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 14, 2019**

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** (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 November 14, 2019, Rubius Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2019. 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 November 14, 2019, furnished herewith.

EXHIBIT INDEX

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99.1	Press Release issued by Rubius Therapeutics, Inc. on November 14, 2019, furnished herewith.

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 14, 2019

RUBIUS THERAPEUTICS, INC.

By: /s/ Andrew M. Oh
Andrew M. Oh
Chief Financial Officer

Exhibit 99.1

Rubius Therapeutics Reports Third Quarter 2019 Financial Results and Operational Progress

CAMBRIDGE, Mass., November 14, 2019 (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 third quarter 2019 financial results and provided an overview of operational progress.

"Over the last quarter, our team has successfully manufactured RTX-134 for our Phase 1b trial for the treatment of patients with phenylketonuria. Our clinical sites are actively recruiting patients, and we plan to announce when we have treated the first patient. In order for us to share follow up data from the first patients treated in the study, we expect to report initial clinical results during the first quarter of 2020," said Pablo J. Cagnoni, M.D., chief executive officer of Rubius Therapeutics. "We continue to make good progress with our entire pipeline, having presented preclinical oncology data showcasing the versatility and potential power of the RED PLATFORM®. We remain on track to file our first oncology Investigational New Drug application for RTX-240 by early 2020."

Recent Highlights and Upcoming Milestones

- Over the third quarter, Rubius Therapeutics successfully manufactured RTX-134 for our Phase 1b trial for the treatment patients with phenylketonuria (PKU).
- Rubius has clinical sites actively recruiting patients and plans to announce when the first patient has been treated.
- In order for Rubius to share follow up data from the first patients treated in the study, the Company expects to report initial clinical results during the first quarter of 2020, including:
    - Preliminary safety;
    - Longevity of RTX-134 in circulation; and
    - Proof-of-mechanism as measured by production of trans-cinnamic acid, a metabolite of phenylalanine when degraded by phenylalanine ammonia lyase, or PAL.
- On November 8, 2019, Rubius presented preclinical data at the SITC Annual Meeting, supporting its lead artificial antigen presenting cell program, RTX-321, for the treatment of HPV 16-positive tumors.
    - RTX-321 is an allogeneic artificial antigen presenting cell engineered to express, on the cell surface, an HPV peptide antigen, 4-1BBL and IL-12 to mimic human T cell-APC interactions. RTX-321 is currently in IND-enabling studies.
    - Proof-of-concept data generated in a B16-F10 melanoma mouse model demonstrated successful engineering of artificial antigen presenting cells against a melanoma tumor-associated antigen, gp100, that significantly expanded antigen-specific T cells and eliminated lung metastases with limited, reversible toxicity.
- On October 29, 2019, Rubius Therapeutics was issued U.S. Patent No. 10,456,421 covering Red Cell Therapeutic™ (RCT) compositions comprising 4-1BBL and their use for the treatment of cancer. 4-1BBL is expressed on the cell surface of each of the Company's lead oncology product candidates: RTX-240, RTX-224 and RTX-321.
    - Today, in total, Rubius Therapeutics has nine issued U.S. patents, including five composition of matter patents, 32 patent families and more than 150 pending patent applications worldwide.
- On October 27, 2019, Rubius Therapeutics presented preclinical data at the AACR-NCI-EORTC, demonstrating the ability to engineer RCTs to create loadable artificial antigen presenting cells for personal neoantigens.
    - RTX-aAPCs with peptide-loaded MHC constructs functionally engaged TCRs and achieved robust expansion of primary cytomegalovirus (CMV)-specific T cells in healthy donor PBMCs with prior exposure to CMV.
    - Rubius Therapeutics' loadable aAPC system has the potential to generate aAPCs containing multiple neoantigens in a single therapeutic.
- The Company continued to strengthen its leadership team by appointing Maiken Keson-Brookes as chief legal officer and corporate secretary.

Third Quarter Financial Results

Net loss for the third quarter of 2019 was $47.0 million or $0.59 per common share, compared to $26.4 million or $0.42 per common share in the third quarter of 2018.

