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 9, 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 August 9, 2021, Rubius Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 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 August 9, 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: August 9, 2021

RUBIUS THERAPEUTICS, INC.

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

Exhibit 99.1

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

First Patient Dosed with RTX-240 in Combination with KEYTRUDA® (pembrolizumab) in Ongoing Phase 1/2 Clinical Trial for the Treatment of Patients with Advanced Solid Tumors

New Cohorts Added in Phase 1/2 Trial of Single-Agent RTX-240 in Advanced Solid Tumors
– Enabled by Initial Single-Agent Activity, Additional Emerging Data and Absence of Dose-Limiting Toxicities – Clinical Results Expected to be Reported by End of 2021 or During the First Quarter of 2022

Continuing Enrollment in Phase 1 Clinical Trials of RTX-240 in Relapsed/Refractory Acute Myeloid Leukemia and RTX-321 in Advanced HPV 16-Positive Cancers

CAMBRIDGE Mass., August 9, 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 second quarter 2021 financial results and provided a business update.

“During the quarter, we continued to make excellent progress in advancing our fully owned oncology pipeline,” said Pablo J. Cagnoni, M.D., President and Chief Executive Officer. “Given the favorable emerging safety profile and promising initial clinical activity reported for RTX-240, we initiated a combination Phase 1 arm with pembrolizumab with the goal of providing benefit to patients with cancers that have relapsed or are refractory after treatment with anti-PD-1 or PD-L1 antibodies.”

“Bolstered by the promising clinical activity and safety reported as part of the initial data results in March 2021, and no dose-limiting toxicities observed to date, we are continuing to explore the dose and schedule in new cohorts in the Phase 1 arm of single-agent RTX-240 in advanced solid tumors,” said Christina Coughlin, M.D., Ph.D., Chief Medical Officer. “We plan to present a comprehensive clinical data set from the trial, including data from the new cohorts and longer follow up for all patients.”

Second Quarter 2021 and Recent Highlights

Strengthened Leadership Team

- Dannielle Appelhans was appointed chief operating officer. She will oversee corporate strategy and technical operations. Dannielle brings significant experience in building organizations as they evolve from early- to late-stage development, with a particular focus on clinical and commercial manufacturing and scaling supply chains.

Single-Agent RTX-240 Phase 1/2 Clinical Trial for Advanced Solid Tumors

- During the second quarter, two additional cohorts were added to explore the dose of RTX-240 with a more frequent schedule of administration in the Phase 1 single-agent arm in solid tumors. Enrollment in these cohorts continues.
    - The changes in dose and schedule are supported by initial clinical activity, safety data and no dose-limiting toxicities observed to date along with additional emerging data from dose escalation in the Phase 1 study.
    - The Company currently plans to present comprehensive results from this study at the end of 2021 or during the first quarter of 2022.
- The Company presented preliminary safety and efficacy data from RTX-240 Phase 1/2 clinical trial for advanced solid tumors at the American Association for Cancer Research (AACR) Virtual Annual Meeting on April 10, 2021.
    - The initial safety (n=16) and efficacy (n=15) findings, based on RECIST v1.1., with a data cutoff of February 28, 2021, demonstrated favorable emerging safety results across dose levels with no treatment-related Grade 3/4 adverse events or dose-limiting toxicities.
    - Single-agent activity was demonstrated with two partial responses (1 confirmed and 1 unconfirmed) and six patients with stable disease.
    - RTX-240 stimulated innate and adaptive immunity as demonstrated by the activation and expansion of NK or memory CD8+ T cells in all patients, with 9/16 patients showing activation and expansion in both cell types.
        - Additionally, trafficking data was separately reported as part of the initial data readout on March 15, 2021, which noted that immune cell trafficking of activated NK and T cells into the tumor microenvironment (TME) was observed in two solid tumor biopsies and one acute myeloid leukemia (AML) biopsy.

Phase 1 Arm in Ongoing Phase 1/2 RTX-240 Clinical Trial in Combination with KEYTRUDA® (pembrolizumab) for Advanced Solid Tumors

- The first patient was dosed with RTX-240 in combination with pembrolizumab for the treatment of patients with relapsed/refractory or locally advanced solid tumors in June 2021.
    - To be eligible for the trial, patients must have disease that is relapsed or refractory to an anti-PD-1 or PD-L1 therapy. The study continues to enroll additional patients.

