

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

<input checked="" type="checkbox"/>	<b>QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934</b>
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For the quarterly period ended September 30, 2018  
or

<input type="checkbox"/>	<b>TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934</b>
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For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File No. 001-36297

**Revance Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

<b>Delaware</b>
(State or other jurisdiction of incorporation or organization)

<b>77-0551645</b>
(I.R.S. Employer Identification Number)

7555 Gateway Boulevard Newark, California 94560 (510) 742-3400
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit 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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 statement accounting standards provide 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

Number of shares outstanding of the registrant's common stock, par value \$0.001 per share, as of October 25, 2018: 36,987,667

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“Revance Therapeutics,” the Revance logos and other trademarks or service marks of Revance appearing in this quarterly report on Form 10-Q are the property of Revance Therapeutics, Inc. This Form 10-Q contains additional trade names, trademarks and service marks of others, which are the property of their respective owners. We do not intend our use or display of other companies’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

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PART I. FINANCIAL INFORMATION

ITEM 1. Condensed Consolidated Financial Statements

REVANCE THERAPEUTICS, INC.  
 Condensed Consolidated Balance Sheets  
 (In thousands, except share and per share amounts)  
 (Unaudited)

	September 30, 2018	December 31, 2017
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 45,132	\$ 282,896
Short-term investments	163,260	—
Prepaid expenses and other current assets	7,492	2,315
Total current assets	215,884	285,211
Property and equipment, net	13,493	9,250
Restricted cash	730	580
Other non-current assets	2,944	658
<b>TOTAL ASSETS</b>	<b>\$ 233,051</b>	<b>\$ 295,699</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 7,341	\$ 6,805
Accruals and other current liabilities	15,718	12,225
Deferred revenue, current portion	8,749	—
Financing obligations	—	1,872
Total current liabilities	31,808	20,902
Derivative liability associated with Medicis settlement	2,763	2,613
Deferred revenue, net of current portion	13,009	—
Deferred rent	3,373	3,339
<b>TOTAL LIABILITIES</b>	<b>50,953</b>	<b>26,854</b>
Commitments and Contingencies (Note 8)		
<b>STOCKHOLDERS' EQUITY</b>		
Common stock, par value \$0.001 per share — 95,000,000 shares authorized as of September 30, 2018 and December 31, 2017; 36,992,122 and 36,516,075 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	37	37
Additional paid-in capital	826,352	810,975
Accumulated other comprehensive loss	(133)	—
Accumulated deficit	(644,158)	(542,167)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>182,098</b>	<b>268,845</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 233,051</b>	<b>\$ 295,699</b>

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

## REVANCE THERAPEUTICS, INC.

**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
**(In thousands, except share and per share amounts)**  
**(Unaudited)**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	\$ 2,362	\$ 75	\$ 3,242	\$ 225
Operating expenses:				
Research and development	21,848	21,643	66,968	59,357
General and administrative	14,155	9,148	40,505	25,511
Total operating expenses	36,003	30,791	107,473	84,868
Loss from operations	(33,641)	(30,716)	(104,231)	(84,643)
Interest income	996	341	3,099	999
Interest expense	—	(104)	(44)	(439)
Change in fair value of derivative liability associated with Medicis settlement	(45)	(44)	(150)	(211)
Other expense, net	(144)	(128)	(626)	(386)
Net loss	(32,834)	(30,651)	(101,952)	(84,680)
Unrealized gain (loss) on available for sale securities	90	72	(133)	3
Comprehensive loss	\$ (32,744)	\$ (30,579)	\$ (102,085)	\$ (84,677)
Basic and Diluted net loss attributable to common stockholders	\$ (32,834)	\$ (30,651)	\$ (101,952)	\$ (84,680)
Basic and Diluted net loss per share attributable to common stockholders (Note 2)	\$ (0.91)	\$ (1.01)	\$ (2.82)	\$ (2.86)
Basic and Diluted weighted-average number of shares used in computing net loss per share attributable to common stockholders	36,272,445	30,270,260	36,116,745	29,623,805

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

**REVANCE THERAPEUTICS, INC.**
**Condensed Consolidated Statements of Cash Flows**  
**(In thousands)**  
**(Unaudited)**

	Nine Months Ended September 30,	
	2018	2017
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (101,952)	\$ (84,680)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,251	1,096
Amortization of premium (discount) on investment	(904)	382
Change in fair value of derivative liability associated with Medicis settlement	150	211
Stock-based compensation expense	12,422	9,820
Capitalized interest	(16)	(37)
Effective interest on financing obligations	44	217
Gain on disposal of fixed assets	(1,480)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,141)	4,632
Other non-current assets	(1,919)	(488)
Accounts payable	793	2,749
Accruals and other liabilities	1,889	(848)
Deferred revenue	21,758	—
<b>Net cash used in operating activities</b>	<b>(73,105)</b>	<b>(66,946)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(5,367)	(2,037)
Proceeds from maturities of investments	50,000	60,655
Proceeds from sales of property and equipment	1,537	—
Purchases of investments	(212,197)	(36,028)
Payment for acquisition of in-process research and development	(100)	(100)
<b>Net cash provided by (used in) investing activities</b>	<b>(166,127)</b>	<b>22,490</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from issuance of common stock, net of at-the-market offering commissions	—	38,760
Principal payments made on financing obligations	(932)	(2,727)
Net settlement of restricted stock awards for employee taxes	(1,906)	(430)
Proceeds from the exercise of stock options and employee stock purchase plan	4,822	2,116
Payment of offering costs	(366)	(441)
<b>Net cash provided by financing activities</b>	<b>1,618</b>	<b>37,278</b>
NET DECREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(237,614)	(7,178)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH — Beginning of period	283,476	64,082
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH — End of period	<b>\$ 45,862</b>	<b>\$ 56,904</b>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>		
Cash paid for interest	\$ 16	\$ 259
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:</b>		
Property and equipment purchases included in accounts payable and accruals and other current liabilities	\$ 920	\$ 429
Deferred offering costs	\$ —	\$ 11

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

REVANCE THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements  
(Unaudited)

**1. The Company and Basis of Presentation**

Revance Therapeutics, Inc., or the Company, was incorporated in Delaware on August 10, 1999 under the name Essentia Biosystems, Inc. The Company commenced operations in June 2002 and on April 19, 2005, changed its name to Revance Therapeutics, Inc. The Company is a clinical-stage biotechnology company focused on the development, manufacturing and commercialization of novel botulinum toxin products for multiple aesthetic and therapeutic indications. The Company is leveraging its proprietary portfolio of botulinum toxin type A compounds, formulated with its patented and proprietary peptide technology, to address unmet needs in large and growing neuromodulator markets. The Company's proprietary peptide technology enables delivery of botulinum toxin type A through two investigational drug product candidates, DaxibotulinumtoxinA for Injection (RT002), or RT002 injectable, and DaxibotulinumtoxinA Topical ("topical" or "our topical product candidate"). The Company is pursuing clinical development for RT002 injectable in a broad spectrum of aesthetic and therapeutic indications and is planning to conduct preclinical development of its topical product candidate. The Company holds worldwide rights for all indications of RT002 injectable and the pharmaceutical uses of its proprietary peptide technology.

Since commencing operations in 2002, the Company has devoted substantially all of its efforts to identifying and developing product candidates for the aesthetic and therapeutic pharmaceutical markets, recruiting personnel and raising capital, and preclinical and clinical development of, and manufacturing development for, RT002 injectable and topical. The Company has never been profitable and has not yet commenced commercial operations.

Since the Company's inception, the Company has incurred losses and negative cash flows from operations. The Company has not generated significant revenue from product sales to date and will continue to incur significant research and development and other expenses related to its ongoing operations. During the nine months ended September 30, 2018, the Company recorded a net loss of \$102.0 million and used \$73.1 million of cash for operating activities. As of September 30, 2018, the Company had a working capital surplus of \$184.1 million and an accumulated deficit of \$644.2 million. The Company has funded its operations primarily through the issuance and sale of common stock, convertible preferred stock, notes payable, and convertible notes. As of September 30, 2018, the Company had capital resources consisting of cash, cash equivalents, and investments of \$208.4 million. The Company believes that its existing cash, cash equivalents and investments will allow the Company to fund its operating plan through at least the next 12 months following the issuance of this Form 10-Q and may identify additional capital resources to fund its operations.

***Basis of Presentation***

The accompanying unaudited Condensed Consolidated Financial Statements, in the opinion of management, include all adjustments which the Company considers necessary for the fair statement of the Condensed Consolidated Balance Sheets at the date of the balance sheets and the Condensed Consolidated Statements of Operations and Comprehensive Loss and Condensed Consolidated Statements of Cash Flows for the interim periods covered. The Condensed Consolidated Balance Sheet for the year ended December 31, 2017 was derived from audited financial statements, but does not include all disclosures required by generally accepted accounting principles in the United States of America, or US GAAP. The interim results presented herein are not necessarily indicative of the results of operations that may be expected for the full fiscal year ending December 31, 2018, or any other future period.

The Condensed Consolidated Financial Statements should be read in conjunction with the Company's audited Consolidated Financial Statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the Securities and Exchange Commission, or SEC, on March 2, 2018.

The Condensed Consolidated Financial Statements of the Company include the Company's accounts and those of its wholly-owned subsidiaries, and have been prepared in conformity with accounting principles generally accepted in the United States of America, or US GAAP. The Company operates in one segment.

***Principles of Consolidation***

The Condensed Consolidated Financial Statements include the accounts of the company and its wholly-owned subsidiaries. All intercompany transactions have been eliminated.

**REVANCE THERAPEUTICS, INC.**  
**Notes to Condensed Consolidated Financial Statements — (Continued)**  
**(Unaudited)**

***At-The-Market Offering***

In March 2016, the Company entered into an At-The-Market Issuance Sales Agreement, or the 2016 ATM Agreement, with Cowen and Company, LLC, or Cowen, under which the Company may offer and sell common stock having aggregate proceeds of up to \$75.0 million from time to time through Cowen, the Company's sales agent. Sales of common stock through Cowen under the 2016 ATM agreement will be made by means of ordinary brokers' transactions on the Nasdaq Global Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by the Company and Cowen. Cowen will sell the common stock from time to time, based upon instructions from the Company. The Company agreed to pay Cowen a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Cowen under the ATM Agreement. During the nine months ended September 30, 2017, the Company sold 1,802,651 shares of its common stock under the 2016 ATM Agreement at a weighted average price of \$22.17 per share resulting in net proceeds of \$38.2 million, which was comprised of gross proceeds after commissions of \$38.8 million net of offering expenses of \$0.6 million of which \$0.2 million was paid in 2016 and \$0.4 million was paid in 2017.

In March 2018, the Company terminated the 2016 ATM Agreement and entered into a Controlled Equity Offering sales agreement, or the 2018 ATM Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, under which the Company may offer and sell common stock having aggregate proceeds of up to \$125.0 million from time to time through Cantor Fitzgerald as our sales agent. Sales of common stock through Cantor Fitzgerald under the 2018 ATM Agreement will be made by means of ordinary brokers' transactions on the Nasdaq Global Market or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by the Company and Cantor Fitzgerald. Cantor Fitzgerald will sell the common stock from time to time, based upon instructions from the Company. The Company agreed to pay Cantor Fitzgerald a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Cantor Fitzgerald under the 2018 ATM Agreement. No sales of common stock have taken place under the 2018 ATM Agreement as of September 30, 2018.

**2. Summary of Significant Accounting Policies**

Significant accounting policies are described in Note 2 to the Consolidated Financial Statements in Item 15 of the Company's Annual Report on Form 10-K for the year ended December 31, 2017. There have been no changes to the Company's significant accounting policies during the nine months ended September 30, 2018, except as described below.

***Use of Estimates***

The preparation of Condensed Consolidated Financial Statements in conformity with US GAAP requires management to make estimates and assumptions that affect the amounts reported in the Condensed Consolidated Financial Statements and accompanying notes. Such management estimates include revenue recognition, deferred revenue, accruals, stock-based compensation, the fair value of a derivative liability, and the valuation of deferred tax assets. The Company bases its estimates on historical experience and on assumptions that it believes are reasonable, however, actual results could differ significantly from those estimates.

***Revenue***

Effective January 1, 2018, the Company adopted Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606) using the full retrospective transition method. The Company evaluated its prior contractual revenue arrangement with Precision Dermatology, Inc., which was acquired by Valeant Pharmaceuticals International Inc., or Valeant, in 2014. After Valeant notified the Company that it intended to terminate the asset purchase and royalty agreement in 2015, the Company continued to receive royalties of \$75,000 each quarter until November 2017 when the Company and Valeant entered into an Asset Transfer Agreement to finalize the termination of the asset purchase and royalty agreement and Valeant returned the Relastin® intellectual property rights to the Company. Based on its evaluation, the Company determined that the new guidance had no impact to the revenue recognized prior to January 1, 2018 and, accordingly, had no impact on the accumulated deficit as of January 1, 2018.

**REVANCE THERAPEUTICS, INC.**  
**Notes to Condensed Consolidated Financial Statements — (Continued)**  
**(Unaudited)**

The Company elected to use certain practical expedients permitted for the adoption of ASC 606 (Note 3). The adoption had no impact on the Company's financial position, results of operations or liquidity. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services.

To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Licenses of intellectual property

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are determined to not represent distinct performance obligations, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring proportional performance for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of proportional performance each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone payments

At the inception of each arrangement that includes development, regulatory or commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. ASC 606 suggests two alternatives to use when estimating the amount of variable consideration: the expected value method and the most likely amount method. Under the expected value method, an entity considers the sum of probability-weighted amounts in a range of possible consideration amounts. Under the most likely amount method, an entity considers the single most likely amount in a range of possible consideration amounts. Whichever method is used should be consistently applied throughout the life of the contract; however, it is not necessary for the Company to use the same approach for all contracts. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation (as determined to be appropriate) on a relative stand-alone selling price basis. The Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability or achievement of each such milestone and any related constraint, and if necessary, adjusts its estimates of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Up-front payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these



**REVANCE THERAPEUTICS, INC.**  
**Notes to Condensed Consolidated Financial Statements — (Continued)**  
**(Unaudited)**

arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. As a practical expedient, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

***Net Loss per Share Attributable to Common Stockholders***

The Company's basic net loss per share attributable to common stockholders is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period, which includes vested restricted stock awards. The diluted net loss per share attributable to common stockholders is computed by giving effect to all potential dilutive common stock equivalents outstanding for the period. The diluted net loss per share attributable to common stockholders also includes vested restricted stock awards and, if the effect is not anti-dilutive, unvested restricted stock awards. For purposes of this calculation, options to purchase common stock, unvested restricted stock, and common stock warrants are considered common stock equivalents.

The following common stock equivalents were excluded from the computation of diluted net loss per share for the periods presented because including them would have been antidilutive:

	As of September 30.	
	2018	2017
Outstanding common stock options	3,491,751	3,381,927
Outstanding common stock warrants	34,113	41,595
Unvested restricted stock awards	679,541	640,931
Shares expected to be purchased on December 31 under the 2014 ESPP	16,712	14,778

***Recently Adopted Accounting Pronouncements***

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, to expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. Under ASU 2018-07, equity-classified share-based payment awards to non-employees are measured at fair value on the grant date and the probability of satisfying performance conditions must be considered for equity-classified non-employee share-based payment awards with such conditions. ASU 2018-07 does not specify the period(s) or manner of expense recognition for share-based payment awards to non-employees other than to require that recognition occur in the same period(s) and in the same manner as if the grantor had paid cash for the goods or services. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company early adopted ASU 2018-07 as of July 1, 2018, and remeasured all outstanding equity-classified non-employee share-based payment awards at fair value as of the adoption date, and also recognized a cumulative-effect increase to the Company's opening 2018 accumulated deficit balance of less than \$0.1 million in connection with the adoption and remeasurement.

In March 2018, the FASB issued ASU 2018-05, *Income Taxes (Topic 740) - Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118*. This standard amends Accounting Standards Codification 740, Income Taxes (ASC 740) to provide guidance on accounting for the tax effects of the Tax Cuts and Jobs Act (the Tax Reform Act) pursuant to Staff Accounting Bulletin No. 118, which allows companies to complete the accounting under ASC 740 within a one-year measurement period from the Tax Act enactment date. This standard is effective upon issuance. The Company continues to assess the accounting impact resulting from the Tax Reform Act. The Company has substantially completed the accounting assessment with regard to the tax effects associated with an intra-entity transfer of certain intellectual property rights with the enactment of Tax Reform Act, this resulted in an increase in net operating loss of \$39.6 million and increased the SAB 118 estimated impact from the Tax Reform Act by \$5.2 million to deferred taxes. In all aspects, the Company will continue to make and refine calculations as additional analysis is completed. As of September 30, 2018, the Company performed additional analysis and estimated re-measurement of certain deferred taxes to be \$68.1 million which continues to be fully offset by a valuation allowance. The Company has substantially completed its assessment, except for the impact related to deferred taxes, and expects to complete the accounting assessment during the one-year measurement period provided by SAB 118.

**REVANCE THERAPEUTICS, INC.**  
**Notes to Condensed Consolidated Financial Statements — (Continued)**  
**(Unaudited)**

In May 2017, the FASB issued ASU 2017-09, *Scope of Modification Accounting (Topic 718)*, which amends the scope of modification accounting for share-based payment arrangements. The amendment provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. ASU 2017-09 is effective for fiscal years beginning after December 15, 2017, with early adoption permitted. The adoption of this standard on January 1, 2018 did not impact the Company's Condensed Consolidated Financial Statements.

In October 2016, the FASB issued ASU 2016-16, *Income Taxes - Intra-Entity Transfers of Assets Other Than Inventory*, which requires entities to recognize income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. The amendments in ASU 2016-16 are effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within those annual reporting periods and requires a modified retrospective method of adoption. As of January 1, 2018, the Company adopted ASU 2016-16 and determined this standard did not have a financial statement impact on the Company's Condensed Consolidated Financial Statements as the Company has a full valuation allowance.

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers*, which sets forth a single, comprehensive revenue recognition model for all contracts with customers to improve comparability. Subsequently, the FASB issued several standards related to ASU 2014-09 (collectively, the "New Revenue Standard"), including the most recent ASU, ASU 2017-14, *Income Statement - Reporting Comprehensive Income (Topic 220)*, and *Revenue Recognition (Topic 605)*, *Revenue from Contracts with Customers (Topic 606)*, which was issued in November 2017. The New Revenue Standard requires revenue recognition to depict the transfer of goods or services to customers in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. In addition, the New Revenue Standard requires expanded disclosures. This New Revenue Standard permits the use of either the retrospective or cumulative effect transition method when adopted. As of January 1, 2018, the Company adopted the New Revenue Standard on a retrospective basis and determined there was no material impact to the Company's Condensed Consolidated Financial Statements.

