

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended **June 30, 2018**

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File No. **001-38359**

resTORbio, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

**500 Boylston Street, 12th Floor
Boston, MA**

(Address of principal executive offices)

81-3305277

(I.R.S. Employer
Identification No.)

02216

(Zip Code)

(857) 315-5521

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Non-accelerated filer (Do not check if a small reporting company)

Accelerated filer

Small reporting company

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of August 8, 2018, the registrant had 28,048,315 shares of common stock, \$0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our plans to develop and commercialize RTB101 alone or in combination with everolimus and other product candidates for the targeted indications and patient populations, including the therapeutic potential and clinical benefits thereof;
- our planned future clinical trials for RTB101 alone or in combination with everolimus, whether conducted by us or by any future collaborators, including the timing of initiation of these trials and of the anticipated results;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the rate and degree of market acceptance and clinical utility of any products for which we receive regulatory approval;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy;
- our ability to identify additional product candidates with significant commercial potential;
- our plans to enter into collaborations for the development and commercialization of product candidates;
- the potential benefits of any future collaboration;
- our expectations related to the use of proceeds from our initial public offering;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- developments relating to our competitors and our industry; and
- the impact of government laws and regulations.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the “Risk Factors” section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this Quarterly Report on Form 10-Q and the documents that we reference herein and have filed or incorporated by reference as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Item 1. Condensed Consolidated Financial Statements.

resTORbio, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(In thousands, except share and per share data)

	June 30, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 51,353	\$ 53,349
Marketable securities	74,570	—
Prepaid expenses	2,398	792
Deferred offering costs	—	929
Other current assets	51	84
Total current assets	128,372	55,154
Restricted cash	84	—
Property and equipment, net	324	39
Total assets	<u>\$ 128,780</u>	<u>\$ 55,193</u>
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable (including related party amounts of \$37 and \$32 as of June 30, 2018 and December 31, 2017, respectively)	\$ 4,523	\$ 1,515
Accrued liabilities	6,568	3,987
Funding advance	500	—
Total current liabilities	11,591	5,502
Other liabilities	25	—
Total liabilities	<u>11,616</u>	<u>5,502</u>
Commitments and contingencies (see Note 10)		
Redeemable convertible preferred stock:		
Redeemable convertible preferred stock, Series A, \$0.0001 par value, no and 15,527,951 shares authorized, issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	—	41,674
Redeemable convertible preferred stock, Series B, \$0.0001 par value, no and 4,792,716 shares authorized, issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	—	39,946
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value, 10,000,000 and no shares authorized as of June 30, 2018 and December 31, 2017, respectively; no shares issued and outstanding as of June 30, 2018 and December 31, 2017	—	—
Common stock, \$0.0001 par value, 150,000,000 and 30,000,000 shares authorized as of June 30, 2018 and December 31, 2017, respectively; 28,048,315 and 5,659,089 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively; 28,046,315 and 4,562,640 shares vested as of June 30, 2018 and December 31, 2017, respectively	3	1
Additional paid-in capital	174,420	1,849
Accumulated deficit	(57,229)	(33,779)
Accumulated other comprehensive loss	(30)	—
Total stockholders' equity (deficit)	<u>117,164</u>	<u>(31,929)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 128,780</u>	<u>\$ 55,193</u>

See accompanying notes to these condensed consolidated financial statements.

resTORbio, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(In thousands, except share and per share data)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Operating expenses:				
Research and development	\$ 11,845	\$ 3,420	\$ 19,951	\$ 6,714
General and administrative	2,268	637	4,362	700
Total operating expenses	<u>14,113</u>	<u>4,057</u>	<u>24,313</u>	<u>7,414</u>
Loss from operations	(14,113)	(4,057)	(24,313)	(7,414)
Other income, net	522	—	863	—
Loss before income taxes	(13,591)	(4,057)	(23,450)	(7,414)
Income tax expense	—	—	—	—
Net loss	<u>\$ (13,591)</u>	<u>\$ (4,057)</u>	<u>\$ (23,450)</u>	<u>\$ (7,414)</u>
Net loss per share, basic and diluted	<u>\$ (0.48)</u>	<u>\$ (0.94)</u>	<u>\$ (0.95)</u>	<u>\$ (2.09)</u>
Weighted-average common shares used in computing net loss per share, basic and diluted	<u>28,046,315</u>	<u>4,302,231</u>	<u>24,802,713</u>	<u>3,550,198</u>
<i>Other comprehensive loss:</i>				
Net loss	\$ (13,591)	\$ (4,057)	\$ (23,450)	\$ (7,414)
Unrealized losses on marketable securities, net of income tax expense	(30)	—	(30)	—
Comprehensive loss	<u>\$ (13,621)</u>	<u>\$ (4,057)</u>	<u>\$ (23,480)</u>	<u>\$ (7,414)</u>

See accompanying notes to these condensed consolidated financial statements.

resTORbio, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(In thousands)

	Six Months Ended June 30,	
	2018	2017
Operating activities:		
Net loss	\$ (23,450)	\$ (7,414)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of discount on marketable securities	(57)	—
Depreciation and amortization expense	31	—
Stock-based compensation expense	1,583	210
Expense related to acquisition of intellectual property (see Note 6)	—	3,157
Changes in operating assets and liabilities:		
Restricted cash	(84)	—
Prepaid expenses and other current assets	(1,573)	(532)
Accounts payable	3,119	2,247
Accrued liabilities	2,819	193
Funding advance	500	—
Other liabilities	25	—
Net cash used in operating activities	<u>(17,087)</u>	<u>(2,139)</u>
Investing activities:		
Purchases of property and equipment	(304)	(51)
Purchases of marketable securities	(74,543)	—
Net cash used in investing activities	<u>(74,847)</u>	<u>(51)</u>
Financing activities:		
Proceeds from issuance of Series A redeemable convertible preferred stock	—	5,500
Proceeds from initial public offering, net of issuance costs	89,938	—
Net cash provided by financing activities	<u>89,938</u>	<u>5,500</u>
Net (decrease) increase in cash and cash equivalents	(1,996)	3,310
Cash and cash equivalents at beginning of period	53,349	—
Cash and cash equivalents at end of period	<u>\$ 51,353</u>	<u>\$ 3,310</u>
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable	\$ 12	\$ —
Conversion of redeemable convertible preferred stock into common stock	\$ 81,620	\$ —

See accompanying notes to these condensed consolidated financial statements.

resTORbio, Inc.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Organization

resTORbio, Inc. (collectively referred to with its wholly-owned, controlled subsidiary, resTORbio Securities Corp. as “resTORbio” or the “Company”) was incorporated in the State of Delaware on July 5, 2016. The Company is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for the treatment of aging-related diseases and conditions. The Company’s principal operations are located in Boston, Massachusetts.

Since inception, the Company has been primarily involved in research and development activities. The Company devotes substantially all of its efforts to product research and development, initial market development and raising capital. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks similar to those of other early stage companies, including dependence on key individuals, competition from other companies, the need for development of commercially viable products and the need to obtain adequate additional financing to fund the development of its product candidates. The Company is also subject to a number of risks similar to other companies in the life sciences industry, including regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, the need to obtain additional financing, compliance with government regulations, protection of proprietary technology, dependence on third parties, product liability and dependence on key individuals.

Reverse Stock Split

On January 12, 2018, the Company effected a one-for-1.2804 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company’s redeemable convertible preferred stock (see Note 8). Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

Initial Public Offering

On January 30, 2018, the Company completed its initial public offering (“IPO”), whereby the Company sold 6,516,667 shares of its common stock (inclusive of 850,000 shares of common stock sold by the Company pursuant to the full exercise of an overallotment option granted to the underwriters in connection with the offering) at a price of \$15.00 per share. The shares began trading on The Nasdaq Global Select Market on January 26, 2018. The aggregate net proceeds received by the Company from the offering were approximately \$89.4 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company of \$8.4 million. Upon the closing of the IPO, all outstanding shares of redeemable convertible preferred stock converted into 15,870,559 shares of common stock and all unvested shares of restricted stock automatically vested. Additionally, the Company is now authorized to issue 150,000,000 shares of common stock and 10,000,000 shares of preferred stock.

