20,871
General and administrative	12,664	13,535
Total operating expenses	48,850	34,406
Loss from operations	(48,850)	(34,406)
Other income, net	364	1,825
Net loss	\$ (48,486)	\$ (32,581)
Net loss per share, basic and diluted	\$ (0.60)	\$ (0.42)
Weighted average common shares outstanding, basic and diluted:	80,271,848	77,544,089

Rubius Therapeutics, Inc.
Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	March 31, 2020	December 31, 2019
Cash, cash equivalents and investments	\$ 241,391	\$ 283,287
Total assets	348,327	394,841
Total liabilities	113,170	120,628
Total stockholders' equity	235,157	274,213

###

Contacts:

Lori Melançon
Vice President, Corporate Communications and Investor Relations
+1 (617) 949-5296

lori.melancon@rubiustx.com

Media Contact:

Dan Budwick
1AB
+1 (973) 271-6085

dan@1abmedia.com