***Recent Accounting Pronouncements***

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurements (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 modifies the disclosure requirements for fair value measurements in Topic 820 based on the objectives of the FASB Concepts Statement, Conceptual Framework for Financial Reporting - Chapter 8: Notes to Financial Statements which aims to improve the effectiveness of notes to financial statements while allowing for the appropriate exercise of discretion by reporting entities based on materiality. The main provisions of ASU 2018-13 include the removal or modification of certain non-essential disclosure requirements and the addition of new disclosure requirements for public companies related to the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period, and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years beginning after December 15, 2018 with early adoption permitted. The Company does not expect the adoption of the new standard to have a material impact on the Company's Condensed Consolidated Financial Statements.

In July 2018, the FASB issued ASU 2018-10, *Leases (Topic 842), Codification Improvements* and ASU 2018-11 *Leases (Topic 842), Targeted Improvements*, to provide additional guidance for the adoption of Topic 842. ASU 2018-10 clarifies certain provisions and correct unintended applications of the guidance such as the application of implicit rate, lessee reassessment of lease classification, and certain transition adjustments that should be recognized to earnings rather than to stockholders' equity. ASU 2018-11 provides an alternative transition method and practical expedient for separating contract components for the adoption of Topic 842. In February 2016, the FASB issued ASU 2016-02 *Leases (Topic 842)* which requires an entity to recognize assets and liabilities arising from a lease for both financing and operating leases with terms greater than 12 months. ASU 2018-11, ASU 2018-10, and ASU 2016-02 (collectively, "the new lease standards") are effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the effect the new lease standards will have on its Condensed Consolidated Financial Statements; however, the Company anticipates recognizing assets and liabilities arising from any leases that meet the requirements under the new lease standards on the adoption date and including qualitative and quantitative disclosures in the Company's Notes to the Condensed Consolidated Financial Statements.

## REVANCE THERAPEUTICS, INC.

## Notes to Condensed Consolidated Financial Statements — (Continued)

(Unaudited)

In July 2018, the FASB issued ASU 2018-09, *Codification Improvements*. The amendments in ASU 2018-09 affect a wide variety of Topics in the FASB Codification and apply to all reporting entities within the scope of the affected accounting guidance. The Company has evaluated ASU 2018-09 in its entirety and determined that the amendments related to Topic 718-740, *Compensation-Stock Compensation-Income Taxes*, are the only provisions that currently apply to the Company. The amendments in ASU 2018-09 related to Topic 718-740, *Compensation-Stock Compensation-Income Taxes*, clarify that an entity should recognize excess tax benefits related to stock compensation transactions in the period in which the amount of the deduction is determined. The amendments in ASU 2018-09 related to Topic 718-740 are effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company does not expect the adoption of the new standard to have a material impact on the Company's Condensed Consolidated Financial Statements.

In February 2018, the FASB issued ASU 2018-02, *Income Statement - Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, to address specific consequences of the Tax Reform Act. The update allows a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Reform Act. ASU 2018-02 is effective January 1, 2019, with early adoption permitted, and is to be applied either in the period of adoption or retrospectively to each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Reform Act is recognized. The Company is currently evaluating the impact of the new standard on the Company's Condensed Consolidated Financial Statements.

### 3. Collaboration and License Revenue

#### *Agreement Terms*

On February 28, 2018, the Company and Mylan Ireland Limited, or Mylan, a wholly-owned indirect subsidiary of Mylan N.V., entered into a collaboration agreement or the Mylan Collaboration, pursuant to which the Company and Mylan will collaborate exclusively, on a world-wide basis (excluding Japan), to develop, manufacture, and commercialize a biosimilar to the branded biologic product (onabotulinumtoxinA) marketed as BOTOX®.

Under the Mylan Collaboration, the Company is responsible for conducting initial non-clinical development activities with the goal of preparing for and conducting a scientific advice meeting with the FDA to receive feedback as to whether a biosimilar biological pathway is feasible for BOTOX®. The Company is solely responsible for these initial activities and the related costs. Upon completion of the initial activities, Mylan may decide whether to continue the development of the biosimilar. If the development is continued, the Company will be primarily responsible for (a) non-clinical development activities, (b) clinical development activities in North America, and (c) manufacturing and supply of clinical drug substance and drug product; and Mylan will be primarily responsible for (a) clinical development activities outside of North America (excluding Japan) (the "ex-U.S. Mylan territories"), (b) regulatory activities, and (c) commercialization for any approved product. The Company will be solely responsible for an initial portion of non-clinical development costs. The remaining portion of any non-clinical development costs and clinical development costs for obtaining approval in the U.S. and Europe will be shared equally between the parties, and Mylan will be responsible for all other clinical development costs and commercialization expenses. The Company and Mylan will form a joint steering committee, consisting of an equal number of members from the Company and Mylan, to oversee and manage the development, manufacture and commercialization of the biosimilar. The parties will also enter into a separate agreement, within six months, covering supply of drug substance and drug product. In addition, Mylan may elect to have the drug product manufactured by another party, including a third-party contract manufacturing organization or a Mylan affiliate; however, Mylan may not manufacture or have manufactured the drug substance, rights to which are retained by the Company.

Under the Mylan Collaboration, the Company granted Mylan an exclusive, world-wide license (excluding Japan) to the Company's intellectual property rights for the development and commercialization of the biosimilar. The Company retained all rights in Japan and has retained rights in the U.S. and ex-U.S. Mylan territories to develop and manufacture the biosimilar for Mylan to commercialize.

Mylan paid the Company a non-refundable upfront payment of \$25 million with contingent payments of up to \$100 million in the aggregate, upon the achievement of specified clinical and regulatory (i.e. biosimilar biological pathway) milestones and of specified, tiered sales milestones of up to \$225 million. The upfront payment does not represent a financing

**REVANCE THERAPEUTICS, INC.**  
**Notes to Condensed Consolidated Financial Statements — (Continued)**  
**(Unaudited)**

component for the transfer of goods or services. The contingent payments would be payable following Mylan's decision to continue development services for Initial Phase and Phase 3 clinical trials and upon meeting certain milestones. In addition, Mylan would pay the Company low to mid-double digit royalties on any sales of the biosimilar in the U.S., mid-double digit royalties on any sales in Europe, and high single digit royalties on any sales in other ex-U.S. Mylan territories. However, the Company agreed to waive royalties for U.S. sales, up to a limit of \$50 million in annual sales, during the first approximately four years after commercialization to defray launch costs.

The term of the collaboration will continue, on a country-by-country basis, in perpetuity until terminated by either party pursuant to the terms of the Mylan Collaboration. Either party may terminate the agreement for breach by, or bankruptcy of, the other party. Mylan may terminate the Mylan Collaboration if a biosimilar development pathway is not deemed viable, with such determination only occurring after an advisory meeting with the U.S. Food and Drug Administration, or FDA. Further, Mylan may terminate the Collaboration in its entirety or on a region-by-region basis. All rights, including licenses, and obligations terminate in the country or countries for which termination applies, with limited exceptions for royalty-bearing licenses to certain intellectual property rights, and rights to certain data, for the continued development and sale of the biosimilar in the country or countries for which termination applies.

***Revenue Recognition***

The Company identified the following material promises within the Agreement: (1) intellectual property license, or IP license, for technology and know-how related to the biosimilar, (2) the performance of initial development services for the biosimilar prior to the FDA advisory meeting, (3) the performance of development services, during the Initial Phase and Phase 3 clinical trials for the biosimilar through the filing of an Investigational New Drug, or IND, application by the Company, and (4) manufacturing services to provide drug substance or drug product during the initial development, development, and commercialization periods.

The Company considered that the license has standalone functionality and is capable of being distinct. However, the Company determined that the license is not distinct from the development and manufacturing services within the context of the agreement because the development and manufacturing services significantly increase the utility of the intellectual property.

Specifically, the Company's development, manufacturing and commercialization license can only provide benefit to Mylan in combination with the Company's development services during initial development, the Initial Phase study, and the Phase 3 study. The IP related to the biosimilar platform, which is proprietary to the Company, is the foundation for the development activities related to the treatment for all indications. The manufacturing services are a necessary and integral part of the development services as they could only be conducted utilizing the outcomes of these services. Given the development services under the Mylan Collaboration are expected to involve significant further development of the initial IP, the Company has concluded that the development and compound supply services are not distinct from the license, and thus the license, development services and compound supply services are combined into a single performance obligation. The nature of the combined performance obligation is to provide development and manufacturing services to Mylan under the arrangement.

The Company, following an evaluation, determined that Mylan's option to decide whether to continue the development after the FDA feedback is received represents a material right, because it includes consideration for the IP license, and provides economic value for the duration of the entire development period, defined as the initial development through regulatory approval. Further, in accordance with ASC 606, the Company elected to use a practical alternative to estimating the standalone fair value selling price of the material right, which is based on the cost of expected services to be provided for the duration of the contract.

In accordance with ASC 606, transaction price is defined as the amount of consideration to which an entity expects to be entitled in exchange for promised goods or services to a customer. The Company estimated the transaction price for the Mylan Collaboration using the most likely amount method. In order to determine the transaction price, the Company evaluated all of the payments to be received during the duration of the contract, which included milestones and consideration payable by Mylan. Other than the upfront payment, all other milestones and consideration the Company may earn under the Mylan agreement are subject to uncertainties related to development achievements, Mylan's rights to terminate the agreement, and estimated effort for cost-sharing payments. Components of such estimated effort for cost-sharing payments include both

**REVANCE THERAPEUTICS, INC.**  
**Notes to Condensed Consolidated Financial Statements — (Continued)**  
**(Unaudited)**

internal and external costs. Consequently, the transaction price does not include any milestones and considerations that, if included, could result in a probable significant reversal of revenue when related uncertainties become resolved. Sales-based milestones and royalties reflect consideration for the value of the IP license, which is predominant in our agreement with Mylan. These milestones are not included in the transaction price until the subsequent sales occur. The initial estimated transaction price of \$81 million included the \$25 million upfront payment, \$40 million of development milestones, and estimated variable consideration for cost-sharing payments from Mylan. The Company re-evaluates the transaction price in each reporting period and upon a change in circumstances, and during the three months ended September 30, 2018, there were no changes to the estimated transaction price. As of September 30, 2018, the transaction price allocated to undelivered performance obligations is \$77.2 million.

The Company estimates revenue recognized and deferred revenue based on the estimated cost of services incurred over the estimated cost of services to be provided for the development period. The development period is estimated to extend through 2022. However, it is possible that this period will change and is assessed at each reporting date. For the three and nine months ended September 30, 2018, the Company recognized revenue related to development services rendered of \$2.4 million and \$3.2 million, respectively. As of September 30, 2018, the Company estimated short-term and long-term deferred revenue of \$8.7 million and \$13.0 million, respectively. The Company estimates that, if the option is exercised, long-term deferred revenue will be recognized over the completion of the Initial Phase and Phase 3 study development period. Nonetheless, it is reasonably possible that our estimated cost of total services to be provided could change.

#### **4. Medicis Settlement**

In July 2009, the Company entered into a license agreement with Medicis Pharmaceutical Corporation, or Medicis, granting Medicis worldwide aesthetic and dermatological rights to the Company's investigational botulinum toxin type A product candidates. In October 2012, the Company entered into a settlement and termination agreement with Medicis. The terms of the settlement provided for the reacquisition of the rights related to all territories of RT002 injectable and RT001 topical from Medicis and for consideration payable by the Company to Medicis of up to \$25.0 million, comprised of (i) an upfront payment of \$7.0 million, which was paid in 2012, (ii) a proceeds sharing arrangement payment of \$14.0 million due upon specified capital raising achievements by the Company, of which \$6.9 million was paid in 2013 and \$7.1 million in 2014, and (iii) a product approval payment of \$4.0 million to be paid upon the achievement of regulatory approval for RT002 injectable or RT001 topical by the Company. Medicis was subsequently acquired by Valeant Pharmaceuticals International, Inc. in December 2012.

The Company determined that the settlement provisions related to the proceeds sharing arrangement payment in (ii) above and product approval payment in (iii) above were derivative instruments that require fair value accounting as a liability and periodic fair value remeasurements until settled.

As of September 30, 2018, the Company determined the fair value of its liability for the product approval payment was \$2.8 million, which was measured by assuming a term of 1.75 years, a risk-free rate of 2.76% and a credit risk adjustment of 6.00%. The Company's assumption for the expected term is based on an expected Biologics License Application, or BLA, approval in 2020. The Company did not make any payments under the Product Approval Payment during the nine months ended September 30, 2018.

**REVANCE THERAPEUTICS, INC.**  
**Notes to Condensed Consolidated Financial Statements — (Continued)**  
**(Unaudited)**

**5. Cash Equivalents and Investments**

The Company's cash equivalents and investments consist of money market funds, U.S. treasury securities, and U.S. government agency obligations, which are classified as available-for-sale securities.

The following table is a summary of amortized cost, unrealized gain and loss, and fair value (in thousands):

	September 30, 2018				December 31, 2017			
	Gross Unrealized				Gross Unrealized			
	Cost	Gains	Losses	Fair Value	Cost	Gains	Losses	Fair Value
Money market funds	\$ 37,573	\$ —	\$ —	\$ 37,573	\$ 236,744	\$ —	\$ —	\$ 236,744
U.S. treasury securities	100,243	—	(85)	100,158	—	—	—	—
U.S. government agency obligations	63,150	—	(48)	63,102	—	—	—	—
Total cash equivalents and available-for-sale securities	<u>\$ 200,966</u>	<u>\$ —</u>	<u>\$ (133)</u>	<u>\$ 200,833</u>	<u>\$ 236,744</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 236,744</u>
Classified as:								
Cash equivalents				\$ 37,573				\$ 236,744
Short-term investments				163,260				—
Total cash equivalents and available-for-sale securities				<u>\$ 200,833</u>				<u>\$ 236,744</u>

There have been no significant realized gains or losses on available-for-sale securities for the periods presented. No significant available-for-sale securities held as of September 30, 2018 have been in a continuous unrealized loss position for more than 12 months, and unrealized gains and losses are included in "accumulated other comprehensive loss" within stockholders' equity on the Condensed Consolidated Balance Sheets. As of September 30, 2018, unrealized losses on available-for-sale investments are not attributed to credit risk and are considered temporary. The Company believes that it is more-likely-than-not that investments in an unrealized loss position will be held until maturity or the cost basis of the investment will be recovered. The Company believes it has no other-than-temporary impairments on its securities as it does not intend to sell these securities and does not believe it is more likely than not that it will be required to sell these securities before the recovery of their amortized cost basis. To date, the Company has not recorded any impairment charges on marketable securities related to other-than-temporary declines in fair value. Our cash equivalents and short-term investments are due within one year.

***Related Party Transactions***

Of the Company's total cash, cash equivalents, and short-term investments of \$208.4 million and \$282.9 million as of September 30, 2018 and December 31, 2017, respectively, the Company held cash equivalents and short-term investments with a total fair value of \$97.2 million and \$150.7 million, respectively, in an investment account with a related party, J.P. Morgan Securities LLC. As of September 30, 2018, JPMorgan Chase & Co. and its wholly owned subsidiaries JPMorgan Chase Bank, National Association (NA), J.P. Morgan Investment Management Inc., and JPMorgan Asset Management (UK) Limited held approximately 3.7 million shares of the Company's common stock, which represents approximately 10.03% of the Company's outstanding common stock. J.P. Morgan Securities LLC, who acts as a custodian and trustee for certain Company investments, is an affiliate of JPMorgan Chase Bank, NA.

**REVANCE THERAPEUTICS, INC.**  
**Notes to Condensed Consolidated Financial Statements — (Continued)**  
**(Unaudited)**

**6. Fair Value Measurements**

The Company determines the fair value of certain financial assets and liabilities using three levels of inputs as follows:

- Level 1 — Observable inputs, such as quoted prices in active markets for identical assets or liabilities;
- Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3 — Valuations based on unobservable inputs to the valuation methodology and including data about assumptions market participants would use in pricing the asset or liability based on the best information available under the circumstances.

The carrying values of cash, prepaid expenses and other current assets, accounts payable, and accruals and other current liabilities approximate fair value due to the short maturities of these instruments.

The Company measures and reports certain financial instruments as assets and liabilities at fair value on a recurring basis. The fair value of these instruments was as follows (in thousands):

	As of September 30, 2018			
	Fair Value	Level 1	Level 2	Level 3
<b>Assets</b>				
Money market funds	\$ 37,573	\$ 37,573	\$ —	\$ —
U.S. treasury securities	100,158	100,158	—	—
U.S. government agency obligations	63,102	—	63,102	—
Total assets measured at fair value	<u>\$ 200,833</u>	<u>\$ 137,731</u>	<u>\$ 63,102</u>	<u>\$ —</u>

<b>Liabilities</b>				
Derivative liability associated with Medicis settlement	\$ 2,763	\$ —	\$ —	\$ 2,763
Total liabilities measured at fair value	<u>\$ 2,763</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,763</u>

	As of December 31, 2017			
	Fair Value	Level 1	Level 2	Level 3
<b>Assets</b>				
Money market funds	\$ 236,744	\$ 236,744	\$ —	\$ —
Total assets measured at fair value	<u>\$ 236,744</u>	<u>\$ 236,744</u>	<u>\$ —</u>	<u>\$ —</u>

<b>Liabilities</b>				
Derivative liability associated with Medicis settlement	\$ 2,613	\$ —	\$ —	\$ 2,613
Total liabilities measured at fair value	<u>\$ 2,613</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,613</u>

The fair value of the U.S. government agency obligations is estimated by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, prepayment/default projections based on historical data, and other observable inputs. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. The Company did not transfer any assets or liabilities measured at fair value on a recurring basis between Level 1 and Level 2 during the nine months ended September 30, 2018 and the year ended December 31, 2017.



**REVANCE THERAPEUTICS, INC.**  
**Notes to Condensed Consolidated Financial Statements — (Continued)**  
**(Unaudited)**

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments as follows (in thousands):

	<b>Derivative Liability Associated with Medicis Settlement</b>
Fair value as of December 31, 2017	\$ 2,613
Change in fair value	150
Fair value as of September 30, 2018	\$ 2,763

The fair value of the derivative liability resulting from the Medicis litigation settlement was determined by estimating the timing and probability of the related regulatory approval and multiplying the payment amount by this probability percentage and a discount factor based primarily on the estimated timing of the payment and a credit risk adjustment (Note 4). Generally, increases or decreases in these unobservable inputs would result in a directionally similar impact to the fair value measurement of this derivative instrument. The significant unobservable inputs used in the fair value measurement of the Product Approval Payment derivative are the expected timing and probability of the payments at the valuation date and the credit risk adjustment.

