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 September 30, 2019

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	**81-3305277**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
500 Boylston Street, 13th Floor Boston, MA	**02116**
(Address of principal executive offices)	**(Zip Code)**

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	TORC	The Nasdaq Global Select Market

Indicate by check mark whether the registrant (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 every Interactive Data File required to be submitted 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 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller 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 November 1, 2019, the registrant had 36,443,631 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 rapalogs, such as everolimus or sirolimus, and other product candidates for the targeted indications and patient populations, including the therapeutic potential and clinical benefits thereof;
- our ongoing and future clinical trials for RTB101 alone or in combination with rapalogs, such as everolimus or sirolimus, whether conducted by us or by any future collaborators;
- the timing of initiation and the anticipated results of our ongoing and future clinical trials for RTB101 alone or in combination with rapalogs, such as everolimus or sirolimus;
- 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 cash, cash equivalents and marketable securities;
- 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)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 23,621	$ 7,042
Marketable securities	93,641	100,986
Prepaid expenses	3,998	1,491
Other current assets	21	15
Total current assets	121,281	109,534
Restricted cash	245	84
Property and equipment, net	437	321
Total assets	$ 121,963	$ 109,939
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,973	$ 2,989
Accrued liabilities	2,220	2,727
Total current liabilities	12,193	5,716
Other liabilities	6	19
Total liabilities	12,199	5,735
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $0.0001 par value, 150,000,000 shares authorized as of September 30, 2019 and December 31, 2018; 36,443,631 and 28,055,344 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively; 36,443,631 and 28,054,344 shares vested as of September 30, 2019 and December 31, 2018, respectively	4	3
Additional paid-in capital	234,893	175,635
Accumulated deficit	(125,242)	(71,393)
Accumulated other comprehensive gain (loss)	109	(41)
Total stockholders' equity	109,764	104,204
Total liabilities and stockholders' equity	$ 121,963	$ 109,939

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 22,118	$ 6,765	$ 47,523	$ 26,716
General and administrative	3,043	2,267	8,498	6,629
Total operating expenses	25,161	9,032	56,021	33,345
Loss from operations	(25,161)	(9,032)	(56,021)	(33,345)
Other income, net	725	625	2,203	1,488
Loss before income taxes	(24,436)	(8,407)	(53,818)	(31,857)
Income tax expense	12	—	31	—
Net loss	$ (24,448)	$ (8,407)	$ (53,849)	$ (31,857)
Net loss per share, basic and diluted	$ (0.68)	$ (0.30)	$ (1.51)	$ (1.23)
Weighted-average common shares used in computing net loss per share, basic and diluted	36,217,040	28,046,723	35,585,980	25,895,933
Other comprehensive gain (loss):				
Net loss	$ (24,448)	$ (8,407)	$ (53,849)	$ (31,857)
Unrealized (loss) gain on marketable securities	(61)	(46)	150	(76)
Comprehensive loss	$ (24,509)	$ (8,453)	$ (53,699)	$ (31,933)

See accompanying notes to these condensed consolidated financial statements.

resTORbio, Inc.
Condensed Consolidated Statement of Stockholders' Equity
(Unaudited)
(In thousands, except share data)

	Common Stock		Additional Paid In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Shareholders Equity
	Shares	Amount				
Balance at December 31, 2018	28,054,344	$ 3	$ 175,635	$ (71,393)	$ (41)	$ 104,204
Issuance of common stock upon closing of public offering, net of issuance costs of $3,455	7,200,000	1	46,584	—	—	46,585
Vesting of restricted shares	500	—	1	—	—	1
Stock-based compensation expense	—	—	662	—	—	662
Net loss	—	—	—	(11,069)	—	(11,069)
Unrealized gain on marketable securities	—	—	—	—	73	73
Balance at March 31, 2019	35,254,844	4	222,882	(82,462)	32	140,456
Issuance of common stock upon closing of public offering, net of issuance costs of $228	487,934	—	3,163	—	—	3,163
Issuance of common stock pursuant to the at-the-market offering, net of issuance costs of $64	62,663	—	582	—	—	582
Vesting of restricted shares	500	—	—	—	—	—
Vesting of restricted stock units, net of shares withheld for taxes	4,423	—	(15)	—	—	(15)
Exercise of stock options	7,029	—	6	—	—	6
Stock-based compensation expense	—	—	944	—	—	944
Net loss	—	—	—	(18,332)	—	(18,332)
Unrealized gain on marketable securities	—	—	—	—	138	138
Balance at June 30, 2019	35,817,393	4	227,561	(100,794)	170	126,941
Issuance of common stock pursuant to the at-the-market offering, net of issuance costs of $221	625,137	—	6,135	—	—	6,135
Vesting of restricted stock units, net of shares withheld for taxes	1,101	—	(5)	—	—	(5)
Stock-based compensation expense	—	—	1,202	—	—	1,202
Net loss	—	—	—	(24,448)	—	(24,448)
Unrealized loss on marketable securities	—	—	—	—	(61)	(61)
Balance at September 30, 2019	36,443,631	$ 4	$ 234,893	$ (125,242)	$ 109	$ 109,764

See accompanying notes to these condensed consolidated financial statements.

resTORbio, Inc.
Condensed Consolidated Statement of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(Unaudited)
(In thousands, except share data)

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Common Stock		Additional Paid In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Shareholders Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2017	15,527,951	$ 41,674	4,792,716	$ 39,946	4,562,640	$ 1	$ 1,849	$ (33,779)	$ —	$ (31,929)
Conversion of convertible preferred stock into common stock upon the closing of initial public offering	(15,527,951)	(41,674)	(4,792,716)	(39,946)	15,870,559	1	81,619	—	—	81,620
Issuance of common stock upon closing of initial public offering, net of issuance costs of $8,379	—	—	—	—	6,516,667	1	89,369	—	—	89,370
Vesting of restricted shares	—	—	—	—	1,096,449	—	865	—	—	865
Stock-based compensation expense	—	—	—	—	—	—	316	—	—	316
Net loss	—	—	—	—	—	—	—	(9,859)	—	(9,859)
Balance at March 31, 2018	—	—	—	—	28,046,315	3	174,018	(43,638)	—	130,383
Stock-based compensation expense	—	—	—	—	—	—	402	—	—	402
Net loss	—	—	—	—	—	—	—	(13,591)	—	(13,591)
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	(30)	(30)
Balance at June 30, 2018	—	—	—	—	28,046,315	3	174,420	(57,229)	(30)	117,164
Vesting of restricted shares	—	—	—	—	500	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	629	—	—	629
Net loss	—	—	—	—	—	—	—	(8,407)	—	(8,407)
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	(46)	(46)
Balance at September 30, 2018	—	$ —	—	$ —	28,046,815	$ 3	$ 175,049	$ (65,636)	$ (76)	$ 109,340

