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 10, 2021

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

Delaware	**001-38586**	**46-2688109**
(State or other jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

399 Binney Street, Suite 300 Cambridge, MA	**02139**
(Address of registrant's principal executive office)	**(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 10, 2021, Rubius Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2021. 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 10, 2021, furnished herewith.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 10, 2021

RUBIUS THERAPEUTICS, INC.

By: /s/ Jose Carmona
Jose Carmona
Chief Financial Officer

Exhibit 99.1

Rubius Therapeutics Reports First Quarter 2021 Financial Results and Provides Business Update

Positive Initial Data from Phase 1/2 Trial of RTX-240 in Advanced Solid Tumors Demonstrated Single-Agent Activity Providing Initial Validation of the RED PLATFORM®;
Dose Optimization and Enrollment Continues

Continued Progress in Advancing Clinical Programs with Further Enrollment in Phase 1 RTX-240 Acute Myeloid Leukemia and RTX-321 Advanced HPV 16-Positive Cancer Trials

On Track for Several Anticipated Data Milestones and Catalysts in 2021, and Supported by a Strong Balance Sheet

CAMBRIDGE Mass., May 10, 2021 (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 called Red Cell Therapeutics™, today reported first quarter 2021 financial results and provided a business update.

“We had a great start to the year by reporting initial positive data from our ongoing Phase 1/2 clinical trial of RTX-240 in patients with advanced solid tumors, which provided evidence of the broad potential of the RED PLATFORM® across our entire pipeline of cancer and autoimmune programs,” said Pablo J. Cagnoni, M.D., president and chief executive officer of Rubius Therapeutics. “With several expected clinical milestones from our pipeline, the coming year is poised to be an exciting one for patients, our employees and shareholders.”

Enabled by the RED PLATFORM, Red Cell Therapeutics’ (RCTs) are expected to provide advantages over other therapies by potentially generating a broad anti-tumor response with limited side effects and a wide therapeutic window given the biodistribution of RCTs to the vasculature and spleen. Additionally, RCTs do not have the complex supply chain and administration logistics of other cell therapies, as RCTs are designed to be prepared in the pharmacy, administered in an outpatient setting and do not require lymphodepletion prior to administration.

First Quarter 2021 Highlights

RTX-240 Phase 1/2 Clinical Program for Advanced Solid Tumors

On March 15, 2021, the Company reported preliminary safety (n=16) and efficacy (n=15) findings based on RECIST v1.1., with a data cutoff of February 28, 2021. The key takeaways from the initial data were:

- RTX-240 demonstrated favorable emerging safety results across dose levels:
    - There were no treatment-related Grade 3/4 adverse events and no dose-limiting toxicities. The most common treatment-related Grade 1/2 adverse events were fatigue, chills, nausea, decreased appetite and arthralgias. There was a single Grade 1 event of liver toxicity.
- Single-agent activity was observed with two partial responses:
    - A confirmed partial response (PR) in a patient with metastatic anal cancer and an unconfirmed PR in a patient with metastatic uveal melanoma. Both patients' disease had progressed on prior anti-PD-1 therapy.
    - Stable disease (SD) was observed in six patients, including four individual patients with stable disease for at least 12 weeks, (one each with non-small cell lung cancer, soft tissue sarcoma, pancreatic cancer and prostate cancer).
- Pharmacodynamic effects observed included the activation and/or expansion of the key natural killer (NK) and/or T cells types in all patients (n=16).
- Observed evidence of immune cell trafficking of activated NK and T cells into the tumor microenvironment in two solid tumor biopsies and one AML biopsy.

Dose optimization and enrollment continues in the RTX-240 Phase 1/2 advanced solid tumor study. The Company plans to present additional data from the study this year.

Phase 1 Arm in Ongoing Phase 1/2 RTX-240 Clinical Trial in Relapsed/Refractory Acute Myeloid Leukemia (AML)

- RTX-240 is currently being evaluated as a single-agent in a Phase 1 arm of the ongoing Phase 1/2 clinical trial of RTX-240 in patients with relapsed/refractory AML.
- As of May 10, 2021, Rubius is enrolling patients in the third and fourth dose cohorts, in accordance with the statistical design of the study, which allows enrollment of two dose cohorts simultaneously.
- On March 15, 2021, the Company presented preliminary trafficking data from the first patient in the trial, indicating strong accumulation of activated, granzyme B-positive NK and T cells in the bone marrow, which is the site of disease in AML.

RTX-321 Artificial Antigen-Presenting Cell (aAPC) Development Program for Human Papillomavirus (HPV) 16-Positive Cancers

- Dosing additional patients in the Phase 1 clinical trial of RTX-321 in patients with advanced HPV 16-positive cancers, including cervical, head and neck and anal cancer.
- RTX-321 has a unique frozen drug substance formulation, enabling a potential truly off-the-shelf product with a shelf life of up to several years.
    - Following liquid reformulation, RTX-321 has an in-vial shelf life of approximately 52 days.

Presentations at Medical Conferences

- Preliminary safety and efficacy data from RTX-240 Phase 1/2 Clinical Trial for advanced solid tumors was presented at the American Association for Cancer Research (AACR) Virtual Annual Meeting on April 10, 2021.