Liquidity

In the course of its development activities, the Company has sustained operating losses and expects such losses to continue over the next several years. The Company’s ultimate success depends on the outcome of its research and development activities. The Company has incurred net losses from operations since inception and has an accumulated deficit of \$57.2 million as of June 30, 2018. On January 30, 2018, the Company completed its IPO whereby the Company sold 6,516,667 shares of its common stock for aggregate net proceeds of approximately \$89.4 million. As of June 30, 2018, the Company had \$125.9 million of cash, cash equivalents, and marketable securities, which the Company believes will be sufficient to fund the Company’s current operating plan through at least the next twelve months.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements are unaudited. The unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) for interim financial information and, in the opinion of management, reflect all adjustments of a normal recurring nature necessary for a fair statement of the Company’s financial position as of June 30, 2018 and the results of operations and cash flows for the interim periods ended June 30, 2018 and 2017. The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017 that was filed with the Securities and Exchange Commission (“SEC”) on March 29, 2018 (the “2017 Form 10-K”). Interim results are not necessarily indicative of results for a full year or for any other interim period.

The condensed consolidated financial statements include the accounts of resTORbio, Inc. and its wholly owned subsidiary, resTORbio Securities Corp. All inter-company transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities, as of the date of the condensed consolidated financial statements, and the reported amounts of any expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to accrued liabilities, income taxes, and stock-based compensation expense. Management bases its estimates on historical experience, and on various other market-specific relevant assumptions that management believes to be reasonable, under the circumstances. Actual results may differ from those estimates or assumptions.

Summary of Significant Accounting Policies

The significant accounting policies and estimates used in the preparation of the condensed consolidated financial statements are described in the Company's audited financial statements as of and for the year ended December 31, 2017, and the notes thereto, which are included in the 2017 Form 10-K. There have been no material changes in the Company's significant accounting policies during the three and six months ended June 30, 2018, except as noted below.

Marketable securities

The Company classifies marketable securities with remaining maturities when purchased of greater than three months as available-for-sale. Marketable securities with a remaining maturity date greater than one year are classified as non-current. Available-for-sale securities are maintained by investment managers and consist of U.S. treasury securities and U.S. government agency securities. Available-for-sale securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' equity until realized. Any premium or discount arising at purchase is amortized and/or accreted to interest income and/or expensed over the life of the instrument.

If any adjustment to fair value reflects a decline in the value of the investment, the Company considers all available evidence to evaluate the extent to which the decline is "other-than-temporary" and, if so, marks the investment to market through a change to the Company's statement of operations and comprehensive loss.

Restricted Cash

The Company maintains a letter of credit for the benefit of the landlord in connection with the Company's office lease. As of June 30, 2018 and December 31, 2017, restricted cash (non-current) consisted of \$0.1 million and \$0, respectively, held for the benefit of the landlord in connection with the Company's office lease.

Fair Value Measurements

Fair value is defined as the price at which an asset could be exchanged in a current transaction between knowledgeable, willing parties. The authoritative accounting guidance describes a fair value hierarchy based on three levels of inputs that may be used to measure fair value, of which the first two are considered observable and the last is considered unobservable. These levels of inputs are as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3—Unobservable inputs that reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

The following table summarizes assets measured at fair value on a recurring basis at June 30, 2018 (in thousands):

Description	June 30, 2018	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Money market funds (included in cash and cash equivalents)	\$ 36,430	\$ 36,430	\$ —	\$ —
U.S. treasury securities (included in cash and cash equivalents)	14,923	14,923	—	—
U.S. treasury securities (included in marketable securities)	74,570	74,570	—	—
Total	<u>\$ 125,923</u>	<u>\$ 125,923</u>	<u>\$ —</u>	<u>\$ —</u>

The following table summarizes assets measured at fair value on a recurring basis at December 31, 2017 (in thousands):

Description	December 31, 2017	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Money market funds (included in cash and cash equivalents)	\$ 53,349	\$ 53,349	\$ —	\$ —
Total	<u>\$ 53,349</u>	<u>\$ 53,349</u>	<u>\$ —</u>	<u>\$ —</u>

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. Should the planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations. The Company recorded deferred offering costs of \$0 and \$0.9 million as of June 30, 2018 and December 31, 2017, respectively.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is recorded using the straight-line method over the estimated useful lives of the respective assets. Depreciation begins at the time the asset is placed in service. Maintenance and repairs that do not improve or extend the lives of the respective assets are expensed to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the consolidated balance sheet and the resulting gain or loss is reflected in the consolidated statements of operations.

The estimated useful lives of property and equipment are as follows:

	Useful Life (in years)
Leasehold improvements	Lesser of useful life or remaining lease term
Laboratory and manufacturing equipment	2-8 years
Computer equipment and software	1-5 years
Furniture and Fixtures	3-5 years
Office Equipment	3-5 years
Software	3-5 years

Recently Adopted Accounting Pronouncements

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation* (Topic 718): Scope of Modification Accounting (“ASU 2017-09”). ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The guidance is effective for annual periods beginning after December 15, 2017, with early adoption permitted, including adoption in any interim period for which financial statements have not yet been issued. The Company adopted the provisions of ASU 2017-09 on January 1, 2018. No modifications of share-based payment awards have occurred as of June 30, 2018.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases* (“ASU 2016-02”), which requires a lessee to recognize a right-of-use asset and a lease liability for operating leases, initially measured at the present value of the future lease payments, in the balance sheet. ASU 2016-02 also requires a lessee to recognize a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. This new guidance is effective for fiscal years beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the potential effects of adopting the provisions of ASU 2016-02 on its consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows* (“ASU 2016-18”), which requires that amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2018 and interim periods in fiscal years beginning after December 15, 2019 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. The Company does not expect the impact of ASU 2016-18 to be material to its consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, *Accounting for Certain Financial Instruments with Down Round Features* (“ASU 2017-11”), which updates the guidance related to the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. Under ASU 2017-11, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity’s own stock. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share (“EPS”) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. ASU 2017-11 is effective for public entities for all annual and interim periods beginning after December 15, 2019. Early adoption is permitted. The Company does not expect the impact of ASU 2017-11 to be material to its consolidated financial statements.

3. Marketable Securities

As of June 30, 2018, the fair value of marketable securities by type of security was as follows (in thousands):

Description	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government agency securities and treasuries	\$ 74,600		\$ 30	74,570
Total	\$ 74,600	\$ —	\$ 30	\$ 74,570

The Company did not have any marketable securities as of December 31, 2017.

The estimated fair value and amortized cost of the Company’s available-for-sale securities by contractual maturity are summarized as follows (in thousands):

	June 30, 2018	
	Amortized Cost	Fair Value
Due in one year or less	\$ 74,600	74,570
Total	\$ 74,600	\$ 74,570

4. Property and equipment, net

Property and equipment, net consists of the following:

	June 30, 2018	December 31, 2017
	(In thousands)	
Leasehold improvements	\$ 65	\$ —
Machinery and equipment	38	38
Furniture and fixtures	171	—
Computers	55	6
Office equipment	9	—
Software	22	—
Total property and equipment	360	44
Less: accumulated depreciation	(36)	(5)
Property and equipment, net	\$ 324	\$ 39

Depreciation expense was \$31,000 and \$0 for the six months ended June 30, 2018 and 2017, respectively.

5. Accrued Liabilities

Accrued liabilities consist of the following:

	June 30, 2018	December 31, 2017
	(In thousands)	
Accrued payroll and related expenses	\$ 497	\$ 394
Accrued research and development expenses	5,866	3,250
Deferred offering costs	—	238
Other	205	105
Total accrued liabilities	\$ 6,568	\$ 3,987

6. License Agreements

Novartis License Agreement

On March 23, 2017, the Company entered into an exclusive license agreement with Novartis International Pharmaceutical Ltd. (“Novartis”). Under the agreement, Novartis granted the Company an exclusive, field-restricted, worldwide license, to certain intellectual property rights owned or controlled by Novartis, to develop, commercialize and sell one or more therapeutic products comprising RTB101 or RTB101 in combination with everolimus in a fixed dose combination. The exclusive field under the license agreement is for the treatment, prevention and diagnosis of disease and other conditions in all indications in humans and animals.

