

Edgar Filing: Revance Therapeutics, Inc. - Form 10-Q

Revance Therapeutics, Inc.  
Form 10-Q  
November 10, 2015

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File No. 001-36297

Revance Therapeutics, Inc.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

77-0551645  
(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer  Accelerated filer

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

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

Edgar Filing: Revance Therapeutics, Inc. - Form 10-Q

Number of shares outstanding of the registrant's common stock, par value \$0.001 per share, as of November 9, 2015:  
28,062,233

---

Table of Contents

## Table of Contents

	Page
<u>PART I. FINANCIAL INFORMATION</u>	
Item 1. <u>Condensed Consolidated Financial Statements</u>	<u>4</u>
<u>Condensed Consolidated Balance Sheets at September 30, 2015 and December 31, 2014 (unaudited)</u>	<u>4</u>
<u>Condensed Consolidated Statement of Operations and Comprehensive Loss for the Three and Nine Months ended September 30, 2015 and 2014 (unaudited)</u>	<u>5</u>
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months ended September 30, 2015 and 2014 (unaudited)</u>	<u>6</u>
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	<u>8</u>
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>20</u>
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	<u>32</u>
Item 4. <u>Controls and Procedures</u>	<u>32</u>
<u>PART II. OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	<u>33</u>
Item 1A. <u>Risk Factors</u>	<u>33</u>
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>61</u>
Item 3. <u>Defaults Upon Senior Securities</u>	<u>62</u>
Item 4. <u>Mine Safety Disclosures</u>	<u>62</u>
Item 5. <u>Other Information</u>	<u>62</u>
Item 6. <u>Exhibits</u>	<u>62</u>
<u>Signatures</u>	<u>63</u>
<u>Exhibit Index</u>	<u>63</u>

“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.

---

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. Condensed Consolidated Financial Statements

3

---

Table of Contents

## REVANCE THERAPEUTICS, INC.

## REVANCE THERAPEUTICS, INC.

## Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

(Unaudited)

	September 30, 2015	December 31, 2014
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$90,494	\$171,032
Short-term investments	51,364	—
Restricted cash, current portion	35	75
Prepaid expenses and other current assets	1,604	1,624
Total current assets	143,497	172,731
Property and equipment, net	19,254	19,274
Long-term investments	2,357	—
Restricted cash, net of current portion	400	435
Other non-current assets	6	29
<b>TOTAL ASSETS</b>	<b>\$165,514</b>	<b>\$192,469</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$2,731	\$3,149
Accruals and other current liabilities	5,990	4,145
Financing obligation, current portion	3,018	307
Notes payable, current portion and net of discount	—	2,635
Total current liabilities	11,739	10,236
Financing obligation, net of current portion	6,176	598
Derivative liabilities associated with Medicis settlement	1,481	1,541
Deferred rent	3,762	3,725
<b>TOTAL LIABILITIES</b>	<b>23,158</b>	<b>16,100</b>
Commitments and Contingencies (Note 9)		
<b>STOCKHOLDERS' EQUITY</b>		
Common stock, par value \$0.001 per share — 95,000,000 shares authorized both as of September 30, 2015 and December 31, 2014, respectively; 24,313,222 and 23,774,465 shares issued and outstanding as of September 30, 2015 and December 31, 2014, respectively	24	24
Additional paid-in capital	452,501	435,142
Accumulated other comprehensive income	10	—
Accumulated deficit	(310,179)	(258,797)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>142,356</b>	<b>176,369</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$165,514</b>	<b>\$192,469</b>
The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.		

Table of Contents

## REVANCE THERAPEUTICS, INC.

## Condensed Consolidated Statement of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Revenue	\$75	\$75	\$225	\$308
Operating expenses:				
Research and development	13,016	8,600	32,573	24,261
General and administrative	5,827	5,300	18,183	14,250
Total operating expenses	18,843	13,900	50,756	38,511
Loss from operations	(18,768 )	(13,825 )	(50,531 )	(38,203 )
Interest income	68	14	144	18
Interest expense	(390 )	(228 )	(834 )	(10,336 )
Change in fair value of derivative liabilities associated with the convertible notes	—	—	—	4,032
Changes in fair value of derivative liabilities associated with Medicis settlement	13	67	60	(426 )
Change in fair value of common stock warrant liability	—	—	—	(2,151 )
Change in fair value of convertible preferred stock warrant liability	—	—	—	(210 )
Loss on settlement of preferred stock warrant	—	—	—	(1,356 )
Other expense, net	(98 )	(5 )	(221 )	(73 )
Net loss	(19,175 )	(13,977 )	(51,382 )	(48,705 )
Unrealized gain on available for sale securities	22	—	10	—
Comprehensive loss	\$(19,153 )	\$(13,977 )	\$(51,372 )	\$(48,705 )
Net loss attributable to common stockholders (Note 12):				
Basic	\$(19,175 )	\$(13,977 )	\$(51,382 )	\$(48,705 )
Diluted	\$(19,175 )	\$(13,977 )	\$(51,382 )	\$(48,705 )
Net loss per share attributable to common stockholders:				
Basic	\$(0.81 )	\$(0.60 )	\$(2.17 )	\$(2.70 )
Diluted	\$(0.81 )	\$(0.60 )	\$(2.17 )	\$(2.70 )
Weighted-average number of shares used in computing net loss per share attributable to common stockholders:				
Basic	23,755,199	23,331,104	23,625,869	18,009,537
Diluted	23,755,199	23,331,104	23,625,869	18,009,537

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

Table of Contents

## REVANCE THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows  
(In thousands)  
(Unaudited)

	Nine Months Ended September 30,	
	2015	2014
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$(51,382 )	\$(48,705 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,586	1,561
Amortization of premium on investment	364	—
Amortization of discount on debt and capital leases	5	1,198
Amortization of debt issuance cost	39	148
Change in fair value of derivative liabilities associated with the convertible notes	—	(4,032 )
Changes in fair value of derivative liabilities associated with Medicis settlement	(60 )	426
Change in fair value of common stock warrant liability	—	2,151
Change in fair value of convertible preferred stock warrant liability	—	210
Loss on settlement of preferred stock warrant	—	1,356
Loss on extinguishment of 2013 Notes	—	8,331
Stock-based compensation expense	7,314	4,611
Interest for 2013 Notes and Essex Notes upon issuance, non-cash	—	271
Capitalized interest	—	(649 )
Effective interest on financing obligation	226	66
Loss on disposal of fixed assets	29	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(134 )	(2,654 )
Other non-current assets	24	(1,238 )
Accounts payable	(477 )	(3,524 )
Accruals and other current liabilities	3,096	1,178
Payments against Medicis liabilities	—	(7,073 )
Deferred rent	152	500
Deferred revenue	—	(83 )
Net cash used in operating activities	(39,218 )	(45,951 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(2,849 )	(5,444 )
Purchases of investments	(54,087 )	—
Change in restricted cash	75	75
Net cash used in investing activities	(56,861 )	(5,369 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from issuance of common stock, net of deferred follow-on public offering costs	—	131,882
Proceeds from issuance of common stock, net of deferred initial public offering costs	—	102,672
Proceeds from issuance of convertible notes and notes payable	—	6,750
Proceeds from issuance of common stock, net of deferred at-the-market offering costs	10,154	—
Principal payments made on capital leases and financing obligation	(1,768 )	(146 )
Net settlement of restricted stock awards to settle employee taxes	(762 )	—





Table of Contents

## REVANCE THERAPEUTICS, INC.

Principal payments made on notes payable	(2,652	) (6,230	)
Proceeds from sale and leaseback financing	9,831	—	
Proceeds from the exercise of stock options and employee stock purchase plan	738	1,402	
Payments to settle warrants	—	(1,438	)
Net cash provided by financing activities	15,541	234,892	
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(80,538	) 183,572	
CASH AND CASH EQUIVALENTS — Beginning of period	171,032	3,914	
CASH AND CASH EQUIVALENTS — End of period	90,494	187,486	
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:			
Cash paid for interest	564	971	
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:			
Property and equipment purchases included in accounts payable and accruals and other current liabilities	95	832	
Write-off of fixed assets	28	—	
Conversion of Series E-1, E-2, E-3, E-4 and E-5 preferred stock into common stock	—	123,982	
Conversion of 2013 Notes into common stock	—	26,206	
Issuance of common stock upon net exercise of common stock warrants in connection with IPO	—	6,490	
Fair value in excess of debt host for derivative liabilities associated with convertible notes	—	1,050	
Deferred public offering costs	84	4,574	
Conversion of preferred stock warrants to common stock warrants	—	1,441	
Conversion of Essex Notes into financing obligations	—	1,095	
Termination of stock option repurchase right	—	58	
Issuance of common stock warrants in connection with the 2013 Notes	—	981	
Issuance of convertible preferred stock warrants	—	80	
The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.			

Table of Contents

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 specialty biopharmaceutical 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, combined with its patented TransMTS® peptide delivery system to address unmet needs in large and growing neurotoxin markets. Revance's proprietary TransMTS technology enables delivery of botulinum toxin type A through two investigational drug product candidates, RT001, also referred to as RTT150 (Botulinum Toxin Type A) Topical Gel, and RT002, or RTT150 (Botulinum Toxin Type A) for Injection. The Company is pursuing clinical development for RT001 and RT002 in a broad spectrum of aesthetic and therapeutic indications. The Company holds worldwide rights for all indications of RT001, RT002, and its TransMTS technology platform.

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. The Company has devoted predominantly all of its resources to preclinical, clinical, and manufacturing development of RT001 and RT002. The Company has never been profitable and has not 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. For the three and nine months ended September 30, 2015, the Company had a net loss of \$19.2 million and \$51.4 million and used \$39.2 million of cash for operating activities during the nine months ended September 30, 2015. As of September 30, 2015, the Company had a working capital surplus of \$131.8 million and an accumulated deficit of \$310.2 million. The Company has funded its operations primarily through the sale and issuance of common stock, convertible preferred stock, notes payable, and convertible notes. As of September 30, 2015, the Company had capital resources consisting of cash, cash equivalents, and investments of \$144.2 million. The Company believes that its existing cash, cash equivalents, and investments will allow the Company to fund its operations for at least the next 12 months.

Follow-on Public Offering

In November 2015, the Company completed a public offering, pursuant to which the Company issued 3,737,500 shares of common stock at \$36.00 per share, including the exercise of the underwriters' option to purchase 487,500 additional shares of common stock, for gross proceeds of \$134.6 million.

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 Results of Operations and Comprehensive Loss and Cash Flows for the interim periods covered and the Condensed Consolidated Financial Position of the Company at the date of the balance sheets. The December 31, 2014 Condensed Consolidated Balance Sheet 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, 2015, 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

Edgar Filing: Revance Therapeutics, Inc. - Form 10-Q

December 31, 2014, which was filed with the Securities and Exchange Commission, or SEC, on March 4, 2015. The Condensed Consolidated Financial Statements of the Company include the Company's accounts and those of the Company's wholly-owned subsidiary and have been prepared in conformity with US GAAP.

Table of Contents

REVANCE THERAPEUTICS, INC.

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

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, 2014. There have been no changes to the Company's significant accounting policies during the three and nine months ended September 30, 2015, except as described below.

