
**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 13, 2018

RESTORBIO, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38359

(Commission File Number)

81-3305277
(IRS Employer
Identification No.)

**500 Boylston Street, 12th Floor
Boston, MA 02116**
(Address of principal executive offices, including zip code)

(857) 315-5521
(Registrant's telephone number, including area code)

Not Applicable
(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 (see General Instructions A.2. below):

- 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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 13, 2018, resTORbio, Inc. announced its financial results for the quarter ended September 30, 2018. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Report on Form 8-K and 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 (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 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	<u>Press release issued by resTORbio, Inc. on November 13, 2018, furnished herewith.</u>

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 13, 2018

resTORbio, Inc.

By: /s/ Chen Schor

Chen Schor

President and Chief Executive Officer

resTORbio Reports Third Quarter 2018 Financial Results

Additional positive data from Phase 2b trial further support RTB101's potential in reducing the incidence of respiratory tract infections (RTIs) in high-risk elderly patients

Initiation of pivotal Phase 3 program of RTB101 in RTIs expected in 1H19

Initiation of a Phase 2a trial of RTB101 in combination with a rapalog in Parkinson's disease by the end of 1Q19

BOSTON, Massachusetts, November 13, 2018 – resTORbio, Inc. (NASDAQ:TORC), a clinical-stage biopharmaceutical company focused on helping people live healthier longer through the development and commercialization of novel therapeutics for the treatment of aging-related diseases, today provided a corporate update and reported financial results for the third quarter ended September 30, 2018.

“Our recent accomplishments highlight the therapeutic potential of TORC1 inhibition to decrease the incidence of respiratory tract infections by enhancing immune function in the elderly,” said Chen Schor, Co-Founder, President and CEO of resTORbio. “The additional results from our Phase 2b trial, showing that RTB101 10 mg once daily (QD) reduced both the incidence of RTIs and severity of RTI symptoms, support our strategy to further evaluate RTB101 in high-risk elderly in a planned pivotal Phase 3 program. We also observed signals in our Phase 2b trial that RTB101 may reduce the incidence of urinary tract infections (UTIs), and we are developing our strategy for this indication. We continue to explore the potential benefits of TORC1 inhibition in ameliorating aging-related diseases such as neurodegenerative diseases, and look forward to expanding our pipeline with the initiation of a Phase 2a trial in Parkinson's disease by the end of the first quarter of 2019.”

Recent Highlights and Outlook

Additional Positive Results from Phase 2b Trial Support Planned Pivotal Phase 3 Program in RTIs: In October 2018, resTORbio announced additional positive results from its dose-ranging Phase 2b trial of RTB101 in RTIs. The results supported and expanded upon topline results from the Phase 2b trial previously announced in July 2018, in which RTB101 10 mg QD demonstrated a statistically significant 30.6% reduction in the percentage of patients with laboratory-confirmed RTIs during the 16-week treatment period compared to placebo (p=0.025).

During the 16-week treatment period, RTB101 10 mg QD decreased the severity of laboratory-confirmed RTI symptoms compared to placebo, with a 52.1% reduction in the percentage of patients with severe laboratory-confirmed RTI symptoms (odds ratio (OR)=0.437; p=0.034). During the 16-week treatment period and the additional 8-week follow-up period off study drug (for a total of 24 weeks), RTB101 10 mg QD decreased the incidence of laboratory-confirmed RTIs compared to placebo, with a 27.5% reduction in the percentage of patients with laboratory-confirmed RTIs (OR=0.623; p=0.030).

Detailed results from this Phase 2b trial will be submitted for presentation at upcoming medical meetings, and the Company plans to hold an end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in the first quarter of 2019.

Pre-specified Analyses from Phase 2b Trial Demonstrate Potential of RTB101 in Other Infections: The Phase 2b trial results reported in October 2018 also demonstrated from pre-specified analyses that treatment with RTB101 decreased the incidence of all infections and UTIs. RTB101 10 mg QD decreased the incidence of all infections during the 16-week treatment period compared to placebo, with a 23.6% reduction in the percentage of patients with any infection (OR=0.653; p=0.032). RTB101 10 mg twice daily decreased the incidence of UTIs during the 16-week treatment period compared to placebo, with a 74.6% reduction in the percentage of patients with one or more UTIs (OR= 0.211; p=0.027). The Company is developing its clinical strategy for RTB101 in UTIs, including dose selection.

Initiation of Phase 2 Trial in Parkinson's Disease Expected by the End of the First Quarter of 2019: Selective and broad inhibition of TORC1 has been shown to extend lifespan and ameliorate several aging-related diseases in preclinical studies, including neurodegenerative disease. TORC1 inhibition with RTB101, in combination with rapalogs, such as sirolimus or everolimus, may induce autophagy, the process by which cells break down and recycle damaged aggregated proteins and cellular components. As neurodegenerative diseases such as Parkinson's disease are associated with the accumulation of aggregated toxic proteins, the induction of autophagy with RTB101 in combination with rapalogs may have potential therapeutic benefit for patients with Parkinson's disease. The Company plans to initiate a Phase 2a trial in patients with Parkinson's disease by the end of the first quarter of 2019.