## 7. Notes Payable and Financing Obligations

### *Essex Capital Notes*

On December 20, 2013, the Company signed a Loan and Lease Agreement (Original Agreement) to borrow up to \$10.8 million in the form of Secured Promissory Notes from Essex Capital, or the Essex Notes, to finance the completion and installation of the Company's RT001 topical commercial fill/finish line, or the Fill/Finish Line. In December 2013 and January 2014, the Company withdrew a total of \$5.0 million under the terms of the Original Agreement. In May 2014, pursuant to the terms of the Original Agreement, the Company sold equipment to Essex Capital, resulting in partial settlement of the outstanding loan balance of \$1.1 million, and leased the equipment back for fixed monthly payments to be paid over 3 years.

On December 17, 2014, the Company entered into the First Amendment to the Loan and Lease Agreement (First Amendment) with Essex Capital. Under the terms of the First Amendment, the Company agreed to repay the outstanding debt balance of \$3.9 million and issued a warrant to purchase 44,753 shares of common stock.

In February 2015, the Company executed the Second Amendment to the Loan and Lease Agreement (Second Amendment), under which the term of the facility was extended to April 15, 2015 and the purchase price for the remainder of the equipment was increased by \$0.1 million to approximately \$9.8 million. Concurrently with this sale, the Company leased the equipment back from Essex Capital for a fixed monthly payment to be paid monthly over 3 years.

None of the leases qualified for sale-leaseback accounting due to the Company's continuing involvement in the equipment. Therefore, the Company accounted for these transactions as financing obligations using the effective interest rate method.

The leases provide for the option to purchase the leased equipment for 10% of the original purchase amount and, in June 2015, the Company exercised its option to purchase the remainder of the equipment sold and leased back from Essex Capital for 10% of the original purchase amount, or approximately \$1.1 million, at the conclusion of the lease terms. In May 2017, the Company paid \$0.1 million to purchase the equipment sold and leased back from Essex Capital in May 2014.

The Company paid principal and interest payments on the Essex Capital Lease of \$0.9 million during the first quarter of 2018. In April 2018, the Company paid \$1.0 million to purchase the remaining equipment sold and leased back, which excludes sales and use taxes paid, from Essex Capital and there are no remaining commitments or liabilities payable to Essex Capital.



**REVANCE THERAPEUTICS, INC.**  
**Notes to Condensed Consolidated Financial Statements — (Continued)**  
**(Unaudited)**

## 8. Commitments and Contingencies

### *Facility Lease*

In January 2010, the Company entered into a non-cancelable facility lease (the "Lease") that requires monthly payments through January 2022. This facility is used for research, manufacturing, and administrative functions.

In February 2014, the Company extended the term of the Lease by thirty-six (36) months to January 2025. In May 2018, the Company further extended the term of the Lease for its existing facility by twenty-four (24) months to January 2027 and amended the lease to expand the existing premises by approximately nineteen thousand square feet, commencing on January 1, 2019. Under the terms of the amended lease agreements, the payments escalate over the term of the lease with the exception of a decrease in payments at the beginning of 2022. The Company recognizes the expense on a straight-line basis over the life of the existing lease. Rent expense was \$1.4 million and \$1.3 million for the three months ended September 30, 2018 and 2017, respectively, and \$4.1 million and \$4.0 million for the nine months ended September 30, 2018 and 2017, respectively.

In November 2017, the Company entered into a non-cancelable equipment operating lease that requires sixty (60) equal monthly payments through October 2022. Lease payments total \$0.2 million during the entire lease term.

As of September 30, 2018, the aggregate total future minimum lease payments under non-cancelable operating leases were as follows (in thousands):

<b>Year Ending December 31,</b>	
2018	\$ 1,409
2019	6,399
2020	6,722
2021	6,920
2022 and thereafter	28,936
Total payments	<u>\$ 50,386</u>

### *Other Milestone-Based Commitments*

The Company has one remaining future milestone payment to List Laboratories of \$2.0 million due and payable on the achievement of a certain regulatory milestone. The Company is also obligated to pay royalties to List Laboratories on future sales of botulinum toxin products.

In June 2016, the Company entered into an asset purchase agreement with Botulinum Toxin Research Associates, Inc., or BTRX (the "BTRX Purchase Agreement"). Under the BTRX Purchase Agreement, the Company acquired all rights, title and interest in a portfolio of botulinum toxin-related patents and patent applications from BTRX and was granted the right of first negotiation and first refusal with respect to other botulinum toxin-related patents owned or controlled by BTRX. In exchange, the Company agreed to an upfront expenditure of \$2.0 million of which \$1.8 million was paid immediately, \$0.1 million was paid in June 2017, and the remaining \$0.1 million was paid in May 2018. The Company also has obligations to pay Botulinum Toxin Research Associates, Inc. (BTRX) up to \$16.0 million upon the satisfaction of specified milestones relating to the Company's product revenue, intellectual property, and clinical and regulatory events. As of September 30, 2018, a one-time intellectual property development milestone liability of \$1.0 million has been recorded and included in accruals and other current liabilities.

In April 2016, the Company entered into an agreement with BioSentinel, Inc. to in-license their technology and expertise for research and development and manufacturing purposes. In addition to minimum quarterly use fees, the Company has a one-time future milestone payment of \$0.3 million payable to BioSentinel, Inc. upon the achievement of regulatory approval.

**REVANCE THERAPEUTICS, INC.**  
**Notes to Condensed Consolidated Financial Statements — (Continued)**  
**(Unaudited)**

***Purchase Commitments***

On March 14, 2017, the Company entered into a Technology Transfer, Validation and Commercial Fill/Finish Services Agreement (the “Services Agreement”) and Statement of Work (“SoW”) with Ajinomoto Althea, Inc., a contract development and manufacturing organization (“Althea”). Under the Services Agreement, Althea has agreed, among other things, to provide the Company with a future source of commercial fill/finish services for the Company’s neuromodulator products. The Services Agreement has an initial term that will expire in 2024, unless terminated sooner by either party. In accordance with the Services Agreement, the Company will have minimum purchase obligations based on its production forecasts. Since inception of the Services Agreement through September 30, 2018, the Company has made non-refundable advanced payments of \$1.9 million in accordance with the terms of this arrangement. The advanced payments are amortized and recorded to expenses over the period the services are rendered by Althea. The remaining services are cancellable at any time, with the Company required to pay costs incurred through the cancellation date.

***Contingencies***

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. The Company expects that contingencies related to regulatory approval milestones will only become probable once such regulatory outcome is achieved. The Company is not subject to any known current pending legal matters or claims that would have a material adverse effect on its financial position, results of operations or cash flows.

***Indemnification***

The Company enters into standard indemnification agreements in the ordinary course of business. Pursuant to these arrangements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology. The term of these indemnification agreements is generally perpetual after the execution of the agreement. The maximum potential amount of future payments the Company could be required to make under these agreements is not determinable because it involves claims that may be made against the Company in the future, but have not yet been made. The Company has not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

The Company has entered into indemnification agreements with its directors and officers that may require the Company to indemnify them against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of the individual.

No amounts associated with such indemnifications have been recorded during the three and nine months ended September 30, 2018.

**9. Stockholders' Equity**

**Convertible Preferred Stock**

As of September 30, 2018 and December 31, 2017, the Company had 5,000,000 shares of convertible preferred stock authorized with a par value of \$0.001 per share and no preferred stock issued and outstanding.

**Warrants**

As of September 30, 2018 and December 31, 2017, the Company had outstanding warrants to purchase 34,113 shares of common stock at an exercise price per share of \$14.95 and which expire in 2020.

**REVANCE THERAPEUTICS, INC.**  
**Notes to Condensed Consolidated Financial Statements — (Continued)**  
**(Unaudited)**

**Stock Option Plan***2014 Equity Incentive Plan and 2014 Inducement Plan*

On January 1, 2018, the number of shares of common stock reserved for issuance under the Company's 2014 Equity Incentive Plan, or 2014 EIP, automatically increased by 4% of the total number of shares of the Company's common stock outstanding on December 31, 2017, or 1,460,643 shares. During the nine months ended September 30, 2018, the Company granted stock options for 826,450 shares of common stock and 299,400 restricted stock awards under the 2014 EIP. As of September 30, 2018, there were 1,749,448 shares available for issuance under the 2014 EIP.

During the nine months ended September 30, 2018, there were 110,000 stock options and 16,000 restricted stock awards granted under the 2014 Inducement Plan (the "2014 IN"). As of September 30, 2018, there were 167,737 shares available for issuance under the 2014 IN.

The grant-date fair value of the employee stock options under the 2014 EIP and 2014 IN was estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Expected term (in years)	6.1	6.0	6.0	6.0
Expected volatility	59.0%	66.6%	60.5%	67.8%
Risk-free interest rate	2.8%	2.0%	2.7%	2.1%
Expected dividend rate	—%	—%	—%	—%

*Fair Value of Common Stock.* The fair value of the shares of common stock is based on the Company's stock price as quoted by the Nasdaq Global Market.

*Expected Term.* The expected term for employees, non-employee directors, and non-employee consultants is based on the simplified method, as the Company's stock options have the following characteristics: (i) granted at-the-money; (ii) exercisability is conditioned upon service through the vesting date; (iii) termination of service prior to vesting results in forfeiture; (iv) limited exercise period following termination of service; and (v) options are non-transferable and non-hedgeable, or "plain vanilla" options, and the Company has a limited history of exercise data. Prior to the adoption of ASU 2018-07 on July 1, 2018 (Note 2), the expected term for non-employee consultants was based on the remaining contractual term.

*Expected Volatility.* The expected volatility is based on the historical volatility of a group of similar entities combined with the historical volatility of the Company. In evaluating similarity, the Company considered factors such as industry, stage of life cycle, capital structure, and size.

*Risk-Free Interest Rate.* The risk-free interest rate is based on U.S. Treasury constant maturity rates with remaining terms similar to the expected term of the options.

*Expected Dividend Rate.* The Company has not and does not plan to pay dividends in the foreseeable future, and therefore used an expected dividend rate of zero percent in the valuation model.

*Forfeitures.* The Company accounts for forfeitures as they occur.

During the three and nine months ended September 30, 2018, the Company issued and had outstanding options and awards for non-employee consultants which have continued to vest in accordance with the 2014 EIP. During the three and nine months ended September 30, 2017, there were outstanding options and awards issued to non-employee consultants which have continued to vest in accordance with the 2014 EIP.

**REVANCE THERAPEUTICS, INC.**  
**Notes to Condensed Consolidated Financial Statements — (Continued)**  
**(Unaudited)**

The fair value of the stock options outstanding for non-employee consultants is calculated in accordance with the provisions of ASU 2018-07 (Note 2) for the three and nine months ended September 30, 2018, and the provisions of ASC 505-50 for the three and nine months ended September 30, 2017, using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Expected term (in years)	5.5	8.9	5.5	8.9
Expected volatility	59.4%	68.1%	59.4%	68.6%
Risk-free interest rate	2.8%	2.2%	2.8%	2.2%
Expected dividend rate	—%	—%	—%	—%

**2014 Employee Stock Purchase Plan**

On January 1, 2018, the number of shares of common stock reserved for issuance under the Company's 2014 Employee Stock Purchase Plan, or 2014 ESPP, automatically increased by the maximum of 300,000 shares. As of September 30, 2018, there were 1,198,039 shares available for issuance under the 2014 ESPP.

The fair value of the option component of the shares purchased under the 2014 ESPP was estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Expected term (in years)	0.5	0.5	0.5	0.5
Expected volatility	42.2%	46.6%	50.2%	59.1%
Risk-free interest rate	2.4%	1.1%	2.0%	0.9%
Expected dividend rate	—%	—%	—%	—%

*Fair Value of Common Stock.* The fair value of the shares of common stock is based on the Company's stock price.

*Expected Term.* The expected term is based on the term of the purchase period under the 2014 ESPP.

*Expected Volatility.* The expected volatility is based on the historical volatility of the Company's common stock.

*Risk-Free Interest Rate.* The risk-free interest rate is based on U.S. Treasury constant maturity rates with remaining terms similar to the expected term.

*Expected Dividend Rate.* The Company has never paid dividends and does not plan to pay dividends in the foreseeable future, and therefore used an expected dividend rate of zero percent in the valuation model.

**Total Stock-Based Compensation**

Total stock-based compensation expense related to options, restricted stock awards, and ESPP for employees, non-employee directors, and non-employee consultants was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Research and development	\$ 1,836	\$ 1,534	\$ 5,627	\$ 4,341
General and administrative	2,256	1,612	6,795	5,479
Total stock-based compensation expense	\$ 4,092	\$ 3,146	\$ 12,422	\$ 9,820

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our Condensed Consolidated Financial Statements and the accompanying notes appearing elsewhere in this Quarterly Report on this Form 10-Q and in our other Securities and Exchange Commission, or SEC, filings, including our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 2, 2018. The words "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements. The following discussion and analysis contains forward-looking statements within meaning of the Private Securities Litigation Reform Act of 1995.*

*These forward-looking statements include, but are not limited to, statements concerning the following:*

- our expectations regarding the results, timing and completion of our clinical trials and regulatory submissions needed for the approval of RT002 injectable for the treatment of glabellar (frown) lines, muscle movement disorders, including cervical dystonia, and plantar fasciitis, in the United States, Europe and other countries;*
- our expectations regarding our future development of RT002 injectable and our topical product candidate for other indications, including upper limb spasticity and chronic migraine;*
- our expectations regarding the development of future product candidates;*
- the potential for commercialization by us of RT002 injectable, if approved;*
- our expectations regarding the potential market size, opportunity and growth potential for RT002 injectable and our topical product candidate, if approved for commercial use;*
- our belief that RT002 injectable and our topical product candidate can expand overall demand for botulinum toxin;*
- our ability to build our own sales and marketing capabilities, or seek collaborative partners including distributors, to commercialize our product candidates, if approved;*
- our ability to manufacture in our facility and to scale up our manufacturing capabilities and those of future third-party manufacturers if our product candidates are approved;*
- estimates of our expenses, future revenue, capital requirements and our needs for additional financing;*
- the timing or likelihood of regulatory filings and approvals;*
- our ability to advance product candidates into, and successfully complete, clinical trials;*
- the implementation of our business model, and strategic plans for our business, product candidates and technology;*
- the initiation, timing, progress and results of future preclinical studies and clinical trials and our research and development programs;*
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;*
- our ability to establish collaborations or obtain additional funding;*
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act;*
- our financial performance, including future revenue targets; and*
- developments and projections relating to our competitors and our industry.*

*These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in "Risk Factors" included in Part II, Item 1A and elsewhere in this report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is neither possible for management to predict all risks nor assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this report may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.*

## Overview

Revance Therapeutics, Inc. is a clinical-stage biotechnology company focused on the development, manufacturing, and commercialization of novel botulinum toxin products for multiple aesthetic and therapeutic indications. We are leveraging our proprietary portfolio of botulinum toxin type A compounds, formulated with our patented and proprietary peptide technology, to address unmet needs in large and growing neuromodulator markets. Our proprietary peptide technology enables delivery of botulinum toxin type A through two investigational drug product candidates, DaxibotulinumtoxinA for Injection (RT002), or RT002 injectable, and DaxibotulinumtoxinA Topical ("topical" or "our topical product candidate"). We are pursuing clinical development for RT002 injectable and our biosimilar product candidate, and are planning to conduct additional preclinical development for topical. Neither formulation of our product candidates contains albumin or any other animal or human-derived materials. We believe this reduces the risk of the transmission of certain viral diseases. We hold worldwide rights for all indications of RT002 injectable and topical, and the pharmaceutical rights to our proprietary peptide technology.

Since commencing operations in 2002, we have devoted substantially all of our efforts to identifying and developing our product candidates for the aesthetic and therapeutic indications, recruiting personnel, raising capital, and preclinical and clinical development of, and manufacturing capabilities for, RT002 injectable and our topical product candidate. We have retained all worldwide rights to develop and commercialize RT002 injectable and our topical product candidate. We have not filed for approval with the FDA for the commercialization of RT002 injectable or our topical product candidate to treat any indication, and we have not generated any revenue from product sales for RT002 injectable or our topical product candidate.

### *DaxibotulinumtoxinA for Injection (RT002 or RT002 Injectable)*

RT002 injectable is a novel, injectable formulation of botulinum toxin type A designed to be a targeted and long-acting treatment. We believe RT002 injectable may provide delivery of botulinum toxin to intended treatment sites, while potentially reducing the unwanted spread of botulinum toxin to adjacent areas. We believe, and our preclinical and clinical studies indicate, that this delivery, enabled by our proprietary peptide technology, may result in high response rates and long duration of effect. We are studying RT002 injectable for aesthetic indications, such as glabellar (frown) lines and therapeutic indications, such as cervical dystonia and plantar fasciitis. We believe RT002 injectable has the potential to expand into additional aesthetic and therapeutic indications in the future.

#### *Glabellar Lines*

Glabellar, or frown lines, are the result of the gathering of the tissue between the eyebrows into a fold. They are caused by the repeated action of underlying muscles associated with facial expression. Years of squinting and frowning tend to leave deep wrinkles in the skin between the eyebrows and on the bridge of the nose, across the forehead and at the corners of the eyes. On many people, frown lines produce an angry or sad look that detracts from a pleasant facial appearance. Physical, emotional and social reasons for treating frown lines and forehead furrows include improved appearance and enhanced self-esteem.

In October 2015, we reported results from BELMONT, a Phase 2 active comparator, placebo-controlled clinical trial for the treatment of glabellar lines against BOTOX® Cosmetic. The 24-week data showed that RT002 injectable achieved its primary efficacy measurement for all doses of RT002 injectable and that such efficacy was highly statistically significant as compared to placebo. In addition, the 40 Unit dose of RT002 injectable demonstrated a 23.6-week median duration versus BOTOX® Cosmetic with an 18.8-week median duration. Across all cohorts, RT002 injectable appeared to be generally safe and well-tolerated.

We are in Phase 3 clinical development for RT002 injectable for the treatment of glabellar lines. In December 2017, we announced top-line results for the SAKURA 1 and SAKURA 2 pivotal trials.

Both SAKURA 1 and SAKURA 2 met the primary composite endpoint by delivering highly statistically significant improvement against placebo in reducing the severity of glabellar lines. The percentage of RT002-treated patients who had none or mild wrinkles and achieved at least a two-point improvement from baseline on both validated physician and patient assessments was 73.6 percent in SAKURA 1 and 74.0 percent in SAKURA 2 compared to placebo ( $p < 0.0001$ ) at Week 4. Also, at that time point, 88 percent of RT002-treated patients in SAKURA 1 and 91 percent of RT002 patients in SAKURA 2 said they were very satisfied or satisfied with their treatment experience.

