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 11, 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))

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 8.01. Other Events.

On March 11, 2019, Rubius Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has cleared the Company's Investigational New Drug application for RTX-134, an allogeneic, off-the-shelf cellular therapy for the potential treatment of patients with phenylketonuria. A copy of the press release issued in connection with the announcement is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by Rubius Therapeutics, Inc. on March 11, 2019.

EXHIBIT INDEX

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99.1	Press Release issued by Rubius Therapeutics, Inc. on March 11, 2019.

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 11, 2019

RUBIUS THERAPEUTICS, INC.

By: /s/ Pablo J. Cagnoni
Pablo J. Cagnoni
Chief Executive Officer

Exhibit 99.1

Rubius Therapeutics Announces FDA Clearance of Investigational New Drug Application for First-Ever Red Cell Therapeutic, RTX-134, for Treatment of Phenylketonuria

CAMBRIDGE, Mass., Mar. 11, 2019 (GLOBE NEWSWIRE) — Rubius Therapeutics, Inc. (Nasdaq:RUBY), a biopharmaceutical company that is generating red blood cells and bioengineering them into an entirely new class of cellular medicines, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application for RTX-134, an allogeneic, off-the-shelf cellular therapy for the potential treatment of patients with phenylketonuria (PKU). The Phase 1b clinical trial is expected to be the first-ever clinical investigation of genetically engineered red blood cells. The Company plans to begin enrollment during the second quarter of 2019, with initial clinical data expected during the second half of 2019.

"The clearance of the RTX-134 IND is a historic event for Rubius as we advance one step closer to treating patients with phenylketonuria, an inherited metabolic disorder that is characterized by the body's inability to metabolize the essential dietary amino acid, phenylalanine. PKU is a devastating disease that when not properly treated can cause intellectual disability, delayed development, impaired cognitive function and, in some cases, irreversible brain damage," said Pablo J. Cagnoni, M.D., chief executive officer of Rubius. "Our goal with RTX-134 is to overcome this brain-threatening metabolic disorder by providing patients with a safe and effective treatment option to lower phenylalanine levels via infrequent administration, allowing people with PKU to return to a normal diet."

RTX-134 is a Red Cell Therapeutic™ (RCT) product candidate that is genetically engineered to express the enzyme phenylalanine ammonia lyase (PAL) inside the cell. RTX-134 is designed to circulate in the blood stream and degrade toxic levels of phenylalanine that accumulate due to a deficiency in the phenylalanine hydroxylase (PAH) enzyme. Compared to current therapeutic interventions, RTX-134 may have a more sustained treatment effect given the 120-day circulating time of red blood cells and may have a lower incidence of immune-driven adverse events, including the formation of neutralizing antibodies to the therapeutic enzyme, which often results in a reduction in efficacy. As a result, RTX-134 may provide a more efficacious and convenient treatment option to patients.

About the RTX-134-01 Phase 1b Clinical Trial

The Phase 1b clinical trial is an open-label, single-dose safety, tolerability and pharmacokinetics study of RTX-134 in adults with PKU. The primary objectives of the study are to evaluate preliminary safety, longevity of the RTX-134 cells in circulation, to obtain proof-of-mechanism as measured by production of trans-cinnamic acid (the byproduct of PAL) and select a preliminary dose and schedule. Rubius expects to report initial data during the second half of 2019. Following FDA review of the data from the Phase 1b study, the Company plans to investigate multi-dose administration of RTX-134 to further evaluate safety and efficacy.

About Rubius Therapeutics

Rubius Therapeutics is a biopharmaceutical company that is generating red blood cells and bioengineering them into an entirely new class of cellular medicines. The Company's proprietary RED PLATFORM® is designed to genetically engineer and culture Red Cell Therapeutics™ that are selective, potent, ready-to-use allogeneic cellular therapies. Rubius is leveraging three distinct therapeutic modalities — cellular shielding, potent cell-cell interaction and tolerance induction for the potential treatment of rare enzyme disorders, cancer and autoimmune diseases. 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 therapeutic potential of our Red Cell Therapeutics and our strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "goal," "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 related to the planned timing, enrollment and results for our Phase 1b clinical trial for RTX-134 for the treatment of phenylketonuria, our expectations regarding the results from our Phase 1b clinical trial for RTX-134 and the FDA's review of the results therefrom, our expectations regarding the ability of RTX-134 to treat phenylketonuria the planned timing for additional IND applications, the expected timing and progress of preclinical and clinical data for our product candidates, our ability to meet the objectives of our planned clinical trials and demonstrate the safety and efficacy of our product candidates, the planned timing for our selection of an autoimmune disease clinical candidate, our ability to fund the development of our Red Cell Therapeutic product candidates, the development of our Red Cell Therapeutic product candidates and their therapeutic potential, whether and when, if at all, our Red Cell Therapeutic product candidates will receive approval from the U.S. Food and Drug Administration and for which, if any, indications, competition from other biotechnology companies, and other risks identified in our SEC filings, including our Form 10-Q for the quarter ended September 30, 2018, 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.

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