See accompanying notes to these condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2019	2018
Operating activities:		
Net loss	$ (53,849)	$ (31,857)
Adjustments to reconcile net loss to net cash used in operating activities:		
Accretion on marketable securities	(901)	(305)
Depreciation and amortization expense	90	55
Loss on disposal of property and equipment	35	—
Stock-based compensation expense	2,808	2,212
Changes in operating assets and liabilities:		
Restricted cash	(161)	(84)
Prepaid expenses and other current assets	(2,513)	(769)
Accounts payable	6,975	2,807
Accrued liabilities	(507)	(386)
Funding advance	—	500
Other liabilities	(13)	22
Net cash used in operating activities	(48,036)	(27,805)
Investing activities:		
Purchases of property and equipment	(241)	(333)
Maturities of marketable securities	105,500	—
Purchases of marketable securities	(97,104)	(92,293)
Net cash provided by (used in) investing activities	8,155	(92,626)
Financing activities:		
Proceeds from public offering, net of issuance costs	49,748	89,938
Proceeds from at-the-market offering, net of issuance costs	6,726	—
Taxes paid related to net share settlement of restricted stock units	(20)	—
Proceeds from exercising stock options	6	—
Net cash provided by financing activities	56,460	89,938
Net increase (decrease) in cash and cash equivalents	16,579	(30,493)
Cash and cash equivalents at beginning of period	7,042	53,349
Cash and cash equivalents at end of period	$ 23,621	$ 22,856
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable	$ —	$ 2
Conversion of redeemable convertible preferred stock into common stock	$ —	$ 81,620
Issuance costs associated with at-the-market offering included in accounts payable	$ 9	$ —

See accompanying notes to these condensed consolidated financial statements.

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 developing innovative medicines that target the biology of aging to prevent or treat aging-related diseases. 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, product liability, and dependence on third parties and key individuals.

Public Offering

On March 22, 2019, the Company completed an underwritten public offering, whereby the Company sold 7,200,000 shares of its common stock at a price of $6.95 per share. The aggregate net proceeds received by the Company from the offering were approximately $46.6 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company of $3.5 million. In addition, the Company granted the underwriters a 30-day option to purchase up to an additional 1,080,000 shares of common stock at the public offering price, less underwriting discounts and commissions. On April 10, 2019, the Company sold an additional 487,934 shares of its common stock at a price of $6.95 per share. The aggregate net proceeds received by the Company were approximately $3.2 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company of $0.2 million. The remainder of the option expired unexercised.

At-the-Market Offering

On February 1, 2019, the Company filed a Registration Statement on Form S-3 (the "Shelf") with the Securities and Exchange Commission (the "SEC") in relation to the registration of common stock, preferred stock, warrants and/or units of any combination thereof (collectively, the "Securities"). The Company also simultaneously entered into a Controlled Equity Offering Sales Agreement (the "Sales Agreement") with SVB Leerink LLC and Cantor Fitzgerald & Co. (collectively, the "Sales Agents"), to provide for the offering, issuance and sale by the Company of up to an aggregate of $50.0 million of its common stock from time to time in "at-the-market" offerings under the Shelf and subject to the limitations thereof. The Company will pay to the Sales Agents cash commissions of 3.0 percent of the gross proceeds of sales of common stock under the Sales Agreement. Beginning in June 2019 through September 30, 2019, based on settlement date, the Company sold approximately 688,000 shares of common stock at a weighted-average selling price of $10.18 per share in accordance with the Sales Agreement for aggregate net proceeds of $6.7 million, after payment of cash commissions of 3.0 percent of the gross proceeds to the Sales Agent and incurred issuance costs of approximately $75,000 related to legal, accounting, and other fees in connection with the sale. As of September 30, 2019, $43.0 million remained available for sale under the Sales Agreement.

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 $125.2 million as of September 30, 2019. As of September 30, 2019, the Company had $117.3 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 from the date of filing this Quarterly Report on Form 10-Q.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements are unaudited. The unaudited condensed consolidated 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 September 30, 2019 and the results of operations and cash flows for the interim periods ended September 30, 2019 and 2018. 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, 2018 that was filed with the Securities and Exchange Commission ("SEC") on March 18, 2019 (the "2018 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, 2018, and the notes thereto, which are included in the 2018 Form 10-K. There have been no material changes in the Company's significant accounting policies during the three and nine months ended September 30, 2019.

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 September 30, 2019 (in thousands):

Description	September 30, 2019	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Cash	$ 8	$ 8	$ —	$ —
Money market funds (included in cash and cash equivalents)	23,613	23,613	—	—
U.S. treasury securities (included in marketable securities)	93,641	93,641	—	—
Total	$ 117,262	$ 117,262	$ —	$ —

The following table summarizes assets measured at fair value on a recurring basis at December 31, 2018 (in thousands):

Description	December 31, 2018	Active Markets (Level 1)	Observable Inputs (Level 2)	Unobservable Inputs (Level 3)
Money market funds (included in cash and cash equivalents)	$ 6,804	$ 6,804	$ —	$ —
U.S. treasury securities (included in cash and cash equivalents)	238	238	—	—
U.S. treasury securities (included in marketable securities)	100,986	100,986	—	—
Total	$ 108,028	$ 108,028	$ —	$ —