There were several secondary endpoints used to evaluate duration of effect, including the proportion of patients achieving none or mild response on IGA-FWS compared to placebo, median duration for time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS, and median duration for time to return to baseline on both IGA-FWS and PFWS. The percentage of RT002-treated patients who achieved a none or mild response on IGA-FWS was 35.3 percent in SAKURA 1 and 29.4 percent

at SAKURA 2 compared to placebo ( $p < 0.0001$ ) at Week 24. The median duration for time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS for RT002-treated patients was 24.0 weeks for SAKURA 1 and 23.9 weeks for SAKURA 2. The median duration for time to return to baseline wrinkle severity on both IGA-FWS and PFWS for RT002-treated patients was 27.7 weeks for SAKURA 1 and 26.0 weeks for SAKURA 2. For comparison, an additional exploratory duration endpoint was evaluated, which mirrors the duration measure used in the BELMONT Phase 2 study. This endpoint, was the median duration of greater or equal to 1 point improvement from baseline on IGA-FWS for RT002-treated patients, and the results were 24.1 weeks for both SAKURA 1 and SAKURA 2, and 23.6 weeks for BELMONT.

In addition to SAKURA 1 and SAKURA 2, the SAKURA Phase 3 program includes a long-term, open-label safety trial (SAKURA 3), which is designed to evaluate the long-term safety and duration of RT002 injectable for the treatment of moderate to severe glabellar lines in adults following both single and repeat treatment administration. In the fourth quarter of 2017, we completed enrollment of more than 2,500 subjects at 66 sites in the U.S. and Canada for SAKURA 3. Depending on the number of treatments and duration of follow-up, a subject may be on trial for a maximum of 86 weeks. We have designed SAKURA 3 to support a safety database adequate for both domestic and international marketing applications. Assuming successful completion of our SAKURA Phase 3 program in the fourth quarter of 2018, we plan to file marketing applications first in the United States in the first half of 2019, followed by the European Union, Canada, and certain Latin American and Asian countries. If approved, we believe RT002 injectable has the potential to address significant unmet needs in these geographies.

#### *Cervical Dystonia*

We have also been developing RT002 for the treatment of cervical dystonia, a muscle movement disorder. Muscle movement disorders, such as cervical dystonia, are neurological conditions that affect a person's ability to control muscle activity in one or more areas of the body. In 2015, we initiated a Phase 2 dose-escalating, open-label clinical study of RT002 injectable to evaluate the safety, preliminary efficacy, and duration of effect of RT002 injectable in subjects with moderate to severe isolated cervical dystonia.

In May 2017, we announced positive 24 week topline results for all three cohorts from the Phase 2 trial. The topline data demonstrated a median duration of at least 24 weeks for each of the three cohorts. The topline data also displayed a clinically significant impact on cervical dystonia signs and symptoms. At Week 4, RT002 injectable showed a clinically significant mean reduction of 38% from baseline across all three cohorts. This reduction continued to increase to 50% at Week 6 for all subjects, was 42% at Week 12 and was maintained at or above 30% through Week 24. The topline data also showed that RT002 injectable appeared to be generally safe and well-tolerated through Week 24 in all three cohorts. There were no serious adverse events and no dose-dependent increase in adverse events. The treatment-related adverse events were generally transient and mild to moderate in severity, with one case of neck pain reported as severe. The most common adverse events were dysphagia, or difficulty in swallowing (14%), of which all cases were mild in severity, injection site redness (8%), injection site bruising (5%), injection site pain (5%), muscle tightness (5%) and muscle weakness (5%).

In November 2017, the FDA granted orphan drug status to DaxibotulinumtoxinA for Injection for the treatment of cervical dystonia in adults. Additionally, in November 2017, we completed our End-of-Phase 2 meeting with the FDA and received Scientific Advice from the EMA regarding RT002 for the treatment of cervical dystonia.

Based on the Phase 2 safety and efficacy results and guidance from the FDA and EMA, we announced in June 2018 the initiation of patient dosing in our ASPEN Phase 3 clinical program. The ASPEN Phase 3 clinical program consists of two trials to evaluate the safety and efficacy of RT002 for the treatment of cervical dystonia in adults including: a randomized, double-blind, placebo-controlled, parallel group trial and an open-label, long-term safety trial. The program is expected to enroll approximately 300 patients in each of the two studies at multiple sites in the United States, Canada, and Europe.

#### *Plantar Fasciitis*

We are also developing RT002 for the treatment of plantar fasciitis. Plantar fasciitis is a painful affliction caused by inflammation of the ligament running along the bottom of the foot and is the most common cause of heel pain for patients who visit podiatrists and orthopedic foot and ankle surgeons. In 2016, we initiated a Phase 2 prospective, randomized, double-blinded, placebo-controlled trial of RT002 injectable in the therapeutic indication of plantar fasciitis. This study evaluated the safety and efficacy of a single administration of RT002 injectable in reducing the signs and symptoms of plantar fasciitis. The primary efficacy endpoint was the reduction in the visual analog scale (VAS) for pain in the foot at eight weeks and subjects were followed for 16 weeks following treatment. In January 2018, we announced the interim 8-week Phase 2 results for the plantar fasciitis trial. The trial's primary endpoint, the reduction in the patient-reported visual analog scale (VAS) for pain at Week 8, showed a robust impact on pain, with a greater than 50% reduction for patients treated with RT002. In the intent-to-treat population, a mean reduction in the VAS score of 54.2% from baseline was achieved with RT002, compared with a 42.6% reduction in the placebo group, which upon further subgroup analysis, was driven primarily by a strong placebo response in the

control group at three of the five study sites. While the results are not statistically significant ( $p=0.39$ ), RT002 provided patients with considerable pain relief. Similar numeric trends were seen in the secondary and exploratory endpoints. RT002 appeared to be generally safe and well-tolerated through Week 8. The majority of adverse events in both treatment groups were mild in severity. There were no treatment-related serious adverse events. The most common treatment-related adverse events for RT002 and placebo were injection site pain (10.0 percent and 10.3 percent) and muscle weakness (3.3 percent and 3.4 percent), both respectively, all of which were classified as mild in severity. We completed the 16-week trial which showed a 58 percent reduction of pain from baseline along with a strong placebo response, with the difference between the treatment groups not being statistically significant. We plan to initiate another Phase 2, double-blind, placebo-controlled trial utilizing two doses of RT002 in the fourth quarter of 2018.

#### *Other indications*

In April 2018, we announced two new clinical programs for RT002, including adult upper limb spasticity and chronic migraine.

Adult upper limb spasticity is a chronic neurologic disorder accompanied by spasms and tightness of muscles secondary to stroke, multiple sclerosis or spinal injuries. According to Global Industry Analytics, Inc., or GIA, the global opportunity for botulinum toxin for the treatment of muscle movement disorders, which includes upper limb spasticity, was estimated to be approximately \$1.1 billion in 2017. We plan to initiate a Phase 2 study in adult upper limb spasticity in the fourth quarter of 2018.

Migraine headache is a central nervous system disorder characterized as moderate to severe headache and often includes other symptoms such as nausea and vomiting. Migraine headache affects more than 38 million people in the United States, of which more than 3 million of whom suffer from chronic migraine headache. Chronic migraine headache is both undertreated and underdiagnosed and is defined as more than fifteen headache days per month over a three month period of which more than eight are migrainous, in the absence of medication overuse. According to GIA, the global opportunity for botulinum toxin for the treatment of chronic migraine was estimated to be approximately \$600 million in 2017. In 2019, we plan to initiate a Phase 2 study to treat chronic migraine.

#### ***DaxibotulinumtoxinA Topical***

Our topical product candidate presents several potential advantages, including painless topical administration, no bruising, ease of use and limited dependence on administration technique by physicians and medical staff. We believe these potential advantages may improve the experience of patients undergoing botulinum toxin procedures and could make our topical product candidate suitable for multiple indications in the future.

We discontinued clinical development of our topical product candidate in 2016 and are planning to conduct additional preclinical work for topical in therapeutic and aesthetic applications where botulinum toxin has shown efficacy and is particularly well suited for injection-free treatments.

#### ***OnabotulinumtoxinA Biosimilar***

On February 28, 2018, we entered into a collaboration and license agreement with Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V., pursuant to which we will collaborate with Mylan exclusively, on a world-wide basis (excluding Japan), to develop, manufacture and commercialize a biosimilar to the branded biologic product (onabotulinumtoxinA) marketed as BOTOX®. As part of the agreement Mylan agreed to pay a non-refundable upfront payment of \$25 million with contingent payments of up to \$100 million, in the aggregate, upon the achievement of specified clinical and regulatory (i.e. biosimilar biological pathway) milestones and of specified, tiered sales milestones of up to \$225 million. We plan to request an initial advisory meeting with the FDA on the biosimilar pathway in November 2018.



## Results of Operations

### Revenue

The following table presents our revenue for the periods indicated and related changes from the prior period.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
	(In thousands, except percentages)					
Milestone	\$ 2,362	\$ —	100%	\$ 3,242	\$ —	100%
Relastin Royalty	—	75	(100)%	—	225	(100)%
Total revenue	<u>\$ 2,362</u>	<u>\$ 75</u>	<u>3,049%</u>	<u>\$ 3,242</u>	<u>\$ 225</u>	<u>1,341%</u>

Our total revenue for the three and nine months ended September 30, 2018 increased compared to the same period in 2017, primarily due to revenue recognized from the collaboration and license agreement with Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V. (“Mylan”). On February 28, 2018, we entered into a collaboration and license agreement (the “Agreement”) with Mylan pursuant to which we will collaborate with Mylan exclusively, on a world-wide basis (excluding Japan), to develop, manufacture and commercialize a biosimilar to the branded biologic product (onabotulinumtoxinA) marketed as BOTOX®. As part of the Agreement Mylan paid us a non-refundable upfront payment of \$25 million with contingent payments of up to \$100 million, in the aggregate, upon the achievement of specified clinical and regulatory (i.e. biosimilar biological pathway) milestones and of specified, tiered sales milestones of up to \$225 million. The Company estimates revenue recognized based on the estimated cost of services incurred over the estimated cost of services to be provided for the development period.

We recognized royalty revenue during the three and nine months ended September 30, 2017 related to the Relastin asset purchase and royalty agreement. In August 2011, we entered into the Relastin asset purchase and royalty agreement to sell the business related to our Relastin product line, to Precision Dermatology, Inc., or PDI. The Relastin asset purchase and royalty agreement provided for a minimum royalty payment of \$0.3 million per year, to be paid quarterly for up to 15 years from the execution date. PDI was subsequently acquired by Valeant Pharmaceuticals International, Inc., or Valeant, in July 2014. On April 23, 2015, we received notice from Valeant terminating the asset purchase and royalty agreement effective as of July 23, 2015. The Company was entitled to the minimum royalty payment until Valeant returned the Relastin® intellectual property rights to the Company. In November 2017, Revance and Valeant entered into an Asset Transfer Agreement to finalize the termination of the asset purchase and royalty agreement and Valeant returned the Relastin® intellectual property rights to the Company. The Company does not have any current plans for future development of Relastin® and its focus is primarily on the development of RT002 injectable.

### Operating Expenses

Our operating expenses consist of research and development expenses and general and administrative expenses. The largest component of our operating expenses is our personnel costs including stock-based compensation. We expect our expenses to increase in the near term as we initiate and complete additional clinical trials and associated programs related to RT002 injectable for the treatment of glabellar lines and indications in muscle movement and other disorders, such as cervical dystonia, plantar fasciitis, upper limb spasticity, chronic migraine, and our biosimilar product candidate.

#### Research and Development Expenses

We recognize research and development expenses as they are incurred. Since our inception, we have focused on our clinical development programs and the related research and development. We have been developing RT002 injectable, our topical, and biosimilar product candidates and we have typically shared our employees, consultants and infrastructure resources across both programs. Our research and development expenses consist primarily of:

- salaries and related expenses for personnel in research and development functions, including stock-based compensation;
- expenses related to the initiation and completion of clinical trials for RT002 injectable and our topical product candidate, including expenses related to production of clinical supplies;
- fees paid to clinical consultants, clinical trial sites, clinical research organizations (CROs) and other vendors, including all related fees for investigator grants, patient screening fees, laboratory work and statistical compilation and analysis;
- other consulting fees paid to third parties;
- expenses related to establishment and maintenance of our own manufacturing facilities;

- expenses related to the manufacture of drug substance and drug product supplies for ongoing and future preclinical and clinical trials;
- expenses to support our product development and establish manufacturing capabilities to support potential future commercialization of any products for which we may obtain regulatory approval;
- expenses related to license fees and milestone payments under in-licensing agreements;
- expenses related to compliance with drug development regulatory requirements in the United States, the European Union and other foreign jurisdictions; and
- depreciation and other allocated expenses.

Our research and development expenditures are subject to numerous uncertainties primarily related to the timing and cost needed to complete our respective projects. Further, the development timelines, probability of success and development expenses can differ materially from expectations and the completion of clinical trials may take several years or more depending on the type, complexity, novelty and intended use of a product candidate. Accordingly, the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development. We expect our research and development expenses to increase as we continue our clinical development of RT002 injectable for the treatment of glabellar lines, cervical dystonia, plantar fasciitis, upper limb spasticity, chronic migraine, our biosimilar product candidate and any future new indications, or if the FDA requires us to conduct additional clinical trials for approval.

Our research and development expenses fluctuate as projects transition from one development phase to the next. Depending on the stage of completion and level of effort related to each development phase undertaken, we may reflect variations in our research and development expense. We expense both internal and external research and development expenses as they are incurred. We typically share employees, consultants and infrastructure resources between the RT002 injectable and our topical programs. We believe that the strict allocation of costs by product candidate would not be meaningful. As such, we generally do not track these costs by product candidate.

Our research and development expenses are summarized as follows:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
	(In thousands, except percentages)					
Clinical and regulatory	10,633	12,964	(18)%	34,408	32,375	6 %
Manufacturing and quality	5,452	5,302	3 %	17,958	15,838	13 %
Research	3,811	1,678	127 %	8,657	6,417	35 %
Stock-based compensation	1,836	1,534	20 %	5,627	4,341	30 %
Other expenses	116	165	(30)%	318	386	(18)%
Total research and development expenses	21,848	21,643	1 %	66,968	59,357	13 %

#### *Clinical and regulatory costs*

Clinical expenses include personnel costs, and external clinical trial costs for clinical sites, clinical research organizations, central laboratories, data management, contractors and regulatory activities associated with the development of RT002 injectable and our topical, including clinical trials of RT002 injectable for the improvement of glabellar lines, cervical dystonia and plantar fasciitis. For the three months ended September 30, 2018 and 2017, clinical and regulatory costs totaled \$10.6 million, or 49%, and \$13.0 million, or 60%, of research and development expenses for the respective periods. For the nine months ended September 30, 2018 and 2017, clinical and regulatory costs totaled \$34.4 million, or 51%, and \$32.4 million, or 55%, of research and development expenses for the respective periods.

Clinical and regulatory costs for the three and nine months ended September 30, 2018 decreased by 18% and increased by 6%, respectively, compared to the same periods in 2017. The decrease for the three months ended September 30, 2018 is primarily due to the SAKURA program winding down, offset by increasing activity for the clinical programs related to cervical dystonia and upper limb spasticity. The increase for the nine months ended September 30, 2018 is primarily due to the Phase 3 clinical trial for cervical dystonia implementation costs, offset by a decrease in clinical trial costs related to glabellar lines and plantar fasciitis as the respective trials wind down. We expect our clinical and regulatory costs to increase in the near term as we initiate and complete clinical trials and other associated programs related to RT002 for the treatment of glabellar lines, cervical dystonia, plantar fasciitis, upper limb spasticity, chronic migraine, and other indications, and the Company's anticipated BLA submission upon the completion and success of the clinical trials for the RT002 glabellar lines indication.

### *Manufacturing and quality efforts*

Manufacturing and quality efforts include personnel and occupancy expenses, external contract manufacturing costs and pre-approval manufacturing of drug product used in research and our development of RT002 injectable. Manufacturing and quality efforts also include raw materials, lab supplies, and storage and shipment of our product to support quality control and assurance activities. These costs do not include clinical costs associated with the development of RT002 injectable. For the three months ended September 30, 2018 and 2017, costs associated with our manufacturing and quality efforts totaled \$5.5 million, or 25%, and \$5.3 million, or 24%, of research and development expenses for the respective periods. For the nine months ended September 30, 2018 and 2017, costs associated with our manufacturing and quality efforts totaled \$18.0 million, or 27%, and \$15.8 million, or 27%, of research and development expenses for the respective periods.

Manufacturing and quality efforts for the three and nine months ended September 30, 2018 increased by 3% and 13%, respectively, compared to the same periods in 2017, primarily due to increased costs related to hiring additional personnel and outside services to address compliance requirements and infrastructure build-out, partially offset by sale of certain property and equipment. We expect our manufacturing and quality efforts to continue to increase as the Company approaches commercialization.

### *Research costs*

Research costs include expenses for personnel, contract research organizations, consultants, raw materials, and lab supplies used to conduct preclinical research and development of RT002 injectable, our topical, and biosimilar product candidates. For the three months ended September 30, 2018 and 2017, costs associated with our preclinical development totaled, \$3.8 million, or 17%, and \$1.7 million, or 8%, of research and development expenses for the respective periods. For the nine months ended September 30, 2018 and 2017, costs associated with our preclinical development totaled, \$8.7 million, or 13%, and \$6.4 million, or 11%, of research and development expenses for the respective periods.

Research expenses for the three and nine months ended September 30, 2018 increased by 127% and 35%, respectively compared to the same periods in 2017 primarily due to increased consulting costs on research projects. We expect our research costs to increase as the Company expands into other indications.

### *Research and development stock-based compensation*

Stock-based compensation for research and development for the three and nine months ended September 30, 2018 increased by \$0.3 million and \$1.3 million, respectively, compared to the same periods in 2017, primarily due to an increase in employee headcount and an increase in stock price.

### *Other research and development expenses*

Other research and development expenses include license fees for BioSentinel, Inc.'s technology and expertise for research and development and manufacturing purposes. The license fee costs represent approximately 1% or less of research and development expenses in all periods presented.

### *General and Administrative Expenses*

We expect that our general and administrative expenses will increase with the continued development of, and if approved, the commercialization of RT002 injectable. The following table presents our general and administration expenses for the periods indicated and related changes from the prior period.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
	(In thousands, except percentages)					
Finance and administration	8,559	5,869	46%	22,358	16,691	34%
Commercial	3,340	1,667	100%	11,352	3,341	240%
Stock-based compensation	2,256	1,612	40%	6,795	5,479	24%
Total general and administrative expenses	14,155	9,148	55%	40,505	25,511	59%

### *Finance and administration*

Finance and administration expenses consist primarily of personnel and consulting costs, for employees in our finance, information technology, investor relations, legal, human resources and other administrative functions. Other significant expenses include rent, insurance, and professional fees for accounting and legal services, including legal services associated with obtaining

and maintaining patents and litigation. Finance and administration expenses for the three and nine months ended September 30, 2018 increased by 46% and 34%, respectively, compared to the same periods in 2017, primarily due to increased costs related to personnel and consulting costs to support the Company's infrastructure and patent costs of approximately \$1.0 million.