Use of Estimates

The preparation of 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 the fair value of common stock, stock-based compensation, fair value of convertible preferred stock and warrants, fair value of derivatives, and the valuation of deferred tax assets. The Company bases its estimates on historical experience and also on assumptions that it believes are reasonable, however, actual results could significantly differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investment securities with original maturities at the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents may include cash on deposit, money market funds, and debt securities.

Investments

Short-term investments generally consist of securities with original maturities greater than three months and remaining maturities of less than one year, while long-term investments generally consist of securities with remaining maturities greater than one year. The Company determines the appropriate classification of its investments at the time of purchase and reevaluates such determination at each balance sheet date. All of its investments are classified as available-for-sale and carried at fair value, with the change in unrealized gains and losses reported as a separate component of other comprehensive income (loss) on the Condensed Consolidated Statements of Operations and Comprehensive Loss and accumulated as a separate component of stockholders' equity on the Condensed Consolidated Balance Sheets. Interest income, net includes interest, dividends, amortization of purchase premiums and discounts, realized gains and losses on sales of securities and other-than-temporary declines in the fair value of investments, if any. The cost of securities sold is based on the specific-identification method. The Company monitors its investment portfolio for potential impairment on a quarterly basis. If the carrying amount of an investment in debt securities exceeds its fair value and the decline in value is determined to be other-than-temporary, the carrying amount of the security is reduced to fair value and a loss is recognized in operating results for the amount of such decline. In order to determine whether a decline in value is other-than-temporary, the Company evaluates, among other factors, the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, and its intent and ability to hold the security to maturity or forecasted recovery. The Company mitigates its credit risk by investing in money market funds and U.S. government agency obligations which limits the amount of investment exposure as to credit quality and maturity.

Fair Value of Financial Instruments

The Company uses fair value measurements to record fair value adjustments to certain financial and non-financial assets and liabilities to determine fair value disclosures. The accounting standards define fair value, establish a framework for measuring fair value, and require disclosures about fair value measurements. Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities

required to be recorded at fair value, the principal or most advantageous market in which the Company would transact are considered along with assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of nonperformance. The accounting standard for fair value establishes a fair value hierarchy based on three levels of inputs, the first two of which are considered observable and the last unobservable, that requires an entity to maximize the use of observable

Table of Contents

## REVANCE THERAPEUTICS, INC.

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

inputs and minimize the use of unobservable inputs when measuring fair value. A financial instrument's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The three levels of inputs that may be used to measure fair value are 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.
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.

## Accounting Pronouncements

In August 2014, the FASB issued Accounting Standard Update No. 2014-15, Presentation of Financial Statements - Going Concern (Subtopic 205-40), which will require management to assess an entity's ability to continue as a going concern at each annual and interim period. Related footnote disclosures will be required if conditions give rise to substantial doubt about an entity's ability to continue as a going concern within one year of the report issuance date. If conditions do not give rise to substantial doubt, no disclosures will be required specific to going concern uncertainties. The guidance defines substantial doubt using a likelihood threshold of "probable" similar to the current use of that term in U.S. GAAP for loss contingencies and provides example indicators. The guidance is effective for reporting periods ending after December 15, 2016, and early adoption is permitted. The Company is currently evaluating the impact of the adoption of this guidance on the Company's financial statements.

## 3. Medicis Settlement

In October 2012, the Company entered into a settlement and termination agreement with Medicis Pharmaceutical Corporation, or Medicis. Medicis was subsequently acquired by Valeant Pharmaceuticals International, Inc. in December 2012. The terms of the settlement provided for the reacquisition of the rights related to all territories of RT001 and RT002 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 the remaining \$7.1 million was paid in 2014, and (iii) \$4.0 million to be paid upon the achievement of regulatory approval for RT001 or RT002 by the Company, or Product Approval Payment.

As of September 30, 2015, the Company determined the fair value of its liability for the Product Approval Payment was \$1.5 million, which was measured by assuming a term of 3.75 years, a risk-free rate of 1.09% and a credit risk adjustment of 7.25%. The Company's assumption for the expected term is based on an expected Biologics License Application, or BLA, approval in 2019. The Company did not make any payments under the Product Approval Payment during the nine months ended September 30, 2015.

Table of Contents

## REVANCE THERAPEUTICS, INC.

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

## 4. Cash Equivalents and Investments

The Company's cash equivalents and investments consist of money market funds 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, 2015				December 31, 2014			
	Cost	Gross Unrealized		Fair Value	Cost	Gross Unrealized		Fair Value
		Gains	Losses			Gains	Losses	
Money market funds	\$72,454	\$—	\$—	\$72,454	\$166,038	\$—	\$—	\$166,038
U.S. government agency obligations	53,711	12	(2 )	53,721	—	—	—	—
Total cash equivalents and available-for-sale securities	\$126,165	\$12	\$(2 )	\$126,175	\$166,038	\$—	\$—	\$166,038

Classified as:

Cash equivalents				\$72,454				\$166,038
Short-term investments				51,364				—
Long-term investments				2,357				—
Total cash equivalents and available-for-sale securities				\$126,175				\$166,038

As of September 30, 2015 and December 31, 2014, the remaining contractual maturities of available-for-sale securities were less than two years.

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, 2015 have been in a continuous unrealized loss position for more than 12 months. As of September 30, 2015, unrealized losses on available-for-sale investments are not attributed to credit risk and are considered to be 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 believes it is not 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.

Table of Contents

## REVANCE THERAPEUTICS, INC.

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

## 5. Fair Value Measurements

The Company measures and reports certain financial instruments as assets and liabilities at fair value on a recurring basis. These liabilities, consisting of the Medicis settlement, are considered Level 3 instruments, while the assets, consisting of money market funds and U.S. government agency obligations, are considered Level 1 and Level 2 instruments, respectively. The fair value of these instruments was as follows (in thousands):

	As of September 30, 2015			
	Fair Value	Level 1	Level 2	Level 3
<b>Assets</b>				
Money market funds	\$72,454	\$72,454	\$—	\$—
U.S. government agency obligations	53,721	—	53,721	—
Total assets measured at fair value	\$126,175	\$72,454	\$53,721	\$—
<b>Liabilities</b>				
Derivative liabilities associated with the Medicis settlement	\$1,481	\$—	\$—	\$1,481
Total liabilities measured at fair value	\$1,481	\$—	\$—	\$1,481
	As of December 31, 2014			
	Fair Value	Level 1	Level 2	Level 3
<b>Assets</b>				
Money market funds	\$166,038	\$166,038	\$—	\$—
Total assets measured at fair value	\$166,038	\$166,038	\$—	\$—
<b>Liabilities</b>				
Derivative liabilities associated with the Medicis settlement	\$1,541	\$—	\$—	\$1,541
Total liabilities measured at fair value	\$1,541	\$—	\$—	\$1,541

The fair value of the U.S. government agency obligations are 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 to or from Level 1 and Level 2 during the nine months ended September 30, 2015 and the year ended December 31, 2014.

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):

Derivative Liability  
Associated with the  
Medicis Settlement



Edgar Filing: Revance Therapeutics, Inc. - Form 10-Q

Fair value as of December 31, 2014	\$1,541	
Change in fair value	(60	)
Fair value as of September 30, 2015	\$1,481	

12

---

Table of Contents

REVANCE THERAPEUTICS, INC.

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

The fair value of the derivative liability resulting from the Medicis litigation settlement, specifically the derivative related to the Product Approval Payment (Note 3), 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. 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.

6. Notes Payable and Financing Obligation

Hercules Notes Payable

In September 2011, the Company entered into a loan and security agreement with Hercules Technology Growth Capital for \$22.0 million, referred to as the Hercules Notes Payable.

The Hercules Notes Payable, which matured in March 2015 and has been repaid in full, was collateralized by all assets of the Company, and bore interest at the greater of (i) 9.85% per annum or (ii) 9.85% per annum plus the difference of the prime rate less 3.25% per annum and contained covenants that required, among other things, that the Company seek consent from Hercules prior to certain corporate changes and provide certain unaudited financial information within 45 days after the end of each quarter and within 90 days after each year end. Starting in July 2012, the loan was repaid in 33 equal monthly payments of principal and interest of \$0.8 million plus an end of term payment of \$0.5 million if the loan is prepaid, or \$0.4 million if paid upon maturity. In March 2015, the Hercules Notes Payable was repaid in full, including the end of term payment of \$0.4 million.

In connection with the Hercules Notes Payable, the Company issued warrants to purchase 17,977 shares of Series D convertible preferred stock at \$66.75 per share, which converted to warrants to purchase common stock upon the Company's initial public offering, or IPO. The fair value of the warrants of \$0.1 million was recorded as a debt discount and was amortized to interest expense using the straight-line method over the loan term. The Company incurred \$0.5 million of debt issuance costs in connection with the Hercules Notes Payable which was also amortized to interest expense over the loan term.

The Company made principal and interest payments on the Hercules Notes Payable of \$0 and \$2.6 million and \$2.3 million and \$6.9 million during the three and nine months ended September 30, 2015 and 2014, respectively.

Essex Capital Notes

On December 20, 2013, the Company signed a Loan and Lease 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 commercial fill/finish line, or the Fill/Finish Line. Under the Loan and Lease Agreement, with the issuance of each Note, the Company issued warrants to purchase its capital stock. The Essex Notes incurred interest at 11.5% per annum through the completion of the IPO in February 2014 and 10.375% per annum thereafter. In December 2013, the Company drew down \$2.5 million under short-term notes pursuant to the Loan and Lease Agreement, and an additional \$2.5 million in January 2014. In May 2014, pursuant to the terms of this agreement, the Company sold equipment to Essex Capital, resulting in partial settlement of the outstanding loan balance of \$1.1 million, and sold and leased the equipment back from Essex Capital for fixed monthly payments to be paid over 3 years. This transaction did not qualify for sale-leaseback accounting due to the Company's continuing involvement in the equipment. Therefore, the Company accounted for this transaction as a financing obligation using the effective interest rate method.

On December 17, 2014, the Company entered into the First Amendment to the Loan and Lease Agreement with Essex Capital. Under the terms of this Amendment, the Company repaid the outstanding debt balance of \$3.9 million and issued warrants to purchase 44,753 shares of common stock. Additionally, the Company made interest payments on the Essex Notes in the amount of \$0.1 million and \$0.3 million for the three and nine months ended September 30,

2014. In February 2015, the Company executed the Second Amendment to the Loan and Lease Agreement, under which the term of the facility was extended to April 15, 2015, and the purchase price of the equipment was increased by \$0.1 million to approximately \$9.8 million. In accordance with the terms of the Loan and Lease Agreement, in April 2015, the Company sold equipment to Essex Capital for approximately \$9.8 million, and concurrently with this sale, entered into a lease for the equipment with a fixed monthly payment to be paid over 3 years. This transaction also did not qualify for sale-leaseback accounting due to the Company's continuing involvement in the equipment. Therefore, the Company accounted for this transaction as a financing obligation using the effective interest rate method.

Table of Contents

## REVANCE THERAPEUTICS, INC.

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

In June 2015, the Company exercised its option to purchase all 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.