In the third quarter of 2019, Rubius invested $33.5 million in research and development (R&D) related to its novel RED PLATFORM® and towards expanding and advancing its product pipeline, as compared to $14.4 million in the third quarter of 2018. This year-over-year increase was driven primarily by $8.6 million in incremental R&D program spending in preparation for the Company's Phase 1b clinical trial for RTX-134 and towards preclinical activities for Rubius' lead oncology programs, including RTX-240. In addition, $7.8 million in incremental R&D spending was driven by increased R&D headcount, a move into larger facilities and purchasing lab supplies to support Rubius' goal of delivering four to five INDs across 2019 and 2020. Contract research costs increased by $1.9 million and R&D stock-based compensation also increased by $0.8 million.

G&A expenses were $15.0 million during the second quarter of 2019, as compared to $13.2 million for the third quarter of 2018. The higher costs were primarily driven by a $2.1 million increase in personnel and facility costs due to increased headcount in the general and administrative function, as well asincreases in professional fees and infrastructure costs to support the Company's growth.

Nine Month Financial Results

Net loss for the first nine months of 2019 was $119.0 million or $1.52 per common share, compared to $62.0 million or $2.33 per common share in the first nine months of 2018.

In the nine months ended September 30, 2019, Rubius invested $81.9 million in R&D related to its novel RED PLATFORM® and towards expanding and advancing its product pipeline, as compared to $35.2 million in the first nine months of 2018. This year-over-year increase was largely due to an additional $22.4 million in R&D personnel, external research and facilities and lab supplies to support the Company's pipeline expansion in 2019 and 2020 and $19.8 million in R&D program spending, including preparing for the RTX-134 Phase 1b clinical trial and preclinical activities for Rubius' lead oncology programs, including RTX-240. R&D stock-based compensation also increased by $4.5 million.

G&A expenses were $42.3 million during the first nine months of 2019, as compared to $27.3 million for the same period in 2018. The higher costs were primarily driven by a $7.6 million increase in stock-based compensation and a $7.4 million increase in personnel costs and facility costs due to increased headcount in our general and administrative function, as well as increases in professional fees and infrastructure costs to support the Company's growth.

Cash Position

As of September 30, 2019, cash, cash equivalents and investments were $324.7 million as compared to $404.1 million as of December 31, 2018, providing Rubius with a cash runway into 2021. During the year, the Company used $81.5 million of cash to fund operations and $27.4 million to fund capital expenditures, including work related to the buildout of Rubius' manufacturing facility. In addition, during the year, the Company drew down a second tranche of $25.0 million from its $75.0 million loan agreement with Solar Capital in June 2019, which leaves a third tranche of $25.0 million that can be drawn through June 2020, subject to the satisfaction of certain financial covenants.

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 rare diseases, cancer and autoimmune diseases by leveraging three distinct therapeutic modalities — cellular shielding, potent cell-cell interaction and tolerance induction. For more information, visit **www.rubiustx.com**, or follow us on **Twitter** and **LinkedIn**.

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, recruitment, enrollment and results for our preclinical and clinical activities, including the Phase 1b clinical trial for RTX-134 for the treatment of PKU, our ability to further develop our RCT product candidates, our manufacturing process, our expectations regarding the therapeutic potential of our RCTs, our expectations regarding new members of our leadership team 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 RCT 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 September 30, 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 September 30,		For the nine months ended September 30,	
	2019	2018	2019	2018
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	33,530	14,363	81,919	35,230
General and administrative	14,952	13,191	42,254	27,311
Total operating expenses	48,482	27,554	124,173	62,541
Loss from operations	(48,482)	(27,554)	(124,173)	(62,541)
Other income (expense), net	1,467	1,192	5,187	529
Net loss	$ (47,015)	$ (26,362)	$ (118,986)	$ (62,012)
Net loss per share, basic and diluted	$ (0.59)	$ (0.42)	$ (1.52)	$ (2.33)
Weighted average common shares outstanding, basic and diluted:	79,115,305	62,311,111	78,357,791	26,662,233

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

	September 30, 2019	December 31, 2018
Cash, cash equivalents and investments	$ 324,689	$ 404,051
Total assets	432,272	479,109
Total liabilities	124,929	86,101
Total stockholders' equity and convertible preferred stock	307,343	393,008

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