There have been no changes to the valuation methods utilized by the Company during the three and nine months ended September 30, 2019 and 2018. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of financial instruments between levels during the three and nine months ended September 30, 2019 and 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 adoption of this standard is expected to have an impact on the amount of the Company's assets and liabilities presented. The Company expects to utilize the new transition method described in ASU No. 2018-11 and use the effective date as the Company's date of initial application for the new standard. The Company expects to elect the available package of practical expedients in transition which would allow it to not re-assess whether existing or expired arrangements contain a lease, the lease classification of existing or expired leases, or whether previous initial direct costs would qualify for capitalization under the new lease standard. As of September 30, 2019, the Company has not elected to early adopt the guidance or determined the effect that the adoption of this guidance will have 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. For non-public entities and emerging growth companies that choose to take advantage of the extended transition period, 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. The Company expects to adopt the new standard as of December 31, 2019 and 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. For non-public entities and emerging growth companies that choose to take advantage of the extended transition period, 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.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"), which intends to simplify aspects of share-based compensation issued to non-employees by making the guidance consistent with the accounting for employee share-based compensation. For public entities, ASU 2018-07 is required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. For non-public entities and emerging growth companies that choose to take advantage of the extended transition period, ASU 2018-07 is effective for annual periods beginning after December 15, 2019. Early adoption is permitted for all entities but no earlier than the Company's adoption of ASU No. 2016-10, *Revenue from Contracts with Customers* ("ASC 606"). The Company is currently evaluating the impact that the adoption of ASU 2018-07 will have on its consolidated financial statements.

3. Marketable Securities

As of September 30, 2019, 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	$ 93,532	$ 109	$ —	$ 93,641
Total	$ 93,532	$ 109	$ —	$ 93,641

As of December 31, 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	$ 101,027	$ —	$ (41)	$ 100,986
Total	$ 101,027	$ —	$ (41)	$ 100,986

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

	September 30, 2019	
	Amortized Cost	Fair Value
Due in one year or less	$ 93,532	$ 93,641
Total	$ 93,532	$ 93,641

	December 31, 2018	
	Amortized Cost	Fair Value
Due in one year or less	$ 101,027	$ 100,986
Total	$ 101,027	$ 100,986

4. Property and equipment, net

Property and equipment, net consists of the following:

	September 30, 2019	December 31, 2018
	(In thousands)	
Leasehold improvements	$ —	$ 65
Machinery and equipment	38	38
Furniture and fixtures	397	194
Computers	111	76
Office equipment	11	11
Software	22	22
Total property and equipment	579	406
Less: accumulated depreciation and amortization	(142)	(85)
Property and equipment, net	$ 437	$ 321

Depreciation and amortization expense was $34,000 and $90,000 for the three and nine months ended September 30, 2019, respectively. Depreciation and amortization expense was $24,000 and $55,000 for the three and nine months ended September 30, 2018, respectively.

5. Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2019	December 31, 2018
	(In thousands)	
Accrued payroll and related expenses	$ 1,533	$ 1,189
Accrued research and development expenses	514	1,028
Other	173	510
Total accrued liabilities	$ 2,220	$ 2,727

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.

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

Milestone payments to Novartis are recorded as research and development expenses in the condensed consolidated statements of operations once achievement of each associated milestone 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 payment in May 2017. In May 2019, the Company initiated a Phase 3 clinical trial for the first indication, triggering another milestone payment of $2.5 million under the agreement. As of September 30, 2019, none of the remaining clinical milestones, regulatory milestones, sales milestones, or royalties is probable.

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, 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 and comprehensive loss 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 no obligations to deliver specified products or technology.

For funds received under the Funding Agreement, 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. No qualifying expenses were incurred during the three and nine months ended September 30, 2019 and 2018. As of September 30, 2019, $0.5 million qualifying expenses have been incurred. Therefore, all amounts received have been recorded as a reduction of the research and development expense.

8. Preferred Stock and Common Stock

As of September 30, 2019, the Company had 10,000,000 shares of preferred stock and 150,000,000 shares of common stock authorized. None of the authorized preferred stock and 36,443,631 shares of common stock were issued and outstanding as of September 30, 2019.

Reserve for future issuance

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

	September 30, 2019	December 31, 2018
Options issued and outstanding	2,285,322	1,122,677
Unvested restricted stock units	17,160	24,960
Options available for future grants	1,303,121	1,350,582
Shares available for issuance under the 2018 ESPP	555,583	275,030
Total	4,161,186	2,773,249

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 were 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 initial public offering completed in January 2018, 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 were initially reserved for issuance under the 2018 Plan were 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. On January 1, 2019, as a result of the foregoing evergreen provision, the number of shares of common stock available for issuance under the 2018 Plan automatically increased from 2,200,260 to 3,322,473 shares.

Since the date of effectiveness of the 2018 Plan, the Company has not and 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 condensed consolidated statements of operations as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 633	$ 229	$ 1,409	$ 955
General and administrative	569	400	1,399	1,257
Total stock-based compensation expense	$ 1,202	$ 629	$ 2,808	$ 2,212

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, 2018	1,350,582	1,122,677	$ 11.63	9.22	
Shares reserved for issuance	1,122,213				
Options granted	(1,286,524)	1,286,524	8.66		
Options exercised	—	(7,029)	0.79		
Options cancelled	116,850	(116,850)	10.25		
Outstanding, September 30, 2019	1,303,121	2,285,322	10.05	9.05	$ 1,360
Exercisable, September 30, 2019		373,574	11.40	8.33	387
Vested and expected to vest, September 30, 2019		2,285,322	8.63	9.05	1,360

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 September 30, 2019. A total of 7,029 options were exercised for cash proceeds of approximately $6,000 during the nine months ended September 30, 2019.

During the nine months ended September 30, 2019, the Company granted options to employees and directors to purchase an aggregate of 1,276,684 common shares with a weighted-average grant date fair value of $6.69 per share. During the nine months ended September 30, 2019, the Company granted options to non-employees to purchase an aggregate of 9,840 common shares with a weighted-average grant date fair value of $7.61 per share. The expense related to options granted to employees and directors for the three and nine months ended September 30, 2019 was $1.2 million and $2.7 million, respectively. The expense related to options granted to non-employees for the three and nine months ended September 30, 2019 was $18,000 and $66,000, respectively. The expense related to options granted to employees and directors was $0.6 million and $1.2 million for the three and nine months ended September 30, 2018, respectively. The expense related to options granted to non-employees was $37,000 and $64,000, for the three and nine months ended September 30, 2018, respectively.