As of September 30, 2015, the aggregate total future minimum lease payments under the financing obligation were as follows (in thousands):

Year Ending December 31,	
2015	\$1,054
2016	4,217
2017	3,971
2018	949
Total payments	\$10,191

## 7. Convertible Notes, Warrants, and Related Derivatives

## 2013 Convertible Notes, Common Stock Warrants, and Related Derivatives

In February 2014, in connection with the Company's IPO, the 2013 Notes with a principal amount of \$23.7 million, accrued interest through the date of the IPO, remaining interest due through October 7, 2014, and derivative liability totaling \$26.2 million converted into 1,637,846 shares of the Company's common stock.

In connection with the issuance of the 2013 Notes, the Company issued warrants to purchase 409,450 shares of common stock, which were net exercised for 405,594 shares of common stock upon the IPO.

Additionally, the 2013 Notes had conversion and redemption features which were determined to be embedded derivatives, requiring bifurcation and separate fair value accounting. Immediately prior to the conversion, the Company determined that the fair value of the derivative liabilities associated with the convertible notes was reduced to \$1.9 million, the value of interest due to note holders from the date of the IPO through the maturity date of the loan in October 2014.

Upon the conversion of the 2013 Notes into shares of common stock, the Company applied extinguishment accounting resulting in a loss of \$8.3 million. As of the date of conversion, the Company was in compliance with all covenants in the 2013 Notes.

During the three months ended March 31, 2014, the Company recognized non-cash interest expense of \$9.6 million related to the 2013 Notes, including amortization of warrant-related debt discount of approximately \$0.4 million up to the date of conversion, amortization of the derivative-related debt discount of \$0.6 million up to the date of conversion, accrued interest of \$0.3 million up to the date of conversion and a loss on extinguishment of \$8.3 million upon conversion of the 2013 Notes into common stock.

Table of Contents

## REVANCE THERAPEUTICS, INC.

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

## 8. Interest Expense

Interest expense, includes cash and non-cash components with the non-cash components consisting of (i) interest recognized from the amortization of debt issuance costs, which were capitalized on the Condensed Consolidated Balance Sheets and are generally derived from cash payments related to the issuance of convertible notes and notes payable, (ii) interest recognized from the amortization of debt discounts, which were capitalized on the Condensed Consolidated Balance Sheets and derived from the issuance of warrants and derivatives issued in conjunction with convertible notes and notes payable, (iii) interest recognized on the 2013 convertible notes, or 2013 Notes, which was not paid but rather converted into shares of common stock, (iv) interest capitalized for assets constructed for use in operations, (v) interest related to the extinguishment of debt, which is classified as a loss on debt extinguishments, and (vi) effective interest recognized on the financing obligation. The capitalized amounts related to the debt issuance costs and debt discounts are generally amortized to interest expense over the term of the related debt instruments. The interest expense by cash and non-cash components is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Interest expense				
Cash related interest expense (1)	\$(264)	) \$(276)	) \$(564)	) \$(971)
Non-cash interest expense				
Non-cash interest expense — debt issuance costs	—	(48)	) (39)	) (148)
Non-cash interest expense — warrant and derivative related debt discounts	—	(76)	) (5)	) (219)
Non-cash interest expense — convertible notes	—	—	—	(1,250)
Loss on extinguishment of 2013 Notes	—	—	—	(8,331)
Effective interest on financing obligation	(126)	) (66)	) (226)	) (66)
Non-cash capitalized interest expense (2)	—	238	—	649
Total non-cash interest expense	(126)	) 48	(270)	) (9,365)
Total interest expense	\$(390)	) \$(228)	) \$(834)	) \$(10,336)

(1) Cash related interest expense includes interest payments to Hercules Notes Payable, Essex Notes, and Financing Obligations.

(2) Interest expense capitalized pursuant to Accounting Standards Codification Topic 835, Interest.

## 9. Commitments and Contingencies

## Facility Lease

In January 2010, the Company entered into a non-cancelable facility lease that requires monthly payments through January 2022. This facility will be 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. Under the terms of the lease agreement, the payments escalate over the term of the lease with the exception of a decrease in

payments at the beginning of 2022; however, the Company recognizes the expense on a straight-line basis over the life of the lease.

15

---

Table of Contents

## REVANCE THERAPEUTICS, INC.

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

Rent expense was \$1.3 million and \$3.9 million for each of the three and nine months ended September 30, 2015 and 2014. As of September 30, 2015, the aggregate total future minimum lease payments under non-cancelable operating leases were as follows (in thousands):

Year Ending December 31,	
2015	\$1,269
2016	5,222
2017	5,394
2018	5,578
2019 and thereafter	32,354
Total payments	\$49,817

**Other Milestone-Based Commitments**

The Company has one remaining obligation to make a future milestone payment to List Laboratories that becomes due and payable on the achievement of a certain regulatory milestone. The Company is obligated to pay royalties to List Laboratories on future sales of botulinum toxin products. The Company also has one remaining future milestone payment of \$4.0 million due and payable to Valeant Pharmaceuticals International, Inc. upon the achievement of regulatory approval for RT001 or RT002 (Note 3).

**Purchase Commitments**

The Company has certain commitments from outstanding purchase orders primarily related to clinical trial development and other costs related to the Company's manufacturing facility. These agreements, which total \$22.4 million, are cancellable at any time with the Company required to pay all 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. As of May 2015, the Company became subject to a securities class action complaint, captioned City of Warren Police and Fire Retirement System v. Revance Therapeutics Inc., et al, CIV 533635, which was filed on behalf of City of Warren Police and Fire Retirement System in the Superior Court for San Mateo County, California against the Company and certain of its directors and executive officers at the time of the June 2014 follow-on public offering, and the investment banking firms that acted as the underwriters in the follow-on public offering. In general, the complaint alleges that the defendants misrepresented the then-present status of the RT001 clinical program and made false and misleading statements regarding the formulation, manufacturing and efficacy of its drug candidate, RT001, for the treatment of lateral canthal lines at the time of the follow-on public offering. The complaint has been brought as a purported class action on behalf of those who purchased common stock in the follow-on public offering and seeks unspecified monetary damages and other relief.

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. At this time, neither the outcome of this matter, nor an estimate of the maximum potential exposure or the range of possible loss can be determined. The Company believes that the class action lawsuit is without merit and intends to vigorously defend the action. Nevertheless, this litigation, as any other litigation, is subject to uncertainty and there can be no assurance that this litigation will not have a material adverse effect on the Company's business, results of operations, financial position or cash flows.





Table of Contents

REVANCE THERAPEUTICS, INC.

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

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 to date.

10. Warrants

As of September 30, 2015, the Company has warrants to purchase 198,662 shares of common stock outstanding and no convertible preferred stock warrants outstanding.

11. Equity

Common Stock Outstanding

As of September 30, 2015, the Company had 24,313,222 shares of common stock outstanding. In March 2015, the Company entered into an At-The-Market Issuance Sales Agreement, or the ATM agreement, with Cowen and Company, LLC, or Cowen, under which the Company may offer and sell our common stock having aggregate proceeds of up to \$50.0 million from time to time through Cowen as our sales agent. Sales of common stock through Cowen 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 use commercially reasonable efforts to sell the common stock from time to time, based upon instructions from the Company (including any price, time or size limits or other customary parameters or conditions we may impose). 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. As of September 30, 2015, the Company sold 352,544 shares of common stock under the ATM agreement at a weighted average price of \$30.76 per share resulting in net proceeds of approximately \$10.1 million, after underwriting discounts, commissions, and other offering expenses. As of September 30, 2015, common stock for aggregate gross proceeds of \$39.2 million remained available under this facility, subject to certain conditions as specified in the ATM agreement.

2014 Equity Incentive Plan

On January 1, 2015, 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, 2014, or 950,978 shares. During the nine months ended September 30, 2015, the Company granted stock options for 725,838 shares of common stock and 157,286 restricted stock awards under the 2014 EIP, including a stock option grants for 90,000 shares to non-employee directors. As of September 30, 2015, there were 286,984 shares available for issuance under the 2014 EIP.

2014 Inducement Plan

As of September 30, 2015, there were 145,571 shares available for issuance under the 2014 Inducement Plan, or 2014 IN.

The 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:

17

---

Table of Contents

## REVANCE THERAPEUTICS, INC.

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

	Three Months Ended		Nine Months Ended September		
	September 30,		30,		
	2015	2014	2015	2014	
Expected term (in years)	6.1	6.2	6.3	6.1	
Expected volatility	61.3	% 61.5	% 62.7	% 57.4	%
Risk-free interest rate	1.7	% 1.6	% 1.5	% 1.9	%
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 as quoted by the NASDAQ. Prior to the IPO, the fair value of the shares of common stock underlying the stock options had historically been determined by the Board of Directors. Because there was no public market for the Company's common stock, the Board of Directors had determined fair value of the common stock at the time of grant of the option by considering a number of objective and subjective factors including valuation of comparable companies, sales of convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock, and general and industry specific economic outlook, amongst other factors.

Expected Term. The expected term for employees and directors 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 limited history of exercise data. The expected term for non-employees is based on the remaining contractual term.

Expected Volatility. Since the Company was a private entity until February 2014 with no historical data regarding the volatility of its common stock, the expected volatility used is based on volatility of a group of similar entities. In evaluating similarity, the Company considered factors such as industry, stage of life cycle, capital structure, and size. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available.

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 never paid any dividends and does not plan to pay dividends in the foreseeable future, and, therefore, used an expected dividend rate of zero in the valuation model.

Forfeitures. The Company is required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting option forfeitures and record stock based compensation expense only for those awards that are expected to vest. To the extent actual forfeitures differ from the estimates, the difference will be recorded as a cumulative adjustment in the period that the estimates are revised.

The fair value of the stock options granted to non-employees is calculated at each reporting date using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Three Months Ended		Nine Months Ended		
	September 30,		September 30,		
	2015	2014	2015	2014	
Expected term (in years)	8.2	8.9	8.4	9.1	
Expected volatility	73.5	% 57.2	% 72.4	% 57.5	%
Risk-free interest rate	2.0	% 2.5	% 2.0	% 2.5	%

Edgar Filing: Revance Therapeutics, Inc. - Form 10-Q

Expected dividend rate — % — % — % — %

2014 Employee Stock Purchase Plan

On January 1, 2015, 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 1% of the total number of shares of the Company's capital stock outstanding on December 31, 2014, or 237,744 shares. As of September 30, 2015, there were 404,073 shares available for issuance under the 2014 ESPP.

18

---

Table of Contents

## REVANCE THERAPEUTICS, INC.

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

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		Nine Months Ended		
	September 30,		September 30,		
	2015	2014	2015	2014	
Expected term (in years)	0.5	0.5	0.5	0.5	
Expected volatility	50.8	% 42.5	% 50.5	% 46.4	%
Risk-free interest rate	0.1	% 0.1	% 0.1	% 0.1	%
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.

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

**Expected Volatility.** Since the Company was a private entity until February 2014 with no historical data regarding the volatility of its common stock, the expected volatility used is based on volatility of a group of similar entities. In evaluating similarity, the Company considered factors such as industry, stage of life cycle, capital structure, and size. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company's common stock becomes available.

