
**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): August 14, 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, 12th Floor
Boston, MA
(Address of principal executive offices)

02116
(Zip Code)

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

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))

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 2.02 Results of Operations and Financial Condition

On August 14, 2019, resTORbio, Inc. announced its financial results for the quarter ended June 30, 2019. A copy of the press release 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 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, 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 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	Press release issued by resTORbio, Inc. on August 14, 2019, 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: August 14, 2019

resTORbio, Inc.

By: /s/ Chen Schor _____

Chen Schor

President and Chief Executive Officer

resTORbio Reports Second Quarter 2019 Financial Results and Corporate Update

– Quarter highlighted by initiation and early completion of enrollment of Phase 3 PROTECTOR 1 trial; topline data expected by early first quarter of 2020 –

BOSTON, MA, August 14, 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 reported financial results for the second quarter ended June 30, 2019 and provided a corporate update.

“We believe our significant clinical progress year-to-date positions us well for the second half of 2019 and into 2020,” said Chen Schor, co-founder, president and CEO of resTORbio. “The interest from patients and investigators in our PROTECTOR 1 trial combined with the focused execution by our highly experienced team, enabled us to complete enrollment ahead of previously disclosed clinical timelines. We now expect topline data from this study by early first quarter of 2020. PROTECTOR 2 is planned to begin in the fourth quarter of this year, in conjunction with the cold and flu season in the northern hemisphere. We continue to move quickly to develop RTB101 as the first potential medicine to enhance immune function and thereby reduce the incidence of illness associated with respiratory tract infections. In parallel, our Phase 1b/2a trial of RTB101 in combination with sirolimus in Parkinson’s disease continues to enroll patients. Beyond our clinical efforts, we continue to generate data that we believe further support the mechanism of action of RTB101. We are also leveraging our deep understanding of aging biology and TORC1 to evaluate new potential product candidates.”

Second Quarter and Recent Highlights and Outlook

- **RTB101 Phase 3 PROTECTOR Program in Clinically Symptomatic Respiratory Illness Advancing Ahead of Previously Disclosed Clinical Timelines:** During the second quarter, resTORbio initiated a global Phase 3 PROTECTOR program in adults 65 years of age and older, excluding current smokers and chronic pulmonary disease (COPD) patients. The program consists of two randomized, double-blind, placebo-controlled clinical trials to evaluate the safety and efficacy of RTB101 10 mg given orally once daily for 16 weeks during winter cold and flu season. The primary endpoint of both trials is the reduction in the percentage of patients with clinically symptomatic respiratory illness, defined as illness associated with a respiratory tract infection (RTI) based on prespecified diagnostic criteria.

In July 2019, the company announced early completion of enrollment of 1,024 patients in PROTECTOR 1, its first Phase 3 trial of RTB101 in clinically symptomatic respiratory illness. Topline data from PROTECTOR 1 is now anticipated by early first quarter of 2020. PROTECTOR 2, the second Phase 3 trial, is planned to begin in the fourth quarter of 2019, with topline data expected in mid-2020.

Additional Phase 2b Proof-of-Concept Data for RTB101 Presented at the American Thoracic Society (ATS) International Conference

In a press release dated May 20, 2019, resTORbio announced presentation of additional data at ATS from a prespecified analysis of its Phase 2b trial of RTB101 in patients 65 years of age and older with asthma. RTIs are one of the most common causes of asthma exacerbations, and the majority of RTIs are caused by many different types of viruses, most of which lack current treatments. Among Phase 2b participants 65 years of age and older with asthma, RTB101 10 mg once daily was observed to reduce the rate of laboratory-confirmed RTIs by 78.7% ($p=0.001$) and the rate of all RTIs (with or without laboratory confirmation) by 66.4% ($p=0.003$) as compared to placebo. RTB101 10 mg once daily was also observed to reduce the incidence of RTIs caused by multiple different viruses, including rhinovirus, the most common viral cause of asthma exacerbations.

- **Phase 1b/2a Dose Escalation Trial in Parkinson’s Disease (PD) Ongoing, with Data Expected in 2020:** Inhibition of TORC1 has been shown to extend lifespan and ameliorate a number of aging-related diseases across multiple preclinical species, including preclinical models of neurodegenerative diseases such as PD.

In April 2019, resTORbio initiated a Phase 1b/2a trial in patients with PD. The multicenter, randomized, double-blind, placebo-controlled trial is evaluating the safety and tolerability of RTB101 alone or in combination with

sirolimus when given once weekly for 4 weeks to patients with mild to moderate PD who are already on standard-of-care therapy. The company expects data from this trial in 2020.