#### *Commercial*

Commercial expenses consist primarily of market research, public relations, promotion and advertising costs. Commercial expenses for the three and nine months ended September 30, 2018 increased by 100% and 240%, respectively, compared to the same periods in 2017, due to increased costs related to personnel, consulting costs, and pre-commercial initiatives to support our anticipated future product launch for the RT002 glabellar lines indication.

#### *General and administrative stock-based compensation*

Stock-based compensation for general and administrative expenses increased by \$0.6 million and \$1.3 million, respectively, compared to the same periods in 2017, primarily due to an increase in employee headcount and an increase in stock price.

### ***Non-Operating Income and Expenses***

#### *Interest Income*

Interest income consists primarily of interest income earned on our deposit, money market fund, and investment balances. We expect interest income to vary each reporting period depending on our average deposit, money market fund, and investment balances during the period and market interest rates.

#### *Interest Expense*

Interest expense primarily consists of the interest charges associated with our financing obligations and capitalized interest. Interest expense, includes cash and non-cash components with the non-cash components consisting of effective interest recognized on the financing obligations and interest capitalized for assets constructed for use in operations.

#### *Change in Fair Value of Derivative Liability Associated with Medicis Settlement*

The Product Approval Payment associated with Medicis settlement is classified as a liability on our Condensed Consolidated Balance Sheet. This liability is remeasured to fair value at each balance sheet date with the corresponding gain or loss from the adjustment recorded in the Condensed Consolidated Statements of Operations and Comprehensive Loss. We will continue to record adjustments to the fair value of the Medicis settlement derivative liability until the Product Approval Payment has been paid. The loss recorded during the three and nine months ended September 30, 2018 reflects an increase to the valuation of the derivative liability based on assumptions related to the development of RT002 injectable for glabellar lines.

#### *Total Net Non-Operating Income (Expenses)*

Our total net non-operating income (expense) for the three and nine months ended September 30, 2018 increased by \$0.7 million and \$2.3 million, respectively, compared to the same period in 2017, primarily due to an increase in interest income offset by a decrease in interest expense and the change in fair value of the derivative liability associated with the Medicis settlement. Interest income for the three and nine months ended September 30, 2018 increased, compared to the same periods in 2017, due to a larger investment fund balance and a higher rate of return on the Company's investments. Interest expense for the three and nine months ended September 30, 2018 decreased, compared to the same period in 2017, primarily due to the decreasing interest on the equipment leases with Essex Capital as the leases approached maturity. The decrease in the change in the fair value of derivative liability associated with the Medicis settlement is primarily due to recording additional expense in 2018 to increase to the valuation of the derivative liability based on time-based discounting and interest rates.

The total net non-operating income (expenses) is as follows:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
(In thousands, except percentages)						
Interest income	\$ 996	\$ 341	192%	\$ 3,099	\$ 999	210%
Interest expense	—	(104)	(100)%	(44)	(439)	(90)%
Change in fair value of derivative liability associated with Medicis settlement	(45)	(44)	2%	(150)	(211)	(29)%
Other income (expense), net	(144)	(128)	13%	(626)	(386)	62%
Total net non-operating income (expenses)	\$ 807	\$ 65	1,142%	\$ 2,279	\$ (37)	(6,259)%

## Liquidity and Capital Resources

Our financial condition is summarized as follows:

	September 30, 2018	December 31, 2017	Change
(In thousands)			
Cash, cash equivalents, and investments	\$ 208,392	\$ 282,896	\$ (74,504)
Financing obligations	—	1,872	(1,872)
Working Capital	184,076	264,309	(80,233)
Stockholders' Equity	182,098	268,845	(86,747)

### Sources and Uses of Cash

Our cash, cash equivalents and investments totaled \$208.4 million at September 30, 2018 compared to \$282.9 million at December 31, 2017, representing a decrease of \$74.5 million. We hold our cash, cash equivalents, and investments in a variety of non-interest bearing bank accounts and interest-bearing instruments subject to investment guidelines allowing for holdings in U.S. government and agency securities and money market accounts. Our investment portfolio is structured to provide for investment maturities and access to cash to fund our anticipated working capital needs.

The decrease in cash, cash equivalents and investments by \$74.5 million was primarily due to cash used in operations, purchases of property and equipment of \$5.4 million, and equipment lease payments on our financing obligations of \$0.9 million. These decreases were primarily offset by the receipt of \$25.0 million of cash proceeds from the upfront collaboration payment from Mylan (Note 3), proceeds from the exercise of stock options and employee stock purchase plan of \$4.8 million, and \$3.1 million from interest income received from investments.

Through September 30, 2018, we have funded substantially all of our operations through the sale and issuance of our common stock, preferred stock, venture debt, and convertible debt. Due to our substantial research and development expenditures, we have generated significant operating losses since our inception. Our expenditures are primarily related to research and development activities. We expect to continue to incur net operating losses for at least the next several years as we advance RT002 injectable through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization. As a result, we will need additional capital to fund our operations which we may obtain from additional financings, public offerings, or other sources. As of September 30, 2018, we had available cash, cash equivalents and investments of \$208.4 million.

We derived the following summary of our Condensed Consolidated Cash Flows for the periods indicated from our unaudited Condensed Consolidated Financial Statements included elsewhere in this Form 10-Q (in thousands):

	Nine Months Ended September 30,	
	2018	2017
Net cash provided by (used in):		
Operating activities	\$ (73,105)	\$ (66,946)
Investing activities	(166,127)	22,490
Financing activities	1,618	37,278

*Cash Flows from Operating Activities*

Our cash used in operating activities is primarily driven by personnel, manufacturing costs, clinical development, and facility related expenditures. The changes in net cash used in operating activities are primarily related to our net loss, working capital fluctuations and changes in our non-cash expenses, all of which are highly variable. Our cash flows from operating activities will continue to be affected principally by our working capital requirements and the extent to which we increase spending on personnel and research and development activities as our business grows.

Net cash used in operating activities for the nine months ended September 30, 2018 of \$73.1 million was primarily due to clinical spend of approximately \$35.0 million to advance the Company's clinical programs toward commercialization; investing in our personnel and talent retention, which represents of approximately \$30.0 million; and professional services and consulting of approximately \$25.0 million, offset by cash receipts of \$25.0 million from Mylan upfront payment (Note 3) and interest received of approximately \$5.0 million. The remaining operating activities related primarily to rent, utilities, supplies, and other general and administrative costs.

Net cash used in operating activities of \$66.9 million in the nine months ended September 30, 2017 was largely due to ongoing clinical trial activities for our RT002 injectable program, including approximately \$20.0 million for payments to clinical trial vendors; investing in our personnel, including those that support the clinical programs, and talent retention, which represents approximately \$20.0 million; and professional services and consulting of approximately \$10.0 million. The remaining operating activities related primarily to rent, utilities, other supplies, and other general and administrative costs, offset by net interest received.

*Cash Flows from Investing Activities*

Net cash used in investing activities for the nine months ended September 30, 2018, and 2017 was primarily due to purchases of property and equipment, proceeds from sale of assets, and fluctuations in the timing of purchases and maturities of investments.

*Cash Flows from Financing Activities*

Net cash provided by or used in financing activities are primarily driven by proceeds from the issuance of our common stock in connection with follow-on offerings (as described below), ATM offerings (as described below), stock option exercises and employee stock plan purchases. Decreases in our cash flows from financing activities are primarily due to principal payments on the equipment lease with Essex Capital and payments to settle employee tax obligations resulting from net settlement of restricted stock awards.

*Follow-On Public Offerings*

In December 2017, the Company completed a follow-on public offering, or the 2017 follow-on offering, pursuant to which the Company issued 5,389,515 shares of common stock at \$31.00 per share, including the exercise of the underwriters' over-allotment option to purchase 550,806 additional shares of common stock, for net proceeds of \$156.9 million, after underwriting discounts, commissions and other offering expenses.

*At-The-Market Offering*

In March 2016, the Company entered into an At-The-Market Issuance Sales Agreement, or the 2016 ATM agreement, with Cowen and Company, LLC, or Cowen, under which the Company may offer and sell common stock having aggregate proceeds of up to \$75.0 million from time to time through Cowen as our sales agent. During the nine months ended September 30, 2017, the Company sold 1,802,651 shares of its common stock under the 2016 ATM Agreement at a weighted average price of \$22.17 per share resulting in net proceeds of \$38.2 million, after underwriting discounts, commissions, and offering expenses.

In March 2018, the Company terminated the 2016 ATM Agreement and entered into a Controlled Equity Offering sales agreement, or the 2018 ATM Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, under which the Company may offer and sell common stock having aggregate proceeds of up to \$125.0 million from time to time through Cantor Fitzgerald as our sales agent. No sales of our common stock have taken place under the 2018 ATM Agreement as of September 30, 2018.

### ***Common Stock***

The Company had outstanding common stock options of 3,499,235, outstanding common stock warrants of 34,113, unvested restricted stock awards of 656,599, and shares expected to be purchased on December 31, 2018 under the 2014 ESPP of 16,238 as of October 25, 2018.

### ***Operating and Capital Expenditure Requirements***

We have not achieved profitability on a quarterly or annual basis since our inception and we expect to continue to incur net losses for the foreseeable future. We expect to make additional capital outlays to increase operating expenditures over the next several years to support the completion of the clinical trials and other associated programs relating to RT002 injectable for the treatment of glabellar lines, cervical dystonia, plantar fasciitis, upper limb spasticity, migraine headache, and other indications, seek regulatory approval, prepare for and, if approved, proceed to commercialization. We believe that our existing capital resources, the net proceeds from our follow-on public and ATM offerings will be sufficient to fund our operations for at least the 12 months following the filing of this Form 10-Q. However, we anticipate that we will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may seek to sell additional equity or issue debt, convertible debt or other securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of debt or convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations, and financial condition.

If adequate funds are not available to us on a timely basis, or at all, we may be required to terminate or delay clinical trials or other development activities for RT002 injectable, and our topical product candidate, and any future product candidates, or delay our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates, if we obtain marketing approval. We may elect to raise additional funds even before we need them if the conditions for raising capital are favorable. Our future capital requirements depend on many factors, including:

- the results of our clinical trials for RT002 injectable and preclinical trials of our topical product candidate or any future product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for RT002 injectable, or any future product candidates including topical;
- the number and characteristics of any additional product candidates we develop or acquire;
- the scope, progress, results and costs of researching and developing and conducting preclinical and clinical trials of RT002 injectable, topical, or any future product candidates;
- the cost of commercialization activities if RT002 injectable or any future product candidates including topical are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing RT002 injectable, topical, or any future product candidates and any products we successfully commercialize and maintaining our related facilities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements including the Mylan collaboration, and the terms of and timing such arrangements;
- the degree and rate of market acceptance of any future approved products;

- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative products or treatments;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- any litigation, including litigation costs and the outcome of such litigation;
- the costs associated with being a public company;

Please see Part II, Item 1A. "Risk Factors" for additional risks associated with our substantial capital requirements.

We have not generated product revenue from RT002 injectable or our topical product candidate, and we do not know when, or if, we will generate such revenue. We do not expect to generate significant product revenue unless or until we obtain marketing approval of, and commercialize RT002 injectable or our topical product candidate. We expect our continuing operating losses to result in increases in cash used in operations over the next several years.

We have based our estimates of future capital requirements on a number of assumptions that may prove to be wrong, and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our ongoing clinical trials of RT002 injectable may encounter technical or other difficulties that could increase our development costs more than we currently expect or the FDA or EMA may require us to conduct additional clinical trials prior to approving RT002 injectable or future products we may develop. Our collaboration with Mylan to develop a biosimilar may or may not be successful. 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 clinical trials beyond 2019.

#### **Critical Accounting Policies**

There have been no material changes in our critical accounting policies during the nine months ended September 30, 2018, as compared to those disclosed in Item 7 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017, filed with the SEC on March 2, 2018, except as described in Note 2 to our Condensed Consolidated Financial Statements included elsewhere in this Form 10-Q.

#### **Contractual Obligations**

Our minimum contractual commitments were reported in our Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the SEC. Our future minimum contractual commitments have not changed materially from the amounts previously reported except for those related to our facility lease as described in Note 8 to our Condensed Consolidated Financial Statements included elsewhere in this Form 10-Q.

#### **Recent Accounting Pronouncements**

Refer to "Recent Accounting Pronouncements" in Note 2 to our Condensed Consolidated Financial Statements included elsewhere in this Form 10-Q.

#### **Off-Balance Sheet Arrangements**

As of September 30, 2018, we did not have any off-balance sheet arrangements or any relationships with any entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.



### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

#### Overview

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in foreign currency exchange rates and interest rates. We do not hold or issue financial instruments for trading purposes.

#### *Interest Rate Sensitivity*

Our exposure to market risk for changes in interest rates relates primarily to our cash, cash equivalents, and investments. We had cash, cash equivalents, and investments of \$208.4 million and \$282.9 million as of September 30, 2018 and December 31, 2017, respectively. As of September 30, 2018, our cash, cash equivalents, and investments were held in deposit, money market funds, and U.S. government agency and treasury obligations. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates in the United States. A hypothetical 10% movement in interest rates would not be expected to have a material impact on our Condensed Consolidated Financial Statements. We mitigate market risk for changes in interest rates by holding our investments in U.S. treasury and government agency obligations to maturity.

#### *Foreign Exchange*

Our operations are primarily conducted in the United States using the U.S. Dollar. However, we conduct limited operations in foreign countries, primarily for clinical and regulatory services, whereby settlement of our obligations is denominated in the local currency. Transactional exposure arises when transactions occur in currencies other than the U.S. Dollar. Transactions denominated in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction with the resulting liabilities being translated into the U.S. Dollar at exchange rates prevailing at the balance sheet date. The resulting gains and losses, which were insignificant for the nine months ended September 30, 2018 and 2017, are included in other expense in the Condensed Consolidated Statements of Operations and Comprehensive Loss. We do not use currency forward exchange contracts to offset the related effect on the underlying transactions denominated in a foreign currency.

#### **ITEM 4. CONTROLS AND PROCEDURES**

##### **Evaluation of Disclosure Controls and Procedures**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Management, with the participation of our principal executive officer and our principal financial and accounting officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial and accounting officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any 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. Based on the evaluation of our disclosure controls and procedures as of September 30, 2018, our principal executive officer and our principal financial and accounting officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

##### **Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2018 that have materially affected, or are 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 litigation relating to claims arising out of our operations. We are not currently involved in any material legal proceedings. We may, however, be involved in material legal proceedings in the future. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position or cash flows.

## ITEM 1A. RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below as well as all other information included in this Form 10-Q, including our Condensed Consolidated Financial Statements, the notes thereto and the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before you decide to purchase shares of our common stock. If any of the following risks actually occurs, our business, prospects, financial condition and operating results could be materially harmed. As a result, the trading price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and stock price.*

*We have marked with an asterisk (\*) those risks described below that reflect substantive changes from, or additions to, the risks described in our Annual Report on Form 10-K for the year ended December 31, 2017.*

### **We are substantially dependent on the clinical and commercial success of our injectable product candidate RT002 injectable.\***

To date, we have invested substantial efforts and financial resources in the research and development of botulinum toxin-based product candidates. Our success as a company is substantially dependent on the clinical and commercial success of RT002 injectable.

We previously completed topical clinical trials for the treatment of lateral canthal lines (crow's feet) and primary axillary hyperhidrosis, but discontinued further clinical development in 2016 following the results of our REALISE 1 Phase 3 clinical trial using topical to treat crow's feet.

We have invested substantial efforts and financial resources in the research and development of RT002 injectable. We are in Phase 3 clinical development for RT002 injectable in North America for the treatment of glabellar lines. During the fourth quarter of 2016, we initiated subject dosing in our SAKURA Phase 3 program. In the first quarter of 2017, we completed patient enrollment in the two pivotal trials of our SAKURA Phase 3 program. In December 2017, we announced positive top-line results for DaxibotulinumtoxinA for Injection (RT002) in alleviating moderate-to-severe glabellar lines in two randomized, double-blind, placebo-controlled pivotal Phase 3 trials to evaluate the safety and efficacy of a single administration of RT002 for the treatment of moderate-to-severe glabellar lines in adults. The SAKURA 1 and SAKURA 2 trials enrolled more than 600 subjects at 30 sites in the United States and Canada. In addition to the two planned pivotal trials, the Phase 3 program includes a long-term open-label safety trial (SAKURA 3), which is designed to evaluate the long-term safety and duration of RT002 injectable for the treatment of moderate to severe glabellar lines in adults following both single and repeat treatment administration. The long-term safety trial enrolled more than 2,500 patients at 66 sites in the U.S. and Canada and is expected to be completed in the fourth quarter of 2018. Depending on the number of treatments and duration of follow-up, a subject may be on trial for a maximum of 86 weeks. We have designed SAKURA 3 to support a safety database adequate for both domestic and international marketing applications. In 2015, we reported positive results from BELMONT, a Phase 2 active comparator clinical trial against BOTOX® Cosmetic. Past results may not be indicative of results from future trials. Assuming successful completion of our SAKURA Phase 3 program in the fourth quarter of 2018, we plan to file marketing applications first in the United States in the first half of 2019, followed by the European Union, Canada, and certain Latin American and Asian countries.

In 2015, we initiated a Phase 2 dose-escalating, open-label clinical study of RT002 injectable for the treatment of cervical dystonia. The Phase 2 study evaluated the safety, preliminary efficacy, and duration of effect of RT002 injectable in subjects with moderate to severe isolated cervical dystonia. The trial was designed to enroll 37 subjects following three sequential treatment cohorts for up to a total of 24 weeks after treatment for each cohort. The trial's first cohort of 12 subjects received a single dose of up to 200 units of RT002 injectable, the second cohort of 12 subjects received between 200 and 300 units, and the third cohort of 13 subjects received from 300 to 450 units. In May 2017, we announced positive topline results from the Phase 2 trial. Past results may not be indicative of results from future trials. In November 2017, the FDA granted orphan drug status to DaxibotulinumtoxinA for Injection for the treatment of cervical dystonia in adults. Additionally, in November 2017, we completed our End-of-Phase 2 meeting with the FDA and received Scientific Advice from the EMA regarding RT002 for the treatment of cervical dystonia. Based on the Phase 2 safety and efficacy results and guidance from the FDA and EMA, we announced in June 2018 the initiation of patient dosing in our ASPEN Phase 3 clinical program. The ASPEN Phase 3 clinical program consists of two trials to evaluate the safety and efficacy of RT002 for the treatment of cervical dystonia in adults including: a randomized, double-blind, placebo-controlled, parallel group trial and an open-label, long-term safety trial. The program is expected to enroll approximately 300 patients in each of the two studies at multiple sites in the United States, Canada, and Europe.