As initial consideration for the licensed rights, the Company issued Novartis Institutes for Biomedical Research (“NIBR”) 2,587,992 shares of the Company’s Series A Preferred Stock. The fair value of the Novartis license was \$3.2 million based on the fair value of the Series A Preferred Stock which was determined to be \$1.22 per share based on an independent third-party valuation, and is recorded as research and development expenses in the consolidated statements of operations.

The agreement may be terminated by either party upon a material breach by the other party that is not cured within 60 days after written notice. The Company may terminate the agreement in its entirety or on a product-by-product or country-by-country basis with or without cause with 60 days’ prior written notice.

Novartis may terminate the portion of the agreement related to everolimus if the Company fails to use commercially reasonable efforts to research, develop and commercialize a product utilizing everolimus for a period of three years. Novartis may terminate the license agreement upon the Company’s bankruptcy, insolvency, dissolution or winding up.

As additional consideration for the license, the Company is required to pay up to an aggregate of \$4.3 million upon the satisfaction of clinical milestones, up to an aggregate of \$24 million upon the satisfaction of regulatory milestones for the first indication approved, and up to an aggregate of \$18 million upon the satisfaction of regulatory milestones for the second indication

approved. In addition, the Company is required to pay up to an aggregate of \$125 million upon the satisfaction of commercial milestones, based on the amount of annual net sales. The Company is also required to pay tiered royalties ranging from a mid single-digit percentage to a low teen-digit percentage on annual net sales of products. These royalty obligations last on a product-by-product and country-by-country basis until the latest of (i) the expiration of the last valid claim of a Novartis patent covering a subject product, (ii) the expiration of any regulatory exclusivity for the subject product in a country, or (iii) the 10th anniversary of the first commercial sale in the country, and are subject to a reduction after the expiration of the last valid claim of a Novartis patent or the introduction of a generic equivalent of a product in a country. Following the last visit of the 400th subject in the Company's Phase 2b clinical trial, Novartis is no longer entitled to sublicense revenue.

Milestone payments to Novartis will be recorded as research and development expenses in the consolidated statements of operations once achievement of each associated milestone has occurred or the achievement is considered probable. In May 2017, the Company initiated a Phase 2b clinical trial for a first indication, triggering the first milestone payment under the agreement. Accordingly, the Company paid the related \$0.3 million milestone in May 2017. As of June 30, 2018, none of the remaining development milestones, regulatory milestones, sales milestones, or royalties had been reached or were probable of achievement.

7. Research Funding Agreement

On March 6, 2018, the Company and the Silverstein Foundation for Parkinson's with GBA (the "Silverstein Foundation") entered into a research funding agreement (the "Funding Agreement"). One of the Company's directors is a co-founder and current trustee of the Silverstein Foundation. Under the terms of the Funding Agreement, the Silverstein Foundation will partially fund the preclinical research, development work, and Phase 2 clinical trial expenses (the "Research") to be conducted and borne by the Company in connection with the development of RTB101 product, alone or in combination with other products (the "Product").

Upon execution of the Funding Agreement, the Silverstein Foundation paid the Company an upfront sum of \$0.5 million (the "Funding Amount"). The Company is entitled to use the Funding Amount solely to conduct the Research and is obligated to repay the Funding Amount in full to the Silverstein Foundation if it successfully conducts a positive Phase 3 clinical trial of the Product for Parkinson's Disease. The Company is solely responsible for commencing and conducting the Research and will furnish periodic progress updates to the Silverstein Foundation throughout the term of the Funding Agreement. After completing the Research, the Company must provide the Silverstein Foundation with a formal report describing the work performed and the results of the Research.

The Company recognizes proceeds received from the Silverstein Foundation as a reduction to research and development expenses, rather than as revenue, in the condensed consolidated statements of operations because the corresponding Funding Agreement does not contain specified performance obligations other than to conduct research on a particular program or in a particular field and contain no obligations to deliver specified products or technology.

For funds received under the agreement with the Silverstein Foundation, the Company recognizes a reduction in research and development expenses in an amount equal to the qualifying expenses incurred in each period, up to the amount funded by the Silverstein Foundation. Funding that has been received by the Company in advance of incurring qualifying expenses is recorded in the condensed consolidated balance sheet as funding advance. As of June 30, 2018, no qualifying expenses have been incurred.

8. Redeemable Convertible Preferred Stock and Common Stock

As of June 30, 2018, the Company had 10,000,000 shares of preferred stock authorized and none issued and outstanding. As of December 31, 2017, the Company had 20,320,667 shares of preferred stock authorized, of which 15,527,951 shares were issued and outstanding and were designated as \$0.0001 par value Series A Preferred Stock and 4,792,716 shares were issued and outstanding and were designated as \$0.0001 par value Series B Preferred Stock.

Upon completion of the Company's initial public offering in January 2018, all the outstanding preferred stock of the Company automatically converted into 15,870,559 shares of the Company's common stock. As of June 30, 2018, no shares of preferred stock were outstanding.

Reserve for future issuance

The Company has reserved the following number of shares of common stock for future issuance upon the conversion of preferred stock, exercise of options or grant of equity awards:

	June 30, 2018	December 31, 2017
Redeemable convertible preferred stock, on an as-converted basis	—	15,870,559
Options issued and outstanding	752,850	195,668
Unvested restricted stock units	24,960	—
Options available for future grants	1,727,438	1,670,341
Shares available for issuance under the 2018 ESPP	275,030	—
Total	<u>2,780,278</u>	<u>17,736,568</u>

On January 12, 2018, the Company effected a one-for-1.2804 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's preferred stock (see Note 1).

9. Stock-based Compensation

In 2017, the Company adopted the 2017 Stock Incentive Plan (the "2017 Plan"). Under the 2017 Plan, a total of 537,914 shares of the Company's common stock have been reserved for the issuance of stock options to employees, directors, and consultants under terms and provisions established by the Board of Directors (the "Board"). Under the terms of the 2017 Plan, options were granted at an exercise price not less than fair market value. The terms of options granted under the 2017 Plan may not exceed ten years. The Board determined the terms and conditions of a Restricted Stock Award, including the conditions for vesting and repurchase (or forfeiture) and the issue price, if any. On October 11, 2017, the Company increased the number of shares of common stock available for issuance under the 2017 Plan from 537,914 shares to 630,662 shares. On November 29, 2017, the Company increased the number of shares of common stock available for issuance under the 2017 Plan from 630,662 shares to 1,866,009 shares.

In connection with the Company's IPO, the Board adopted and the Company's stockholders approved the 2018 Stock Incentive Plan ("2018 Plan"), which became effective on the date immediately preceding the date on which the Company's registration statement became effective. The 2018 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, restricted stock units, stock appreciation rights, and other stock-based awards. The Company's employees, officers, directors, consultants and advisors are eligible to receive awards under the 2018 Plan. The number of shares of common stock that are reserved for issuance under the 2018 Plan are 2,200,260 shares. The 2018 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2019, by 4% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31 or such lesser number of shares as determined by the Board.

Since the effectiveness of the 2018 Plan, the Company will not grant any further awards under the 2017 Plan. However, any shares of common stock subject to awards under the 2017 Plan that expire, terminate, or otherwise are surrendered, canceled, forfeited or repurchased without having been fully exercised or resulting in any common stock being issued will become available for issuance under the 2018 Plan.

Stock-based Compensation Expense

Total stock-based compensation expense is recognized for stock options granted to employees and non-employees and has been reported in the Company's consolidated statements of operations as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Research and development	\$ 101	\$ 43	\$ 726	\$ 105
General and administrative	301	42	857	105
Total stock-based compensation expense	<u>\$ 402</u>	<u>\$ 85</u>	<u>\$ 1,583</u>	<u>\$ 210</u>

Stock Options

The following table summarizes stock option activity under the Plans:

	Shares Available for Grant	Number of Options Outstanding	Weighted- Average Exercise Price per Option	Weighted- Average Remaining Contract Term	Aggregate Intrinsic Value (In thousands)
Outstanding, December 31, 2017	1,670,341	195,668	\$ 4.49	9.67	
Shares reserved for issuance	641,239				
Options granted ⁽¹⁾	(557,182)	557,182	13.72		
Restricted stock granted	(2,000)				
Restricted stock units granted	(24,960)				
Outstanding, June 30, 2018	<u>1,727,438</u>	<u>752,850</u>	11.32	9.50	\$ 966
Exercisable, June 30, 2018		<u>—</u>	<u>—</u>		
Vested and expected to vest, June 30, 2018		752,850	11.32	9.50	\$ 966

(1) The Company granted 7,200 stock options to non-employees during the six months ended June 30, 2018.