Second Quarter 2019 Financial Results

- **R&D Expenses:** Research and development (R&D) expenses were \$16.6 million for the three months ended June 30, 2019 compared to \$11.8 million for the three months ended June 30, 2018. The increase was primarily due to the initiation of the Phase 3 PROTECTOR program for clinically symptomatic respiratory illness and the ongoing Phase 1b/2a for Parkinson's disease.
- **G&A Expenses:** General and administrative (G&A) expenses were \$2.6 million for the three months ended June 30, 2019 compared to \$2.3 million for the three months ended June 30, 2018. The increase was primarily due to an increase in headcount as well as increased operating costs as a result of the company's continued transition from a private company to a public company.
- **Net Loss:** Net loss was \$18.3 million, or \$0.51 per share, for the three months ended June 30, 2019 compared to a net loss of \$13.6 million, or \$0.48 per share, for the three months ended June 30, 2018.
- **Cash, Cash Equivalents and Marketable Securities:** Cash, cash equivalents and marketable securities were \$132.8 million as of June 30, 2019 compared to \$108.0 million as of December 31, 2018. The company expects that its cash, cash equivalents and marketable securities as of June 30, 2019 will be sufficient to fund its operating expenses through 2020.

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 aging-related conditions in preclinical species, including immunosenescence (aging-related decline in immune function). In two Phase 2 clinical trials that enrolled more than 900 older adults, RTB101 was observed to improve immune function by upregulation of pan-antiviral gene expression and to reduce the incidence of RTIs.

About Respiratory Tract Infections in Older Adults

As part of the aging process, the immune system weakens and becomes less effective at detecting and fighting infections such as RTIs. As a result, RTIs are more likely to be of greater severity, prolonged duration, and are more likely to be associated with medical complications in people 65 years of age and older compared to younger adults. In the U.S., RTIs are the fourth leading cause of hospitalization and seventh leading cause of death in people 65 years of age and older. Given that the majority of RTIs are caused by many different types of viruses, most of which lack effective therapies, there remains a significant unmet medical need for an immunotherapy that enhances the ability of the immune system to fight multiple viruses to reduce illness associated with RTIs in older adults.

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 program selectively inhibits TORC1, an evolutionarily conserved pathway that contributes to the decline in function of multiple organ systems, including immune, neurologic 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, express or implied statements or guidance regarding the proposed timing, enrollment, trial design and anticipated results for the PROTECTOR Phase 3 clinical program of RTB101 the company's Phase 1b/2a clinical trial of RTB101 in combination with sirolimus in Parkinson's disease, future plans to develop RTB101

alone or in combination with rapalogs, such as everolimus or sirolimus, including the therapeutic potential and clinical benefits thereof and the potential patient populations that may be addressed by the product candidates, the ongoing and future clinical trials for RTB101, including the timing of the initiation and anticipated results of these trials, the ability to replicate results achieved in the clinical trials in any future trials, resTORbio's cash position and expected cash runway, the expectations regarding its uses of capital, expenses, future accumulated deficit and other second quarter 2019 financial results and its ability to fund operations through 2020, 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.

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 PROTECTOR Phase 3 program; the planned Phase 3 clinical trials in RTIs and/or development of RTB101, either alone or in combination with a rapalog, such as everolimus or sirolimus; the company's ongoing Phase 1b/2a clinical trial of RTB101 in combination with sirolimus in Parkinson's disease; uncertainties related to the results of the clinical trials predictive of future results in connection with future trials, including our Phase 3 clinical trials; the timing and outcome of the 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 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 the company's 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 16,553	\$ 11,845	\$ 25,405	\$ 19,951
General and administrative	2,616	2,268	5,455	4,362
Total operating expenses	19,169	14,113	30,860	24,313
Loss from operations	(19,169)	(14,113)	(30,860)	(24,313)
Other income, net	847	522	1,478	863
Loss before income taxes	(18,322)	(13,591)	(29,382)	(23,450)
Income tax expense	10	—	19	—
Net loss	\$ (18,332)	\$ (13,591)	\$ (29,401)	\$ (23,450)
Net loss per share —basic and diluted	\$ (0.51)	\$ (0.48)	\$ (0.91)	\$ (0.95)
Weighted-average number of common shares used in net loss per share —basic and diluted	35,684	28,046	32,249	24,803

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

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 21,371	\$ 7,042
Marketable securities	111,425	100,986
Prepaid expenses and other current assets	3,292	1,506
Total current assets	136,088	109,534
Restricted cash	245	84
Property and equipment, net	325	321
Total assets	\$ 136,658	\$ 109,939
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 8,242	\$ 2,989
Accrued liabilities	1,464	2,727
Total current liabilities	9,706	5,716
Other liabilities	11	19
Total liabilities	9,717	5,735
Stockholders' equity:		
Common stock	4	3
Additional paid-in capital	227,561	175,635
Accumulated deficit	(100,794)	(71,393)
Accumulated other comprehensive gain (loss)	170	(41)
Total stockholders' equity	126,941	104,204
Total liabilities and stockholders' equity	\$ 136,658	\$ 109,939

Investor and Media Contact

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