As of September 30, 2019, the total unrecognized compensation expense related to unvested options granted to employees and directors was $12.5 million, which the Company expects to recognize over an estimated weighted-average period of 3.00 years. As of September 30, 2019, 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 2.39 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Employees and directors:				
Fair value of common stock	$9.36 - $10.66	$9.03 - $13.94	$6.97 - $10.66	$8.57 - $15.45
Expected term (in years)	6.1	5.9 - 6.1	5.5 - 6.1	5.8 - 6.6
Expected volatility	92.4% - 92.6%	89.8% - 90.6%	92.4% - 104.8%	75.9% - 90.6%
Risk-free interest rate	1.4% - 1.8%	2.8% - 2.9%	1.4% - 2.6%	2.4% - 2.9%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Non-employees:				
Fair value of common stock	$8.84 - $10.26	—	$6.82 - $10.26	$15.45
Expected term (in years)	7.7 - 9.5	—	7.7 - 10.0	10.0
Expected volatility	89.7% - 90.8%	—	89.7% - 94.2%	77.9%
Risk-free interest rate	1.7% - 1.9%	—	1.7% - 2.6%	2.7%
Expected dividend yield	0.0%	—	0.0%	0.0%

Restricted Stock

On April 17, 2018, the Company granted 2,000 shares of restricted stock to a consultant. The restrictions lapsed in four equal quarterly installments and were fully vested on the first anniversary of such grant. Compensation expenses of such unvested shares were 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, 2018	1,000
Vested	(1,000)
Unvested shares — September 30, 2019	—

The Company recognized $0 and $4,000 of stock-based compensation expense related to restricted shares during the three and nine months ended September 30, 2019, respectively. The Company recognized $11,000 and $0.9 million of stock-based compensation expense related to restricted shares during the three and nine months ended September 30, 2018, respectively. As of September 30, 2019, there was no unrecognized stock-based compensation expense related to unvested restricted stock. There were no restricted stock awards issued during the nine months ended September 30, 2019.

Restricted Stock Units

In May 2018, the Company granted 24,960 restricted stock units to an employee with a 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, 2018	24,960
Granted	—
Vested	(7,800)
Unvested shares — September 30, 2019	17,160

The Company recognized $14,000 and $42,000 of stock-based compensation expense related to restricted stock units during the three and nine months ended September 30, 2019, respectively. As of September 30, 2019, there was $0.1 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 2.64 years. There were no restricted stock units granted to employees or non-employees during the three and nine months ended September 30, 2019. The Company recognized $14,000 and $20,000 of stock-based compensation expense related to restricted stock units during the three and nine months ended September 30, 2018, respectively.

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. On January 1, 2019, as a result of the foregoing evergreen provision, the number of shares of common stock available for issuance under the 2018 ESPP automatically increased from 275,030 to 555,583 shares.

10. Commitments and Contingences

In April 2019, the Company amended its multi-year lease agreement to relocate its office space in Boston, Massachusetts under an operating lease agreement. The amended lease term is for a period of seven years from the date of relocation on August 1, 2019. The initial annual base rent of the relocation premises is $0.6 million per year, increasing 2% annually. In connection with the lease amendment, the Company issued a new cash-collateralized letter of credit for the benefit of the landlord in the amount of $0.2 million. Obligations to make future minimum lease payments are as follows (in thousands):

	Minimum Lease Payments
Remainder of 2019	$ 147
2020	594
2021	606
2022	618
2023	630
Thereafter	1,686
Total	$ 4,281

Litigation

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities as of September 30, 2019 and December 31, 2018.

11. Net Loss per Share

The Company computes basic and diluted 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 nine months ended September 30, 2019 and 2018, 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, prior to the use of the treasury stock method, 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 September 30,	
	2019	2018
Options issued and outstanding	2,285,322	667,590
Unvested restricted stock units	17,160	24,960
Total	2,302,482	692,550

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, an affiliate of Novartis, is a shareholder of the Company (See Note 6). In May 2019, the Company initiated a Phase 3 clinical trial for the first indication, triggering a milestone payment of $2.5 million under the license agreement. No other payments have been made to Novartis during the three and nine months ended September 30, 2019 and 2018.

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. The Company received $0 from the Silverstein Foundation during the nine months ended September 30, 2019 and $0 and $0.5 million during the three and nine months ended September 30, 2018, respectively.

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, 2018. 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, 2018, 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 developing innovative medicines that target the biology of aging to prevent or treat aging-related diseases. Our lead program selectively inhibits the target of rapamycin complex 1, or TORC1, an evolutionarily conserved pathway that contributes to the decline in function of multiple organ systems. Our lead product candidate, RTB101, is an oral, selective, and potent inhibitor of TORC1. RTB101 inhibits the phosphorylation of multiple targets downstream of TORC1. TORC1 inhibition has been shown to be of therapeutic benefit in multiple aging-related conditions in preclinical species including immunosenescence (aging-related decline in immune function), suggesting potential benefits in several aging-related diseases. In two Phase 2 clinical trials that enrolled more than 900 older adults, RTB101 was observed to improve immune function by upregulation of pan-antiviral gene expression and to reduce the incidence of respiratory tract infections, or RTIs. In May 2019, we initiated our Phase 3 program to evaluate the safety and efficacy of RTB101 in decreasing the percent of older adults with clinically symptomatic respiratory illness, defined as clinical symptoms consistent with an RTI based on prespecified diagnostic criteria, with or without laboratory-confirmation of a pathogen. Our PROTECTOR Phase 3 program includes two randomized, double-blind, placebo-controlled clinical trials that will evaluate RTB101 10 mg given orally once daily for 16 weeks during winter cold and flu season to adults 65 years of age and older, excluding current smokers and chronic obstructive pulmonary disease, or COPD, patients. The primary endpoint is the reduction in the percentage of subjects with clinically symptomatic respiratory illness with or without laboratory-confirmation of a pathogen. PROTECTOR 1, the first Phase 3 clinical trial, currently ongoing in the southern hemisphere has completed enrollment of 1,024 patients and we expect to announce top-line data from this Phase 3 study by early first quarter of 2020. PROTECTOR 2, the second Phase 3 clinical trial, is planned to begin in the northern hemisphere in the fourth quarter of 2019 and is expected to enroll approximately 1,600 patients. Based on current enrollment expectations for PROTECTOR 2, we expect top-line data from this study in mid-2020.