The aggregate intrinsic values of options outstanding, exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the fair value of the Company's common stock as of June 30, 2018. No options were exercised, cancelled or forfeited during the six months ended June 30, 2018.

During the six months ended June 30, 2018, the Company granted options to employees and directors to purchase an aggregate of 549,982 common shares with a weighted-average grant date fair value of \$9.32 per share. During the six months ended June 30, 2018, the Company granted options to non-employees to purchase an aggregate of 7,200 common shares with a weighted-average grant date fair value of \$12.51 per share. The expense related to options granted to employees and directors for the three and six months ended June 30, 2018 was \$0.4 million and \$0.7 million, respectively. The expense related to options granted to non-employees for the three and six months ended June 30, 2018 was \$24,000 and \$27,000, respectively. During the six months ended June 30, 2017, the Company granted options to employees to purchase an aggregate of 64,460 common shares at a weighted-average grant date fair value of \$0.53 per share. During the six months ended June 30, 2017, the Company granted options to non-employees to purchase an aggregate of 37,488 common shares at a weighted-average grant date fair value of \$0.62 per share. There was no expense related to options granted to employees and non-employees for the three and six months ended June 30, 2017.

As of June 30, 2018, the total unrecognized compensation expense related to unvested employee options was \$5.1 million, which the Company expects to recognize over an estimated weighted-average period of 3.49 years. As of June 30, 2018, the total unrecognized compensation expense related to unvested non-employee options was \$0.2 million, which the Company expects to recognize over an estimated weighted-average period of 3.15 years.

The fair value of stock options for employees and non-employees was estimated using a Black-Scholes option pricing model with the following assumptions:

	Three Months Ended June 30, 2018	Six Months Ended June 30, 2018
Employees:		
Fair value of common stock	\$8.57 - \$9.91	\$8.57 - \$15.45
Expected term (in years)	6.6	5.8 - 6.6
Expected volatility	77.4% - 77.7%	76.1% - 77.7%
Risk-free interest rate	2.6% - 2.8%	2.4% - 2.8%
Expected dividend yield	0.0%	0.0%
Non-employees:		
Fair value of common stock	— \$	15.45
Expected term (in years)	—	10.0
Expected volatility	—	77.9%
Risk-free interest rate	—	2.7%
Expected dividend yield	—	0.0%

Restricted Stock

On July 11, 2016, certain founders purchased 3,772,726 common shares that were subject to a repurchase right upon termination or cessation of services at the original purchase price of \$0.0001 per share, or \$483. The repurchase right lapsed as vesting occurred. Compensation expense of such unvested shares was remeasured at fair value until vested at each reporting date. On April 4, 2017, the non-employee directors became employees of the Company and as a result, compensation expense of the unvested shares was remeasured at fair value and fixed and was being recognized over the remaining vesting period. Upon the closing of the Series A preferred financing, a portion of the unvested shares accelerated and vested in full. Upon the Company's IPO, the remaining unvested shares accelerated and vested in full.

On April 17, 2018, the Company granted 2,000 shares of restricted stock to a consultant. The restrictions will lapse in four equal quarterly installments and will be fully vested on the first anniversary of such grant. Compensation expenses of such unvested shares will be remeasured at fair value until vested at each reporting date.

The summary of restricted stock activity and related information follows:

	Number of Restricted Shares Outstanding
Unvested shares — December 31, 2017	1,096,449
Granted	2,000
Vested	<u>(1,096,449)</u>
Unvested shares — June 30, 2018	<u>2,000</u>

The Company recognized \$10,000, \$85,000, \$0.9 million and \$0.2 million of stock-based compensation expense related to restricted shares during the three and six months ended June 30, 2018 and 2017, respectively. As of June 30, 2018, there was \$15,000 of unrecognized stock-based compensation expense related to unvested restricted stock. This amount is expected to be recognized over a remaining weighted-average period of 0.80 years.

Restricted Stock Units

During the three and six months ended June 30, 2018, the Company granted 24,960 restricted stock units to an employee with a weighted-average grant date fair value of \$9.03 per share.

The summary of restricted stock unit activity and related information follows:

	Number of Restricted Stock Units Outstanding
Unvested shares — December 31, 2017	—
Granted	24,960
Unvested shares — June 30, 2018	<u>24,960</u>

The Company recognized \$6,000 of stock-based compensation expense related to restricted stock units during the three and six months ended June 30, 2018. As of June 30, 2018, there was \$0.2 million of unrecognized stock-based compensation expense related to unvested restricted stock units. This amount is expected to be recognized over a remaining weighted-average period of 3.89 years. There were no restricted stock units granted to employees or non-employees during the three and six months ended June 30, 2017.

2018 Employee Stock Purchase Plan

The Board adopted and the Company's stockholders approved the 2018 Employee Stock Purchase Plan ("2018 ESPP"), which became effective on the date immediately preceding the date on which the Company's registration statement became effective. The 2018 ESPP enables eligible employees to purchase shares of the Company's Common Stock at a discount. The number of shares of common stock that are reserved for issuance under the 2018 ESPP are 275,030 shares. The 2018 ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2019 and increasing each January 1 thereafter through January 1, 2028, by the least of (i) 1% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31; (ii) 543,926 shares or (iii) such number of shares as determined by the ESPP administrator.

10. Commitments and Contingences

Litigation

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities as of June 30, 2018 and December 31, 2017.

11. Net Loss per Share

The Company computes basic and diluted earnings (losses) per share using a methodology that gives effect to the impact of outstanding participating securities (the "two-class" method). Basic net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period and excludes any dilutive effects of share-based awards. Diluted net loss per share is computed giving effect to all potential dilutive common shares, including common stock issuable upon exercise of stock options, convertible preferred stock, and unvested restricted common stock. As the Company had net losses for the three and six months ended June 30, 2018 and 2017, there is no income allocation required under the two-class method or dilution attributed to weighted average shares outstanding in the calculation of diluted loss per share.

The following potentially dilutive securities have been excluded from the calculation of diluted net loss per share because including them would have had an anti-dilutive effect (in common stock equivalent shares):

	As of June 30,	
	2018	2017
Redeemable convertible preferred stock	—	4,244,598
Options issued and outstanding	752,850	—
Total	752,850	4,244,598

12. Related Party Transactions

Since the Company's incorporation in July 2016, the Company has engaged in transactions with related parties.

The Company is a party to an intellectual property license agreement with Novartis. In addition, NIBR is a shareholder of the Company (See Note 6). No payments have been made to Novartis during the three and six months ended June 30, 2018. During the three and six months ended June 30, 2017, the Company made payments to Novartis for milestones achieved pursuant to the license agreement.

The Company is a party to a Funding Agreement with the Silverstein Foundation, an entity in which one of the Company's directors is a co-founder and current trustee (See Note 7). The Company received \$0 and \$0.5 million from the Silverstein Foundation during the three and six months ended June 30, 2018, respectively. No funds were received during the three and six months ended June 30, 2017.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion should be read in conjunction with our condensed consolidated financial statements and accompanying footnotes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related footnotes included in our Annual Report on Form 10-K for the year ended December 31, 2017. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q includes forward-looking statements that involve risks and uncertainties. Actual results may differ significantly from those projected in the forward-looking statements. Factors that might cause future results to differ materially from those projected in the forward-looking statements include, but are not limited to, those set forth in Item 1A, "Risk Factors" and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2017, as supplemented by our subsequent filings with the SEC. Unless the context indicated otherwise, all references herein to our company include our wholly-owned subsidiary, resTORbio Securities Corp.

