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 4, 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 November 8, 2021, Rubius Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 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 Item 2.02 of this Current Report on Form 8-K, as well as 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 4, 2021, Christina Coughlin, M.D., Ph.D, notified the Company of her intention to resign as the Company's chief medical officer, effective as of November 12, 2021, to pursue another opportunity. In connection with her resignation, Dr. Coughlin has agreed to provide consulting and transition services to the Company through December 31, 2021.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by Rubius Therapeutics, Inc. on November 8, 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: November 8, 2021

RUBIUS THERAPEUTICS, INC.

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

Exhibit 99.1

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

U.S. Food and Drug Administration (FDA) Clears Investigational New Drug Application for RTX-224, Rubius' Third Oncology Candidate

Clinical Results Expected by Year-End or First Quarter 2022 in Phase 1 Trials of Single-Agent RTX-240 in Advanced Solid Tumors and Relapsed/Refractory Acute Myeloid Leukemia (AML)

Laurence "Larry" Turka, M.D., Promoted to Head of Research & Translational Medicine

CAMBRIDGE Mass., November 8, 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™ (RCT) for the treatment of cancer and autoimmune diseases, today reported third quarter 2021 financial results and provided a business update.

"With the clearance of our latest IND application for RTX-224, we will have three Red Cell Therapeutic™ product candidates for the potential treatment of cancer in the clinic, demonstrating continued strong execution across preclinical and clinical development as well as manufacturing," said Larry Turka, M.D., chief scientific officer and head of research and translational medicine. "As shown in our preclinical studies, RTX-224 is designed to activate CD8+ and CD4+ T cells, promote antigen presentation and activate and expand NK cells to produce a broad and potent anti-tumor T cell response in solid tumor cancers with known sensitivity to T cell killing, including tumor types with high mutational burden, PD-L1 expression and prior responsiveness to checkpoint inhibitors."

Dr. Turka has been promoted to chief scientific officer and head of research & translational medicine. Joining Rubius Therapeutics as chief scientific officer in January 2020, Larry is an internationally recognized physician-scientist in autoimmunity and translational immunology with a distinguished career working in academia and, more recently, in the biotechnology industry where he has built a portfolio of novel therapies targeting immune cells.

"Larry's impressive record of scientific achievement in immunology and ability to foster an environment of innovation has been instrumental in integrating our preclinical and clinical development programs. As Rubius enters a period of potentially significant clinical data generation, we look forward to leveraging Larry's expertise in translational medicine and building our clinical development strategy," said Pablo J. Cagnoni, M.D., president and chief executive officer.

Along with this leadership change, chief medical officer Christina Coughlin, M.D., Ph.D., will be leaving Rubius Therapeutics to pursue another opportunity as chief executive officer, and she will continue to serve as an advisor to the Company during a transition period following her resignation. The Company thanks her for her contributions to Rubius and wishes her the best in the next chapter of her career.

Third Quarter 2021 and Recent Highlights

Clinical Development in Oncology

- Enrollment continues across Rubius' portfolio of Red Cell Therapeutics for the treatment of cancer:
  - The Phase 1 arms of single-agent RTX-240 in advanced solid tumors and relapsed/refractory AML.
    - The Company plans to present comprehensive results by the end of 2021 or during the first quarter of 2022.
  - The Phase 1 arm of the ongoing Phase 1/2 RTX-240 clinical trial in combination with KEYTRUDA® (pembrolizumab) for advanced solid tumors.
    - To be eligible for the trial, patients must have disease that is relapsed or refractory to an anti-PD-1 or PD-L1 therapy. 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.
  - The Phase 1 clinical trial of RTX-321 in patients with advanced HPV 16-positive cancers, including cervical, head & neck cancers, and anal cancer.
    - The company plans to present initial clinical results during the first quarter of 2022.
- U.S. FDA cleared the IND application for RTX-224, Rubius' third oncology product candidate.
  - The company expects to dose its first patient during the first quarter of 2022.

Peer-Reviewed Publications and Poster Presentations at Medical Conferences

- The Company plans to present preclinical data for RTX-224 at the upcoming Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting on November 12th at 8:00 a.m. ET.
  - The data indicates that RTX-224 activates immune cells in the spleen and blood, leading to their trafficking into the tumor microenvironment to deliver an antitumor effect in preclinical models.
- 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.

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 cohorts of RTX-240;
- Report initial clinical data from the Phase 1 arm of the RTX-240 clinical trial in relapsed/refractory AML at the end of 2021 or during the first quarter of 2022; and
- Report initial Phase 1 clinical data from RTX-321 for the treatment of HPV 16-positive cancers by the first quarter of 2022.
- Initiate Phase 1 clinical trial for RTX-224 in advanced solid tumors during the first quarter of 2022.