- With its mechanism of action as a broad immune agonist, RTX-240 may have synergy with immune checkpoint inhibition and potentially overcome resistance to PD-1 inhibition.
- Preliminary data from single-agent RTX-240 Phase 1 study reported in March 2021, showed early evidence of favorable immune-permissive changes in the TME, including increased expression of PD-L1 and/or increased ratio of M1/M2 macrophages after treatment with RTX-240 in three out of four patient biopsies, suggesting single-agent RTX-240 is able to induce changes in the TME that have been associated with response to checkpoint
inhibition.

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

- 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 R/R AML.
- Based on the initial clinical and pharmacodynamic data observed in the single-agent solid tumor Phase 1 arm, the Company implemented a more frequent dose administration schedule and added an additional cohort in the R/R AML arm of the trial.
    - Dosing has been completed in the first four dose cohorts and enrollment in an additional dose cohort is expected to begin in the third quarter of 2021.
- Given the mechanism of RTX-240 in activating and expanding NK and T cells and its preliminary favorable safety profile seen to date, RTX-240 could potentially provide benefit as a maintenance therapy for AML patients in remission following chemotherapy or stem cell transplantation.

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

- Enrollment continues in the Phase 1 clinical trial of RTX-321 in patients with advanced HPV 16-positive cancers, including cervical, head & neck cancers, and anal cancer.

Peer-Reviewed Publications and Poster Presentations at Medical Conferences

- In July 2021, the manuscript entitled "Anti-Tumor Effects of RTX-240: an Engineered Red Blood Cell Expressing 4-1BB Ligand and Interleukin-15" was published in the peer-reviewed journal *Cancer Immunology, Immunotherapy,* highlighting preclinical findings for RTX-240, which demonstrated that RTX-240 activates and expands CD8+ T cells and NK cells in vitro and in vivo generating potent anti-tumor activity in both a colorectal and melanoma model.
- In May 2021, the manuscript entitled, "Engineered Red Blood Cells as an Off-the-Shelf Allogeneic Anti-Tumor Therapeutic" was published in the peer-reviewed journal *Nature Communications* highlighting preclinical findings for RTX-321, which demonstrated that the surrogate of RTX-321 induced a broad immune response, epitope spreading and memory formation in preclinical models.

- 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.

Near-Term Catalysts and Operational Objectives

- Present additional clinical data from the RTX-240 solid tumor Phase 1 clinical trial at the end of 2021 or during the first quarter of 2022;
- 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;
- 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.

Second Quarter Financial Results

Net loss for the second quarter of 2021 was $50.2 million or $0.56 per common share, compared to $37.9 million or $0.47 per common share in the second quarter of 2020.

In the second quarter of 2021, Rubius invested $36.1 million in research and development (R&D) related to its novel RED PLATFORM® and towards expanding and advancing its product pipeline, as compared to $26.1 million in the second quarter of 2020. This year-over-year increase was principally due to a $9.1 million increase in costs incurred for the Company's lead cancer programs, including, RTX-240 and RTX-321, primarily CRO and internal manufacturing costs incurred in connection with both arms of its Phase 1/2 clinical trial of RTX-240 for the treatment of solid tumors and AML and for its Phase 1 clinical trial of RTX-321 for the treatment of HPV 16-positive cancers. Additionally, personnel-related costs increased $1.2 million for additions to headcount to support the Company's expanded operations and stock-based compensation expense increased by $1.0 million. Increases in oncology program expenses, personnel-related costs and stock-based compensation expense were offset by a $1.5 million reduction in contract R&D, laboratory supplies and research materials driven primarily by a shift in research activities to support clinical programs.

General and administrative (G&A) expenses were $13.9 million during the second quarter of 2021, as compared to $11.6 million for the second quarter of 2020. The higher costs were driven by a $1.0 million increase in personnel-related costs to support rising headcount in the Company's general and administrative function, including recruitment costs, as well as a $0.9 million increase in professional and consultant fees and facility-related expenses.

Six Month Financial Results

Net loss for the first six months of 2021 was $92.5 million or $1.08 per common share, compared to $86.3 million or $1.07 per common share in the first six months of 2020.