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

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

**Total Stock-Based Compensation**

Total stock-based compensation expense related to options and restricted stock awards granted to employees and nonemployees and the employee stock purchase plan was allocated as follows (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Research and development	\$1,182	\$557	\$2,879	\$1,644
General and administrative	1,408	1,728	4,435	2,967
Total stock based compensation expense	\$2,590	\$2,285	\$7,314	\$4,611

**Accumulated Other Comprehensive Income (Loss)**

The following table summarizes the changes in accumulated other comprehensive income (loss) by component (in thousands):

	Unrealized Gains and Losses on Available-for-Sale Securities
Balance at December 31, 2014	\$—
Other comprehensive income (loss) before reclassifications	10
Reclassifications from accumulated other comprehensive income (loss)	—
Net current period other comprehensive income (loss)	10
Balance at September 30, 2015	\$10



Table of Contents

## REVANCE THERAPEUTICS, INC.

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

## 12. Net Loss per Share Attributable to Common Stockholders

The following table sets forth the computation of the Company's basic and diluted net loss per share attributable to common stockholders for the three and nine months ended September 30, 2015 and 2014 (in thousands, except for share and per share amounts):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Net loss attributable to common stockholders, basic	\$(19,175 )	\$(13,977 )	\$(51,382 )	\$(48,705 )
Net loss attributable to common stockholders, diluted	\$(19,175 )	\$(13,977 )	\$(51,382 )	\$(48,705 )
Net loss per share attributable to common stockholders				
Basic	\$(0.81 )	\$(0.60 )	\$(2.17 )	\$(2.70 )
Diluted	\$(0.81 )	\$(0.60 )	\$(2.17 )	\$(2.70 )
Weighted-average shares used in computing net loss per share attributable to common stockholders:				
Basic	23,755,199	23,331,104	23,625,869	18,009,537
Diluted	23,755,199	23,331,104	23,625,869	18,009,537

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,	
	2015	2014
Stock options	2,374,055	1,877,949
Common stock warrants	198,662	153,909
Unvested restricted stock awards	308,193	253,625
Shares expected to be purchased on December 31 under the 2014 ESPP	7,945	6,426

## 13. Subsequent Events

In November 2015, the Company completed a public offering, pursuant to which the Company issued 3,737,500 shares of common stock at \$36.00 per share, including the exercise of the underwriters' option to purchase 487,500 additional shares of common stock, for gross proceeds of \$134.6 million.

On October 31, 2015, we entered into a separation agreement with Arthur P. Bertolino, M.D., Ph.D., our Chief Medical Officer and Executive Vice President, pursuant to which he resigned his employment with the Company, effective as of December 31, 2015. Dr. Bertolino will not be entitled to cash severance payments in connection with his departure; however, the Company agreed to accelerate vesting for a portion of his outstanding stock options and restricted stock awards, such that if he remains employed with the Company through November 15, 2015, an aggregate of 76,286 stock options and 23,740 restricted stock awards will have vested. If he remains employed through December 31, 2015, an aggregate of 114,428 stock options and 35,610 restricted stock awards will have vested.

Table of Contents

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, 2014, filed with the SEC on March 4, 2015. The words “believe,” “will,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “expect,” “predict,” “potentially,” 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 and the timing of clinical trials in our development of RT001 for the treatment of crow’s feet, hyperhidrosis or other indications;
- our expectations regarding the results and the timing of clinical trials of RT002 for the treatment of glabellar lines, muscle movement disorders, including cervical dystonia, or other indications;
- our expectations regarding our future development of RT001 and RT002 for other therapeutic or aesthetic indications;
- our expectation regarding the timing of our regulatory submissions for approval of RT001 for the treatment of crow’s feet in the United States, Europe and other countries or for the treatment of hyperhidrosis in the United States;
- the potential for commercialization of RT001 and RT002, if approved, by us;
- our expectations regarding the potential market size, opportunity and growth potential for RT001 and RT002, if approved for commercial use;
- our belief that RT001 and RT002 can expand the overall botulinum toxin market;
- 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 transfer manufacturing from third parties to our facility and to scale up our manufacturing capabilities 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, 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; and
- developments and projections relating to our competitors and our industry.



Table of Contents

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 not possible for our management to predict all risks, nor can we 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.

---

Table of Contents

## Overview

Revance Therapeutics, Inc. is a clinical-stage specialty biopharmaceutical 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, combined with our patented TransMTS® peptide delivery system, to address unmet needs in large and growing neurotoxin markets. Our proprietary TransMTS technology enables delivery of botulinum toxin type A through two investigational drug product candidates, RT001, also referred to as RTT150 (Botulinum Toxin Type A) Topical Gel, and RT002, or RTT150 (Botulinum Toxin Type A) for Injection. We are pursuing clinical development for RT001 and RT002 in a broad spectrum of aesthetic and therapeutic indications. We hold worldwide rights for all indications of RT001, RT002, and our TransMTS technology platform.

RT001 has the potential to be the first commercially available non-injectable dose form of botulinum toxin type A. We are studying RT001 for aesthetic indications, such as crow's feet (wrinkles around the eyes, also known as lateral canthal lines), and therapeutic indications, such as hyperhidrosis (excessive sweating). RT002 is a novel, injectable formulation of botulinum toxin type A designed to be a targeted and long-lasting injectable botulinum toxin type product. We are studying injectable RT002 for aesthetic indications, such as glabellar (frown) lines, and therapeutic uses, such as muscle movement disorders, including cervical dystonia. Both products may have the potential to expand into additional aesthetic and therapeutic indications in the future.

## RT002 or RTT150 (Botulinum Toxin Type A) for Injection

We are developing RT002, an injectable formulation of botulinum toxin type A, for indications where deep delivery of the botulinum toxin is required and a long-lasting effect is desired. We believe RT002 may provide targeted delivery of botulinum toxin to intended treatment sites, while reducing the unwanted spread of botulinum toxin to adjacent areas. We believe, and our preclinical and clinical studies indicate, that this targeted delivery, enabled by our proprietary peptide technology, may permit safe administration of higher doses of botulinum toxin and may result in long-lasting effect. We have demonstrated these properties in preclinical studies and have tested RT002 in a four-cohort, dose escalating, open-label Phase 1/2 clinical trial outside of the United States for the treatment of glabellar lines, the vertical lines between the eyebrows and above the nose. Data from this clinical trial indicated that RT002 appears to be well tolerated and met efficacy endpoints at all four doses. We also reported duration of effect of seven months from the last cohort of this trial, the only cohort for which duration of effect was measured.

Based upon the results to date, we are further developing RT002 for the treatment of glabellar lines and reported interim results from BELMONT, a Phase 2, active comparator, placebo-controlled clinical trial against the market leader BOTOX® Cosmetic, on October 29, 2015. The topline interim data from the trial showed that RT002 achieved its primary efficacy measurement at four weeks for all doses of RT002 and that such efficacy was highly statistically significant as compared to placebo. In addition, the 40 Unit dose of RT002 demonstrated a 23.6-week median duration versus BOTOX® Cosmetic with an 18.8-week median duration. Across all cohorts, RT002 appeared to be generally safe and well-tolerated. We plan to report final results from our BELMONT trial and conduct an End-of-Phase 2 meeting with the United States Food and Drug Administration, or FDA, in the first half of 2016. We then expect to begin Phase 3 clinical studies of RT002 for the treatment of glabellar lines in the second half of 2016. If approved, we believe RT002 has the potential to satisfy significant unmet needs in this market.

We have also initiated a Phase 2 dose-escalating, open-label clinical study of RT002 in the therapeutic indication of cervical dystonia. The Phase 2 study will evaluate safety, preliminary efficacy, and duration of effect of RT002 for injection in subjects with moderate-to-severe isolated cervical dystonia symptoms of the neck. We expect to release interim results in 2016. The category of muscle movement disorders, which includes cervical dystonia, accounts for a large proportion of therapeutic neurotoxin sales globally.

Table of Contents

RT001 or RTT150 (Botulinum Toxin Type A) Topical Gel

We are developing and plan to commercialize RT001 for indications where topical application provides a meaningful advantage over injectable administration. RT001 is designed to have primary advantages, which include 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 make RT001 suitable for multiple indications.

The first indications we are pursuing are in the fields of dermatology and plastic surgery. If approved, we believe RT001 can expand the overall botulinum toxin aesthetic market by appealing to new patients who would prefer a needle-free approach to treatment. The aesthetic dermatology market is attractive because we believe that patients in this market tend to be open to trying new products and are willing to pay for aesthetic procedures out of pocket, reducing reliance on reimbursement. We are focused on this market not only because of its size and growth potential but also because, in the United States and Europe, this market can be easily accessed by a specialty sales force and distributor network.

We are in a Phase 3 development program of RT001 in North America for the treatment of crow's feet. During the third quarter of 2015, we initiated REALISE 1, a pivotal Phase 3 clinical trial designed to evaluate the safety and efficacy of a single, bilateral administration of RT001 topical gel compared to placebo in subjects with moderate to severe crow's feet. We expect to report efficacy data from this study in the first half of 2016. To date, we have conducted seventeen clinical trials with RT001 for the treatment of crow's feet, with a total of over 1,600 subjects. In two of our Phase 2b clinical trials, RT001 demonstrated a statistically significant and clinically meaningful reduction in crow's feet visible to both physicians and subjects. After completing our Phase 2b clinical trials, we modified the formulation of the RT001 diluent. We then conducted a Phase 3 clinical trial with this new diluent formulation to evaluate the efficacy and safety of RT001. Data generated from this clinical trial were inconsistent with the data from our previous three Phase 2b clinical trials for the treatment of crow's feet. Specifically, we observed no improvement from baseline in either the placebo or RT001 group. We initiated two open-label studies to further assess our RT001 investigational topical drug product candidate. Following analysis of the data available from these open-label studies, taken together with our analysis of prior studies and early data from newly developed clinical methods, we decided to proceed with a RT001 U.S. Phase 3 clinical trial for the treatment of crow's feet. Our clinical and other studies have consistently indicated that RT001 appears to be well tolerated with no serious adverse events related to the study drug or study treatment procedures or other safety concerns.

We are also developing RT001 for therapeutic applications where botulinum toxin has shown efficacy and that are particularly well suited for needle-free treatments. We have completed initial Phase 2 clinical trials for the treatment of primary axillary, or underarm, hyperhidrosis, and for the prevention of chronic migraine headache. In the third quarter of 2015, we initiated an additional randomized, double-blinded, dose-ranging, placebo-controlled Phase 2 clinical trial designed to evaluate the safety and efficacy of a single, bilateral application of RT001 Topical Gel for the treatment of primary axillary hyperhidrosis and, in the fourth quarter of 2015, completed enrollment for the trial. We expect to report interim results later in the fourth quarter of 2015.

Since commencing operations in 2002, we have devoted substantially all our efforts to identifying and developing product candidates for the aesthetic and therapeutic markets, recruiting personnel and raising capital. We have devoted predominantly all of our resources to the preclinical and clinical development of, and manufacturing capabilities for, RT001 and RT002. We have retained all rights to develop and commercialize RT001 and RT002 worldwide. We have not filed for approval with the FDA for the commercialization of RT001 or RT002 and we have not generated any revenue from product sales for RT001 or RT002.