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for the treatment of aging-related diseases. Our lead program has demonstrated in several clinical trials, including a randomized, placebo-controlled trial, the potential to treat multiple diseases of aging for which there are no approved therapies. The decline in immune function that occurs during aging, or immunosenescence, increases susceptibility to a variety of diseases, including respiratory tract infections, or RTIs, that significantly contribute to morbidity and mortality in the elderly. Our approach focuses on the mechanistic target of rapamycin, or mTOR, pathway, an evolutionarily conserved pathway that regulates aging, and specifically on selective inhibition of the target of rapamycin complex 1, or TORC1. Our initial focus is on the development of RTB101, an orally administered, small molecule, potent TORC1 inhibitor, alone and in combination with other mTOR inhibitors such as everolimus—as a first-in-class immunotherapy program designed to improve immune function and thereby reduce the incidence of RTIs in the elderly, regardless of the causative pathogen. We licensed the worldwide rights to our TORC1 program, including RTB101 alone or in combination with everolimus or other mTOR inhibitors, from Novartis International Pharmaceutical Ltd., or Novartis, in March 2017. We are evaluating RTB101 alone and in combination with everolimus in a Phase 2b clinical trial for the reduction of RTI incidence in the elderly and reported top-line data from this trial in July 2018. In this trial, RTB101 demonstrated a statistically significant and clinically meaningful reduction in the percentage of patients with one or more laboratory-confirmed RTIs during the 16-week treatment period compared to placebo, the primary endpoint of the study, with the 10 mg once daily dose. Greater TORC1 inhibition with RTB101 10 mg in combination with everolimus 0.1 mg did not meet the primary endpoint, suggesting that that less TORC1 inhibition with RTB101 10 mg once daily may have greater benefit in high-risk elderly patients. In addition, RTB101 demonstrated a statistically significant reduction in the incidence of laboratory-confirmed RTIs in the pre-specified analysis of asthma patients 65 years and older treated with RTB101 10mg once daily as well as in laboratory-confirmed RTIs in the pre-specified analysis of patients 85 years and older treated with RTB101 10mg once daily.

Since our inception in July 2016, we have devoted substantially all of our resources to: identifying, acquiring, and developing our product candidate portfolio; organizing and staffing our company; raising capital; developing manufacturing capabilities; conducting clinical trials; and providing general and administrative support for these operations. To date, we have primarily financed our operations through the issuance and sale of our redeemable convertible preferred stock and our initial public offering of our common stock, or IPO. Upon the closing of our IPO in January 2018, we received aggregate net proceeds from the IPO of approximately \$89.4 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

We have never generated revenue and have incurred significant net losses since inception. Our net losses were \$1,000, \$33.8 million and \$23.5 million, for the period from July 5, 2016 (inception) through December 31, 2016, for the year ended December 31, 2017 and for the six months ended June 30, 2018, respectively. As of June 30, 2018, we had an accumulated deficit of \$57.2 million. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- invest significantly to further develop and seek regulatory approval for RTB101 alone or in combination with everolimus, including to advance our product candidate into a Phase 3 program;
- expand our pipeline of potential product candidates, including the initiation of at least one additional proof of concept trial in at least one additional indication;
- require the manufacture of larger quantities of our product candidates for clinical development and potential commercialization;
- hire additional clinical, scientific, management and administrative personnel;

- ultimately establish a sales, marketing and distribution infrastructure or collaborate with third parties to commercialize any drugs for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other assets and technologies; and
- add additional operational, financial and management information systems and processes to support our ongoing development efforts, any future manufacturing or commercialization efforts and our transition to operating as a public company.

We believe that our cash, cash equivalents and marketable securities as of June 30, 2018 will be sufficient to fund our operations through 2020. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for a product candidate or enter into collaborative agreements with third parties, which we expect will take a number of years and the outcome of which is subject to significant uncertainty. Additionally, we currently use third parties such as contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, to carry out our preclinical and clinical development activities and we do not yet have a sales organization. If we obtain regulatory approval for our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. To fund our current and future operating plans, we will need additional capital, which we may obtain through one or more equity offerings, debt financings or other third-party funding, including potential strategic alliances and licensing or collaboration arrangements. We may, however, be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our current product candidates, or any additional product candidates, if developed. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our preclinical and clinical development efforts. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

Novartis License Agreement

On March 23, 2017, we entered into a license agreement with Novartis, pursuant to which we were granted an exclusive, field-restricted, worldwide license to certain intellectual property rights owned or controlled by Novartis, including patents, patent applications, proprietary information, know-how and other intellectual property, to develop, commercialize and sell one or more therapeutic products comprising RTB101 or RTB101 and everolimus in a fixed dose combination. Under the license agreement, we have been licensed a patent portfolio of ten patent families directed to composition of matter of RTB101 and its salts, formulations of everolimus and methods of using RTB101 and everolimus to enhance the immune response among others. The exclusive field under the license agreement is for the treatment, prevention and diagnosis of diseases and other conditions in all indications in humans and animals.

As initial consideration for the license, we issued Novartis Institutes for Biomedical Research, Inc., or NIBR, 2,587,992 shares of our Series A Preferred Stock.

The agreement may be terminated by either party upon a material breach of obligation by the other party that is not cured within 60 days after written notice. We may terminate the agreement in its entirety or on a product-by-product or country-by-country basis with or without cause with 60 days' prior written notice.

Novartis may terminate the portion of the agreement related to everolimus if we fail to use commercially reasonable efforts to research, develop and commercialize a product utilizing everolimus for a period of three years. Novartis may terminate the license agreement upon our bankruptcy, insolvency, dissolution or winding up.

As additional consideration for the license, we are required to pay up to an aggregate of \$4.3 million upon the satisfaction of clinical milestones, up to an aggregate of \$24 million upon the satisfaction of regulatory milestones for the first indication approved, and up to an aggregate of \$18 million upon the satisfaction of regulatory milestones for the second indication approved. In addition, we are required to pay up to an aggregate of \$125 million upon the satisfaction of commercial milestones, based on the amount of annual net sales. We are also required to pay tiered royalties ranging from a mid-single digit percentage to a low-teen digit percentage on annual net sales of products. These royalty obligations last on a product-by-product and country-by-country basis until the latest of (i) the expiration of the last valid claim of a Novartis patent covering a subject product, (ii) the expiration of any regulatory exclusivity for the subject product in a country, or (iii) the 10th anniversary of the first commercial sale in the country, and are subject to a reduction after the expiration of the last valid claim of a Novartis patent or the introduction of a generic equivalent of a product in a country. Following the last visit of the 400th subject in our Phase 2b clinical trial, Novartis is no longer entitled to sublicense revenue.

Milestone payments to Novartis will be recorded as research and development expenses in our consolidated statements of operations once achievement of each associated milestone has occurred or the achievement is considered probable. In May 2017, we initiated a Phase 2b clinical trial for a first indication, triggering the first milestone payment under the agreement. Accordingly, we paid the related \$0.3 million payment in May 2017. As of June 30, 2018, none of the remaining development milestones, regulatory milestones, sales milestones, or royalties had been reached or were probable of achievement. We also enter into contracts in the normal course of business with various third parties for preclinical research studies, clinical trials, testing and other services. These contracts generally provide for termination upon notice, and therefore we believe that our noncancelable obligations under these agreements are not material.

Financial Operations Overview

Revenue

We have not generated any revenue from the sale of our products, and we do not expect to generate any revenue unless and until we obtain regulatory approval of and commercialize RTB101, alone or in combination with everolimus, or enter into collaboration arrangements.

Operating Expenses

Research and Development

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- personnel costs, which include salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with consultants, third-party contract organizations and investigative clinical trial sites that conduct research and development activities on our behalf;
- costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical studies and clinical trials; and
- lab supplies and equipment used for internal research and development activities.

We have not provided program costs since inception because historically we have not tracked or recorded our research and development expenses on a program-by-program basis. We use our personnel and infrastructure resources across multiple research and development programs directed toward developing our TORC1 program and for identifying and developing product candidates. We manage certain activities such as contract research and manufacturing of RTB101 alone or in combination with everolimus and our discovery programs through our third-party vendors, and do not track the costs of these activities on a program-by-program basis.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in developing a sustainable and scalable manufacturing process for our product candidates, as our programs advance into later stages of development and we continue to conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Because of the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration and completion costs of the current or future preclinical studies and clinical trials or if, when, or to what extent we will generate revenues from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- successful completion of preclinical studies and Investigational New Drug-enabling, or IND, studies;

- successful enrollment in, and completion of, clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies and treatment options;
- a continued acceptable safety profile following approval;
- enforcing and defending intellectual property and proprietary rights and claims; and
- achieving desirable medicinal properties for the intended indications.

