

**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 9, 2020

RUBIUS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of Incorporation)

001-38586
(Commission
File Number)

46-2688109
(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 9, 2020, Rubius Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended September 30, 2020. 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 9, 2020 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 9, 2020

RUBIUS THERAPEUTICS, INC.

By: /s/ Jose Carmona

Jose Carmona

Chief Financial Officer



**Rubius Therapeutics Reports Third Quarter 2020 Financial Results
and Strong Execution Across the Pipeline**

**Completed Dosing of Fourth Cohort in RTX-240 Phase 1/2
Solid Tumor Clinical Trial**

**Dosed First Patient in RTX-240 Phase 1 Relapsed/Refractory
Acute Myeloid Leukemia Clinical Trial**

**Filed Investigational New Drug Application with U.S. Food and Drug Administration for RTX-321 for Human Papillomavirus 16-Positive
Cancers with Frozen Drug Substance**

CAMBRIDGE, Mass., November 9, 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 called Red Cell Therapeutics™, today reported third quarter 2020 financial results and provided an overview of operational progress.

“Rubius Therapeutics continues to demonstrate strong execution across our pipeline of Red Cell Therapeutics for the treatment of cancer. Our IND filing for RTX-321 included, for the first time, frozen drug substance as part of the manufacturing process, resulting in a truly off-the-shelf cellular therapy with a potential shelf life of up to several years,” said Pablo J. Cagnoni, M.D., president and chief executive officer of Rubius Therapeutics. “As we continue to escalate the dose in the RTX-240 solid tumor trial, we are assessing the safety profile and biological effects of RTX-240 on innate and adaptive immune responses. We believe that by demonstrating that RTX-240 is working as intended to induce anti-tumor innate and adaptive immunity, we can unlock the potential of the RED PLATFORM® across our entire pipeline of cancer and autoimmune programs.”

Third Quarter and Recent Highlights

RTX-240 Phase 1/2 Clinical Program for Advanced Solid Tumors or Relapsed/Refractory Acute Myeloid Leukemia (AML)

- Completed dosing of the fourth cohort in the Phase 1/2 solid tumor clinical trial
 - Assessing the safety profile and biological effects of RTX-240 on innate and adaptive immune responses by measuring biomarkers associated with activation and proliferation of NK and T cells in both peripheral blood and paired tumor biopsy samples across dose levels
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- Dosed the first patient with relapsed or refractory AML in second Phase 1 arm of ongoing RTX-240 clinical trial
- Demonstrating robust momentum in manufacturing and producing clinical supply of RTX-240 for both arms in the Phase 1/2 clinical trial of RTX-240

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

- Filed an IND with U.S. FDA for RTX-321 for the treatment of HPV 16-positive cancers
 - o For the first time, the IND filing includes frozen drug substance as part of the manufacturing process, resulting in a truly off-the-shelf cellular therapy with a potential shelf life of up to several years
- Conducting manufacturing in support of planned GMP clinical supply needs for the RTX-321 clinical trial

Leadership Team

- Strengthened the leadership team by appointing Jose “Pepe” Carmona as chief financial officer
 - o Pepe brings to Rubius extensive experience in global finance and operations, as well as a track record of financing clinical-stage and commercial biotech companies

Preclinical Data Presentations

- This morning, Rubius presented preclinical data from its lead clinical oncology candidate, RTX-240, at the Society for Immunotherapy of Cancer’s Annual Meeting, demonstrating:
 - o RTX-240 increased CD8 T cell and NK cell expansion and activation in vitro when compared to a combination of 4-1BB agonist antibody plus recombinant IL-15, which was directly correlated with the percentage of 4-1BBL and IL-15TP expressed on the cell surface
 - o RTX-240 expanded CD56^{dim} NK cells, a cell population with high cytotoxicity
 - o RTX-240 promoted NK cell-killing of a myeloid leukemia cell line, K562, which was accompanied by increased NK cell degranulation and activation
 - o A murine surrogate for RTX-240, mRBC-240, promoted significant expansion of CD8 T cells and NK cells in vivo in a murine model of colorectal cancer (CT26)
 - o mRBC-240 demonstrated potent antitumor activity in a B16F10 melanoma model that was directly correlated with the expansion of terminally differentiated NK cells in the tumors
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- Presented preclinical data at the Federation of Clinical Immunology Societies Annual Meeting and the American Association of Cancer Research Tumor Immunology and Immunotherapy Conference, from its lead aAPC program, RTX-321, for the treatment of HPV 16-positive tumors demonstrating:
 - o RTX-321 and its mouse surrogates demonstrated a dual mechanism of action in vivo
 - § Functions as an aAPC to boost antigen-specific CD8+ T cell responses
 - § Promotes antigen-independent stimulation of both innate and adaptive immune responses
 - o Mouse surrogates of RTX-321 promote tumor control, memory formation and epitope spreading in tumor models in vivo
 - o Treatment with the RTX-321 mouse surrogate results in minimal, reversible effects in vivo, likely due to biodistribution to the vasculature and spleen
 - o RTX-321 functions as an aAPC to boost HPV 16 antigen-specific T cells in vitro
 - o RTX-321 promotes HPV 16-independent adaptive and innate immune responses in vitro

Third Quarter Financial Results

Net loss for the third quarter of 2020 was \$40.9 million or \$0.51 per common share, compared to \$47.0 million or \$0.59 per common share in the third quarter of 2019.