We have funded substantially all of our operations through the sale and issuance of our common stock, preferred stock, venture debt and convertible debt. On November 9, 2015, we completed a follow-on public offering, pursuant to which we issued 3,737,500 shares of common stock at \$36.00 per share, including the exercise of the underwriters' option to purchase 487,500 additional shares of common stock, for gross proceeds of \$134.6 million. In March 2015, we entered into an At-The-Market, or ATM, sales agreement, or the ATM agreement, with Cowen and Company, LLC, or Cowen, under which we may offer and sell our common stock having aggregate proceeds of up to \$50.0 million from time to time. As of September 30, 2015, we sold 352,544 shares of our common stock under the ATM

agreement at a weighted average price of \$30.76 per share resulting in net proceeds of approximately \$10.1 million, after underwriting discounts, commissions and other offering expenses. On June 19, 2014, we completed a follow-on public offering, pursuant to which we issued 4,600,000 shares of

Table of Contents

common stock at \$30.50 per share, including the exercise of the underwriters' option to purchase 600,000 additional shares of common stock, for net proceeds of \$131.3 million, after underwriting discounts, commissions and other offering expenses. On February 6, 2014, we completed our initial public offering, or IPO, for sale of 6,900,000 shares of common stock at \$16.00 per share, including the exercise of the underwriters' option to purchase an additional 900,000 shares of common stock, for net proceeds of \$98.6 million, after underwriting discounts, commissions and other offering expenses. We also raised \$23.7 million through the issuance of convertible notes in the fourth quarter of 2013 and January 2014.

We have never been profitable and, as of September 30, 2015, had an accumulated deficit of \$310.2 million. We incurred net losses of \$19.2 million and \$51.4 million and \$14.0 million and \$48.7 million in the three and nine months ended September 30, 2015 and 2014, respectively. As of September 30, 2015, we had cash, cash equivalents, and investments of \$144.2 million. We expect to continue to incur net operating losses for at least the next several years as we advance RT001 and RT002 through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization. We have the ability to manufacture our own botulinum toxin type A product to support our clinical trials and eventually, our commercial production. Additionally, we currently utilize third party clinical research organizations, or CROs, to carry out our clinical development and we do not yet have a sales organization. We will need substantial additional funding to support our operating activities, especially as we approach anticipated regulatory approval in the United States and other territories and begin to establish our sales capabilities. Adequate funding may not be available to us on acceptable terms, or at all. 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.

## Results of Operations

## Revenue

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

	Three Months Ended			Nine Months Ended		
	September 30,			September 30,		
	2015	2014	Change	2015	2014	Change
	(In thousands, except percentages)					
Relastin Royalty	\$75	\$75	—%	\$225	\$225	—%
Licensing Revenue	—	—	N/A	—	83	100%
Total revenue	\$75	\$75	—%	\$225	\$308	(3)%

Our total revenue for the three months ended September 30, 2015 remained unchanged, compared to the same period in 2014, due to minimum royalty payment obligations pursuant to the Relastin royalty agreement. We entered into the Relastin royalty agreement in August 2011, to sell the business related to our Relastin® product line, to Precision Dermatology, Inc., or PDI. The Relastin royalty agreement provided for minimum royalty payment of \$0.3 million per year, to be paid quarterly for up to 15 years from the execution date; however, the royalty agreement could be terminated with 90 days' notice with the rights to the Relastin product line reverting back to us. 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 royalty agreement effective as of July 23, 2015; however, as of September 30, 2015, reversion of the Relastin intellectual property rights had not been completed and we are entitled to the minimum royalty payment until such rights are reverted back to us. We recognized the annual minimum royalty payment on a pro rata basis in the amount of \$0.1 million and \$0.2 million for each of the three and nine months ended September 30, 2015 and 2014 as set forth in the Relastin asset purchase agreement.

Our total revenue for the nine months ended September 30, 2015 decreased by 3%, compared to the same period in 2014, due to a decrease in license revenue in connection with an exclusive technology evaluation agreement with Procter & Gamble.

In June 2013, we received an upfront payment of \$0.3 million, which was initially recorded as deferred revenue and recognized over the estimated performance period. During the three months ended March 31, 2014, the remaining \$0.1 million of the upfront payment related to the exclusive technology evaluation agreement was recognized as

license revenue.  
Operating Expenses

25

---

Table of Contents

	Three Months Ended			Nine Months Ended		
	September 30, 2015	2014	Change	September 30, 2015	2014	Change
	(In thousands, except percentages)					
Research and development	\$13,016	\$8,600	51%	\$32,573	\$24,261	34%
General and administrative	5,827	5,300	10%	18,183	14,250	28%
Total operating expenses	\$18,843	\$13,900	36%	\$50,756	\$38,511	32%

**Research and Development Expenses**

Research and development expenses for the three and nine months ended September 30, 2015 increased by 51% and 34%, respectively, compared to the same periods in 2014, primarily due to increased costs related to personnel, stock-based compensation, pre-clinical and toxicology studies, and clinical trial expenditures, which increased primarily due to our ongoing RT002 Phase 2 study for the treatment of glabellar lines and initiation of our RT001 Phase 2 study for the treatment of hyperhidrosis, our RT002 Phase 2 study for the treatment of cervical dystonia, and our RT001 Phase 3 program for the treatment of moderate to severe lateral canthal lines.

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 RT001 and RT002 programs.

Stock-based compensation for research and development was \$1.2 million and \$2.9 million and \$0.6 million and \$1.6 million for the three and nine months ended September 30, 2015 and 2014, respectively.

**General and Administrative Expenses**

General and administrative expenses for the three and nine months ended September 30, 2015 increased by 10% and 28%, respectively, compared to the same periods in 2014, primarily due to increased costs related to personnel, legal matters, and stock-based compensation offset by a decrease in professional fees. Following our IPO, in February 2014, we incurred increased costs related to personnel and administrative activities to support the operation of a public company.

Stock-based compensation for general and administration was \$1.4 million and \$4.4 million and \$1.7 million and \$3.0 million for the three and nine months ended September 30, 2015 and 2014, respectively.

**Other Expense****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. To date, our interest income has not been significant in any individual period.

**Interest Expense**

Interest expense primarily consists of the interest charges associated with our convertible notes, notes payable, financing obligations, capital lease obligations, and capitalized interest. Notes payable under our term loan agreement with Hercules bore interest at a rate which was the greater of (i) 9.85% per annum or (ii) 9.85% per annum plus the difference of the prime rate less 3.25%. The interest charge on our convertible notes and capital lease obligations was fixed at the inception of the related transaction based on the incremental borrowing rate in effect on such date. Our interest expense also includes cash and non-cash components with the non-cash components consisting of (i) interest recognized from the amortization of debt issuance costs, which were capitalized on the Condensed Consolidated Balance Sheets and are generally derived from cash payments related to the issuance of convertible notes and notes payable, (ii) interest recognized from the amortization of debt discounts, which were capitalized on the Condensed Consolidated Balance Sheets, and derived from the issuance of warrants and derivatives issued in conjunction with convertible notes and notes payable, (iii) interest recognized on the 2013 convertible notes, or 2013 Notes, which was

not paid but rather converted into shares of common stock, (iv) interest capitalized for assets

26

---



Table of Contents

constructed for use in operations, (v) interest related to the extinguishment of debt, which is classified as a loss on debt extinguishments, and (vi) effective interest recognized on the financing obligation. The capitalized amounts related to the debt issuance costs and debt discounts are generally amortized to interest expense over the term of the related debt instruments.

Additionally, our note payable with Hercules matured and was fully paid off in March 2015.

The interest expense by cash and non-cash components is as follows:

	Three Months Ended September 30, 2015			Nine Months Ended September 30, 2015		
	2014	Change	2014	Change		
	(In thousands, except percentages)					
Interest expense						
Cash related interest expense <sup>(1)</sup>	\$ (264 )	(4)%	\$ (971 )	(42)%		
Non-cash interest expense						
Non-cash interest expense — debt issuance costs	—	(100)%	(39 )	(74)%		
Non-cash interest expense — warrant and derivative related debt discounts	—	(100)%	(5 )	(98)%		
Non-cash interest expense — convertible notes	—	N/A	(1,250 )	(100)%		
Loss on extinguishment of 2013 Notes	—	N/A	(8,331 )	(100)%		
Non-cash interest expense - financing obligation	(126 )	91%	(66 )	242%		
Non-cash capitalized interest expense <sup>(2)</sup>	\$—	(100)%	\$649	(100)%		
Total non-cash interest expense	\$ (126 )	(363)%	\$ (9,365 )	(97)%		
Total interest expense	\$ (390 )	71%	\$ (834 )	(92)%		

(1) Cash related interest expense included interest payments to the Hercules Facility, Essex Capital Facility, and Financing Obligations.

(2) Interest expense capitalized pursuant to Accounting Standards Codification Topic 835, Interest.

Interest expense for the three months ended September 30, 2015 increased by 71%, compared to the same period in 2014, primarily due to an increase in interest expense for the financing obligations offset by a lower weighted average of debt outstanding and a decrease in capitalization of interest expense for construction-in-progress.

Interest expense for the nine months ended September 30, 2015 decreased by 92%, compared to the same period in 2014, primarily due to the loss on extinguishment of the 2013 Notes, conversion of the 2013 Notes into common stock, and less cash paid for interest expense on the Hercules Notes Payable offset by a decrease in capitalization of interest expense for construction-in-progress. In February 2014, our IPO triggered an acceleration of interest on the 2013 Notes through the end of the notes, which combined with the outstanding principal balance, then converted into 1,637,846 shares of common stock.

#### Change in Fair Value of Derivative Liabilities Associated with Convertible Notes

Our derivative liabilities associated with 2013 Notes were classified as liabilities on our Condensed Consolidated Balance Sheets and 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 recorded the fair value of the derivative liabilities as a debt discount, which was amortized using the effective interest method over the term of the 2013 Notes. The amortization of this debt discount was accelerated upon the completion of our IPO with the corresponding expense recorded in our Condensed Consolidated Statement of Operations and

Comprehensive Loss. See Note 7 to our Condensed Consolidated Financial Statements included elsewhere in this Form 10-Q.

Change in Fair Value of Derivative Liabilities Associated with the Medicis Settlement

The Product Approval Payment associated with the Medicis settlement is classified as a liability on our Condensed Consolidated Balance Sheet. This liability will be remeasured to fair value at each balance sheet date with the corresponding

27

---

Table of Contents

gain or loss from the adjustment recorded in the Condensed Consolidated Statement 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.

**Change in Fair Value of Common Stock Warrant Liability**

Common stock warrants issued in connection with the 2013 Notes were classified as liabilities on our Condensed Consolidated Balance Sheet and required remeasurement at each balance sheet date. Upon the completion of our IPO, these common stock warrants liabilities were remeasured to fair value and settled in conjunction with the cashless net exercise of these warrants. See Note 7 to our Condensed Consolidated Financial Statements included elsewhere in this Form 10-Q.

**Change in Fair Value of Convertible Preferred Stock Warrant Liability**

Our previously outstanding convertible preferred stock warrants were classified as liabilities on our Condensed Consolidated Balance Sheets at fair value as they were contingently redeemable because they obligated us to transfer assets to the holders at a future date under certain circumstances, such as a deemed liquidation event. The convertible preferred stock warrants were remeasured to fair value at each balance sheet date with the corresponding gain or loss from the adjustment recorded in the Condensed Consolidated Statement of Operations and Comprehensive Loss.