A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the U.S. Food and Drug Administration, or FDA, or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development. We expect our research and development expenses to increase for the foreseeable future as we continue the development of product candidates.

General and Administrative

General and administrative expenses consist primarily of personnel costs, costs related to maintenance and filing of intellectual property, depreciation expense and other expenses for outside professional services, including legal, human resources, audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation expense. We expect our general and administrative expenses to increase for the foreseeable future due to anticipated increases in headcount to advance our product candidates and as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, or the SEC, The Nasdaq Global Select Market, additional insurance expenses, investor relations activities and other administration and professional services.

Other Income, Net

Other income, net, consists primarily of interest income earned on cash, cash equivalents and marketable securities.

Results of Operations

Comparison of the Three Months Ended June 30, 2018 and 2017

	Three Months Ended June 30,	
	2018	2017
Operating expenses:		
Research and development	\$ 11,845	\$ 3,420
General and administrative	2,268	637
Total operating expenses	14,113	4,057
Loss from operations	(14,113)	(4,057)
Other income, net	522	—
Net loss	<u>\$ (13,591)</u>	<u>\$ (4,057)</u>

Research and Development

Research and development expenses increased to \$11.8 million for the three months ended June 30, 2018, and were primarily attributable to \$8.9 million of costs related to clinical trials, including the ongoing Phase 2b clinical trial, \$1.9 million of costs related to contract research and supplies, \$0.2 million of costs related to external consulting incurred to supplement our research and development personnel, and \$0.8 million of personnel costs, including stock-based compensation. Research and development expenses were \$3.4 million for the three months ended June 30, 2017, and were primarily attributable to \$2.4 million of costs related to clinical trials, including the ongoing Phase 2b clinical trial, \$0.3 million of costs related to contract research and supplies, \$0.2 million of costs related to external consulting incurred to supplement our research and development personnel, \$0.2 million of personnel costs, including stock-based compensation, and \$0.3 million of costs associated with our license agreement.

General and Administrative

General and administrative expenses increased to \$2.3 million for the three months ended June 30, 2018, and were primarily attributable to \$1.4 million of personnel, including stock-based compensation, and \$0.8 million of professional services fees, including costs related to intellectual property, legal and filing costs, accounting costs, insurance, and external consulting costs incurred to supplement our personnel. General and administrative expenses were \$0.6 million for three months ended June 30, 2017, and were primarily attributable to \$0.2 million of personnel, including stock-based compensation, and \$0.4 million of professional services fees, including costs related to intellectual property, legal and filing costs, accounting costs, insurance, and external consulting costs incurred to supplement our personnel.

Other Income, Net

Other income, net was \$0.5 million for the three months ended June 30, 2018, and primarily consisted of interest income. Other income, net was \$0 for the three months ended June 30, 2017.

Comparison of the Six Months Ended June 30, 2018 and 2017

	Six Months Ended June 30,	
	2018	2017
Operating expenses:		
Research and development	\$ 19,951	\$ 6,714
General and administrative	4,362	700
Total operating expenses	24,313	7,414
Loss from operations	(24,313)	(7,414)
Other income, net	863	—
Net loss	<u>\$ (23,450)</u>	<u>\$ (7,414)</u>

Research and Development

Research and development expenses increased to \$20.0 million for the six months ended June 30, 2018, and were primarily attributable to \$14.7 million of costs related to clinical trials, including the ongoing Phase 2b clinical trial, \$3.0 million of costs related to contract research and supplies, \$0.3 million of costs related to external consulting incurred to supplement our research and development personnel, and \$1.9 million of personnel costs, including stock-based compensation. Research and development expenses were \$6.7 million for the six months ended June 30, 2017, and were primarily attributable to \$2.4 million of costs related to clinical trials, including the ongoing Phase 2b clinical trial, \$0.3 million of costs related to contract research and supplies, \$0.2 million of costs related to external consulting incurred to supplement our research and development personnel, \$0.3 million of personnel costs, including stock-based compensation, and \$3.5 million of costs associated with our license agreement.

General and Administrative

General and administrative expenses increased to \$4.4 million for the six months ended June 30, 2018, and were primarily attributable to \$2.8 million of personnel, including stock-based compensation, and \$1.6 million of professional services fees, including costs related to intellectual property, legal and filing costs, accounting costs, insurance, and external consulting costs incurred to supplement our personnel. General and administrative expenses were \$0.7 million for six months ended June 30, 2017, and were primarily attributable to \$0.3 million of personnel, including stock-based compensation, and \$0.4 million of professional services fees, including costs related to intellectual property, legal and filing costs, accounting costs, insurance, and external consulting costs incurred to supplement our personnel.

Other Income, Net

Other income, net was \$0.9 million for the six months ended June 30, 2018, and primarily consisted of interest income. Other income, net was \$0 for the six months ended June 30, 2017.

Liquidity, Capital Resources and Plan of Operations

In January 2018, we closed our IPO and received aggregate net proceeds of approximately \$89.4 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

Since inception, we have not generated any revenue from any sources, including from product sales, and have incurred significant operating losses and negative cash flows from our operations. We have funded our operations to date primarily with proceeds from our IPO and the sale of shares of our redeemable convertible preferred stock. As of June 30, 2018, we had \$125.9 million in cash, cash equivalents, and marketable securities and an accumulated deficit of \$57.2 million.

Our primary use of cash has been to fund operating expenses, which consist of research and development and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements through 2020, including the completion of a pivotal Phase 3 clinical program for RTB101, and the filing of a New Drug Application, or NDA, with the FDA, assuming a successful outcome in our Phase 3 clinical program. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidate through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. Furthermore, with the closing of our IPO, we have begun to incur additional costs associated with operating as a public company. Accordingly, we will continue to seek funds through equity or debt financings, collaborative or other arrangements, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms, or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

If we need to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our clinical trials, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, and collaborations or licensing arrangements. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If additional funding is required, there can be no assurance that additional funds will be available to us on acceptable terms on a timely basis, if at all. If we are unable to raise capital, we will need to curtail planned activities to reduce costs. Doing so will likely have an unfavorable effect on our ability to execute our business plans.

The following table summarizes our cash flows for the periods indicated:

	<u>Six Months Ended June 30,</u>	
	<u>2018</u>	<u>2017</u>
Net cash used in operating activities	\$ (17,087)	\$ (2,139)
Net cash used in investing activities	(74,847)	(51)
Net cash provided by financing activities	89,938	5,500
Net (decrease) increase in cash and cash equivalents	<u>\$ (1,996)</u>	<u>\$ 3,310</u>

Cash Flows from Operating Activities

Cash used in operating activities for the six months ended June 30, 2018 was \$17.1 million, consisting of a net loss of \$23.5 million adjusted for noncash items including stock-based compensation expense of \$1.6 million. The change in our net operating assets and liabilities from the six months ended June 30, 2018 were due primarily to an increase in accounts payable and accrued liabilities of \$5.9 million primarily due to increased clinical activities and \$0.5 million received from the Silverstein Foundation, which were partially offset by an increase in prepaid expenses and other current assets of \$1.6 million due to prepayments for our research and development activities. Cash used in operating activities for the six months ended June 30, 2017 was \$2.1 million, consisting of a net loss of \$7.4 million adjusted for noncash items including stock-based compensation expense of \$0.2 million and expense related to the acquisition of intellectual property of \$3.2 million. The change in our net operating assets and liabilities from the six months ended June 30, 2017 were due primarily to an increase in accounts payable and accrued liabilities of \$2.7 million primarily due to increased clinical activities, which were partially offset by an increase in prepaid expenses and other current assets of \$0.8 million due to prepayments for our research and development activities.

Cash Flows from Investing Activities

Cash used in investing activities for the six months ended June 30, 2018 was \$74.8 million and consisted primarily of the purchases of marketable securities. Cash used in investing activities for the six months ended June 30, 2017 was \$51,000 and consisted of the purchases of property and equipment.