In April of 2019, we initiated a Phase 1b/2a clinical trial of RTB101 alone or in combination with sirolimus in Parkinson's disease, or PD. PD is a progressive neurodegenerative disease that affects approximately 7.5 million people worldwide. The incidence of PD increases rapidly in people 60 years of age and older, with a mean age at diagnosis of 70.5 years. Glucocerebrosidase, or GBA1, gene mutations are the most common of the currently known PD genetic mutations and up to 10 percent of people with PD in the United States carry it. Patients with PD develop shaking, rigidity, slowness of movement and difficulty walking. PD may be attributed in part to neuronal damage caused by the accumulation within neurons of abnormal aggregates containing the protein α-synuclein. Preclinical studies in mouse models of PD have shown that mTOR inhibition can induce autophagy, reduce α-synuclein accumulation and decrease neuronal cell death. Therefore, induction of autophagy with RTB101 in combination with a rapalog, such as sirolimus, may have therapeutic benefit for patients with PD. The four-week, multicenter, 2:1 randomized, double-blind, placebo-controlled Phase 1b/2a trial is evaluating the safety and tolerability of RTB101 alone or in combination with sirolimus in PD. We plan to enroll 45 patients with mild to moderate PD who are already on standard-of-care therapy, including those with and without glucocerebrosidase mutations. Patients are expected to be enrolled into five cohorts and dosed once-weekly with RTB101 300 mg alone or in combination with three dose levels of sirolimus (2 mg, 4 mg and 6 mg). The planned primary endpoint of the trial is safety and tolerability, and secondary endpoints will include exposure in blood, plasma and cerebrospinal fluid, or CSF. The planned exploratory endpoints include biomarkers in plasma and CSF, and various clinical assessments. We expect data from this trial in 2020.

The decline in immune function that occurs during aging, or immunosenescence, increases susceptibility to a variety of diseases, including RTIs, that significantly contribute to morbidity and mortality in older adults. Our initial focus is on the development of RTB101 as a first-in-class immunotherapy designed to improve immune function and thereby reduce illness associated with RTIs in older adults regardless of the causative pathogen. Our TORC1 immunotherapy approach is supported by two randomized, placebo-controlled Phase 2 clinical trials which enrolled more than 900 older adults and provided statistically significant (defined as nominal $p < 0.05$) and clinically meaningful results. In 2018, we reported results from our exploratory dose-ranging, randomized, placebo-controlled Phase 2b clinical trial in 652 elderly patients at increased risk of RTI-associated morbidity and mortality defined as aged 85 and over, or 65-84 with one or more comorbidities including: asthma, COPD, type 2 diabetes mellitus, or T2DM, or current smoker. The results from this trial demonstrated a statistically significant and clinically meaningful 30.6% reduction in the percentage of patients with one or more laboratory-confirmed RTIs, the primary endpoint of the trial, in the RTB101 10 mg once daily cohort compared to the placebo cohort. Prespecified analyses of the patient populations enrolled in the trial demonstrated (i) a statistically significant 52.1% reduction in the percentage of patients with severe laboratory-confirmed RTI symptoms in the RTB101 10 mg once daily cohort compared to the placebo cohort, (ii) a statistically significant 66.7%, 68.9%, and 25.3% reduction in the prespecified endpoint of patients 85 and older, 65 and older with asthma and 65 and older with T2DM, respectively, with one or more laboratory-confirmed RTIs in the RTB101 10 mg once daily cohort compared to the placebo cohort, and (iii) no reduction in the incidence of laboratory-confirmed RTIs in patients who were current smokers or with COPD in the RTB101 10 mg once daily cohort compared to the placebo cohort. The lack of efficacy observed in current smokers and patients with COPD is consistent with preclinical data suggesting that mTOR inhibition exacerbates cigarette smoke-induced lung inflammation in COPD. The combination of RTB101 + everolimus and the RTB101 10 mg twice daily did not meet the primary endpoint, suggesting that less TORC1 inhibition with RTB101 10 mg once daily may be more beneficial for reducing the incidence of RTIs in high risk older adults. We believe the collective results from our Phase 2a and Phase 2b clinical trials that enrolled more than 900 older adults suggest that RTB101 10 mg once daily, if successfully developed and approved, may improve the function of the aging immune system and reduce the incidence of clinically symptomatic respiratory illness in older adults. In our Phase 3 program, we are enrolling subjects 65 and older, excluding current smokers and COPD patients.

We observed additional positive results from prespecified analyses for any infection and urinary tract infections, or UTIs, in our Phase 2b trial, such as (i) a statistically significant 23.6% reduction in the percentage of patients with any infection in the RTB101 10 mg once daily cohort compared to the placebo cohort, (ii) a statistically significant 74.6% reduction in the percentage of patients with one or more UTIs in the RTB101 10 mg twice daily cohort and (iii) a 34.4% reduction in patients with one or more UTIs in the RTB101 10 mg once daily cohort. Recent scientific findings, including those published in the scientific journals *Cell*, *Nature* and *Science*, suggest that aging and aging-related conditions, such as immunosenescence, may be attributable not only to random cellular wear and tear, but also to specific intra-cellular signaling pathways, including the mTOR pathway. mTOR is a protein kinase that signals via two multiprotein complexes, known as TORC1 and TORC2. TORC1 inhibition has been observed to prolong lifespan, enhance immune function, ameliorate heart failure, enhance memory and mobility, decrease adiposity, and delay the onset of aging-related diseases in multiple animal studies. Specifically, with respect to enhanced immune function, TORC1 inhibition was observed in preclinical studies to rejuvenate blood, or hematopoietic, stem cell function, increase infection-fighting white blood cell production and enhance antibody-mediated, or adaptive, immunity. On the other hand, TORC2 inhibition has been observed to decrease lifespan in preclinical studies and cause unwanted side effects of hyperlipidemia and hyperglycemia in certain animals and humans. Therefore, based on these observations and data from more than 900 patients enrolled in our Phase 2a and Phase 2b clinical trials, we believe our TORC1 program has the potential to improve immune function and counteract immunosenescence in the elderly.