Upon the IPO in February 2014, these preferred stock warrants were remeasured to fair value and converted into common stock warrants with the corresponding liability reclassified to additional paid in capital.

	Three Months Ended			Nine Months Ended		
	September 30,		Change	September 30,		Change
	2015	2014		2015	2014	
	(In thousands, except percentages)					
Interest income	\$68	\$14	385%	\$144	\$18	699%
Interest expense	(390 )	(228 )	71%	(834 )	(10,336 )	(92)%
Change in fair value of derivative liabilities associated with convertible notes	—	—	N/A	—	4,032	(100)%
Change in fair value of derivative liabilities associated with the Medicis settlement	13	67	(81)%	60	(426 )	(114)%
Change in fair value of common stock warrant liability	—	—	N/A	—	(2,151 )	(100)%
Change in fair value of convertible preferred stock warrant liability	—	—	N/A	—	(210 )	(100)%
Loss on settlement of preferred stock warrant	—	—	N/A	—	(1,356 )	(100)%
Other expense, net	(98 )	(5 )	1,857%	(221 )	(73 )	203%
Total other expense	\$(407 )	\$(152 )	168%	\$(851 )	\$(10,502 )	(92)%

Our total other expense for the three months ended September 30, 2015 increased by 168%, compared to the same period in 2014, primarily due to an increase in interest expense, which is described above, offset by a decrease in the fair value of the Medicis derivative liabilities associated with the Medicis settlement.

Our total other expense for the nine months ended September 30, 2015 decreased by 92%, compared to the same period in 2014, primarily due to a decrease in interest expense, which is described above, a decrease in the fair value of the Medicis derivative liabilities, no loss on settlement of preferred stock warrants in the current period, and other one-time charges related to our IPO, including conversion of common stock warrants and our convertible notes into common stock upon the IPO and conversion of preferred stock warrants into equity-based common stock warrants.



Table of Contents

## Liquidity and Capital Resources

As of September 30, 2015, we had capital resources consisting of cash, cash equivalents, and investments of \$144.2 million, a decrease of \$26.8 million, from December 31, 2014. In April 2015, we received \$9.8 million from the sale of equipment to Essex Capital and concurrently entered into a three year lease agreement for such equipment. In March 2015, we entered into the ATM agreement with Cowen under which we may offer and sell our common stock having aggregate proceeds of up to \$50.0 million from time to time. As of September 30, 2015, we sold 352,544 shares of our common stock under the ATM agreement at a weighted average price of \$30.76 per share resulting in net proceeds of approximately \$10.1 million, after underwriting discounts, commissions and other offering expenses. As of September 30, 2015, common stock for aggregate gross proceeds of \$39.2 million remained available under this facility, subject to certain conditions as specified in the ATM agreement.

Since our inception, we have incurred losses and negative cash flows from our operations. For the three and nine months ended September 30, 2015, we had a net loss of \$19.2 million and \$51.4 million, respectively. For the nine months ended September 30, 2015, we used \$39.2 million of cash to fund operating activities. As of September 30, 2015, we had a working capital surplus of \$131.8 million and an accumulated deficit of \$310.2 million. We believe that our existing cash, cash equivalents, and investments, including net proceeds from our IPO of \$98.6 million, net proceeds from our June 2014 follow-on public offering of \$131.3 million, net proceeds from our ATM offering of \$10.1 million, gross proceeds from our November 2015 follow-on public offering of \$134.6 million and proceeds of \$10.9 million from sale of equipment to Essex Capital will allow us to fund our operations for at least the next 12 months.

## Cash Flows

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,	
	2015	2014
Net cash used in operating activities	\$ (39,218	) \$(45,951
Net cash used in investing activities	(56,861	) (5,369
Net cash provided by financing activities	15,541	234,892

## Cash Flows from Operating Activities

Our cash used in operating activities is primarily driven by personnel-related expenditures, manufacturing costs, clinical development costs, and costs related to our facilities. 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.

Cash used in operating activities of \$39.2 million during the nine months ended September 30, 2015 resulted primarily from our net loss of \$51.4 million, offset by stock-based compensation expense of \$7.3 million, depreciation expense of \$1.6 million, and other adjustments of \$0.6 million. The \$2.7 million increase in our net operating assets and liabilities was primarily due to an increase in accruals and other current liabilities and deferred rent by \$3.2 million offset by decreases in prepaid and other current assets, other non-current assets, and accounts payable by \$0.5 million.

Cash used in operating activities of \$46.0 million for the nine months ended September 30, 2014 resulted in part from our net loss of \$48.7 million, non-cash adjustments for the revaluation of derivative liabilities associated with our convertible notes of \$4.0 million, and capitalized interest of \$0.6 million offset by loss on extinguishment of our 2013 Notes of \$8.3 million, revaluation of common stock warrant liability of \$2.2 million, loss on extinguishment of warrant liability upon exercise of put option by warrant holder of \$1.4 million, amortization of debt discounts of \$1.2 million, revaluation of convertible preferred stock warrant liability of \$0.2 million, stock-based compensation expense of \$4.6 million, depreciation expense of \$1.6 million, revaluation of derivative liability associated with Medicis

settlement of \$0.4 million, and interest upon issuance of new debt of \$0.3 million. The \$12.9 million decrease in our net operating assets and liabilities was primarily due to a decrease for payments to Medicis of \$7.1 million and decreases in prepaid and other current assets, other non-current assets, accounts payable, and deferred revenue by \$7.5 million offset by an increase in accruals and other current liabilities and deferred rent by \$1.7 million.

## Table of Contents

### Cash Flows from Investing Activities

Cash used in investing activities was \$56.9 million for the nine months ended September 30, 2015 consisting of \$54.1 million for purchases of investments and \$2.8 million in purchases of property and equipment which were partially offset by a reduction of our restricted cash of \$0.1 million.

Cash used in investing activities of \$5.3 million for the nine months ended September 30, 2014 consisting of \$5.4 million in purchases of property and equipment which were partially offset by a reduction of our restricted cash of \$0.1 million.

### Cash Flows from Financing Activities

Cash provided by financing activities was \$15.5 million for the nine months ended September 30, 2015 comprised of proceeds of \$10.2 million from issuance of common stock in connection with our ATM offering, net of deferred offering costs, and proceeds from sale of equipment to Essex Capital of \$9.8 million, and proceeds from the exercise of stock options and ESPP of \$0.8 million offset by principal payments on our notes payable of \$2.7 million, principal payments on our financing obligation and capital leases of \$1.8 million, and net settlement of restricted stock awards to settle employee tax obligations of \$0.8 million.

Cash provided by financing activities of \$234.9 million for the nine months ended September 30, 2014 primarily comprised of net proceeds of \$102.7 million from issuance of common stock in connection with our IPO in February 2014, net proceeds of \$131.8 million from issuance of common stock in connection with our follow-on public offering in June 2014, proceeds of \$6.7 million from issuance of convertible notes and note payable, and proceeds from exercise of stock options and ESPP of \$1.4 million. These increases were partially offset by principal payments on our notes payable of \$6.2 million, principal payments on our financing obligation and capital leases of \$0.1 million, and payments to settle warrants of \$1.4 million.

### 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 our cash expenditures to increase in the near term as we initiate and complete clinical trials and other associated programs relating to RT001 for the treatment of crow's feet and hyperhidrosis and as we initiate and complete additional clinical trials and associated programs related to RT002 for the treatment of glabellar lines and indications in muscle movement disorders, such as cervical dystonia. We believe that our existing capital resources will be sufficient to fund our operations for at least the next 12 months. However, we anticipate that we will need to raise substantial additional capital in the future to fund our operations. In order to meet these additional cash requirements, we may seek to sell additional equity or convertible debt securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of 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 RT001, RT002 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 RT001 and RT002;

• the timing of, and the costs involved in, obtaining regulatory approvals for RT001, RT002 or any future product candidates;

• the number and characteristics of any additional product candidates we develop or acquire;

• the scope, progress, results and costs of researching and developing RT001, RT002 or any future product candidates, and conducting preclinical and clinical trials;

30

---



Table of Contents

• the cost of commercialization activities if RT001, RT002 or any future product candidates are approved for sale, including marketing, sales and distribution costs;

• the cost of manufacturing RT001, RT002 or any future product candidates and any products we successfully commercialize;

• our ability to establish and maintain strategic collaborations, licensing or other arrangements and the terms of and timing such arrangements;

• the degree and rate of market acceptance of any future approved products;

• the emergence, availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;

• any litigation, including litigation costs and the outcome of such litigation;

• any product liability or other lawsuits related to our products;

• the expenses needed to attract and retain skilled personnel;

• 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.

Please see “Item 1A. Risk Factors” for additional risks associated with our substantial capital requirements.

We have not generated revenue from RT001 or RT002 and we do not know when, or if, we will generate such revenue. We do not expect to generate significant revenue unless or until we obtain marketing approval of, and commercialize RT001 or RT002. 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 RT001 and RT002 may encounter technical or other difficulties that could increase our development costs more than we currently expect or the FDA may require us to conduct additional clinical trials prior to approving RT001 or RT002. 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 2015.

**Critical Accounting Policies**

There have been no material changes in our critical accounting policies during the three and nine months ended September 30, 2015, as compared to those disclosed in Item 7 in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, filed with the SEC on March 4, 2015, except as described within Note 2 of 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, 2014, as filed with the SEC. In April 2015, we received \$9.8 million from the sale of equipment to

Essex Capital and concurrently entered into a three year lease agreement for such equipment. Except with respect to the foregoing, our future minimum contractual commitments have not changed materially from the amounts previously reported.

Off-Balance Sheet Arrangements

31

---

Table of Contents

As of September 30, 2015, 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**

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 \$144.2 million and \$171.0 million as of September 30, 2015 and December 31, 2014, respectively. As of September 30, 2015, our cash, cash equivalents, and investments were held in deposit, money market fund accounts, and U.S. government agency 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.

**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 are 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 three and nine months ended September 30, 2015 and 2014, are included in other expense in the Condensed Consolidated Statements of Operations and Comprehensive Loss. A hypothetical 10% movement in foreign currency rates would not be expected to have a material impact on our Condensed Consolidated Financial Statements. 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 chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2015. 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 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, 2015, our chief executive officer and chief financial 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 nine months ended September 30, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

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. On May 1, 2015, a securities class action complaint, captioned City of Warren Police and Fire Retirement System v. Revance Therapeutics Inc., et al, CIV 533635, was filed on behalf of City of Warren Police and Fire Retirement System in the Superior Court for San Mateo County, California against us and certain of our directors and executive officers at the time of our June 2014 follow-on public offering, and the investment banking firms that acted as the underwriters in our follow-on public offering.

In general, the complaint alleges that the defendants misrepresented the then-present status of our RT001 clinical program and made false and misleading statements regarding the formulation, manufacturing and efficacy of our drug candidate, RT001, for the treatment of lateral canthal lines at the time of our follow-on public offering. The complaint has been brought as a purported class action on behalf of those who purchased our common stock in our follow-on public offering and seeks unspecified monetary damages and other relief.

We believe that the class action lawsuit is without merit and intend to vigorously defend the action. Nevertheless, this litigation, as any other litigation, is subject to uncertainty and there can be no assurance that this litigation will not have a material adverse effect on our business, results of operations, financial position or cash flows.