Cash Flows from Financing Activities

Cash provided by financing activities for the six months ended June 30, 2018 was \$89.9 million from the proceeds from the IPO, net of issuance costs paid in 2018. Cash provided by financing activities for the six months ended June 30, 2017 was \$5.5 million from the issuance of redeemable convertible preferred stock.

Contractual Obligations and Other Commitments

The disclosure of our contractual obligations and commitments was reported in our Annual Report on Form 10-K for the year ended December 31, 2017. There have been no material changes from the contractual commitments and obligations previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017, as updated by our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018.

Off-Balance Sheet Arrangements

We did not have during the previous periods, and we do not currently have, any off-balance sheet arrangements as defined under the rules and regulations of the Securities and Exchange Commission and do not have any holdings in variable interest entities.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Accrued Research and Development Costs

We accrue for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies, clinical trials, and contract manufacturing activities. We record the estimated costs of research and development activities based upon the estimated amount of services provided, and include these costs in accrued liabilities in our consolidated balance sheets and within research and development expenses in our consolidated statements of operations. These costs are a significant component of our research and development expenses. We estimate the amount of work completed through discussions with internal personnel and external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed, the number of patients enrolled and the rate of patient enrollment may vary from our estimates and could result in us reporting amounts that are too high or too low in any particular period. Our accrued expenses are dependent, in part, upon the receipt of timely and accurate reporting from CROs, CMOs and other third-party service providers. To date, there have been no material differences from our accrued expenses to actual expenses.

Research and Development Costs

Research and development costs are expensed as incurred and consist of personnel costs, lab supplies and other costs, as well as fees paid to third parties to conduct research and development activities on our behalf.

Amounts incurred in connection with license agreements are also included in research and development expenses. We record payments made to outside vendors for services performed or goods being delivered for use in research and development activities as either prepaid expenses or accrued expenses, depending on the timing of when services are performed or goods are delivered.

Recently Issued and Adopted Accounting Pronouncements

In May 2017, the FASB issued ASU 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting*, or ASU 2017-09. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The guidance is effective for annual periods beginning after December 15, 2017, with early adoption permitted, including adoption in any interim period for which financial statements have not yet been issued. We adopted the provisions of ASU 2017-09 on January 1, 2018. No modifications of share-based payment awards have occurred as of June 30, 2018.

In February 2016, the FASB issued ASU 2016-02, *Leases (“ASU 2016-02”)*, which requires a lessee to recognize a right-of-use asset and a lease liability for operating leases, initially measured at the present value of the future lease payments, in the balance sheet. ASU 2016-02 also requires a lessee to recognize a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. This new guidance is effective for fiscal years beginning after December 15, 2019. Early adoption is permitted. We are currently evaluating the potential effects of adopting the provisions of ASU 2016-02 on our consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows*, or ASU 2016-18, which requires that amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2018 and should be applied using a retrospective transition method to each period presented. Early adoption is permitted. We do not expect the impact of ASU 2016-18 to be material to our consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, *Accounting for Certain Financial Instruments with Down Round Features*, or ASU 2017-11, which updates the guidance related to the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. Under ASU 2017-11, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity’s own stock. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity classified financial instruments, the amendments require entities that present earnings per share, or EPS, in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. ASU 2017-11 is effective for public entities for all annual and interim periods beginning after December 15, 2019. Early adoption is permitted. We do not expect the impact of ASU 2017-11 will be material to our consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of June 30, 2018, we had cash, cash equivalents and marketable securities of \$125.9 million, primarily comprised of money market mutual funds consisting of U.S. government-backed securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term marketable securities. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

We contract with contract research organizations and contract manufacturers globally. We may be subject to fluctuations in foreign currency rates in connection with certain of these agreements. Transactions denominated in currencies other than the United States dollar are recorded based on exchange rates at the time such transactions arise. We have not engaged in the hedging of our foreign currency transactions to date, we are evaluating the costs and benefits of initiating such a program and may in the future hedge selected significant transactions denominated in currencies other than the U.S. dollar as we expand our international operation and our risk grows. As of June 30, 2018, substantially all of our total liabilities were denominated in the U.S. dollar.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three and six months ended June 30, 2018.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

The Company has established disclosure controls and procedures (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Securities Exchange Act of 1934, as amended, or Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and is accumulated and communicated to management, including the principal executive officer (our Chief Executive Officer) and principal financial officer (our Vice President, Finance), to allow timely decisions regarding required disclosure.

The Company's management, with the participation of the Company's Chief Executive Officer and Vice President, Finance, evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures have been designed to provide reasonable assurance of achieving their objectives. Based on such evaluation, the Company's Chief Executive Officer and Vice President, Finance concluded that the Company's disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2018.

Changes in Internal Control over Financial Reporting

There was no other change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended June 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 1. Legal Proceedings.

From time to time, we may be involved in lawsuits, claims, investigations and proceedings, consisting of intellectual property, commercial, employment and other matters which arise in the ordinary course of business. While the outcome of any such proceedings cannot be predicted with certainty, as of June 30, 2018, we were not party to any legal proceedings that we would expect to have a material adverse impact on our financial position, results of operations or cash flow.

Item 1A. Risk Factors.

You should consider carefully the following risk factors, together with those set forth in Part I, Item 1A in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, and in all of the other information included or incorporated in this report. The following risk factors represent new risk factors or those containing changes, including material changes, to the risk factors set forth in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2017. If any of the previously identified or following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

We depend on the successful initiation and completion of clinical trials for RTB101 alone or in combination with everolimus. The positive clinical results, if any, obtained in prior or ongoing clinical trials may not be predictive of future results or repeated in later-stage clinical trials.

Before obtaining regulatory approval for the sale of RTB101, alone or in combination with everolimus, or any other potential product candidate, we must conduct additional clinical trials to demonstrate safety and efficacy in humans. The regulatory requirements for demonstrating efficacy and safety for obtaining approval for reducing the incidence of RTIs or other indications with RTB101 alone or in combination with everolimus may differ. We have not completed the clinical trials necessary to support an application for approval to market RTB101 alone or in combination with everolimus. Successful completion of such clinical trials is a prerequisite to submitting an NDA to the FDA and, consequently, the ultimate approval and commercial marketing of RTB101 alone or in combination with everolimus or any other potential product candidate. A failure of one or more clinical trials can occur at any stage of testing. We need to complete our ongoing Phase 2b clinical trial of RTB101 alone and in combination with everolimus, and subsequently the requisite Phase 3 clinical trials prior to a submission for regulatory approval. We have conducted limited safety studies in humans to date and have only recently announced top-line data from our Phase 2b clinical program to assess the safety, tolerability and efficacy of RTB101, alone or in combination with everolimus, in elderly patients. While we observed activity signals of RTB101 in this clinical trial in certain cohorts, not all cohorts that we investigated responded to RTB101 treatment, alone or in combination with everolimus. Additional toxicity and metabolism studies may be required by the FDA or other regulatory agencies. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in late stage clinical development, even after seeing promising results in earlier clinical trials.

We may experience a number of unforeseen events during, or as a result of, clinical trials for RTB101, alone or in combination with everolimus, or any other potential product candidate that could adversely affect the costs, timing, or successful completion of our clinical trials, including:

- regulators or other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators, and/or institutional review boards or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of RTB101, alone or in combination with everolimus, or any other potential product candidate may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of subjects or patients required for clinical trials of RTB101, alone or in combination with everolimus, or any other potential product candidate may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of RTB101, alone or in combination with everolimus, or any other potential product candidate for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocol submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to resubmit to an Institutional Review Board, or IRB, and regulatory authorities for re-examination;
- regulators, institutional review boards or data monitoring committees may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials of RTB101, alone or in combination with everolimus, or any other potential product candidate may be greater than we anticipate;
- regulators, institutional review boards or other reviewing bodies may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, or the supply or quality of RTB101, everolimus or the fixed dose combination of RTB101 and everolimus or any other potential product candidate or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval; and
- RTB101, alone or in combination with everolimus, or any other potential product candidate may have undesirable side effects or other unexpected characteristics.