The reduced ability of older adults to effectively detect and fight infections is most commonly manifested in their susceptibility to RTIs and the negative effects such infections have on their overall health. RTIs are the fourth leading cause of hospitalization in people age 65 and over, and the eighth leading cause of death in people age 65 and over, contributing to high healthcare costs that are three to five times higher than for the older population than for the younger population. Furthermore, antibiotics, which are ineffective against viruses, are often prescribed indiscriminately to treat RTIs, which may cause side effects and contribute to the growing global problem of antibiotic resistance. As people aged 65 years and older represent the fastest growing population in the world, we believe there is significant unmet medical need for innovative therapeutic options for reducing the incidence of RTIs by improving the function of the aging immune system.

We believe our approach to addressing RTIs in older adults possesses several clinical and commercial advantages. Our TORC1 program offers an immunotherapy approach that has the potential to address a broad range of viral and bacterial pathogens. Statistically significant and clinically meaningful reductions in RTI incidence were observed in our Phase 2a and Phase 2b clinical trials with RTB101 10 mg once daily. We believe the risk-to-benefit ratio of our program observed in clinical studies to date is well-suited for the older adult population due to the following observations: our oral product candidates were well-tolerated in elderly subjects, none of the participants in the active treatment arms experienced a serious adverse event that was related to the study drug, and the doses investigated in our Phase 2b clinical trial were 60 to 240 times lower than maximum tolerated doses established in prior clinical trials for other indications. In May 2019, we initiated our Phase 3 program to evaluate the safety and efficacy of RTB101 in decreasing the percent of older adults with clinically symptomatic respiratory illness, defined as clinical symptoms consistent with an RTI based on prespecified diagnostic criteria, with or without laboratory-confirmation of a pathogen. We plan to conduct pivotal clinical trials and to seek regulatory approval for commercialization of RTB101 in the United States and Europe. Separate pivotal trials may be conducted to support potential approvals in Japan and China. In some markets, we may collaborate with third parties for the development and commercialization of our product candidates.

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 common stock. In March 2019, we completed an underwritten public offering. We received aggregate net proceeds from the offering of approximately $46.6 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. In addition, we granted the underwriters a 30-day option to purchase up to an additional 1,080,000 shares of common stock at the public offering price, less underwriting discounts and commissions. In April 2019, the underwriters exercised their option and purchased an additional 487,934 shares of common stock at a price of $6.95 per share. We received aggregate net proceeds of approximately $3.2 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. On February 1, 2019, we filed a Registration Statement on Form S-3 (the “Shelf”) with the Securities and Exchange Commission (the “SEC”) in relation to the registration of common stock, preferred stock, warrants and/or units of any combination thereof (collectively, the “Securities”). We also simultaneously entered into a Controlled Equity Offering Sales Agreement (the “Sales Agreement”) with SVB Leerink LLC and Cantor Fitzgerald & Co. (collectively, the “Sales Agents”), to provide for the offering, issuance, and sale up to an aggregate of $50.0 million of our common stock from time to time in “at-the-market” offerings under the Shelf and subject to the limitations thereof. Beginning in June 2019 through September 30, 2019, we sold approximately 688,000 shares of common stock at a weighted-average selling price of $10.18 per share in accordance with the Sales Agreement for aggregate net proceeds of $6.7 million, after payment of cash commissions of 3.0 percent of the gross proceeds to the Sales Agent and incurred issuance costs of approximately $75,000 related to legal, accounting, and other fees in connection with the sale As of September 30, 2019, $43.0 million remained available for sale under the Sales Agreement.

We have never generated revenue and have incurred significant net losses since inception. Our net losses were $37.6 million and $53.7 million, for the year ended December 31, 2018 and for the nine months ended September 30, 2019, respectively. As of September 30, 2019, we had an accumulated deficit of $125.2 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 a rapalog, such as everolimus or sirolimus, including completing our PROTECTOR Phase 3 program;
- expand our pipeline of potential product candidates, including the initiation of at least one additional proof of concept trial in an additional indication;
- require the manufacture of larger quantities of our product candidates for clinical development and potentially 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 September 30, 2019 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 International Pharmaceutical Ltd. ("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 for RTB101 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., ("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 with 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.

Milestone payments to Novartis are recorded as research and development expenses in our condensed consolidated statements of operations and comprehensive loss 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 the first indication, triggering the first milestone payment under the agreement. Accordingly, we paid the related $0.3 million payment in May 2017. In May 2019, we initiated a Phase 3 clinical trial for the first indication, triggering a milestone payment of $2.5 million under the agreement. As of September 30, 2019, none of the remaining clinical milestones, regulatory milestones, sales milestones, or royalties was probable.

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 a rapalog, such as everolimus or sirolimus.

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 expenses;
- 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 a rapalog, such as everolimus or sirolimus, 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 period 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 manufacturing, 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 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 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.

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, 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 September 30, 2019 and 2018

	Three Months Ended September 30,	
	2019	2018
	(in thousands)	
Operating expenses:		
Research and development	$ 22,118	$ 6,765
General and administrative	3,043	2,267
Total operating expenses	25,161	9,032
Loss from operations	(25,161)	(9,032)
Other income, net	725	625
Loss before income taxes	(24,436)	(8,407)
Income tax expense	12	—
Net loss	$ (24,448)	$ (8,407)

Research and Development

Research and development expenses increased to $22.1 million for the three months ended September 30, 2019, and were primarily attributable to $17.0 million of costs from third-party contract organizations and investigative clinical trial sites related to clinical trials, including the ongoing Phase 3 clinical program, $2.0 million of costs related to preclinical studies and the production of preclinical and clinical materials, $0.5 million of costs related to external consulting incurred to supplement our research and development personnel, and $2.6 million of personnel costs, including stock-based compensation. Research and development expenses were $6.8 million for the three months ended September 30, 2018 and were primarily attributable to $2.6 million of costs from third-party contract organizations and investigative clinical trial sites related to clinical trials, including the Phase 2b clinical trial, $2.7 million of costs related to preclinical studies and the production of preclinical and clinical materials, $0.4 million of costs related to external consulting incurred to supplement our research and development personnel, and $1.1 million of personnel costs, including stock-based compensation.