Corporate Updates

- In August 2018, resTORbio announced the appointment of Jeffrey Chodakewitz, M.D., to its Board of Directors.
- In September 2018, resTORbio announced the appointment of Meredith Manning as Chief Commercial Officer.
- In November 2018, resTORbio announced the appointment of Michael Grissinger to its Board of Directors.

Third Quarter 2018 Financial Results

- **R&D Expenses:** R&D expenses were \$6.8 million for the three months ended September 30, 2018 compared to \$3.3 million for the three months ended September 30, 2017. The increase was primarily attributable to the Company's Phase 2b trial.
- **G&A Expenses:** General and administrative expenses were \$2.3 million for the three months ended September 30, 2018 compared to \$0.6 million for the three months ended September 30, 2017. The increase was primarily attributable to an increase in headcount as well as increased operating costs as a result of the Company's transition from a private company to a public company, including legal, accounting, insurance and investor relations expenses.
- **Net Loss:** Net loss was \$8.4 million, or \$0.30 per share, for the three months ended September 30, 2018 compared to a net loss of \$3.3 million, or \$0.75 per share, for the three months ended September 30, 2017.
- **Cash Position:** Cash, cash equivalents and marketable securities were \$115.4 million as of September 30, 2018. The Company expects that its cash, cash equivalents and marketable securities as of September 30, 2018 will be sufficient to fund its operating expenses through 2020.

About resTORbio

resTORbio, Inc. is a clinical stage biopharmaceutical company targeting TORC1 and other biological pathways that regulate aging to develop innovative medicines with the potential to extend healthy lifespan. resTORbio's lead program is selectively targeting TORC1, an evolutionarily conserved pathway that contributes to the decline in function of multiple organ systems, including the immune, cardiovascular and central nervous systems. Learn more about resTORbio, Inc. at <https://www.restorbio.com>.

Forward Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws. Investors are cautioned that statements in this press release which are not strictly historical statements, including, without limitation, express or implied statements or guidance regarding our plans to develop and commercialize RTB101 alone or in combination with everolimus or sirolimus, including the therapeutic potential and clinical benefits thereof and the potential patient populations that may be addressed by our product candidates, our ongoing and future clinical trials for RTB101 alone or in combination with everolimus or sirolimus, including the timing of the initiation and anticipated results of these trials, the planned expansion of our pipeline into Parkinson's disease and UTIs, the intended regulatory path for our product candidates and interactions with regulatory authorities, our ability to replicate results achieved in our clinical trials in any future trials, our ability to conduct an end-of-Phase 2 meeting with the U.S. Food and Drug Administration, and our cash position and expected cash runway, constitute forward-looking statements identified by words like "believe," "expect," "may," "will," "should," "seek," "anticipate," or "could" and similar expressions. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated, including, without limitation, risks associated with: the delay of any planned clinical trials and/or development of RTB101, either alone or in combination with everolimus or sirolimus; our ability to successfully demonstrate the efficacy and safety of our lead product candidate; the clinical results for our lead product candidate which may not support further development of additional indications; uncertainties related to the results of our clinical trials not being predictive of future results in connection with future trials; the timing and outcome of our planned interactions with regulatory authorities; and obtaining, maintaining and protecting our intellectual property; as well as those risks more fully discussed in the section entitled "Risk Factors" in the Annual Report on Form 10-K filed by resTORbio, Inc. with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent our views only as of today and should not be relied upon as representing its views as of any subsequent date. resTORbio explicitly disclaims any obligation to update any forward-looking statements.

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RESTORBIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 6,765	\$ 3,333	\$ 26,716	\$ 10,047
General and administrative	2,267	612	6,629	1,312
Total operating expenses	<u>9,032</u>	<u>3,945</u>	<u>33,345</u>	<u>11,359</u>
Loss from operations	(9,032)	(3,945)	(33,345)	(11,359)
Other income, net	625	635	1,488	635
Net loss	<u>\$ (8,407)</u>	<u>\$ (3,310)</u>	<u>\$ (31,857)</u>	<u>\$ (10,724)</u>
Net loss per share —basic and diluted	<u>\$ (0.30)</u>	<u>\$ (0.75)</u>	<u>\$ (1.23)</u>	<u>\$ (2.79)</u>
Weighted-average number of common shares used in net loss per share — basic and diluted	<u>28,047</u>	<u>4,408</u>	<u>25,896</u>	<u>3,839</u>

RESTORBIO, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands)

	September 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 115,378	\$ 53,349
Prepaid expenses and other current assets	1,645	876
Deferred offering costs	—	929
Total current assets	117,023	55,154
Restricted cash	84	—
Property and equipment, net	319	39
Total assets	<u>\$ 117,426</u>	<u>\$ 55,193</u>
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 4,201	\$ 1,515
Accrued liabilities	3,363	3,987
Funding advance	500	—
Total current liabilities	8,064	5,502
Other liabilities	22	—
Total liabilities	8,086	5,502
Redeemable convertible preferred stock	—	81,620
Stockholders' equity (deficit):		
Common stock	3	1
Additional paid-in capital	175,049	1,849
Accumulated deficit	(65,636)	(33,779)
Accumulated other comprehensive loss	(76)	—
Total stockholders' equity (deficit)	109,340	(31,929)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 117,426</u>	<u>\$ 55,193</u>