Third Quarter Financial Results

Net loss for the third quarter of 2021 was $49.0 million or $0.55 per common share, compared to $40.9 million or $0.51 per common share in the third quarter of 2020.

In the third quarter of 2021, Rubius invested $38.0 million in research and development (R&D) related to its novel RED PLATFORM® and towards expanding and advancing its product pipeline, as compared to $28.2 million in the third quarter of 2020. This year-over-year increase was principally due to a $6.8 million increase in costs incurred for the Company's lead cancer programs, RTX-240 and RTX-321, primarily from clinical research organization (CRO) and internal manufacturing costs incurred in connection with the three Phase 1 arms of its Phase 1/2 clinical trial of RTX-240 and for its Phase 1 clinical trial of RTX-321 for the treatment of HPV16-positive cancers. Additionally, personnel-related costs increased $1.6 million principally for additions to headcount to support the Company's expanded operations and stock-based compensation increased by $1.4 million.

General and administrative (G&A) expenses were flat at $12.0 million during the third quarter of 2021, as compared to the third quarter of 2020. While there were increases totaling $1.3 million across professional fees, facility and personnel costs, they were offset by a decline in stock-based compensation expense of $1.2 million following the full vesting of large awards early in the third quarter of 2021.

Nine Month Financial Results

Net loss for the first nine months of 2021 was $141.5 million or $1.62 per common share, compared to $127.2 million or $1.58 per common share in the first nine months of 2020.

In the nine months ended September 30, 2021, Rubius invested $101.8 million in R&D related to its novel RED PLATFORM® and towards expanding and advancing its product pipeline, as compared to $90.5 million in the first nine months of 2020. The year-over-year increase was driven primarily by a $17.7 million increase in costs for the Company's lead cancer programs, including CRO and internal manufacturing costs. These costs were associated with the three arms of its Phase 1/2 clinical trial of RTX-240 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 $7.0 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 increased by $0.6 million. This consisted of $2.8 million in additional stock-based compensation and a $1.7 million increase in personnel and facility related costs, which were partially offset by reductions in contract R&D, laboratory supplies and research materials as research activities shifted to support clinical programs.

G&A expenses were $39.1 million during the first nine months of 2021, as compared to $36.2 million for the same period in 2020. The higher costs were driven by a $2.4 million increase in personnel and facility related costs, as well as a $1.6 million increase in professional and consultant fees. These increases were offset by a decrease in stock-based compensation expense of $1.1 million, following the vesting of large awards early in the third quarter of 2021.

Cash Position

As of September 30, 2021, cash and cash equivalents were $264.0 million, compared to $176.3 million in cash, cash equivalents and investments 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, in June 2021, 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 September 30,		For the nine months ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	38,014	28,209	101,763	90,491
General and administrative	12,035	11,976	39,126	36,241
Total operating expenses	50,049	40,185	140,889	126,732
Loss from operations	(50,049)	(40,185)	(140,889)	(126,732)
Other income (expense), net	1,033	(667)	(637)	(460)
Net loss	$ (49,016)	$ (40,852)	$ (141,526)	$ (127,192)
Net loss per share, basic and diluted	$ (0.55)	$ (0.51)	$ (1.62)	$ (1.58)
Weighted average common shares outstanding, basic and diluted:	89,807,383	80,778,042	87,240,694	80,511,543

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

	September 30, 2021	**December 31, 2020**
Cash, cash equivalents and investments	$ 264,017	$ 176,287
Total assets	361,064	277,794
Total liabilities	136,859	136,234
Total stockholders' equity	224,205	141,560

About Red Cell Therapeutics

Red Cell Therapeutics™ (RCTs™) are a new class of allogeneic, off-the-shelf cellular therapeutic candidates for the treatment of cancer and autoimmune diseases. For the treatment of cancer, 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, off-the-shelf cellular therapy product candidate 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 activating and expanding 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 beliefs about Rubius' execution across preclinical and clinical development, Rubius' plans and expected timing to present clinical results for RTX-240 and RTX-321, beliefs that RTX-240 may have synergy with immune checkpoint inhibition and potentially overcome resistance to PD-1 inhibition, expectations regarding the timing for dosing for the RTX-224 trial, plans to present preclinical data and findings reported in peer-reviewed publications, 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, RTX-321 for the treatment of HPV 16-positive cancers, and RTX-224 and its impact on tumor types with known sensitivity to T cell killing, 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, expectations for our strengthened leadership team, our expectations regarding 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 June 30, 2021, and subsequent filings with the SEC, including our upcoming Form 10-Q for the quarter ended September 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.

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