

**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): May 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 May 15, 2019, resTORbio, Inc. announced its financial results for the quarter ended March 31, 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 8.01 Other Events

On May 14, 2019, the Company issued a press release titled “resTORbio Appoints Lloyd Klickstein, M.D., Ph.D., as Chief Scientific Officer”. A copy of this press release is furnished as Exhibit 99.2 to this report on Form 8-K.

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 May 15, 2019, furnished herewith.
99.2	Press release issued by resTORbio, Inc. on May 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: May 15, 2019

resTORbio, Inc.

By: /s/ Chen Schor

Chen Schor

President and Chief Executive Officer

resTORbio Reports First Quarter 2019 Financial Results and Corporate Update

Initiated first Phase 3 trial, PROTECTOR 1, of RTB101 in clinically symptomatic respiratory illness; top-line data from two pivotal Phase 3 trials expected in mid-2020

Initiated Phase 1b/2a trial of RTB101 in combination with sirolimus in Parkinson's disease (PD)

Completed \$50 million public offering

BOSTON, Massachusetts, May 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 provided a corporate update and reported financial results for the first quarter ended March 31, 2019.

“Our recent clinical accomplishments represent significant progress towards our goal of developing novel therapies that target key aging pathways to treat a range of aging-related diseases,” said Chen Schor, Co-Founder, President and CEO of resTORbio. “The initiation of PROTECTOR 1 and our Phase 1b/2a trial in PD bring us closer to understanding how TORC1 inhibition may improve the function of several organ systems, including improving immune and neurologic function. Our successful follow-on offering provides us with the financial strength to rapidly enroll patients in these trials and prepare to initiate PROTECTOR 2 in the fourth quarter of this year, with the goal of advancing RTB101 toward a potential New Drug Application (NDA) submission. We also remain focused on progressing our discovery efforts to develop additional TORC1 inhibitors as well as clinical candidates targeting other aging pathways.”

Recent Highlights and Outlook

Initiation of Phase 3 Program in Clinical Symptomatic Respiratory Illness: In March 2019, following an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA), resTORbio announced the design of its Phase 3 PROTECTOR program for RTB101 10mg once daily in clinically symptomatic respiratory illness, defined as illness associated with a respiratory tract infection (RTI) based on prespecified diagnostic criteria, with or without laboratory confirmation of a pathogen. resTORbio’s PROTECTOR program consists of two randomized, double-blinded, placebo-controlled Phase 3 clinical trials evaluating the safety and efficacy of RTB101 10mg once daily versus placebo for 16 weeks in patients 65 years of age or older, excluding current smokers and patients with chronic obstructive pulmonary disease. The primary endpoint of both Phase 3 trials is the reduction in the percentage of elderly subjects with clinically symptomatic respiratory illness.

In May 2019, resTORbio announced the initiation of PROTECTOR 1, its first Phase 3 clinical trial. The Company expects to initiate PROTECTOR 2, its second Phase 3 clinical trial, in the fourth quarter of 2019, with top-line data from both trials expected in mid-2020.

Initiation of Phase 1b/2a Trial in PD: In April 2019, resTORbio initiated a Phase 1b/2a trial in patients with PD. The multicenter, randomized, patient and investigator blinded, placebo-controlled Phase 1b/2a 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, including those with and without glucocerebrosidase mutations. Secondary endpoints include exposure in blood, plasma and cerebrospinal fluid (CSF), and exploratory endpoints include biomarkers in plasma and CSF, and various clinical assessments. The Company expects data from this trial in 2020.

Research Grant from the National Institutes of Health (NIH) to Study TORC1 inhibition and Antiviral Immunity: In May 2019, resTORbio was awarded a 5-year grant for up to \$1.5 million from the NIH to study RTB101 and the regulation of antiviral immunity in the elderly.

Appointment of Lloyd Klickstein, M.D., Ph.D., as Chief Scientific Officer Bolsters Ongoing Drug Discovery Efforts: Dr. Klickstein brings to resTORbio a strong background in drug discovery and development for new clinical indications with high unmet medical need. resTORbio is growing its pipeline of programs targeting multiple mechanisms underlying the biology of aging, including additional TORC1 inhibitors and candidates targeting other biochemical pathways underlying the biology of aging.

Corporate Updates

- In May 2019, resTORbio appointed Lloyd Klickstein, M.D., Ph.D., as Chief Scientific Officer.
 - In March 2019, resTORbio closed an underwritten public offering of 7.2 million shares of its common stock at a public offering price of \$6.95 per share, for gross proceeds of approximately \$50.0 million.
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First Quarter 2019 Financial Results

- **R&D Expenses:** Research and development (R&D) expenses were \$8.9 million for the three months ended March 31, 2019 compared to \$8.1 million for the three months ended March 31, 2018. The increase was primarily due to the initiation of the Phase 1b/2a for Parkinson's disease and preparation for the Phase 3 clinical program for clinical symptomatic respiratory illness.
- **G&A Expenses:** General and administrative (G&A) expenses were \$2.8 million for the three months ended March 31, 2019 compared to \$2.1 million for the three months ended March 31, 2018. The increase was primarily due 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 \$11.1 million, or \$0.38 per share, for the three months ended March 31, 2019 compared to a net loss of \$9.9 million, or \$0.46 per share, for the three months ended March 31, 2018.
- **Cash, Cash Equivalents and Marketable Securities:** Cash, cash equivalents and marketable securities were \$143.1 million as of March 31, 2019 compared to \$108.0 million as of December 31, 2018. The Company expects that its cash, cash equivalents and marketable securities as of March 31, 2019 will be sufficient to fund its operating expenses through 2020.