In the third quarter of 2020, Rubius invested \$28.2 million in research and development (R&D) related to its novel RED PLATFORM[®] and towards expanding and advancing its product pipeline, as compared to \$33.5 million in the third quarter of 2019. The year-over-year decrease was driven by a \$7.5 million reduction in costs following the deprioritization of our rare disease pipeline in March 2020. The decrease in rare disease program expenses was offset by \$9.6 million in incremental spend to advance our cancer programs, including costs associated with our Phase 1/2 clinical trial for RTX-240 for the treatment of solid tumors as well as costs associated with preclinical and IND-enabling activities for RTX-321. In addition, R&D expenses not allocated to programs decreased by \$7.4 million driven primarily by reductions in non-program labor, laboratory supplies, research materials and contract research as pre-GMP manufacturing and discovery activities shifted to support the development of clinical candidates.

G&A expenses were \$12.0 million during the third quarter of 2020, as compared to \$15.0 million for the third quarter of 2019. The lower costs were principally driven by a reduction in stock-based compensation expense.

Nine Month Financial Results

Net loss for the first nine months of 2020 was \$127.2 million or \$1.58 per common share, compared to \$119.0 million or \$1.52 per common share in the first nine months of 2019.

In the nine months ended September 30, 2020, Rubius invested \$90.5 million in R&D related to its novel RED PLATFORM[®] and towards expanding and advancing its product pipeline, as compared to \$81.9 million in the first nine months of 2019. The year-over-year increase was driven by \$28.3 million of incremental costs to advance our cancer programs, including costs incurred for our Phase 1/2 clinical trial for RTX-240 for the treatment of solid tumors as well as costs of preclinical and IND-enabling activities for RTX-321. The increase in cancer program costs was offset by a \$12.8 million decrease in expenses related to our rare disease pipeline following the deprioritization of these programs in March 2020. Additionally, costs not allocated to programs decreased by \$6.9 million driven primarily by a shift in manufacturing activities towards the technical development and production of clinical supply for our oncology programs and the shift in discovery activities from the development of clinical candidates towards work to support IND enabling activities.

G&A expenses were \$36.2 million during the first nine months of 2020, as compared to \$42.3 million for the same period in 2019. The lower costs were principally driven by a reduction in stock-based compensation expense.

Cash Position

As of September 30, 2020, cash, cash equivalents and investments were \$207.9 million as compared to \$283.3 million as of December 31, 2019, providing Rubius with a cash runway into 2022. During 2020, the Company used \$97.1 million of cash to fund operations and \$4.5 million to fund capital expenditures, consisting mostly of payments for assets purchased in 2019. In addition, during 2020 the Company drew down the third and final tranche of \$25.0 million pursuant to its \$75.0 million loan agreement with Solar Capital.

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' manufacturing site was recently named 2020 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 with respect to the therapeutic potential of our pipeline of Red Cell Therapeutics, including RTX-240 for the treatment of patients with relapsed/refractory or locally advanced solid tumors and RTX-321 for the treatment of HPV 16-positive cancers, our expectations regarding the timing, enrollment, data from and success of the future cohorts and phases of the clinical trial of RTX-240, our expectations regarding the biological effects of RTX-240 on innate and adaptive immunity, including activation and increased numbers of NK cells and T cells in higher-level dose cohorts in the clinical trial of RTX-240, any timelines related to the IND for RTX-321 and for any clinical trial of RTX-321, 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 June 30, 2020, and subsequent filings with the SEC 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. 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,	
	2020	2019	2020	2019
Revenue	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Research and development	28,209	33,530	90,491	81,919
General and administrative	11,976	14,952	36,241	42,254
Total operating expenses	40,185	48,482	126,732	124,173
Loss from operations	(40,185)	(48,482)	(126,732)	(124,173)
Other income (expense), net	(667)	1,467	(460)	5,187
Net loss	\$ (40,852)	\$ (47,015)	\$ (127,192)	\$ (118,986)
Net loss per share, basic and diluted	\$ (0.51)	\$ (0.59)	\$ (1.58)	\$ (1.52)
Weighted average common shares outstanding, basic and diluted:	80,778,042	79,115,305	80,511,543	78,357,791

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

	September 30, 2020	December 31, 2019
Cash, cash equivalents and investments	\$ 207,904	\$ 283,287
Total assets	312,364	394,841
Total liabilities	139,249	120,628
Total stockholders' equity	173,115	274,213

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Contacts:

Investors

Lori Melançon

Vice President, Corporate Communications and Investor Relations

+1 (617) 949-5296

lori.melancon@rubiustx.com

Media

Marissa Hanify

Director, Corporate Communications

marissa.hanify@rubiustx.com

Dan Budwick

1AB

+1 (973) 271-6085

dan@1abmedia.com