General and Administrative

General and administrative expenses increased to $3.0 million for the three months ended September 30, 2019, and were primarily attributable to $1.7 million of personnel, including stock-based compensation, and $1.3 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 $2.3 million for the three months ended September 30, 2018, and were primarily attributable to $1.3 million of personnel, including stock-based compensation, and $1.0 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 $0.7 million for the three months ended September 30, 2019, and primarily consisted of interest income. Other income, net was $0.6 million for the three months ended September 30, 2018, and primarily consisted of interest income.

Comparison of the nine months ended September 30, 2019 and 2018

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Operating expenses:		
Research and development	$ 47,523	$ 26,716
General and administrative	8,498	6,629
Total operating expenses	56,021	33,345
Loss from operations	(56,021)	(33,345)
Other income, net	2,203	1,488
Loss before income taxes	(53,818)	(31,857)
Income tax expense	31	—
Net loss	$ (53,849)	$ (31,857)

Research and Development

Research and development expenses increased to $47.5 million for the nine months ended September 30, 2019, and were primarily attributable to $30.6 million of costs from third-party contract organizations and investigative clinical trial sites related to clinical trials, including the ongoing Phase 3 clinical program, $6.9 million of costs related to preclinical studies and the production of preclinical and clinical materials, $1.1 million of costs related to external consulting incurred to supplement our research and development personnel, and $6.4 million of personnel costs, including stock-based compensation. In addition, in May 2019, we initiated a Phase 3 clinical trial for the first indication, triggering a milestone payment of $2.5 million under our license agreement with NIBR. Research and development expenses were $26.7 million for the nine months ended September 30, 2018 and were primarily attributable to $17.3 million of costs from third-party contract organizations and investigative clinical trial sites related to clinical trials, including the Phase 2b clinical trial, $5.6 million of costs related to preclinical studies and the production of preclinical and clinical materials, $0.7 million of costs related to external consulting incurred to supplement our research and development personnel, and $3.0 million of personnel costs, including stock-based compensation.

General and Administrative

General and administrative expenses increased to $8.5 million for the nine months ended September 30, 2019, and were primarily attributable to $4.6 million of personnel, including stock-based compensation, and $3.9 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 $6.6 million for the nine months ended September 30, 2018, and were primarily attributable to $4.0 million of personnel, including stock-based compensation, and $2.6 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.

Other Income, Net

Other income, net was $2.2 million for the nine months ended September 30, 2019, and primarily consisted of interest income. Other income, net was $1.5 million for the nine months ended September 30, 2018, and primarily consisted of interest income.

Liquidity, Capital Resources and Plan of Operations

In March 2019, we completed an underwritten public offering and received aggregate net proceeds of approximately $46.6 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. In addition, we granted the underwriters a 30-day option to purchase up to an additional 1,080,000 shares of common stock at the public offering price, less underwriting discounts and commissions. In April 2019, the underwriters exercised their option and purchased an additional 487,934 shares of common stock at a price of $6.95 per share. We received aggregate net proceeds of approximately $3.2 million, after deducting underwriting discounts and commissions and other offering expenses payable by us.

On February 1, 2019, we entered into the Sales Agreement with the Sales Agents, to provide for the offering, issuance and sale by the Company of up to an aggregate of $50.0 million of its common stock from time to time in "at-the-market" offerings under the Shelf and subject to the limitations thereof. Beginning in June 2019 through September 30, 2019, we sold approximately 688,000 shares of common stock at a weighted-average selling price of $10.18 per share in accordance with the Sales Agreement for aggregate net proceeds of $6.7 million, after payment of cash commissions of 3.0 percent of the gross proceeds to the Sales Agent and incurred issuance costs of approximately $75,000 related to legal, accounting, and other fees in connection with the sale. As of September 30, 2019, $43.0 million remained available for sale under the Sales Agreement.

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 the sale of shares of common stock and the sale of shares of our redeemable convertible preferred stock. As of September 30, 2019, we had $117.3 million in cash, cash equivalents, and marketable securities and an accumulated deficit of $125.2 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 our pivotal PROTECTOR Phase 3 program for RTB101. 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. 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:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	$ (48,036)	$ (27,805)
Net cash provided by (used in) investing activities	8,155	(92,626)
Net cash provided by financing activities	56,460	89,938
Net increase (decrease) in cash and cash equivalents	$ 16,579	$ (30,493)

Cash Flows from Operating Activities

Cash used in operating activities for the nine months ended September 30, 2019 was $48.0 million, consisting of a net loss of $53.8 million adjusted for noncash items including stock-based compensation expense of $2.8 million and accretion on marketable securities of $0.9 million. The change in our net operating assets and liabilities for the nine months ended September 30, 2019 were due primarily to an increase in accounts payable and accrued liabilities of $6.5 million and an increase in prepaid expenses and other current assets of $2.5 million primarily due to an increase in clinical activities. In addition, in connection with a lease amendment associated with our office space in Boston, we issued a new cash-collateralized letter of credit for the benefit of the landlord in the amount of $0.2 million. Cash used in operating activities for the nine months ended September 30, 2018 was $27.8 million, consisting of a net loss of $31.9 million adjusted for noncash items including stock-based compensation expense of $2.2 million. The change in our net operating assets and liabilities for the nine months ended September 30, 2018 were due primarily to an increase in accounts payable and accrued liabilities of $2.4 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 $0.8 million due to prepayments for our research and development activities.

Cash Flows from Investing Activities

Cash provided by investing activities for the nine months ended September 30, 2019 was $8.2 million and consisted of $105.5 million from maturities of marketable securities, partially offset by $97.1 million for the purchases of marketable securities and $0.2 million for the purchases of property and equipment. Cash used in investing activities for the nine months ended September 30, 2018 was $92.6 million consisted of $92.3 million for the purchases of marketable securities and $0.3 million for the purchases of property and equipment.