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 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 within the meaning of the Private Securities Litigation Reform Act of 1995. 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 growth as a company and the anticipated contribution of our executives to our operations and progress, our ability to expand our drug discovery capabilities to develop additional TORC1 inhibitors, the timing and anticipated results from our Phase 3 PROTECTOR program for RTB101, the timing and anticipated results of Phase 1b/2a clinical trial of RTB101 in combination with sirolimus in Parkinson's disease, our plans to develop RTB101 alone or in combination with rapalogs, 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 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 expected use of the research grant from the National Institutes of Health and its potential contributions to our current and future clinical trials; our cash position and expected cash runway, our expectations regarding our uses of capital, expenses, future accumulated deficit and other first quarter 2019 financial results, and our ability to fund operations through 2020, 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: our Phase 3 PROTECTOR program for RTB101, our Phase 1b/2a clinical trials of RTB101 either alone or in combination with a rapalog, such as 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 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.

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

	Three Months Ended	
	March 31,	
	2019	2018
Operating expenses:		
Research and development	\$ 8,852	\$ 8,106
General and administrative	2,839	2,094
Total operating expenses	11,691	10,200
Loss from operations	(11,691)	(10,200)
Other income, net	631	341
Loss before income taxes	(11,060)	(9,859)
Income tax expense	9	—
Net loss	\$ (11,069)	\$ (9,859)
Net loss per share —basic and diluted	\$ (0.38)	\$ (0.46)
Weighted-average number of common shares used in net loss per share —basic and diluted	29,015	21,523

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

	March 31,	December 31,
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 7,181	\$ 7,042
Marketable securities	135,910	100,986
Prepaid expenses and other current assets	1,587	1,506
Total current assets	144,678	109,534
Restricted cash	84	84
Property and equipment, net	318	321
Total assets	<u>\$ 145,080</u>	<u>\$ 109,939</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,364	\$ 2,989
Accrued liabilities	1,245	2,727
Total current liabilities	4,609	5,716
Other liabilities	15	19
Total liabilities	4,624	5,735
Stockholders' equity:		
Common stock	4	3
Additional paid-in capital	222,882	175,635
Accumulated deficit	(82,462)	(71,393)
Accumulated other comprehensive gain (loss)	32	(41)
Total stockholders' equity	<u>140,456</u>	<u>104,204</u>
Total liabilities and stockholders' equity	<u>\$ 145,080</u>	<u>\$ 109,939</u>

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resTORbio Appoints Lloyd Klickstein, M.D., Ph.D., as Chief Scientific Officer

BOSTON, Massachusetts, May 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 announced the appointment of Lloyd Klickstein, M.D., Ph.D., as Chief Scientific Officer.

“We are honored to have Lloyd join the executive team at resTORbio,” said Chen Schor, Co-Founder, President and CEO of resTORbio. “Lloyd is an exceptional physician scientist with vast experience in drug discovery and clinical development across a range of aging-related indications. We look forward to Lloyd’s leadership as we evaluate RTB101 in additional diseases of aging, broaden our pipeline to study other TORC1 inhibitors, and bring forward additional clinical candidates that target other aging pathways.”

Dr. Klickstein brings to resTORbio a strong background in drug discovery and development for new clinical indications with high unmet medical need. Prior to joining resTORbio, Dr. Klickstein was the Global Head of Translational Medicine for the New Indication Discovery Unit and the Exploratory Disease Area at Novartis Institutes for Biomedical Research, where he led teams that brought forward multiple innovative programs in a wide array of therapeutic areas including the research and development of small molecules for nonalcoholic steatohepatitis, gene therapy for hearing loss, gene editing for sickle cell anemia, and TORC1 inhibitors for diseases of aging. Before Novartis, Dr. Klickstein was an academic physician-scientist at Brigham and Women’s Hospital (BWH), where he directed a basic research laboratory funded by the National Institutes of Health and maintained an active clinical practice in the Arthritis Center. Dr. Klickstein received a B.S. from Tufts University and an M.D. and Ph.D. from Harvard University. He completed post-graduate clinical training in Internal Medicine, Rheumatology & Immunology at BWH and a post-doctoral research fellowship at the Center for Blood Research in Boston, MA.

“I am eager to join resTORbio at such an exciting time for the Company and the broader field of aging,” said Dr. Klickstein. “To date, substantial preclinical evidence has identified biological mechanisms that regulate the aging process, including the TORC1 pathway, and these data support the potential benefit of TORC1 inhibition for improving the function of aging organ systems. I look forward to working with the team to further harness the biology of aging to create new clinical candidates, as well as to advance the ongoing clinical programs for RTB101 in improving immune and neurologic function.”

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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: our PROTECTOR Phase 3 program; our 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; 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 predictive of future results in connection with future trials, including our Phase 3 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 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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