In 2016, we also initiated a Phase 2 prospective, randomized, double-blinded, placebo-controlled trial of RT002 injectable in the therapeutic indication of plantar fasciitis. This study evaluated the safety and efficacy of a single administration of RT002 injectable in reducing the signs and symptoms of plantar fasciitis. The study completed enrollment of 59 subjects in the United States in October 2017. The study's primary efficacy endpoint is the improvement in the American Orthopedic Foot and Ankle Score (AOFAS). In January 2018, we announced interim 8-week results from this study. We completed the 16-week trial which showed a 58 percent reduction of pain from baseline along with a strong placebo response, with the difference between the treatment groups not being statistically significant. We plan to initiate another Phase 2, double-blind, placebo-controlled trial utilizing two doses of RT002 in the fourth quarter of 2018.

In April 2018, we announced two new clinical programs for RT002, including adult upper limb spasticity and chronic migraine. We plan to initiate a Phase 2 study in adult upper limb spasticity in the fourth quarter of 2018. In 2019, we plan to initiate a Phase 2 study to treat chronic migraine.

Our near-term prospects, including our ability to finance our company and generate revenue, will depend heavily on the successful development, regulatory approval and commercialization of RT002 injectable. Our longer-term prospects will depend on the successful development, regulatory approval and commercialization of RT002 injectable, as well as our topical or any future product candidates. The preclinical, clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- timely completion of, or need to conduct additional, clinical trials, including our clinical trials for RT002 injectable, topical, and any future product candidates, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the number and design of such trials and the accurate and satisfactory performance of third-party contractors;
- our ability to demonstrate the effectiveness and differentiation of our products on a consistent basis as compared to existing or future therapies;
- our ability to demonstrate to the satisfaction of the FDA, the safety and efficacy of RT002 injectable, our topical product candidate, or any future product candidates through clinical trials;
- whether we are required by the FDA or other similar foreign regulatory agencies to conduct additional clinical trials to support the approval of RT002 injectable, our topical product candidate, or any future product candidates;
- our success in educating physicians and patients about the benefits, administration and use of RT002 injectable, our topical product candidate, or any future product candidates, if approved;
- the prevalence and severity of adverse events experienced with our product candidates or future approved products;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- the ability to raise additional capital on acceptable terms and in the time frames necessary to achieve our goals;
- achieving and maintaining compliance with all regulatory requirements applicable to RT002 injectable, our topical product candidate, or any future product candidates or approved products;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative treatments;
- the effectiveness of our own or our future potential strategic collaborators' marketing, sales and distribution strategy and operations;
- our ability to manufacture clinical trial supplies of RT002 injectable, our topical product candidate, or any future product candidates and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP;
- our ability to successfully commercialize RT002 injectable, our topical product candidate, or any future product candidates, if approved for marketing and sale, whether alone or in collaboration with others;
- our ability to enforce our intellectual property rights in and to RT002 injectable, our topical product candidate, or any future product candidates;
- our ability to avoid third-party patent interference or intellectual property infringement claims;
- acceptance of RT002 injectable, our topical product candidate, or any future product candidates, if approved, as safe and effective by patients and the medical community; and
- the continued acceptable safety profile of RT002 injectable, our topical product candidate, or any future product candidates following approval.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates. Accordingly, we

cannot assure you that we will be able to generate sufficient revenue through the sale of RT002 injectable, our topical product candidate, or any future product candidate to continue our business.

**We may be unable to obtain regulatory approval for RT002 injectable, topical product candidate, biosimilar product candidate or future product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business prospects, and our results of operations.\***

To gain approval to market a biologic product such as RT002 injectable, topical or biosimilar, we must provide the FDA and foreign regulatory authorities with data that adequately demonstrate the safety, efficacy and quality of the product for the intended indication applied for in the BLA or other respective marketing applications. The development of biologic products is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, including in Phase 3 development, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, findings made while clinical trials were underway, safety or efficacy observations, including previously unreported adverse events; and the need to conduct further supportive or unanticipated studies, even after initiating Phase 3 trials. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful or that additional supportive studies will not be required, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct.

Specifically, we completed topical clinical trials for the treatment of lateral canthal lines (crow's feet) and primary axillary hyperhidrosis, but discontinued further clinical development in 2016 following the results from our REALISE 1 Phase 3 clinical trial for crow's feet. In addition, we announced in January 2018 that we plan to initiate a second Phase 2 study in plantar fasciitis in the fourth quarter.

Our business currently depends substantially on the successful development, regulatory approval and commercialization of our product candidates. Based on discussion with the FDA at a Pre-Phase 3 meeting in the second quarter of 2016 and the minutes received following the meeting, we submitted an IND in the United States and initiated subject dosing in Phase 3 clinical studies of RT002 injectable for the treatment of glabellar lines in 2016. In the first quarter of 2017, we completed patient enrollment in the two pivotal trials of our SAKURA Phase 3 program and in October 2017, we completed enrollment of SAKURA 3. In December 2017, we announced positive top-line results from the two pivotal trials. We plan to move forward with studies required for submission of a BLA. In June 2018, we announced the initiation of patient dosing in our ASPEN Phase 3 clinical program for RT002 injectable for the treatment of cervical dystonia. The program is expected to enroll approximately 300 patients in each of the two studies at multiple sites in the United States, Canada, and Europe.

Such studies may increase the time, expense and uncertainty of our RT002 injectable development program, including, for example, because results of such studies may indicate to us a further need to refine the RT002 injectable product candidate.

We currently have no drug or biologic products approved for sale, and we may never obtain regulatory approval to commercialize RT002 injectable, or our topical product candidate. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug and biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, and such regulations differ from country to country. We are not permitted to market RT002 injectable in the United States until we receive approval of a BLA from the FDA. We are also not permitted to market RT002 injectable in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries.

The FDA or any foreign regulatory body can delay, limit or deny approval of our product candidates, including RT002 injectable, for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or an applicable foreign regulatory body that RT002 injectable, topical, or any future product candidates are safe and effective for the requested indication;
- our inability to demonstrate preclinical proof of concept of topical or other products in future, new indications;
- the FDA's or an applicable foreign regulatory agency's disagreement with the trial protocol or the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate that clinical and other benefits of RT002 injectable, topical, or any future product candidates outweigh any safety or other perceived risks;
- the FDA's or an applicable foreign regulatory agency's requirement for additional preclinical or clinical studies;
- the FDA's or an applicable foreign regulatory agency's non-approval of the formulation, labeling or the specifications of RT002 injectable, topical, or any future product candidates;

- the FDA's or an applicable foreign regulatory agency's failure to approve our manufacturing processes or facilities, or the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA or an applicable foreign regulatory agency to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs, including biologics, in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for RT002 injectable, topical, or any future product candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA or the applicable foreign regulatory agency also may approve RT002 injectable, our topical product candidate, or any future product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA or applicable foreign regulatory agency may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. Any delay in obtaining, or inability to obtain, applicable regulatory approval for any of our product candidates, and RT002 injectable in particular, would delay or prevent commercialization of RT002 injectable and would materially adversely impact our business, results of operations and prospects.

**We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts.\***

Since our inception, most of our resources have been dedicated to the research and preclinical and clinical development of our botulinum toxin product candidates, RT002 injectable and topical. In particular, our clinical programs for RT002 injectable and topical will require substantial additional funds to complete. We had an accumulated deficit through September 30, 2018 of \$644.2 million and a working capital surplus of \$184.1 million as of September 30, 2018, primarily as a result of our November 2015 and December 2017 follow-on public offerings, and at-the-market, or ATM, offerings in 2015 and 2017. Our recorded net losses were \$32.8 million and \$30.7 million, and \$102.0 million and \$84.7 million, for the three and nine months ended September 30, 2018, and 2017, respectively. We have funded our operations primarily through the sale and issuance of convertible preferred stock, common stock, notes payable and convertible notes. As of September 30, 2018, we had capital resources consisting of cash, cash equivalents and investments of \$208.4 million. We raised aggregate net proceeds of \$126.2 million and \$156.9 million in our follow-on public offerings in November 2015 and December 2017, respectively. In addition, we raised net proceeds of approximately \$10.0 million by selling an aggregate of 352,544 shares of our common stock under the 2015 ATM agreement, which was effectively terminated on March 7, 2016, and raised net proceeds of approximately \$38.2 million by selling an aggregate of 1,802,651 shares of our common stock under the 2016 ATM agreement. In March 2018, we terminated the 2016 ATM Agreement and entered into a Controlled Equity Offering sales agreement, or the 2018 ATM Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, under which the Company may offer and sell common stock having aggregate proceeds of up to \$125.0 million from time to time through Cantor Fitzgerald as our sales agent. No sales of our common stock have taken place under the 2018 ATM Agreement as of September 30, 2018. We believe that we will continue to expend substantial resources for the foreseeable future for the clinical development of RT002 injectable, topical, and development of any other indications and product candidates that we may choose to pursue. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, and manufacturing and supply as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of RT002 injectable and any future product candidates.

We believe that our existing cash, cash equivalents, and investments including the net proceeds from our IPO, follow-on public offerings, and ATM offerings will allow us to fund our operations for at least 12 months following the filing of this Form 10-Q. However, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional capital sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financings may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe that we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including:

- the results of our clinical trials for RT002 injectable and preclinical trials of our topical product candidate or any future product candidates;

- the timing of, and the costs involved in, obtaining regulatory approvals for RT002 injectable, or any future product candidates including topical;
- the number and characteristics of any additional product candidates we develop or acquire;
- the scope, progress, results and costs of researching and developing and conducting preclinical and clinical trials of RT002 injectable, topical, or any future product candidates;
- the cost of commercialization activities if RT002 injectable or any future product candidates including topical are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing RT002 injectable, topical, or any future product candidates and any products we successfully commercialize and maintaining our related facilities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements including the Mylan collaboration, and the terms of and timing such arrangements;
- the degree and rate of market acceptance of any future approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative products or treatments;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- any litigation, including litigation costs and the outcome of such litigation;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, future approved products, if any.

Additional capital may not be available when needed, on terms that are acceptable to us or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials, research, development, manufacturing, sales, marketing or other commercial activities for RT002 injectable, topical, or any future product candidate.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted and the terms of any new equity securities may have a preference over our common stock. 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 or making capital expenditures or specified financial ratios, any of which could restrict our ability to commercialize our product candidates or operate as a business.

**Even if our product candidates receive regulatory approval, they may fail to achieve the broad degree of physician adoption and use necessary for commercial success.\***

The commercial success of RT002 injectable, and any future product candidates including topical, if approved, will depend significantly on the broad adoption and use of the resulting product by physicians for approved indications. The degree and rate of physician adoption of RT002 injectable and any future product candidates, if approved, will depend on a number of factors, including:

- the effectiveness and duration of effect of our product as compared to existing and future therapies;
- physician willingness to adopt a new therapy to treat glabellar lines, cervical dystonia, plantar fasciitis, adult upper limb spasticity, chronic migraine or other aesthetic or therapeutic indications;
- patient satisfaction with the results and administration of our product and overall treatment experience;
- patient demand for the treatment of glabellar lines, cervical dystonia, plantar fasciitis or other aesthetic or therapeutic indications;
- the willingness of third-party payors to reimburse physicians or patients for RT002 injectable and any future products we may commercialize for therapeutic indications; and
- the revenue and profitability that our product will offer a physician as compared to alternative therapies.

If RT002 injectable or any future product candidates are approved for use but fail to achieve the broad degree of physician adoption necessary for commercial success, our operating results and financial condition will be adversely affected.

**Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration and expansion.**

We expect to enter highly competitive pharmaceutical and medical device markets. Successful competitors in the pharmaceutical and medical device markets have the ability to effectively discover therapies, obtain patents, develop, test and obtain regulatory approvals for products, and have the ability to effectively commercialize, market and promote approved products, including communicating the effectiveness, safety and value of products to actual and prospective customers and medical staff. Numerous companies are engaged in the developing, patenting, manufacturing and marketing healthcare products which we expect will compete with those that we are developing. Many of these competitors are large, experienced companies that enjoy significant competitive advantages, such as substantially greater financial, research and development, manufacturing, personnel and marketing resources, greater brand recognition and more experience and expertise in obtaining marketing approvals from the FDA and other regulatory authorities.

Upon marketing approval, the first expected use of our products will be in aesthetic medicine. Competition in aesthetic products is significant and dynamic, and is characterized by rapid and substantial technological development and product innovations. Numerous competitors have obtained patents protecting what they consider to be their intellectual property.

In aesthetic medicine, we plan to seek regulatory approval of RT002 injectable for the treatment of glabellar lines. We anticipate that RT002 injectable, if approved, will face significant competition from existing injectable botulinum toxins as well as unapproved and off-label treatments. Further, if approved, in the future we may face competition for RT002 injectable from biosimilar products and products based upon botulinum toxin. To compete successfully, we will have to demonstrate that the treatment of glabellar lines with RT002 injectable is a worthwhile aesthetic treatment and has advantages over other therapies. Competition could result in reduced profit margins and limited sales, which would harm our business, financial condition and results of operations.

Due to less stringent regulatory requirements, there are many more aesthetic products and procedures available for use in a number of foreign countries than are approved for use in the United States. There are also fewer limitations on the claims that our competitors in certain countries can make about the effectiveness of their products and the manner in which they can market them.

**We currently make our RT002 injectable clinical drug product exclusively in one internal manufacturing facility. We plan to utilize internal and external facilities, including through one or more third-party contractors, in the future to support commercial production if our product candidates are approved. If these or any future facility or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business would be materially harmed.\***

We currently manufacture our own clinical drug product to support RT002 injectable development in one internal manufacturing facility. In March 2017, we entered into a Technology Transfer, Validation and Commercial Fill/Finish Services Agreement, or the Services Agreement, with Ajinomoto Althea, Inc., or Althea, a contract development and manufacturing organization. Under the Services Agreement, Althea will provide us commercial fill/finish services and will serve as a second source of manufacturing for RT002 injectable. We plan to utilize our internal and external Althea facility to support commercial production of RT002 injectable, if approved. If these or any future facility were to be damaged, destroyed or otherwise unable to operate, whether due to earthquakes, fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages or otherwise, or if performance of such manufacturing facilities is disrupted for any other reason, such an event could delay our clinical trials or, if our product candidates are approved, jeopardize our ability to manufacture our products as promptly as our customers expect or possibly at all. If we experience delays in achieving our development objectives, or if we are unable to manufacture an approved product within a timeframe that meets our customers' expectations, our business, prospects, financial results and reputation could be materially harmed.

Currently, we maintain insurance coverage totaling \$22.8 million against damage to our property, equipment and tenant improvements, \$2.0 million in general liability coverage, a \$9.0 million umbrella policy, and an additional \$70.0 million to cover business interruption and research and development restoration expenses, subject to deductibles and other limitations. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.



**Impairment in the carrying value of long-lived assets could negatively affect our operating results.\***

We constructed a fill/finish line dedicated to the manufacture of topical and to support our regulatory license applications. We discontinued further clinical development of topical for the treatment of crow's feet and for the treatment of primary axillary hyperhidrosis in June 2016, following the results from our REALISE 1 Phase 3 clinical trial. During the year ended December 31, 2016, we recorded a loss on impairment of \$9.1 million related to certain components of the topical fill/finish line and other long-lived assets. The Company assessed the topical fill/finish line and these other long-lived assets for impairment indicators and recorded a loss on impairment of \$2.9 million for the year ended December 31, 2017. There were no indicators of impairment for the nine months ended September 30, 2018. As of September 30, 2018, the fill/finish line and these other long-lived assets had net book values of \$2.3 million and less than \$0.1 million, respectively. Under generally accepted accounting principles in the United States, long-lived assets, such as our fill/finish line, are required to be reviewed for impairment whenever adverse events or changes in circumstances indicate a possible impairment. If business conditions or other factors indicate that the carrying value of the asset may not be recoverable, we may be required to record additional non-cash impairment charges. Additionally, if the carrying value of our capital equipment exceeds current fair value as determined based on the discounted future cash flows of the related product, the capital equipment would be considered impaired and would be reduced to fair value by a non-cash charge to earnings, which could negatively affect our operating results. Events and conditions that could result in impairment in the value of our long-lived assets include adverse clinical trial results, changes in operating plans, unfavorable changes in competitive landscape, adverse changes in the regulatory environment, or other factors leading to reduction in expected long-term sales or profitability. We will evaluate the recoverability and fair value of our long-lived assets, including those related to other components of the fill/finish line, each reporting period to determine the extent to which further non-cash charges to earnings are appropriate. Additional impairment in the value of our long-lived assets may materially and negatively impact our operating results.

**We have incurred significant losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future. Currently, we have only one product candidate in clinical trials and no commercial sales, which make it difficult to assess our future viability.\***

We are a clinical-stage biotechnology company. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We are not profitable and have incurred losses in each year since we commenced operations in 2002. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry. To date, we have not obtained any regulatory approvals for any of our product candidates or generated any revenue from product sales relating to RT002 injectable or our topical product candidate. We continue to incur significant research and development and other expenses related to our ongoing clinical trials and operations. We had an accumulated deficit through September 30, 2018 of \$644.2 million and a working capital surplus of \$184.1 million as of September 30, 2018, primarily as a result of our November 2015 and December 2017 follow-on public offerings, and at-the-market, or ATM, offerings in 2015 and 2017. Our recorded net losses were \$32.8 million and \$30.7 million and \$102.0 million and \$84.7 million for the three and nine months ended September 30, 2018, and 2017, respectively. We have funded our operations primarily through the sale and issuance of convertible preferred stock, common stock, notes payable and convertible notes. The net proceeds from the sale of the shares in our November 2015 and December 2017 follow-on public offerings and ATM offerings in 2015 and 2017, after deducting the underwriters' discount, commissions, and other offering expenses related to the respective offerings, were approximately \$126.2 million and \$156.9 million, \$10.0 million and \$38.2 million, respectively. Our capital requirements to implement our business strategy are substantial, including our capital requirements to develop and commercialize RT002 injectable. We believe that our currently available capital is sufficient to fund our operations through at least the next 12 months following the filing of this Form 10-Q.

We expect to continue to incur losses for the foreseeable future, and we anticipate that these losses will increase as we continue our development of, seek regulatory approval for and begin to commercialize RT002 injectable. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals and manufacture, market and commercialize our products successfully. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

**Even if RT002 injectable, topical, biosimilar, or any future product candidates obtain regulatory approval, they may never achieve market acceptance or commercial success.\***

Even if we obtain FDA or other regulatory approvals, RT002 injectable, topical, biosimilar or any future product candidates may not achieve market acceptance among physicians and patients, and may not be commercially successful.