Regulators, institutional review boards of the institutions in which clinical trials are being conducted or data monitoring committees may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Negative or inconclusive results from our clinical trials of RTB101 alone and in combination with everolimus, or any other clinical trial or preclinical studies in animals that we conduct, could mandate repeated or additional clinical trials. We do not know whether any clinical trials that we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market RTB101, alone or in combination with everolimus, or any other potential product candidate. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for RTB101, alone or in combination with everolimus, or any other potential product candidate may be adversely impacted. For example, in a top-line analysis of our Phase 2b clinical trial, we observed that treatment with RTB101 10 mg once daily resulted in a 30.6% decrease in the percentage of patients who developed one or more laboratory-confirmed RTIs as compared to placebo. No decrease was observed in the percentage of patients who developed one or more laboratory-confirmed RTIs in the RTB101 10 mg twice daily cohort or the combination therapy cohort, as compared to placebo. We intend to conduct an end of Phase 2 meeting with the FDA in the fourth quarter of 2018.

Clinical trials must be conducted in accordance with the laws and regulations of the FDA, EMA and regulations and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental

agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under current good manufacturing practice, or cGMP, requirements and other regulations. Furthermore, we rely on CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States and EU may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. and non-EU CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA or the EMA, and different standards of diagnosis, screening and medical care.

We may be subject to additional risks because we are administering RTB101 in combination with other mTOR inhibitors, such as everolimus.

We are evaluating RTB101 in combination with other mTOR inhibitors. The use of RTB101 in combination with other compounds may subject us to risks that we would not face if RTB101 were being administered as a monotherapy. For example, the other mTOR inhibitors, including everolimus, may have safety issues that are improperly attributed to RTB101 or the administration of RTB101 with such other therapies may result in safety issues that such other therapies or RTB101 would not have when used alone. In addition, other mTOR inhibitors with which we may administer RTB101, such as everolimus, could be removed from the market and thus be unavailable for testing or commercial use concomitantly with RTB101. The outcome and cost of developing a product candidate to be used with other compounds is difficult to predict and dependent on a number of factors that are outside our reasonable control. If we experience efficacy or safety issues in our clinical trials in which RTB101 is being administered with everolimus, we may not receive regulatory approval for RTB101, which could prevent us from ever generating revenue or achieving profitability.

The regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable. If clinical trials of RTB101, alone or in combination with everolimus, fail to satisfactorily demonstrate safety and efficacy to the FDA or other regulators, or do not otherwise produce favorable results, we, or any future collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of RTB101 alone or in combination with everolimus.

We, and any future collaborators, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities, such as the EMA, impose similar requirements. The time required to obtain approval by the FDA, EMA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date, we have not submitted an NDA to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for RTB101, alone or in combination with everolimus, or any other product candidate. We, and any future collaborators, must complete additional preclinical or nonclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of RTB101 alone or in combination with everolimus or other drugs is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements, and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if RTB101, alone or in combination with everolimus, or any other product candidate has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the seasonal and geographical RTI rates and size, duration, design, measurements, conduct or analysis of our clinical trials.

Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of RTB101, alone or in combination with everolimus, or any other product candidate that is greater than the actual positive effect, if any. For example, in a top-line analysis of our Phase 2b clinical trial, we observed that certain cohorts responded better to study drug treatment than others, and that certain cohorts did not respond at all. Similarly, in our clinical trials we may fail to detect toxicity of or intolerability caused by RTB101, everolimus or any other product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us, or any future collaborators. Moreover, if we, or any future collaborators, are required to conduct additional clinical trials or other testing of RTB101, alone or in combination with everolimus, or any other product candidate beyond the trials and testing that we or they contemplate, if we or they are unable to successfully complete clinical trials of our product candidates or other testing or the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or there are unacceptable safety concerns associated with our product candidates, we, or any future collaborators may:

- incur additional unplanned costs;
- be delayed in obtaining regulatory approval for our product candidates;
- not obtain regulatory approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- be required to remove the product from the market after obtaining regulatory approval.

Our failure to successfully initiate and complete clinical trials of RTB101, alone or in combination with everolimus, or any other product candidate and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market RTB101, alone or in combination with everolimus, or any other product candidate would significantly harm our business. Our product candidate development costs will also increase if we experience delays in testing or regulatory approvals and we may be required to obtain additional funds to complete clinical trials. We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of RTB101 alone or in combination with everolimus or any other product candidate.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained.

Undesirable side effects caused by RTB101, alone or in combination with everolimus, or any other product candidate could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In clinical trials of RTB101, alone or in combination with everolimus, to date, there were no observed study drug-related serious adverse events in the Phase 2a clinical trial except in the placebo arm. In the Phase 2b clinical trial, 4.5% of subjects in the RTB101 10 mg once daily cohort had a serious adverse event, none of which were related to the study drug, though 4.5% of subjects in that arm discontinued the study drug due to an adverse event. The majority of observed study-drug related adverse events were mild or moderate in severity, transient and resolved without stopping the study drug. However, there can be no guarantee that we would observe a similar tolerability profile of RTB101, alone or in combination with everolimus in future clinical trials. Many compounds that initially showed promise in clinical or earlier stage testing are later found to cause undesirable or unexpected side effects that prevented further development of the compound.

If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, or the Data Safety Monitoring Board, or DSMB, could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-emergent side effects that are deemed to be treatment-related could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, clinical trials of our product candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse consequences could occur:

- regulatory authorities may withdraw their approval of the product, seize the product, or seek an injunction against its manufacture or distribution;
- we, or any future collaborators, may need to recall the product, or be required to change the way the product is administered or conduct additional clinical trials, develop a surveillance program;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- regulatory authorities may require one or more post-market studies;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could harm our business and operations, and could negatively impact our stock price.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of Proceeds from Initial Public Offering of Common Stock

On January 30, 2018, we closed our initial public offering, in which we issued and sold 5,666,667 shares of common stock at a public offering price of \$15.00 per share, and issued an additional 850,000 shares of common stock at a price of \$15.00 per share pursuant to the exercise of the underwriters’ over-allotment option. All of the shares of common stock issued and sold in our initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (Registration No. 333-222373), which was declared effective by the SEC on January 25, 2018. BofA Merrill Lynch, Leerink Partners, and Evercore ISI acted as joint book-running managers for the offering. Wedbush PacGrow acted as a co-manager for the offering. The aggregate gross proceeds to us from our initial public offering, inclusive of the over-allotment exercise, were \$97.8 million. The offering commenced on January 25, 2018, and did not terminate until the sale of all shares offered.

The aggregate net proceeds to us from the public offering, inclusive of the over-allotment exercise, were approximately \$89.4 million, after deducting underwriting discounts and commissions and offering expenses payable by us of approximately \$8.4 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates.

As of June 30, 2018, we estimate that we have used approximately \$17.0 million of our existing cash and cash equivalents at the time of the initial public offering, together with the net proceeds from our initial public offering, to advance our product candidates through clinical trial programs and for working capital and general corporate purposes.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report are set forth on the Exhibit Index, which is incorporated herein by reference.

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended
32.1+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

+ The certifications furnished in Exhibit 32.1 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

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 thereunto duly authorized.

RESTORBIO, INC.

Date: August 9, 2018

By: _____
/s/ Chen Schor
Chen Schor
President and Chief Executive Officer
(Principal executive officer)

Date: August 9, 2018

By: _____
/s/ John J. McCabe
John J. McCabe
Vice President, Finance
(Principal financial and accounting officer)

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES
EXCHANGE ACT OF 1934, AS AMENDED**

I, Chen Schor, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of resTORbio, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Chen Schor

Chen Schor
President and Chief Executive Officer
(Principal Executive Officer)

Dated: August 9, 2018

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) / RULE 15d-14(a) OF THE SECURITIES
EXCHANGE ACT OF 1934, AS AMENDED**

I, John J. McCabe, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of resTORbio, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ John J. McCabe

John J. McCabe

Vice President, Finance

(Principal Financial and Accounting Officer)

Dated: August 9, 2018

CERTIFICATIONS OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of resTORbio, Inc. (the "Company") for the quarter ended June 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned hereby certify, pursuant to 18 U.S.C. Section 1350, that, to the best of their knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Chen Schor

Chen Schor

President and Chief Executive Officer

(Principal Executive Officer)

Dated: August 9, 2018

/s/ John J. McCabe

John J. McCabe

Vice President, Finance

(Principal Financial and Accounting Officer)

Dated: August 9, 2018