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): March 12, 2020

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 230.425)
☐ 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 þ

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 March 12, 2020, Rubius Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended December 31, 2019 and certain other information. 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 March 12, 2020, furnished herewith.

EXHIBIT INDEX

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99.1	Press Release issued by Rubius Therapeutics, Inc. on March 12, 2020, 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: March 12, 2020

RUBIUS THERAPEUTICS, INC.

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

Exhibit 99.1

Rubius Therapeutics Reports Fourth Quarter and Full-Year 2019 Financial Results and Announces Strategic Focus on Oncology and Autoimmunity

RTX-240 Investigational New Drug Application for Solid Tumors Cleared by U.S. FDA

Internal cGMP Manufacturing Ready to Support Upcoming Oncology Clinical Trials

Cash Runway Extended into 2022

Conference Call Scheduled for Today at 8:00 a.m. EST

Cambridge, Mass., March 12, 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 fourth quarter and full-year 2019 financial results and announced its plan to focus on the development of its oncology and autoimmunity pipeline.

This strategic decision allows Rubius to focus on the areas in which its RED PLATFORM^{Ò} may offer the greatest potential to benefit patients. Development in these therapeutic areas is enabled by the Company's investment in internal manufacturing at its Smithfield, RI facility, which is now cGMP ready to produce clinical supply for its lead oncology program, RTX-240, a broad immunostimulatory Red Cell Therapeutic™ for the treatment of solid tumors. The Investigational New Drug (IND) application for RTX-240 has been cleared by the U.S. Food and Drug Administration, and the Company plans to announce when the first patient has been dosed in the Phase 1 clinical trial. As previously announced, Rubius is on track to file an IND for RTX-321, its first artificial antigen-presenting cell for the treatment of HPV-positive cancers, by year-end. The company also expects to manufacture RTX-321 clinical supply at its fully owned manufacturing facility.

"Over the past two years, we have generated exciting oncology preclinical data, demonstrating the ability of our Red Cell Therapeutics to both broadly activate the immune system, and induce tumor-specific responses by activating and expanding antigen-specific T cells with our artificial antigen-presenting cells. By focusing on the development of our oncology and autoimmune pipeline, we believe we will have the greatest opportunity to bring life-saving therapies to patients, enhance shareholder value and extend our cash runway into 2022," said Pablo J. Cagnoni, M.D., president and chief executive officer of Rubius Therapeutics. "With our internal cGMP manufacturing established, we are well positioned to advance this entirely new class of allogeneic cellular medicines."

RTX-240 for the Treatment of Solid Tumors

RTX-240 is an allogeneic cellular therapy that is engineered to broadly stimulate the adaptive and innate immune systems to generate an antitumor response. RTX-240 expresses 4-1BBL and IL-15TP, a fusion of IL-15 and IL-15 receptor alpha, on the cell surface with the goal of improving antitumor activity and overcoming resistance to immunotherapy in patients with solid tumors. RTX-240 may provide a differentiated approach to treating solid tumors or hematologic malignancies in immunotherapy-naïve patients or in patients whose disease has become resistant or refractory to immunotherapies, including checkpoint inhibitors.

RTX-134 Program Update

As a result of the decision to focus on oncology and autoimmunity, the Company is deprioritizing the RTX-134 program for the treatment of phenylketonuria (PKU) and its other rare disease programs. Multiple factors contributed to this decision, including unanticipated delays in the RTX-134 program, primarily due to continued manufacturing challenges at the Company's contract manufacturing organization (CMO), the anticipated high cost associated with producing chronic, high-dose therapy for enzyme deficiencies and the continued momentum of the Company's oncology pipeline. Future capital investments and improvements in manufacturing efficiency, together with enhancements to the RED PLATFORM, may enable Rubius to revisit chronic, high dose-dependent conditions in the future.

As previously announced, the first patient was dosed in the Phase 1b PKU clinical trial of RTX-134 in January 2020. While there were no reported adverse events and RTX-134 administration was well tolerated, the results from the first patient were uninterpretable possibly due, in part, to the low dose of cells administered and the sensitivity of the flow cytometry assay used to detect circulating cells. As a result of the deprioritization, the current Phase 1b clinical trial in PKU will be discontinued.

Autoimmune Program Update

Rubius' autoimmune Red Cell Therapeutics are engineered to express specific autoimmune disease-associated antigens either within the cell or on the cell surface to take advantage of how the body normally maintains self-tolerance, thereby retraining the immune system to no longer see self-antigens as foreign. Red Cell Therapeutics are designed to specifically modulate complex counter-regulatory immune responses, potentially enabling greater efficacy with lower toxicity, and, in some cases, even cures, when compared to currently available non-specific immunosuppressive treatments. Rubius is focusing on T cell-mediated autoimmune diseases and is pursuing Type 1 diabetes, along with a number of other undisclosed programs. The Company expects to provide an update on its preclinical autoimmune pipeline in the future.