The degree and rate of market acceptance of RT002 injectable, topical, biosimilar, or any future product candidates for which we receive approval depends on a number of factors, including:

- the safety and efficacy of the product as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- the proper training and administration of our products by physicians and medical staff;
- the potential and perceived advantages of our products over alternative treatments;
- the cost of treatment in relation to alternative treatments and willingness to pay for our products, if approved, on the part of payors and patients;
- the willingness of patients to pay for RT002 injectable, our topical product candidate, and other aesthetic treatments in general, relative to other discretionary items, especially during economically challenging times;
- the willingness of third-party payors to reimburse physicians or patients for RT002 injectable and any future products we may commercialize for therapeutic indications;
- the relative convenience and ease of administration;
- the prevalence and severity of adverse events; and
- the effectiveness of our sales and marketing efforts.

Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would materially adversely affect our results of operations and delay, prevent or limit our ability to generate revenue and continue our business.

**Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.**

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Furthermore, we rely on contract research organizations, or CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing the committed activities of our CROs, we have limited influence over their actual performance. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Furthermore, final results may differ from interim results. For example, any positive results generated to date in clinical trials for RT002 injectable do not ensure that later clinical trials, including any RT002 injectable clinical trials for the treatment of glabellar lines, will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety profile and efficacy despite having progressed through preclinical studies and initial clinical trials.

A number of companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials. We have suffered similar setbacks with the clinical development of our topical product candidate and we cannot be certain that we will not face other similar setbacks in the future for RT002 injectable or other clinical development programs. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

We have in the past and may in the future experience delays in our ongoing clinical trials, and we do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of subjects on time or be completed on schedule, if at all. Clinical trials can be delayed or aborted for a variety of reasons, including delay or failure to:

- obtain regulatory approval to commence a trial;
- reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain institutional review board, or IRB, approval at each site;
- recruit suitable subjects to participate in a trial;
- have subjects complete a trial or return for post-treatment follow-up;
- ensure clinical sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of product candidate for use in clinical trials.

Subject enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the data safety monitoring board, for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, failure of inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, discovery of unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion or termination of any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

**We have no experience manufacturing our product candidates at full commercial scale. If our product candidates are approved, we will face certain risks associated with scaling up our manufacturing capabilities to support commercial production.**

We have developed an integrated manufacturing, research and development facility located at our corporate headquarters. We manufacture drug substance and finished dose forms of the drug product at this facility that we use for research and development purposes and clinical trials. We do not have experience in manufacturing our product candidates at commercial scale. If our product candidates are approved, we may need to expand our manufacturing facilities, add manufacturing personnel and ensure that validated processes are consistently implemented in our facilities and potentially enter into additional relationships with third-party manufacturers. The upgrade and expansion of our facilities will require additional regulatory approvals. In addition, it will be costly and time-consuming to expand our facilities and recruit necessary additional personnel. If we are unable to expand our manufacturing facilities in compliance with regulatory requirements or to hire additional necessary manufacturing personnel, we may encounter delays or additional costs in achieving our research, development and commercialization objectives, including obtaining regulatory approvals of our product candidates, which could materially damage our business and financial position.

**We currently contract with third-party manufacturers for certain components and services necessary to produce RT002 injectable and expect to continue to do so to support further clinical trials and commercial scale production if RT002 injectable is approved. This increases the risk that we will not have sufficient quantities of RT002 injectable or be able to obtain such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.**

We currently rely on third-party manufacturers for certain components such as bulk peptide and services such as fill/finish services, necessary to produce RT002 injectable for our clinical trials, and we expect to continue to rely on these or other manufacturers to support our commercial requirements if RT002 injectable is approved. In particular, in March 2017, we entered into the Services Agreement with Althea, a contract development and manufacturing organization to provide us commercial fill/finish services and a second source of manufacturing for RT002 injectable. We plan to utilize our internal and external Althea facility to support commercial production of RT002 injectable, if approved. Some of our contracts with our manufacturers contain minimum order and pricing provisions and provide for early termination based on regulatory approval milestones.

Reliance on third-party manufacturers entails additional risks, including the reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party, and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third-party manufacturers may not be able to comply with cGMP or Quality System Regulation, or QSR, or similar regulatory requirements outside the United States. Our failure or the failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or

withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of RT002 injectable, or any other product candidates or products that we may develop. Any failure or refusal to supply the components or services for RT002 injectable or any other product candidates or products that we may develop could delay, prevent or impair our clinical development or commercialization efforts.

**We depend on single-source suppliers for the raw materials necessary to produce our product candidates. The loss of these suppliers, or their failure to supply us with these raw materials, would materially and adversely affect our business.**

We and our manufacturers purchase the materials necessary to produce RT002 injectable for our clinical trials from single-source third-party suppliers. There are a limited number of suppliers for the raw materials that we use to manufacture our product candidates, and we may need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials and, if approved, ultimately for commercial sale. In particular, we outsource the manufacture of bulk peptide through American Peptide Company, Inc., or American Peptide, which was acquired by Bachem.

We do not have any control over the process or timing of the acquisition of raw materials by our manufacturers. Although we generally do not begin a clinical trial unless we believe that we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of RT002 injectable or any future product candidates, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party supplier could considerably delay completion of our clinical trials, product testing and potential regulatory approval of RT002 injectable or any future product candidates. If we or our manufacturers are unable to purchase these raw materials on acceptable terms and at sufficient quality levels or in adequate quantities if at all, the development of RT002 injectable and any future product candidates, or the commercial launch of any approved products, would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of any approved products.

Furthermore, if there is a disruption to our or our third-party suppliers' relevant operations, we will have no other means of producing RT002 injectable or any future product candidates until they restore the affected facilities or we or they procure alternative facilities. Additionally, any damage to or destruction of our or our third party or suppliers' facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

**We currently have limited marketing and sales capabilities and no field sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize RT002 injectable or any other future product candidates, if approved, or generate product revenue.**

We currently have limited marketing and sales capabilities and no field sales organization. To commercialize RT002 injectable or any other future product candidates, if approved, in the United States, Europe and other jurisdictions we seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If RT002 injectable receives regulatory approval, we expect to market RT002 injectable as applicable, through our own sales force in North America, and in Europe and other countries through either our own sales force or a combination of our internal sales force and distributors or partners, which may be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize RT002 injectable or any future product candidates. If we are not successful in commercializing RT002 injectable or any future product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

**To establish our sales and marketing infrastructure and expand our manufacturing capabilities, we will need to increase the size of our organization and we may experience difficulties in managing this growth.\***

As of September 30, 2018, we had 149 employees. We will need to continue to expand our managerial, operational, and other resources to manage our operations and clinical trials, continue our development activities and commercialize RT002 injectable or any other product candidates, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- manage our clinical trials and manufacturing operations effectively;
- identify, recruit, retain, incentivize and integrate additional employees;
- manage our internal development efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

Due to our limited financial resources and our limited experience in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our development and strategic objectives, or disrupt our operations.

**We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.**

Our corporate headquarters and other facilities, including our internal manufacturing facility, are located in the San Francisco Bay Area, which has experienced severe earthquakes. We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our manufacturing facility, enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. In particular, because we manufacture botulinum toxin in our facilities, we would be required to obtain further clearance and approval by state, federal or other applicable authorities to continue or resume manufacturing activities. The disaster recovery and business continuity plans we have in place currently are limited and may not be adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Furthermore, integral parties in our supply chain are geographically concentrated and operating from single sites, thereby increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

**We currently rely on third parties and consultants to conduct all our preclinical studies and clinical trials. If these third parties or consultants do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize RT002 injectable or any future product candidates.**

We do not have the ability to independently conduct preclinical studies or clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, collaborative partners and other third parties, such as CROs and clinical data management organizations, to conduct clinical trials on our product candidates. The third parties with whom we contract for execution of our clinical trials play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, these third parties are not our employees, and except for contractual duties and obligations, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our preclinical studies and clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs and good laboratory practices or GLPs, for conducting, monitoring, recording and reporting the results of clinical and preclinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We also rely on consultants to assist in the execution, including data collection and analysis, of our clinical trials.

In addition, the execution of preclinical studies and clinical trials, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. These third parties may terminate their agreements with us upon as little as 30 days' prior written notice of a material breach by us that is not cured within 30 days. Many of these agreements may also be terminated by such third parties under certain other circumstances, including our insolvency or our failure to comply with applicable laws. In general, these agreements require such third parties to reasonably cooperate with us at our expense for an orderly winding down of services of such third parties under the agreements. If the third parties or consultants conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCP, or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. We may be unable to recover unused funds from these third-parties. If any of the foregoing were to occur, we may not be able to obtain, or may be delayed in obtaining, regulatory approval for, and will not be able to, or may be delayed in our efforts to, successfully commercialize the product candidate being tested in such trials.

**If RT002 injectable is approved for marketing, and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, significant fines, penalties, and sanctions, product liability claims, and our image and reputation within the industry and marketplace could be harmed.**

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug products, such as RT002 injectable, if approved. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may receive warning letters and become subject to significant liability, which would materially harm our business. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry.

Physicians may also misuse our products or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. Furthermore, the use of our products for indications other than those cleared by the FDA may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

Any of these events could harm our business and results of operations and cause our stock price to decline.

**Even if RT002 injectable or any future product candidate is approved for commercialization, if there is not sufficient patient demand for such procedures, our financial results and future prospects will be harmed.**

Treatment of glabellar lines with RT002 injectable is an elective procedure, the cost of which must be borne by the patient, and we do not expect it to be reimbursable through government or private health insurance. The decision by a patient to elect to undergo the treatment of glabellar lines with RT002 injectable or the treatment of other aesthetic indications we may pursue may be influenced by a number of factors, including:

- the success of any sales and marketing programs that we, or any third parties we engage, undertake, and as to which we have limited experience;
- the extent to which physicians recommend RT002 injectable to their patients;
- the extent to which RT002 injectable satisfies patient expectations;
- our ability to properly train physicians in the use of RT002 injectable or such that their patients do not experience excessive discomfort during treatment or adverse side effects;

- the cost, safety and effectiveness of RT002 injectable versus other aesthetic treatments;
- consumer sentiment about the benefits and risks of aesthetic procedures generally and RT002 injectable in particular;
- the success of any direct-to-consumer marketing efforts we may initiate; and
- general consumer confidence, which may be impacted by general economic and political conditions.

Our business, financial results and future prospects will be materially harmed if we cannot generate sufficient demand for RT002 injectable or for any other future product candidate, once approved.

**We are subject to uncertainty relating to third-party reimbursement policies which, if not favorable for RT002 injectable or any future product candidates, could hinder or prevent their commercial success.**

Our ability to commercialize RT002 injectable or any future product candidates for therapeutic indications such as cervical dystonia or plantar fasciitis will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not obtain adequate third-party coverage or reimbursement for RT002 injectable or any future product candidates, or we may be required to sell them at a discount.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of RT002 injectable in determining whether to approve reimbursement for RT002 injectable and at what level. Our business would be materially adversely affected if we do not receive approval for reimbursement of RT002 injectable from private insurers on a timely or satisfactory basis. Our business could also be adversely affected if private insurers, including managed care organizations, the Medicare program or other reimbursing bodies or payors limit the indications for which RT002 injectable will be reimbursed to a smaller patient set than we believe they are effective in treating.

In some foreign countries, particularly Canada and European countries, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products, including RT002 injectable, to other available therapies. If reimbursement for our product is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

**If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any future products we develop.**

We face an inherent risk of product liability lawsuits as a result of the clinical testing of our product candidates and we will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for RT002 injectable or any future product candidates or products we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize any products we develop.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of RT002 injectable or any future products we develop. We currently carry product liability insurance covering our clinical trials in the amount of \$10.0 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing RT002 injectable we intend to expand our insurance coverage to include the sale of RT002 injectable as applicable; however, we may be unable to obtain this liability insurance on commercially reasonable terms.

**We have been, and in the future may be, subject to securities class action and stockholder derivative actions. These, and potential similar or related litigation, could result in substantial damages and may divert management's time and attention from our business.**

We have been, and may in the future be, the target of securities class actions or stockholder derivative claims. On May 1, 2015, a securities class action complaint was filed on behalf of City of Warren Police and Fire Retirement System against us and certain of our directors and executive officers at the time of our follow-on public offering, and the investment banking firms that acted as the underwriters in our follow-on public offering. The Court granted final approval of the Settlement, as set forth in the Stipulation of Settlement, on July 28, 2017. While the litigation has ended, we may be subject to future securities class action and shareholder derivation actions, which may adversely impact our business, results of operations, financial position or cash flows and divert management's time and attention from the business.

**If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop RT002 injectable, topical, or any future product candidates, conduct our clinical trials and commercialize RT002 injectable, topical, or any future products we develop.\***

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We believe that our future success is highly dependent upon the contributions of our senior management, particularly L. Daniel Browne, our President and Chief Executive Officer, Abhay Joshi, Ph.D., our Chief Operating Officer, Caryn G McDowell, our Senior Vice President, General Counsel & Corporate Secretary, and Tobin C. Schilke, our Chief Financial Officer and Principal Financial Officer, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, the completion of our planned clinical trials or the commercialization of RT002 injectable, topical, or any future products we develop.

For example, Lauren P. Silvernail resigned as our Chief Financial Officer and Chief Business Officer, effective as of May 29, 2018. In connection with the departure of Ms. Silvernail, our Board of Directors, on June 20, 2018 appointed Cyril Allouche, our current Head of Finance and Corporate Controller, to serve as our Principal Financial Officer and Principal Accounting Officer on an interim basis. On October 10, 2018 our Board of Directors appointed Tobin C. Schilke to serve as our Chief Financial Officer and Principal Financial Officer effective as of November 5, 2018, which is expected to be Mr. Schilke's employment start date. Mr. Allouche will continue to serve as the Company's Principal Accounting Officer. In addition, Todd Zavodnick resigned as our Chief Commercial Officer and President, Aesthetics and Therapeutics, effective November 2018. In connection with the departure of Mr. Zavodnick, Dustin Sjtus was promoted to interim head of Commercial effective as of November 5, 2018.

Leadership transitions can be inherently difficult to manage. Resignations of executive officers may cause disruption in our business, strategic and employee relationships, which may significantly delay or prevent the achievement of our business objectives. Leadership changes may also increase the likelihood of turnover in other key officers and employees and may cause declines in the productivity of existing employees. The search for a replacement officer may take many months or more, further exacerbating these factors. Identifying and hiring an experienced and qualified executive officer are typically difficult. Periods of transition in senior management leadership are often difficult as the new executives gain detailed knowledge of our operations and may result in cultural differences and friction due to changes in strategy and style. During the transition periods, there may be uncertainty among investors, employees, creditors and others concerning our future direction and performance.

We could experience problems attracting and retaining qualified employees. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense and the turnover rate can be high due to the limited number



of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their previous research output.

**If we are not successful in discovering, developing, acquiring and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.**

Although a substantial amount of our effort will focus on the continued clinical testing and potential approval of RT002 injectable, a key element of our strategy is to discover, develop and commercialize a portfolio of botulinum toxin products for both aesthetic and therapeutic indications. We are seeking to do so through our internal research programs and may explore strategic collaborations for the development or acquisition of new products. While RT002 injectable is in the clinical development stage, topical and all of our other potential product candidates remain in the discovery or preclinical stage. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable; and
- intellectual property rights of third parties may potentially block our entry into certain geographies or make such entry economically impracticable.

If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed and our business will be more vulnerable to problems that we encounter in developing and commercializing RT002 injectable.

**The requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified members of our board of directors.**

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Dodd-Frank Act, the Nasdaq listing rules and other applicable securities rules and regulations. Compliance with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly, and increase demand on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Although we have hired additional employees to comply with these requirements, we may need to hire more employees in the future, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

As a public company that is subject to these rules and regulations we may find it is more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors and qualified executive officers.

**Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.**

Our research and development and manufacturing activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including botulinum toxin type A, a key component of our product candidates, and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. We are licensed with the Centers for Disease Control and Prevention, or CDC and with the California Department of Health, Food and Drug Branch for use of botulinum toxin and to manufacture both the active pharmaceutical ingredient, or API, and the finished product in topical and injectable dose forms. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

**We may use third-party collaborators to help us develop, validate or commercialize any new products, and our ability to commercialize such products could be impaired or delayed if these collaborations are unsuccessful.**

We may license or selectively pursue strategic collaborations for the development, validation and commercialization of RT002 injectable, topical, and any future product candidates. For instance, on February 28, 2018, we and Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V., or Mylan, entered into a collaboration agreement, or the Mylan Agreement, pursuant to which we and Mylan will collaborate exclusively, on a world-wide basis (excluding Japan), to develop, manufacture and commercialize our product candidates. In any third-party collaboration, we would be dependent upon the success of the collaborators to perform their responsibilities with continued cooperation. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to performing their responsibilities under our agreements with them. Our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us. The development, validation and commercialization of our product candidates will be delayed if collaborators fail to conduct their responsibilities in a timely manner or in accordance with applicable regulatory requirements or if they breach or terminate their collaboration agreements with us. Disputes with our collaborators could also impair our reputation or result in development delays, decreased revenues and litigation expenses.

**Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.**

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Furthermore, the demand for aesthetic medical procedures may be particularly vulnerable to unfavorable economic conditions. We do not expect sales of RT002 injectable for the treatment of glabellar lines to be reimbursed by any government or third-party payor and, as a result, demand for the first indications of each of our product candidates will be tied to discretionary spending levels of our targeted patient population. Future global financial crises may cause extreme volatility and disruptions in capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for RT002 injectable, topical, or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current or future economic climate and financial market conditions could adversely impact our business.

**Adverse tax laws or regulations could be enacted or existing laws could be applied to us or our customers, which could increase the costs of our services and adversely impact our business.**

The application of federal, state, local and international tax laws to services provided electronically is evolving. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time (possibly with retroactive effect), and could be applied solely or disproportionately to services provided over the internet. These enactments could adversely affect our sales activity due to the inherent cost increase the taxes would represent and ultimately result in a negative impact on our operating results and cash flows.

In addition, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us (possibly with retroactive effect), which could require us or our customers to pay additional tax amounts, as well as require us or our customers to pay fines or penalties and interest for past amounts. If we are unsuccessful in collecting such taxes from our customers, we could be held liable for such costs, thereby adversely impacting our operating results and cash flows.

Further, we have undertaken certain transactions to realize potential tax efficiencies in support of our expected global business expansion. These transactions are meant to align the global economic ownership of our intellectual property rights with our current and future business operations. We are uncertain as to whether the tax efficiencies sought by this alignment will materialize and may choose to unwind these transactions in the future.