Except as provided above, we are not currently involved in any material legal proceedings.

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, 2014.

Risks Related to Our Business and Strategy

We are substantially dependent on the clinical and commercial success of our product candidates, primarily our topical product candidate RT001 and our injectable product candidate RT002. \*

To date, we have invested most of our efforts and financial resources in the research and development of RT001, also referred to as RTT150 (Botulinum Toxin Type A) Topical Gel, our topical formulation of botulinum toxin. We are in a Phase 3 development program for RT001 for the treatment of crow's feet. In October 2014, we initiated an open-label study designed to confirm successful transfer of the production of our topical RT001 drug product to our manufacturing facility. Following a comprehensive analysis of the data obtained in such study, we subsequently commenced and completed a second open-label study using RT001 in the first half of 2015. Following analysis of the data obtained from these open-label studies, taken together with our analysis of prior studies and early data from newly developed clinical methods, we decided to proceed with a RT001 U.S. pivotal Phase 3 clinical trial for the treatment of crow's feet, which commenced during the third quarter of 2015. To date, we have conducted 17 clinical trials for RT001, with a total of over 1,600 subjects, for the treatment of crow's feet. In the third quarter of 2015, we also initiated a Phase 2 clinical trial for the treatment of primary axillary hyperhidrosis and, in the fourth quarter of 2015, completed enrollment for the trial.

We have also invested in the research and development of an injectable form of botulinum toxin, RT002, also referred to as RTT150 (Botulinum Toxin Type A) for Injection. Based upon the results to date, we are further developing RT002 for the treatment of glabellar lines and reported interim results from BELMONT, a Phase 2 active comparator clinical trial against the market leader BOTOX® Cosmetic, on October 29, 2015. The topline interim data from the trial showed that RT002 achieved

33

---

Table of Contents

its primary efficacy measurement at four weeks for all doses of RT002 and that such efficacy was highly statistically significant as compared to placebo. In addition, RT002 demonstrated a 23.6-week median duration versus BOTOX® Cosmetic with an 18.8-week median duration. Across all cohorts, RT002 appeared to be generally safe and well-tolerated. We plan to report final results from our BELMONT trial and conduct an End-of-Phase 2 meeting with the United States Food and Drug Administration, or FDA, in the first half of 2016. We then expect to begin Phase 3 clinical studies of RT002 for the treatment of glabellar lines in the second half of 2016. If approved, we believe RT002 has the potential to satisfy significant unmet needs in this market. Final results may differ from interim results.

We continue to explore therapeutic indications for muscle movement disorders such as cervical dystonia, which account for a large proportion of neurotoxin therapeutic sales globally, using RT002. In September 2015, we initiated a Phase 2 dose-escalating, open-label clinical study of RT002 in the therapeutic indication of cervical dystonia. 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 RT001 and RT002, as well as any future product candidates. The 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 RT001, RT002 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 duration of effect of our product 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 RT001, RT002 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 RT001, RT002 or any future product candidates;
- the acceptance of parameters for regulatory approval, including our proposed indication, primary endpoint assessment and primary endpoint measurement relating to our lead indications of RT001;
- our success in educating physicians and patients about the benefits, administration and use of RT001, RT002 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 RT001, RT002 or any future product candidates or approved products;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing 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 RT001, RT002 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 RT001, RT002 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 RT001, RT002 or any future product candidates;
- our ability to avoid third party patent interference or intellectual property infringement claims;
- acceptance of RT001, RT002 or any future product candidates, if approved, as safe and effective by patients and the medical community; and
- the continued acceptable safety profile of RT001, RT002 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

34

---



Table of Contents

cannot assure you that we will be able to generate sufficient revenue through the sale of RT001, RT002 or any future product candidate to continue our business.

We may be unable to obtain regulatory approval for RT001, RT002 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 and our results of operations. \*

To gain approval to market a biologic product such as RT001 and RT002, we must provide the FDA and foreign regulatory authorities with data that adequately demonstrate the safety, purity and potency of the product for the intended indication applied for in a Biologics License Application, or BLA, or other respective regulatory filings. 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 and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct. In particular, we have conducted two Phase 2b controlled clinical trials of RT001, in which RT001 met the primary efficacy and all secondary endpoints. We have also conducted one open-label, Phase 2b safety trial, which demonstrated that sequential applications of RT001 appear to be safe and well tolerated, even at an accelerated frequency. However, we have conducted one Phase 3 clinical efficacy trial using a modified diluent formulation, the results of which were inconsistent with our previous Phase 2b clinical trials and which did not show improvement from baseline in either the placebo or RT001 group. In October 2014, we conducted an open-label clinical trial of our topical RT001 drug product. The safety analysis from the 43 subjects enrolled in the open-label trial indicated that RT001 appeared to be well tolerated. The efficacy analysis showed clinically meaningful efficacy measured by the one-point investigator's global assessment, or IGA, and the one-point patient severity assessment, or PSA, as well as in the aggregate for the composite one-point assessment. The two-point response rates for the individual IGA and composite IGA and PSA assessments, however, did not meet the endpoints for the subjects enrolled in the trial. Following a comprehensive analysis of the data obtained in this trial, we determined that the preliminary composite results were not adequate to move forward with our Phase 3 pivotal trial at such time. In the first half of 2015, we then commenced and completed an additional open-label clinical trial using RT001. We designed this study to evaluate the attributes of different RT001 drug products aimed at improving the interaction between our peptide and toxin. The safety analysis from the 69 subjects enrolled in this study indicated that RT001 appeared to be well tolerated. The efficacy analysis for two of the RT001 drug products evaluated in this open-label trial showed clinically meaningful efficacy measured by the one-point IGA and the one-point PSA as well as in the aggregate for the composite one-point assessment. In the same two RT001 drug products evaluated, we observed some two-point composite response but given the small number of subjects enrolled in this trial, the patient response and other results observed are not necessarily predictive of future clinical trial results. Following analysis of the data available from these open-label studies, taken together with our analysis of prior studies and early data from newly developed clinical methods, we decided to proceed with a RT001 U.S. Phase 3 clinical trial for the treatment of crow's feet using a drug product that incorporates attributes of the drug products evaluated in the 2015 open-label trial. If this RT001 drug product, Phase 3 clinical trial or any of our clinical trials do not demonstrate the safety and efficacy to our satisfaction, or to the satisfaction of the FDA, we may be required to conduct additional clinical trials and the timing and our ability to obtain regulatory approval for RT001 could be materially and adversely affected. Our topical product candidate RT001 is currently in Phase 3 development, and our injectable product candidate RT002 is in Phase 2 development. Our business currently depends substantially on their successful development, regulatory approval and commercialization. We currently have no drug or biologic products approved for sale, and we may never obtain regulatory approval to commercialize RT001 or RT002. 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 RT001 or RT002 in the United States until we receive approval of

a BLA from the FDA. We are also not permitted to market RT001 or RT002 in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries.

The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates, including RT001 and RT002, for many reasons, including:

our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that RT001, RT002 or any future product candidates are safe and effective for the requested indication;

35

---

Table of Contents

the FDA's or the applicable foreign regulatory agency's disagreement with our trial protocol or the interpretation of data from preclinical studies or clinical trials;

our inability to demonstrate that clinical and other benefits of RT001, RT002 or any future product candidates outweigh any safety or other perceived risks;

the FDA's or the applicable foreign regulatory agency's requirement for additional preclinical or clinical studies;

the FDA's or the applicable foreign regulatory agency's non-approval of the formulation, labeling or the specifications of RT001, RT002 or any future product candidates;

the FDA's or the 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 the applicable foreign regulatory agencies 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. We are not conducting and do not plan to conduct our U.S. Phase 3 clinical trials for RT001 under a Special Protocol Assessment, or SPA. In the absence of an agreed SPA, there can be no assurance that the FDA will agree with REALISE 1, our Phase 3 pivotal clinical trial protocols.

Further, after our Phase 2 clinical trials, we used the FDA's Formal Dispute Resolution process to obtain confirmation from the FDA that our proposed indication, primary endpoint assessment and primary endpoint measurement were acceptable for continued clinical trials. At the end of this process, the FDA indicated that the final indication would depend on the patient populations studied, the data collected, and the interpretation of the data during the BLA review process. The FDA also indicated its expectation for demonstration of the paralytic mechanism of action in RT001 to be assessed at maximum contraction, or "at smile," to inform its analysis of the risks and benefits of RT001. Our clinical development program for RT001 measures effect "at smile" as an additional assessment endpoint to demonstrate botulinum toxin's effect on the relaxation of muscle at maximum contraction. However, age-related crow's feet of the upper face are the lines visible "at rest," and the primary endpoint of our clinical development program measures the efficacy of RT001 by a composite of physician and patient assessments "at rest."

In August 2014, the FDA issued a Draft Guidance prepared by the Division of Dermatology and Dental Products entitled "Upper Facial Lines: Developing Botulinum Toxin Drug Products." The Draft Guidance, among other things, recommends assessing the primary endpoint measurement for efficacy at maximum contraction, recommends defining treatment success as a score of 0 or 1 and at least a two grade reduction on both investigator and subject assessments, and recommends that review of photographs at maximum contraction by a masked independent committee be a required secondary efficacy measurement. We responded to the FDA's request for public comment on the non-binding Draft Guidance on October 30, 2014 and our response was filed as an exhibit to our Current Report on Form 8-K, filed with the SEC on November 4, 2014. We do not know when the guidance will be finalized, if at all, or the recommendations that will be contained therein. Even if final guidance is issued by the FDA, industry may pursue approval using an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. After consultation with our regulatory consultants, and based on the outcome of our Formal Dispute Resolution and related written confirmation from the FDA that we could proceed with Phase 3 development, we plan to complete our RT001 clinical trials using our current primary endpoint assessment by a composite of investigator and patient assessments "at rest," supplemented by an additional assessment "at smile" to demonstrate the paralytic mechanism of action in RT001 is a botulinum toxin effect.

While the FDA provided written confirmation that our proposed indication, primary endpoint assessment and primary endpoint measurement were acceptable for Phase 3 clinical trials, the FDA has not confirmed that our proposed indication, primary endpoint assessment and primary endpoint measurement are acceptable for regulatory approval. Further, while we did obtain written confirmation with respect to these aspects of our Phase 3 clinical trial designs, there is no assurance that the FDA will approve our BLA for RT001, will agree that the benefits of RT001 outweigh its risks or will not raise new concerns regarding our clinical trial designs.

Even if we eventually complete clinical testing and receive approval of any regulatory filing for RT001, RT002 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 RT001, RT002 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 RT001, in particular, would delay or prevent commercialization of RT001 and would materially adversely impact our business, results of operations and prospects.