Cash Flows from Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2019 was $56.5 million, which consists of $49.7 million, net of issuance costs, from the proceeds from the public offering completed in March and April 2019 and $6.7 million, net of issuance costs, from the proceeds from the at-the-market sales completed from June 2019 through September 2019. Cash provided by financing activities for the nine months ended September 30, 2018 was $89.9 million from the proceeds from the IPO, net of issuance costs paid in 2018.

Contractual Obligations and Other Commitments

As a smaller reporting company, we are not required to provide the disclosure required by Item 303(a)(5) of Regulation S-K.

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 Polices and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of these condensed 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 condensed 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 condensed consolidated balance sheets and within research and development expenses in our condensed consolidated statements of operations and comprehensive loss. These costs are a significant component of our research and development expenses. We estimate the amount of work completed by third-party service providers 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. The majority of our service providers invoice in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make significant judgments and estimates in determining the accrued balance in each reporting period based on the facts and circumstances known at that time. 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

For additional information, please read Recently Issued Accounting Pronouncements in Note 2, Summary of Significant Accounting Policies of the unaudited condensed consolidated financial statements contained in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of September 30, 2019, we had cash, cash equivalents and marketable securities of $117.3 million, primarily invested in U.S. treasury securities and money market mutual funds. 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. As of September 30, 2019, 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 nine months ended September 30, 2019 and 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 September 30, 2019.

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 September 30, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

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 September 30, 2019, 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.

The matters discussed in this Quarterly Report on Form 10-Q include forward looking statements that involve risks and uncertainties. These statements are neither promises nor guarantees but are based on various assumptions by management regarding future circumstances, over many of which resTORbio has little or no control. In addition to the other information set forth in this Quarterly Report on Form 10-Q, careful consideration should be given to the risk factors in Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, and in all of the other information included or incorporated in this report. There have been no material changes to the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2018.

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 September 30, 2019, we estimate that we have used approximately $81.8 million of cash and cash equivalents since 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

Exhibit Number	Description
10.1*	Amendment No. 2 to License Agreement, dated August 20, 2019, by and between the Registrant and Novartis International Pharmaceutical Ltd.
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: November 5, 2019

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

Date: November 5, 2019

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

Amendment No. 2 to License Agreement

This Amendment No. 2 to License Agreement ("Amendment"), dated August 20, 2019 (the "Amendment Effective Date"), amends License Agreement ("Agreement"), made as of March 23, 2017, and first amended October 3, 2017, by and between Novartis International Pharmaceutical Ltd. ("Novartis") and resTORbio, Inc. ("resTORbio"). Novartis and resTORbio are each referred to individually as a "Party" and together as the "Parties."

Pursuant to the Agreement, Novartis has licensed certain intellectual property rights to resTORbio to develop, make, use, and sell products incorporating the compound known as BEZ235 by itself or BEZ235 together with the compound known as RAD001 in the Field (as defined in the Agreement). resTORbio has requested that Novartis transfer to it certain additional data arising from Novartis' prior Development (as defined in the Agreement) of BEZ235. Novartis has agreed to do so under the terms of this Amendment.

NOW, THEREFORE, in consideration of the premises and the mutual covenants set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

Section 1. Transfer of Additional Data.

Novartis will transfer the data described in *Exhibit A* to this Amendment (the "Additional Data") within 10 days after the Amendment Effective Date. The Additional Data will be deemed to be "Novartis Know How" for the purpose of this Agreement. *Notwithstanding the foregoing, the Additional Data is transferred "as is" and without representations or warranties of any kind, and Novartis disclaims any implied warranties of merchantability, fitness for a particular purpose, and/or non-infringement.* resTORbio's use of the Additional Data shall be at its own risk.

Section 2. Ratification and Confirmation.

Nothing in this Amendment is intended to alter or amend the scope of the license set forth in the Agreement or any of the Agreement's other terms and conditions. In all other respects the Agreement is hereby ratified and confirmed.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties, intending to be bound, have caused this Amendment No. 2 to the License Agreement to be executed by their duly authorized representatives.

NOVARTIS INTERNATIONAL PHARMACEUTICAL LTD.

By: /s/ Simone Pfirter
Name: Simone Pfirter
Title: Head General Legal NIBR Europe

By: /s/ Sylvain Beltzung
Name: Sylvain Beltzung
Title: CFO Europe Novartis

resTORbio, INC.

By: /s/ Chen Schor
Name: Chen Schor
Title: President & CEO

Exhibit A

Documents
BEZ235 0613511 Ames TEST 2006-Jun07.pdf
BEZ235 synthesis_muta CT.doc
BEZ235-A7 0613510 Ames TEST 2006-Mar28.pdf
CBEZ235A2101 RAP Module 3 Detailed Statistical Methodology Amendment 1 clean notc.pdf
CBEZ235A2101 RAP Module 3 Detailed Statistical Methodology.pdf
CBEZ235A2101 RAP Module 3 for QTPK analysis_2.pdf
CBEZ235A2101 RAP Module 6 Text tables & figures Amendment 1 clean notc.pdf
CBEZ235A2101 RAP Module 7.1 Deliverables for QTPK analysis_2.pdf
CBEZ235A2101 RAP Module 7.1 Post-text and appendix deliverables Amendment 1 notc.pdf
CBEZ235A2101 RAP Module 8 Programming Specification- Amendment 1.pdf
CBEZ235A2101_blank_CRF_14Feb2013_v04.pdf
cbez235A2101--CSR-section-16.1.9-statistical-methods.pdf
WIL_497500_BEZ235-A2 (EDR)_ames.pdf
BEZ235 0613511 Ames TEST 2006-Jun07.pdf
BEZ235 synthesis_muta CT.doc
BEZ235-A7 0613510 Ames TEST 2006-Mar28.pdf
WIL_497500_BEZ235-A2 (EDR)_ames.pdf

Exhibit 31.1

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   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(s) 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: November 5, 2019

Exhibit 31.2

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    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(s) 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: November 5, 2019

Exhibit 32.1

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 September 30, 2019 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: November 5, 2019

/s/ John J. McCabe

John J. McCabe
Vice President, Finance
(Principal Financial and Accounting Officer)

Dated: November 5, 2019