On December 22, 2017, new legislation that significantly revises the Internal Revenue Code of 1986, as amended, was signed into law. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

**Significant disruptions of information technology systems or breaches of data security could materially adversely affect our business, results of operations and financial condition.\***

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result

in a material disruption of our product development programs. For example, the loss of clinical study data from completed or ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems, corrupts our data or results in the unauthorized disclosure or release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, supervisory bodies, credit reporting agencies, the media or individuals pursuant to various federal, state and foreign data protection, privacy and security laws, regulations and guidelines, if applicable. For example, these may include the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, U.S. state breach notification laws and the EU General Data Protection Regulation (EU) 2016/679, or GDPR. We would also be exposed to a risk of loss, enforcement measures, penalties, fines, indemnification claims or litigation and potential civil or criminal liability, which could materially adversely affect our business, results of operations and financial condition.

**Changes in and failures to comply with U.S. and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and financial performance.\***

We are subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, retention, and security of personal data, such as information that we collect about patients and healthcare providers in connection with clinical trials in the U.S. and abroad. The global data protection landscape is rapidly evolving, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, affect our or our vendors' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulation, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising.

In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In the event that we are subject to HIPAA or other U.S. privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. Many countries in these regions have established or are in the process of establishing privacy and data security legal frameworks with which we, our customers, or our vendors must comply. For example, the EU has adopted the GDPR, which went into effect in May 2018 and introduces strict requirements for processing the personal information of EU subjects, including clinical trial data. The GDPR is likely to increase compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them. The processing of sensitive personal data, such as physical health condition, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for more robust regulatory enforcement and fines of up to €20 million or 4% of the annual global revenue of the noncompliant company, whichever is greater. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

#### **Risks Related to Our Intellectual Property**

**If our efforts to protect our intellectual property related to RT002 injectable, or any future product candidates, including topical and biosimilar, are not adequate, we may not be able to compete effectively.\***

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to RT002 injectable, topical, biosimilar, and our development programs. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thereby eroding our competitive position.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of issued patents. The patent

applications that we own or license may fail to result in issued patents in the United States or foreign countries. Competitors in the field of cosmetics, pharmaceuticals, and botulinum toxin have created a substantial amount of prior art, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. In addition, recent changes to the patent laws of the United States provide additional procedures for third parties to challenge the validity of issued patents. Patents issued from applications filed after March 15, 2013 may be challenged by third parties using the post-grant review procedure which allows challenges for a number of reasons, including prior art, sufficiency of disclosure, and subject matter eligibility.

Under the *inter partes* review procedure, any third party may challenge the validity of any issued U.S. Patent in the United States Patent and Trademark Office, or USPTO, on the basis of prior art. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings as compared to the evidentiary standard relied on in U.S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to RT002 injectable, topical, or any future product candidates is challenged, then it could threaten our ability to commercialize RT002 injectable, topical, or any future product candidates, and could threaten our ability to prevent competitive products from being marketed. Further, if we encounter delays in our clinical trials, the period of time during which we could market RT002 injectable, or any future product candidates under patent protection would be reduced. The results of our REALISE 1 Phase 3 clinical trial may be relevant to our patent strategy for our topical program.

Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act signed into law on September 16, 2011. Among some of the other changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and some of our competitors have substantially greater intellectual property portfolios and financial resources than we have.

We also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain or enforce and any other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents.

In an effort to protect our trade secrets and other confidential information, we require our employees, consultants, collaborators and advisors to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual’s relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. A breach of confidentiality could significantly affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators or advisors have previous employment or consulting relationships. To the extent that our employees, consultants or contractors use any intellectual property owned by others in their work for us, disputes may arise as to the rights

in any related or resulting know-how and inventions. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and other confidential information.

**If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed.**

Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. Competitors in the field of cosmetics, pharmaceuticals and botulinum toxin have developed large portfolios of patents and patent applications in fields relating to our business. For example, there are patents held by third parties that relate to the treatment with botulinum toxin-based products for indications we are currently developing. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product based on our current or future indications, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

**We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time-consuming.**

Competitors may infringe upon our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied.

An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference, derivation, *inter partes* review, post-grant review or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patents or patent applications or those of our licensors or collaborators. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, either alone or with our licensors or collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related

documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

**We may not be able to protect our intellectual property rights throughout the world.**

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States and in some cases may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in domestic and foreign intellectual property laws.

### **Risks Related to Government Regulation**

**Our business and products are subject to extensive government regulation.**

We are subject to extensive, complex, costly and evolving regulation by federal and state governmental authorities in the United States, principally by the FDA, the U.S. Drug Enforcement Administration, or DEA, the CDC, and foreign regulatory authorities. Failure to comply with all applicable regulatory requirements, including those promulgated under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and Controlled Substances Act, may subject us to operating restrictions and criminal prosecution, monetary penalties and other disciplinary actions, including, sanctions, warning letters, product seizures, recalls, fines, injunctions, suspension, revocation of approvals, or exclusion from future participation in the Medicare and Medicaid programs.

After our products receive regulatory approval or clearance, we, and our direct and indirect suppliers, remain subject to the periodic inspection of our plants and facilities, review of production processes, and testing of our products to confirm that we are in compliance with all applicable regulations. Adverse findings during regulatory inspections may result in the implementation of Risk Evaluation and Mitigation Strategies (REMS) programs, completion of government mandated clinical trials, and government enforcement action relating to labeling, advertising, marketing and promotion, as well as regulations governing manufacturing controls noted above.

**The regulatory approval process is highly uncertain and we may not obtain regulatory approval for the commercialization of RT002 injectable or any future product candidates.**

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug and biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor any collaboration partner are permitted to market RT002 injectable or any future product candidates in the United States until we receive approval of a BLA from the FDA. We have not submitted an application or obtained marketing approval for RT002 injectable anywhere in the world. After we submit a BLA for RT002 injectable, the FDA may refuse to file the application if it determines that the application is not sufficiently complete to permit substantive review. Even if filed by FDA, our BLA may receive a Complete Response Letter identifying

deficiencies that must be addressed, rather than an approval. Obtaining regulatory approval of a BLA can be a lengthy, expensive and uncertain process.

In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

- warning letters;
- civil and criminal penalties;
- injunctions;
- withdrawal of approved products;
- product seizure or detention;
- product recalls;
- total or partial suspension of production; and
- refusal to approve pending BLAs or supplements to approved BLAs.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well controlled clinical trials, and to the satisfaction of the FDA or other foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical and clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Administering product candidates to humans may produce undesirable side effects, which could interrupt, delay or halt clinical trials and result in the FDA or other regulatory authorities denying approval of a product candidate for any or all targeted indications.

Regulatory approval of a BLA or BLA supplement is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense expended, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. The FDA can delay, limit or deny approval of a product candidate for many reasons, including the following:

- a product candidate may not be deemed safe, effective, or of required quality;
- FDA officials may not find the data from preclinical studies and clinical trials sufficient;
- the FDA might not approve our third-party manufacturers' processes or facilities; or
- the FDA may change its approval policies or adopt new regulations.

If RT002 injectable or any future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain approval, our business and results of operations will be materially and adversely harmed.

**Even if we receive regulatory approval for RT002 injectable or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, may limit or delay regulatory approval and may subject us to penalties if we fail to comply with applicable regulatory requirements.**

Once regulatory approval has been granted, RT002 injectable or any approved product will be subject to continual regulatory review by the FDA and/or non-U.S. regulatory authorities. Additionally, any product candidates, if approved, will be subject to extensive and ongoing regulatory requirements, including labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we or our collaborators receive for RT002 injectable or any future product candidates may also be subject to limitations on the approved indications for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the applicable regulatory agency approves RT002 injectable or any future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and



reports, registration, as well as continued compliance with cGMP and cGCP for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with RT002 injectable or any future product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us or our strategic collaborators, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

Our ongoing regulatory requirements may also change from time to time, potentially harming or making costlier our commercialization efforts. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or other countries. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

**If we fail to obtain regulatory approvals in foreign jurisdictions for RT002 injectable, or any future product candidates including topical, we will be unable to market our products outside of the United States.**

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing manufacturing, clinical trials, commercial sales and distribution of our future products. Whether or not we obtain FDA approval for a product candidate, we must obtain approval of the product by the comparable regulatory authorities of foreign countries before commencing clinical trials or marketing in those countries. The approval procedures vary among countries and can involve additional clinical testing, or the time required to obtain approval may differ from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not be able to file for regulatory approvals or to do so on a timely basis, and even if we do file, we may not receive the necessary approvals to commercialize our products in geographies outside of the United States.

**If approved, RT002 injectable or any other products may cause or contribute to adverse medical events that we are required to report to regulatory agencies and if we fail to do so, we could be subject to sanctions that would materially harm our business.**

Some participants in our clinical trials have reported adverse events after being treated with RT002 injectable. If we are successful in commercializing RT002 injectable, or any other products including our topical product candidate, the FDA and foreign regulatory agency regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or a foreign regulatory agency could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

**We may in the future be subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback, self-referral, false claims and fraud laws, and any violations by us of such laws could result in fines or other penalties.**

While we do not expect that RT002 injectable, if approved for the treatment of glabellar lines, will subject us to the various U.S. federal and state laws intended to prevent healthcare fraud and abuse, we may in the future become subject to such laws for treatment of other indications. The federal anti-kickback statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in

whole or part by Medicare, Medicaid or other federal healthcare programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state healthcare programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal healthcare programs and the levying of substantial civil and criminal penalties.

The federal False Claims Act, or FCA, imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal healthcare program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. If our marketing or other arrangements were determined to violate anti-kickback or related laws, including the FCA, then our revenues could be adversely affected, which would likely harm our business, financial condition, and results of operations.

State and federal authorities have aggressively targeted medical technology companies for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans, and have often become subject to consent decrees severely restricting the manner in which they conduct business. If we become the target of such an investigation or prosecution based on our contractual relationships with providers or institutions, or our marketing and promotional practices, we could face similar sanctions, which would materially harm our business.

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

**Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of RT002 injectable, topical, or any future product candidates and to produce, market, and distribute our products after clearance or approval is obtained.**

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of RT002 injectable, or any future product candidates including our topical product candidate. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could require, among other things:

- changes to manufacturing methods;
- recall, replacement, or discontinuance of one or more of our products; and
- additional recordkeeping.

Each of these would likely entail substantial time and cost and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products would harm our business, financial condition, and results of operations.

### **Risks Related to the Ownership of Our Common Stock**

**The trading price of our common stock is volatile, and purchasers of our common stock could incur substantial losses.**

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock markets in general and the markets for pharmaceutical biopharmaceutical and biotechnology stocks in particular have experienced extreme volatility that may have been for reasons that are related or unrelated to the operating performance of the issuer. The market price for our common stock may be influenced by many factors, including:

- regulatory or legal developments in the United States and foreign countries;
- results from or delays in clinical trials of our product candidates, including our ongoing SAKURA Phase 3 clinical program in glabellar lines our ongoing ASPEN Phase 3 clinical program in cervical dystonia and our Phase 2 program in plantar fasciitis all with RT002 injectable;
- announcements of regulatory approval or disapproval of RT002 injectable or any future product candidates;
- FDA or other U.S. or foreign regulatory actions or guidance affecting us or our industry;
- introductions and announcements of new products by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts' reports or recommendations;
- quarterly variations in our results of operations or those of our future competitors;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- sales of substantial amounts of our stock by insiders and large stockholders, or the expectation that such sales might occur;
- general economic, industry and market conditions;
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- expiration or termination of our potential relationships with customers and strategic partners; and
- other factors described in this "Risk Factors" section.

These broad market fluctuations may adversely affect the trading price or liquidity of our common stock. In addition, in the past, stockholders have initiated class actions against pharmaceutical companies, including us, following periods of volatility in their stock prices. Such litigation instituted against us could cause us to incur substantial costs and divert management's attention and resources.

**If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.\***

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts may cease to publish research on our company at any time in their discretion. A lack of research coverage may adversely affect the liquidity and market price of our common stock. We will not have any control of the equity research analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company, or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

**Sales of substantial amounts of our common stock in the public markets, or the perception that such sales might occur, could cause the market price of our common stock to drop significantly, even if our business is doing well.\***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. We raised net proceeds of approximately \$10.0 million by selling an aggregate of 352,544 shares of our common stock under the 2015 ATM agreement, which was effectively terminated on March 7, 2016, and raised net proceeds of approximately \$38.2 million by selling an aggregate of 1,802,651 shares of our common stock under the 2016 ATM agreement. In March 2018, the Company terminated the 2016 ATM Agreement and entered into a Controlled Equity Offering sales agreement, or the 2018 ATM Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, under which the Company may offer and sell common stock having aggregate proceeds of up to \$125.0 million from time to time through Cantor Fitzgerald as our sales agent. No sales of our common stock have taken place under the 2018 ATM Agreement as of September 30, 2018.

If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. Any sales of securities by stockholders could have a material adverse effect on the trading price of our common stock.

**Provisions in our corporate charter documents and under Delaware law could discourage takeover attempts and lead to management entrenchment, and the market price of our common stock may be lower as a result.**

Certain provisions in our amended and restated certificate of incorporation and amended and restated bylaws may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by you and other stockholders. For example, our board of directors has the authority to issue up to 5,000,000 shares of preferred stock. Our board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- no cumulative voting in the election of directors;
- the ability of our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- the exclusive right of our board of directors to elect a director to fill a vacancy or newly created directorship;
- stockholders will not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders;
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- the ability of our board of directors, by a majority vote, to amend the bylaws; and
- the requirement for the affirmative vote of at least 66 2/3% or more of the outstanding common stock to amend many of the provisions described above.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that certain investors are willing to pay for our stock.

Our amended and restated certificate of incorporation also provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders.

**A relatively small number of existing stockholders have substantial control over us, which could limit your ability to influence the outcome of key transactions, including a change of control.\***

As of September 30, 2018, our directors, executive officers and each of our stockholders who own greater than 5% of our outstanding common stock and their affiliates, in the aggregate, beneficially owned approximately 53.4% of our common stock. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may have interests that differ from yours and may vote in a way with which you disagree and that may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might affect the market price of our common stock.

**Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.**

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- We will indemnify our directors and officers for serving us in those capacities, or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.
- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

**Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains.**

We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any existing or future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

**We are an "emerging growth company," and if we decide to comply only with reduced disclosure requirements applicable to emerging growth companies, our common stock could be less attractive to investors.**

We are an "emerging growth company," as defined in the JOBS Act and, for as long as we continue to be an "emerging growth company," we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will no longer be an "emerging growth company" at the year ended December 31, 2018. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies that become public can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we have been and will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS*****Recent Sales of Unregistered Securities******Issuer Purchases of Equity Securities***

We have not and do not currently intend to retire or repurchase any of our shares other than providing our employees with the option to withhold shares to satisfy tax withholding amounts due from employees upon the vesting of restricted stock awards in connection with our 2014 Equity Incentive Plan.

<b>Period</b>	<b>Total Number of Shares Purchased (i)</b>	<b>Weighted-Average Price Paid per Share (ii)</b>	<b>Total Number of Share Purchased as Part of Publicly Announced Plan or Programs</b>	<b>Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plan or Programs (in thousands)</b>
July 1 through July 31, 2018	794	\$ 29.04	—	—
August 1 through August 31, 2018	703	26.15	—	—
September 1 through September 30, 2018	2,014	26.43	—	—
Total	<u>3,511</u>	<u>\$ 26.96</u>	—	—

(i) Consists solely of shares that were withheld to satisfy tax withholding amounts due from employees upon the vesting of previously issued restricted stock awards.

(ii) The weighted-average price paid per share is the weighted-average of the fair market prices at which we calculated the number of shares withheld to cover tax withholdings for the employees.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS**

The following exhibits are included herein or incorporated herein by reference:

Exhibit Number	Exhibit Description	Incorporated by Reference to the Company's				Filed Herewith
		Form	File No.	Exhibit No.	Filed On	
3.1	<a href="#">Amended and Restated Certificate of Incorporation</a>	8-K	001-36297	3.1	February 11, 2014	
3.2	<a href="#">Amended and Restated Bylaws</a>	S-1	333-193154	3.4	December 31, 2013	
4.2	<a href="#">Form of Common Stock Certificate</a>	S-1/A	333-193154	4.4	February 3, 2014	
31.1	<a href="#">Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) promulgated under the Exchange Act</a>					X
31.2	<a href="#">Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) promulgated under the Exchange Act</a>					X
32.1†	<a href="#">Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>					X
32.2†	<a href="#">Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

† The certifications attached as Exhibit 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002, and shall not be deemed filed with the Securities and Exchange Commission for purposes of Section 18 of the Exchange Act. Such certifications shall not be deemed incorporated by reference into any filing of Revance Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.

\*\* Users of this data are advised that, pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934 and otherwise are not subject to liability under these sections.

**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.

**REVANCE THERAPEUTICS, INC.**

Date: November 2, 2018

By: /s/ L. Daniel Browne

**L. Daniel Browne**  
**President and Chief Executive Officer**  
**(Duly Authorized Principal Executive Officer)**

Date: November 2, 2018

By: /s/ Cyril Allouche

**Cyril Allouche**  
**Head of Finance and Corporate Controller**  
**(Duly Authorized Principal Financial and Accounting Officer)**



CERTIFICATIONS

I, L. Daniel Browne, certify that:

1. I have reviewed this Form 10-Q of Revance Therapeutics, 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.

Date: November 2, 2018

/s/ L. Daniel Browne

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L. Daniel Browne  
President and Chief Executive Officer  
(Principal Executive Officer)

CERTIFICATIONS

I, Cyril Allouche, certify that:

1. I have reviewed this Form 10-Q of Revance Therapeutics, 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.

Date: November 2, 2018

/s/ Cyril Allouche

Cyril Allouche

Head of Finance and Corporate Controller  
(Duly Authorized Principal Financial and Accounting  
Officer)

**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), L. Daniel Browne, Chief Executive Officer of Revance Therapeutics, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2018, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 2, 2018

**IN WITNESS WHEREOF**, the undersigned has set his hands hereto as of the 2nd day of November, 2018.

/s/ L. Daniel Browne

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L. Daniel Browne

President and Chief Executive Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Revance Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

**CERTIFICATION**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Cyril Allouche, Head of Finance and Corporate Controller of Revance Therapeutics, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2018, to which this Certification is attached as Exhibit 32.2 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 2, 2018

**IN WITNESS WHEREOF**, the undersigned has set his hands hereto as of the 2nd day of November, 2018.

/s/ Cyril Allouche

Cyril Allouche

Head of Finance and Corporate Controller

(Duly Authorized Principal Financial and Accounting Officer)

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Revance Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