Anticipated 2021 Catalysts and Operational Objectives

- Present additional clinical data from the RTX-240 solid tumor Phase 1 clinical trial;
- Select specific solid tumor types that will be pursued in the Phase 2 expansion cohort of RTX-240;
- Report initial clinical data from the Phase 1 arm of the RTX-240 clinical trial in relapsed/refractory AML;
- Initiate the Phase 1 clinical trial of RTX-240 in combination with anti-PD-1 therapy in advanced solid tumors in the second half of 2021;
- Report initial Phase 1 clinical data from RTX-321 for the treatment of HPV 16-positive cancers by the first quarter of 2022; and
- Submit an Investigational New Drug Application for RTX-224 by year-end.

About RTX-240

RTX-240, Rubius Therapeutics' lead oncology program, is an allogeneic, off-the-shelf cellular therapy product candidate that is engineered to simultaneously present hundreds of thousands of copies of the costimulatory molecule 4-1BB ligand (4-1BBL) and IL-15TP (trans-presentation of IL-15 on IL-15Rα) in their native forms. RTX-240 is designed to broadly stimulate the immune system by activating and expanding both NK and memory T cells to generate a potent anti-tumor response.

About RTX-321

RTX-321, Rubius Therapeutics’ second oncology program, is an allogeneic, off-the-shelf aAPC therapy product candidate that is engineered to induce a tumor-specific immune response by expanding antigen-specific T cells. RTX-321 expresses hundreds of thousands of copies of an HPV peptide antigen bound to major histocompatibility complex class I proteins, the costimulatory molecule 4-1BBL and the cytokine IL-12 on the cell surface to mimic human T cell-APC interactions.

First Quarter 2021 Financial Results

Net loss for the first quarter of 2021 was $42.3 million or $0.51 per common share, compared to $48.5 million or $0.60 per common share in the first quarter of 2020.

In the first quarter of 2021, Rubius invested $27.7 million in research and development (R&D) related to its novel RED PLATFORM® and towards expanding and advancing its product pipeline, compared to $36.2 million in the first quarter of 2020. This year-over-year decrease was driven primarily by a $4.9 million reduction in program expenses consisting of a $6.7 million reduction in rare disease program costs, following the deprioritization of the Company's rare disease pipeline in March 2020, partially offset by an increase in costs incurred for the Company's cancer programs, including, RTX-240 and RTX-321. Additionally, platform development, early stage research and other unallocated expenses decreased by $3.6 million due principally to $2.5 million in reductions in contract R&D, laboratory supplies and research materials driven primarily by a shift in activities to support the oncology clinical programs. Personnel-related costs also decreased as a result of non-recurring costs incurred in the first quarter of 2020.

G&A expenses were $13.2 million during the first quarter of 2021, compared to $12.7 million for the first quarter of 2020. The higher costs were primarily driven by an increase in professional and consultant fees related to increased patent costs and an increase in facility-related and other expenses due to higher building operating costs.

During the first quarter of 2021, other income and expenses decreased by $1.8 million, from net income of $0.4 million in the first quarter of 2020, to net expense of $1.4 million. The change was due to a lower average cash balance, lower prevailing interest rates and an increase in outstanding debt following the final borrowing under the Company's debt facility in June 2020.

Cash Position

As of March 31, 2021, cash, cash equivalents and investments were $330.7 million, compared to $176.3 million as of December 31, 2020. During the quarter, the Company received net proceeds, after deducting underwriting discounts and commission, of $188.0 million in connection with its underwritten public offering completed in March 2021.

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. Rubius Therapeutics was named among the 2020 Top Places to Work in Massachusetts by the Boston Globe, and its manufacturing site was recently named 2021 Best Places to Work in Rhode Island by Providence Business News. 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 our expectations regarding the therapeutic potential of our pipeline of Red Cell Therapeutics, including RTX-240 for the treatment of patients with relapsed/refractory or locally advanced solid tumors and its advantages over other therapies and RTX-321 for the treatment of HPV 16-positive cancers, our expectations regarding the timing, enrollment, additional data from and success of the current and future cohorts and phases of the clinical trial of RTX-240, our expectations regarding the biological effects of RTX-240 on innate and adaptive immunity, including activation and increased numbers of NK cells and T cells in the clinical trial of RTX-240, and our expectations regarding the full data set from the Phase 1 clinical trial and its ability to unlock the potential of the RED PLATFORM across our entire pipeline of Red Cell Therapeutics for the treatment of cancer, including our expectations regarding the therapeutic potential of RTX-321, timelines related to the Phase 1 clinical trial of RTX-321 and our release of initial data from such trial, our expectations regarding the timing of an IND for RTX-224, our expectations regarding our ability to expand manufacturing capabilities, our expectations regarding the potential shelf life of our frozen drug substance for RTX-321, our expectations regarding our cash runway and our strategy, business plans and focus. 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, 2020, and subsequent filings with the SEC and risks and uncertainties related to the severity and duration of the impact of COVID-19 on our business and operations. 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.

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

	For the three months ended March 31,	
	2021	**2020**
Revenue	$ -	$ -
Operating expenses:		
Research and development	27,677	36,186
General and administrative	13,240	12,664
Total operating expenses	40,917	48,850
Loss from operations	(40,917)	(48,850)
Other income (expense), net	(1,413)	364
Net loss	$ (42,330)	$ (48,486)
Net loss per share, basic and diluted	$ (0.51)	$ (0.60)
Weighted average common shares outstanding, basic and diluted:	82,314,577	80,271,848

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

	March 31, 2021	**December 31, 2020**
Cash, cash equivalents and investments	$ 330,650	$ 176,287
Total assets	430,230	277,794
Total liabilities	129,247	136,234
Total stockholders' equity	300,983	141,560