Extension of Cash Runway

With the cost savings from the discontinuation of the RTX-134 clinical trial and deprioritization of the other rare disease programs and a reallocation of capital and personnel resources, Rubius' cash runway will be extended into 2022.

Additional Business Updates

Rubius strengthened its leadership team and board of directors by appointing:

- Internationally recognized autoimmunity and translational leader Laurence Turka, M.D., as chief scientific officer;
- Trained oncologist and immunologist, Christina Coughlin, M.D., Ph.D., as chief medical officer, who has extensive experience leading clinical development and translational medicine teams and has a track record of building successful drug development organizations with a particular focus in cellular therapy and oncology; and
- Anne Prener, M.D., Ph.D., to its board of directors, who has significant experience in drug development and commercialization.

Fourth Quarter 2019 Financial Results

Net loss for the fourth quarter of 2019 was $44.5 million or $0.56 per common share, compared to $27.2 million or $0.35 per common share in the fourth quarter of 2018.

In the fourth quarter of 2019, Rubius invested $30.5 million in research and development (R&D) related to its novel RED PLATFORM and towards expanding and advancing its product pipeline, as compared to $16.5 million in the fourth quarter of 2018. This year-over-year increase was driven primarily by $3.9 million in incremental R&D program spending related to the Company's Phase 1b clinical trial for RTX-134 and towards preclinical and IND-enabling activities for Rubius' lead oncology programs, including RTX-240. In addition, $6.0 million in incremental R&D spending was driven by increased R&D headcount, a move into larger facilities and purchasing lab supplies to support expanded research activities. Contract research and development costs increased by $3.3 million and R&D stock-based compensation also increased by $0.8 million.

G&A expenses were $14.9 million during the fourth quarter of 2019, as compared to $12.6 million for the fourth quarter of 2018. The higher costs were primarily driven by a $1.0 million increase in personnel and facility costs due to increased headcount in the general and administrative function, as well as increases in professional fees and infrastructure costs to support the Company's growth.

Full Year 2019 Financial Results

Net loss for the full year 2019 was $163.5 million or $2.08 per common share, compared to $89.2 million or $2.27 per common share for the full year 2018.

For the full year 2019, Rubius invested $112.4 million in R&D related to its novel RED PLATFORM and towards expanding and advancing its product pipeline, compared to $51.8 million for the full year 2018. This year-over-year increase was largely due to an additional $31.8 million in R&D personnel, contract research and development, facilities and lab supplies to support the Company's pipeline expansion and platform investments and $23.7 million in R&D program spending, including costs related to the Company's RTX-134 Phase 1b clinical trial as well as preclinical and IND-enabling activities for Rubius' lead oncology programs, including RTX-240. R&D stock-based compensation also increased by $5.2 million.

G&A expenses were $57.2 million during the twelve months of 2019, as compared to $39.9 million for the same period in 2018. The higher costs were primarily driven by an $8.5 million increase in stock-based compensation and $8.8 million increase in personnel costs, professional and facility fees to support the Company's growth and to operate as a public company.

Cash Position

As of December 31, 2019, cash, cash equivalents and investments were $283.3 million as compared to $404.1 million as of December 31, 2018, providing Rubius with a cash runway into 2022. During the year, the Company used $110.4 million of cash to fund operations and $40.7 million to fund capital expenditures, including work related to the buildout of Rubius' manufacturing facility. In addition, 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.

Conference Call Details

The company will host a conference call and webcast at 8:00 a.m. EST to discuss this update. The audio webcast will be available on the Events and Presentations page within the Investors and Media section of the Rubius Therapeutics website. The update may also be accessed by dialing 1-800-289-0045 (domestic) or 1-615-622-8086 (international) five minutes prior to the start of the call and providing the passcode 6394385. An archived webcast will be accessible for 90 days after the event.

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 clinical trial for RTX-240, our ability to fund the further development of our Red Cell Therapeutic product candidates, statements regarding the operation of our manufacturing facility and availability of supply for our clinical trials, our expectations regarding the therapeutic potential of our Red Cell Therapeutics, including RTX-240 for the treatment of solid tumors, the timelines for us to file additional INDs, and our strategy, 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 December 31,		For the year ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenue	$ -	$ -	$ -	$ -
Operating expenses:				
Research and development	30,500	16,539	112,419	51,769
General and administrative	14,928	12,583	57,182	39,894
Total operating expenses	45,428	29,122	169,601	91,663
Loss from operations	(45,428)	(29,122)	(169,601)	(91,663)
Other income (expense), net	956	1,939	6,143	2,468
Net loss	$ (44,472)	$ (27,183)	$ (163,458)	$ (89,195)
Net loss per share, basic and diluted	$ (0.56)	$ (0.35)	$ (2.08)	$ (2.27)
Weighted average common shares outstanding, basic and diluted:	79,671,342	76,747,827	78,688,878	39,285,468

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

	December 31, 2019	**December 31, 2018**
Cash, cash equivalents and investments	$ 283,287	$ 404,051
Total assets	394,841	479,109
Total liabilities	120,628	86,101
Total stockholders' equity	274,213	393,008

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