In the six months ended June 30, 2021, Rubius invested $63.7 million in R&D related to its novel RED PLATFORM® and towards expanding and advancing its product pipeline, as compared to $62.3 million in the first six months of 2020. The year-over-year increase was driven primarily by a $10.9 million increase in costs incurred for the Company's lead cancer programs. These costs were incurred for its Phase 1/2 clinical trial of RTX-240 for the treatment of solid tumors, including clinical CRO and internal manufacturing costs, as well as costs incurred for its Phase 1 clinical trial of RTX-321 in patients with advanced HPV 16-positive cancers. This increase was partially offset by a $6.7 million reduction in rare disease program costs, following the deprioritization of the Company's rare disease pipeline in March 2020. Additionally, platform development, early-stage research and other unallocated expenses decreased by $2.8 million due principally to reductions in contract R&D, laboratory supplies and research materials as research activities shifted to support clinical programs.

G&A expenses were $27.1 million during the first six months of 2021, as compared to $24.3 million for the same period in 2020. The higher costs were driven by a $1.0 million increase in personnel-related costs, including recruitment costs, as well as a $1.7 million increase in professional and consultant fees and facility-related expenses.

During the first six months of 2021, other income and expenses decreased by $1.9 million, from other income, net of $0.2 million during the first six months of 2020, to other expense, net of $1.7 million. The change was principally due to 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 June 30, 2021, cash, cash equivalents and investments were $298.2 million, compared to $176.3 million as of December 31, 2020. In connection with its underwritten public offering completed in March 2021, the Company received net proceeds of $187.2 million, after deducting underwriting discounts and commission and other offering costs. In addition, during the second quarter, the Company amended its debt facility, postponing principal payments, by two and a half years, until mid-2024.

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

	For the three months ended June 30,		For the six months ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenue	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	36,072	26,096	63,749	62,282
General and administrative	13,851	11,601	27,091	24,265
Total operating expenses	49,923	37,697	90,840	86,547
Loss from operations	(49,923)	(37,697)	(90,840)	(86,547)
Other income (expense), net	(257)	(157)	(1,670)	207
Net loss	$ (50,180)	$ (37,854)	$ (92,510)	$ (86,340)
Net loss per share, basic and diluted	$ (0.56)	$ (0.47)	$ (1.08)	$ (1.07)
Weighted average common shares outstanding, basic and diluted:	89,517,784	80,481,756	85,936,079	80,376,830

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

	June 30, 2021	**December 31, 2020**
Cash, cash equivalents and investments	$ 298,242	$ 176,287
Total assets	396,084	277,794
Total liabilities	131,970	136,234
Total stockholders' equity	264,114	141,560

About Red Cell Therapeutics

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.

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, the Company's 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.

About RTX-224

RTX-224 is an allogeneic cellular therapy that is engineered to express hundreds of thousands of copies of 4-1BBL and IL-12 on the cell surface. In contrast to RTX-240, RTX-224 is designed as a broad immune agonist of both adaptive and innate responses, activating CD8+ and CD4+ T cells, promoting antigen presentation and retaining the ability to activate and expand NK cells. It is expected to produce a broad and potent anti-tumor T cell response, an innate immune response and have anti-tumor activity in those tumor types with known sensitivity to T cell killing, including tumor types with high mutational burden, PD-L1 expression and prior activity of checkpoint inhibitors.

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 Top Places to Work in Massachusetts by the Boston Globe in 2020, and its manufacturing site was recently named 2021 Top 5 Best Places to Work in Rhode Island among medium-sized companies 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 and safety profile 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 interpretations of preliminary data, including indications as to 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, synergies of RTX-240 with immune checkpoint inhibition, the potential for RTX-240 to overcome resistance to PD-1 inhibition and that RTX-240 could provide benefit as a maintenance therapy for certain AML patients, our expectations regarding and plans to present the full data set from the Phase 1 clinical trial, 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, goals for the RTX-240 Phase 1 arm study, expectations for our strengthened leadership team, 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, and subsequent filings with the SEC, including our upcoming Form 10-Q for the quarter ended June 30, 2021, 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.

Contacts:

Investors
Elhan Webb, CFA, Vice President of Investor Relations
elhan.webb@rubiustx.com

Media
Marissa Hanify, Director, Corporate Communications
Marissa.hanify@rubiustx.com

Dan Budwick, 1AB
+1 (973) 271-6085
dan@1abmedia.com