

**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 15, 2019

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, 13th Floor
Boston, MA
(Address of principal executive offices)

02116
(Zip Code)

Registrant's telephone number, including area code: (857) 315-5528

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:

- 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 \$0.0001 per share	TORC	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 (§ 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 8.01 Other Events

On November 15, 2019, resTORbio, Inc. (the “Company”) announced that top line data from the PROTECTOR 1 Phase 3 study, evaluating the safety and efficacy of RTB101 in preventing clinically symptomatic respiratory illness in adults age 65 and older, did not meet its primary endpoint, and that the Company has stopped the development of RTB101 in this indication. A copy of the press release is filed herewith as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by resTORbio, Inc. on November 15, 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: November 15, 2019

resTORbio, Inc.

By: /s/ Chen Schor
Chen Schor
President and Chief Executive Officer



resTORbio Announces That the Phase 3 PROTECTOR 1 Trial of RTB101 in Clinically Symptomatic Respiratory Illness Did Not Meet the Primary Endpoint

— Company stops further development of clinically symptomatic respiratory illness indication but continues development of RTB101 in other aging-related diseases, including Parkinson’s disease —

— Company remains well funded with \$117.3 million in cash, cash equivalents and marketable securities as of September 30, 2019 —

— Management to host conference call at 8:00 a.m. EST today —

BOSTON, MA, November 15, 2019 – resTORbio, Inc., (Nasdaq: TORC), a clinical-stage biopharmaceutical company developing innovative medicines that target the biology of aging to prevent or treat aging-related diseases, today announced that top line data from the PROTECTOR 1 Phase 3 study, evaluating the safety and efficacy of RTB101 in preventing clinically symptomatic respiratory illness (CSRI) in adults age 65 and older, did not meet its primary endpoint, and that it has stopped the development of RTB101 in this indication. RTB101 is an oral, selective, and potent TORC1 inhibitor.

“While we are disappointed in these results, there are extensive preclinical data supporting the potential therapeutic benefit of TORC1 inhibition in multiple aging-related diseases, including Parkinson’s disease, for which we have an active Phase 1b/2a trial of RTB101 alone or in combination with sirolimus,” said Chen Schor, co-founder, president and CEO of resTORbio. “Multiple pre-clinical models have demonstrated that inhibition of TORC1 decreases protein and lipid synthesis, increases lysosomal biogenesis and stimulates the clearance of misfolded protein aggregates, such as toxic synucleins, that cause neuronal toxicity in Parkinson’s disease. We remain committed to exploring the potential benefits of TORC1 inhibition in patients, and we look forward to the data from our Parkinson’s disease trial, which we expect in mid-2020.”

The PROTECTOR 1 Phase 3 trial was a randomized, double-blind, placebo-controlled clinical trial that evaluated the safety and efficacy of RTB101 10mg given once daily for 16 weeks during winter cold and flu season to subjects 65 years of age and older, excluding current smokers and individuals with chronic obstructive pulmonary disease. The primary endpoint of the trial was the reduction in the percentage of subjects with clinically symptomatic respiratory illness, defined as illness associated with a respiratory tract infection, or RTI, based on prespecified diagnostic criteria, with or without laboratory confirmation of a pathogen. The PROTECTOR 1 trial included 1024 patients who were randomized 1:1 to receive RTB101 or placebo administered once daily for 16 weeks. In an analysis of the primary endpoint, the odds of experiencing a CSRI were 0.44 in the placebo cohort and 0.46 in the RTB101 cohort (odds ratio 1.07, p=0.65). The Company plans to conduct detailed analyses of the PROTECTOR 1 study, including additional data on safety and secondary and exploratory endpoints, which are not available at this time, with the goal of gaining insights that may explain the difference in RTB101 activity observed in PROTECTOR 1 as compared to prior Phase 2 studies.

Conference Call Information

Management will host a conference call at 8:00 a.m. EST today to review these pivotal results and provide an update on additional clinical development plans for RTB101. The conference call can be accessed by dialing (877) 356-9149 or (629)-228-0720 (international) and referencing conference ID 6066628 prior to the start of the call. The call will also be webcast via the Internet and will be available under the “Investors & Media” section of the resTORbio website, www.restorbio.com.

About RTB101

RTB101 is an oral, selective, and potent TORC1 inhibitor product candidate. TORC1 inhibition has been shown to be of therapeutic benefit in multiple preclinical models of aging-related diseases including Parkinson’s disease.

About Parkinson’s Disease in Older Adults

Parkinson’s disease, or PD, is a progressive neurodegenerative disease that affects approximately 7.5 million people worldwide. The incidence of PD increases rapidly in people 60 years of age and older, with a mean age at diagnosis of 70.5 years.

About resTORbio

resTORbio, Inc. is a clinical-stage biopharmaceutical company developing innovative medicines that target the biology of aging to prevent or treat aging-related diseases. resTORbio’s lead candidate, RTB101, selectively inhibits TORC1, an evolutionarily conserved pathway that contributes to the decline in function of multiple organ systems, including neurologic, immune and cardiac function. Learn more about resTORbio, Inc. at www.restorbio.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Investors are cautioned that statements in this press release which are not strictly historical statements, including, without limitation, our proposed timing and anticipated results of our Phase 1b/2a clinical trial of RTB101 alone or in combination with sirolimus in patients with mild to severe Parkinson’s disease; our future plans to develop RTB101 alone or in combination with rapalogs, such as everolimus or sirolimus, including the therapeutic potential and clinical benefits thereof; our expectations on the potential patient populations that may be addressed by our product candidates; our ability to replicate results achieved in our clinical trials in any future trials; our cash position and expected cash runway; our expectations regarding our uses of capital, constitute forward-looking statements identified by words such as, but not limited to, “believe,” “expect,” “may,” “will,” “should,” “seek,” “anticipate,” or “could” and similar words or expressions.

Any forward-looking statements in this statement are based on management’s current expectations of future events and 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: our PROTECTOR Phase 3 program; our ongoing Phase 1b/2a clinical trial of RTB101 alone or in combination with sirolimus in Parkinson’s disease; the timing and anticipated results of our clinical trials; the risk that the results of our clinical trials will be predictive of future results in connection with future clinical 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 are neither historical facts nor assurances of future performance. Instead, they represent our beliefs, expectations, assumptions and views only as of today and should not be relied upon as representing our beliefs, expectations, assumptions and views as of any subsequent date. resTORbio explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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