Table of Contents

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 RT001 and RT002. In particular, our U.S. clinical programs for RT001 and RT002 will require substantial additional funds to complete. We have recorded net losses of \$19.2 million and \$51.4 million and \$14.0 million and \$48.7 million for the three and nine months ended September 30, 2015 and 2014, respectively, had an accumulated deficit through September 30, 2015 of \$310.2 million and had a working capital surplus of \$131.8 million as of September 30, 2015, primarily as a result of our IPO, 2014 June follow-on public offering, and ATM offering. 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, 2015, we had capital resources consisting of cash, cash equivalents, and investments of \$144.2 million. On February 6, 2014, we sold 6,900,000 shares of common stock at \$16.00 per share for aggregate net proceeds of \$98.6 million in our IPO, after underwriting discounts, commissions, and other offering expenses. On June 19, 2014, we sold 4,600,000 shares of common stock at \$30.50 per share for aggregate net proceeds of \$131.3 million in our follow-on public offering, after underwriting discounts, commissions, and other offering expenses. In the third quarter of 2015, we sold 352,544 shares of our common stock under the ATM agreement at a weighted average price of \$30.76 per share resulting in net proceeds of approximately \$10.1 million, after underwriting discounts, commissions, and other offering expenses. On November 9, 2015, we completed a follow-on public offering, pursuant to which we issued 3,737,500 shares of common stock at \$36.00 per share, including the exercise of the underwriters' option to purchase 487,500 additional shares of common stock, for gross proceeds of \$134.6 million. We believe that we will continue to expend substantial resources for the foreseeable future for the clinical development of RT001, RT002 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 RT001, RT002 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 offering, and ATM offering will allow us to fund our operations for at least the next 12 months. 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 RT001 and RT002;
- the timing of, and the costs involved in, obtaining regulatory approvals for RT001, RT002 or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the scope, progress, results and costs of researching and developing RT001, RT002 or any future product candidates, and conducting preclinical and clinical trials;
- the cost of commercialization activities if RT001, RT002 or any future product candidates are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing RT001, RT002 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 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 and competing 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;

## Table of Contents

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 RT001, RT002 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 RT001, RT002 and any future product candidates, if approved, will depend significantly on the broad adoption and use of the resulting product by physicians for approved indications, including, in the case of RT001, the treatment of crow's feet and hyperhidrosis, in the case of RT002, the treatment of glabellar lines, and other aesthetic and therapeutic indications that we may seek to pursue. The degree and rate of physician adoption of RT001, RT002 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 therapies;

physician willingness to adopt a new therapy to treat crow's feet, hyperhidrosis, glabellar lines, cervical dystonia or other therapeutic indications;

overcoming any biases physicians or patients may have toward injectable procedures for the treatment of crow's feet, hyperhidrosis or other indications;

patient satisfaction with the results and administration of our product and overall treatment experience;

patient demand for the treatment of crow's feet, hyperhidrosis, glabellar lines, cervical dystonia or other therapeutic indications; and

the revenue and profitability that our product will offer a physician as compared to alternative therapies.

If RT001, RT002 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, obtain patents, develop, test and obtain regulatory approvals for products, as well as 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 development, patenting, manufacture and marketing of health care products competitive with those that we are developing. Many of these potential 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. The aesthetic product market, and the facial aesthetic market in particular, is highly competitive and dynamic, and is characterized by rapid

and substantial technological development and product innovations. This market is also characterized by competitors obtaining

38

---



Table of Contents

patents to protect what they consider to be their intellectual property. We plan to seek regulatory approval of RT001 for the treatment of crow's feet and RT002 for the treatment of glabellar lines.

We anticipate that RT001, if approved for the treatment of crow's feet, will face significant competition from other facial aesthetic products, including injectable botulinum toxins and dermal fillers. If approved, RT001 may also compete with unapproved and off-label treatments. We anticipate that RT002, if approved, will also face significant competition from existing injectable botulinum toxins and dermal fillers, as well as unapproved and off-label treatments. Further, if approved, in the future we may face competition for both RT001 and RT002 from biosimilar products and products based upon botulinum toxin. To compete successfully in the aesthetic market, we will have to demonstrate that the reduction of crow's feet with RT001 or the treatment of glabellar lines with RT002 is a worthwhile aesthetic treatment and has advantages over existing therapies. Competing in the aesthetic market could result in price-cutting, reduced profit margins and limited market share, any of 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 international markets than are approved for use in the United States. There are also fewer limitations on the claims that our competitors in international markets can make about the effectiveness of their products and the manner in which they can market them. As a result, we face more competition in these markets than in the United States.

We currently make our RT001 clinical drug product exclusively in one manufacturing facility and our RT002 clinical drug product in the same and one other external facility. We plan to utilize certain of these facilities 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 RT001 exclusively in a single facility and plan to utilize this facility in the future to support commercial production if our product candidate is approved. The drug product to support RT002 clinical trials is manufactured in the same facility, as well as in an external manufacturing facility. We expect that additional manufacturing capacity would need to be established in the future to support commercial production of RT002 if this product candidate is 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 our 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 \$27.7 million against damage to our property and equipment, \$2.0 million in general liability coverage, a \$9.0 million umbrella policy, and an additional \$35.0 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 have invested a significant amount of capital to build a larger capacity fill-finish line dedicated to the manufacture of our topical product candidate RT001 and to support our regulatory license applications. Under generally accepted accounting principles, 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 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, unfavorable changes in competitive landscape, adverse changes in the regulatory

environment, or other factors leading to reduction in expected long-term sales or profitability.

39

---

Table of Contents

We have a limited operating history and have incurred significant losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future. We have only two product candidates in clinical trials and no commercial sales, which, together with our limited operating history, make it difficult to assess our future viability. \* We are a clinical-stage specialty biopharmaceutical company with a limited operating history. Biopharmaceutical 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. We have only a limited operating history upon which you can evaluate our business and prospects. 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 biopharmaceutical 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 RT001 or RT002. We continue to incur significant research and development and other expenses related to our ongoing clinical trials and operations. We have recorded net losses of \$19.2 million and \$51.4 million and \$14.0 million and \$48.7 million for the three and nine months ended September 30, 2015 and 2014, respectively, had an accumulated deficit through September 30, 2015 of \$310.2 million and had a working capital surplus of \$131.8 million as of September 30, 2015, primarily as a result of our IPO, follow-on public offering, and ATM offering. In February 2014, we closed our IPO. The net proceeds from the sale of the shares in our IPO and our June 2014 follow-on public offering, after deducting the underwriters' discount, commissions, and other offering expenses related to the IPO and follow-on offering were approximately \$98.6 million and \$131.3 million, respectively. In November 2015, the Company also completed a public offering for gross proceeds of \$134.6 million. Our capital requirements to implement our business strategy are substantial, including our capital requirements to develop and commercialize RT001 and RT002. We believe that our currently available capital is sufficient to fund our operations through at least the next 12 months. Given our desired clinical development plans for the next 12 months, our financial statements do not reflect an uncertainty about our ability to continue as a going concern. Accordingly, the financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should we be unable to continue as a going concern. 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, and seek regulatory approvals for, RT001 and RT002, and begin to commercialize RT001 and RT002. 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 RT001, RT002 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, RT001, RT002 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 RT001, RT002 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;
- 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 physicians and patients;
- the willingness of patients to pay for RT001, RT002 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 for RT001, RT002 and any future products we may commercialize;

relative convenience and ease of administration;  
the prevalence and severity of adverse events; and  
the effectiveness of our sales and marketing efforts.

40

---

Table of Contents

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 RT001 or RT002 do not ensure that later clinical trials, including our RT001 Phase 3 clinical trials for the treatment of crow's feet or any RT002 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. In particular, we have conducted two Phase 2b controlled clinical trials of RT001, in which RT001 met the primary efficacy and all secondary endpoints. We have also conducted one open-label, Phase 2b safety trial, which demonstrated that sequential applications of RT001 appear to be safe and well tolerated, even at an accelerated frequency. However, we have conducted one Phase 3 clinical efficacy trial using a modified diluent formulation, the results of which were inconsistent with our previous Phase 2b clinical trials and which did not show improvement from baseline in either the placebo or RT001 group. In October 2014, we conducted an open-label clinical trial of our topical RT001 drug product. The safety analysis from the 43 subjects enrolled in the open-label trial indicated that RT001 appeared to be well tolerated. The efficacy analysis showed clinically meaningful efficacy measured by the one-point investigator's global assessment, or IGA, and the one-point patient severity assessment, or PSA, as well as in the aggregate for the composite one-point assessment. The two-point response rates for the individual IGA and composite IGA and PSA assessments, however, did not meet the endpoints for the subjects enrolled in the trial. Following a comprehensive analysis of the data obtained in this trial, we determined that the preliminary composite results were not adequate to move forward with our Phase 3 pivotal trial at such time.

In the first half of 2015, we then commenced and completed an additional open-label clinical trial using RT001. We designed this study to evaluate the attributes of different RT001 drug products aimed at improving the interaction between our peptide and toxin. The safety analysis from the 69 subjects enrolled in this study indicated that RT001 appeared to be well tolerated. The efficacy analysis for two of the RT001 drug products evaluated in this open-label trial showed clinically meaningful efficacy measured by the one-point IGA and the one-point PSA as well as in the aggregate for the composite one-point assessment. In the same two RT001 drug products evaluated, we observed some two-point composite response but given the small number of subjects enrolled in this trial, the patient response and other results observed are not necessarily predictive of future clinical trial results. Following analysis of the data available from these open-label studies, taken together with our analysis of prior studies and early data from newly developed clinical methods, we decided to proceed with a RT001 U.S. Phase 3 clinical trial for the treatment of crow's feet using a drug product that incorporates attributes of the drug products evaluated in the 2015 open-label trial. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

## Table of Contents

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, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, 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 drug product at this facility that we use for research and development purposes and for clinical trials of our product candidates. We do not have experience in manufacturing our product candidates at commercial scale. To meet our strategic objectives, we currently plan to manufacture a significant portion of our drug substance and commercial products in our own facility. 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. For example, we are building a larger capacity fill-finish line dedicated to our topical product candidate RT001 and to support our regulatory license applications, if approved. In addition, we expect to further scale up our RT002 drug product manufacturing. 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 in obtaining regulatory approvals of our product candidates, which could materially damage our business and financial position.

Table of Contents

We currently contract with third-party manufacturers for certain components necessary to produce RT001 for clinical trials and expect to continue to do so to support commercial scale production if RT001 is approved. This increases the risk that we will not have sufficient quantities of RT001 or 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 necessary to produce RT001 for our clinical trials, including the bulk peptide, diluent and the delivery apparatus and expect to continue to rely on these or other manufacturers to support our commercial requirements if RT001 is 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 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 RT001, RT002 or any other product candidates or products that we may develop. Any failure or refusal to supply the components for RT001, RT002 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 RT001 and RT002 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., the RT001 diluent through Hospira Worldwide, Inc. and our RT001 delivery apparatus through Duobject Medical Systems, Inc. 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 RT001, RT002 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 RT001, RT002 or any future product candidates. If we or our manufacturers are unable to purchase these raw materials on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the development of RT001, RT002 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 RT001, RT002 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 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 sole manufacturing facility, are located in the San Francisco Bay Area, which in the past 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.

Table of Contents

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, 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 RT001, RT002 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, 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 (GLP), for conducting, monitoring, recording and reporting the results of clinical and preclinical trials, respectively 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 with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated or may need to be repeated. 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.



Table of Contents

Our ability to market RT001, if approved, will be limited initially to use for the treatment of crow's feet, and if we want to expand the indications for which we may market RT001 or seek regulatory approval for RT002, we will need to obtain additional regulatory approvals, which may not be granted.

We plan to seek regulatory approval for RT001 in the United States and Europe for the treatment of crow's feet. If RT001 is approved, the applicable regulatory agency will restrict our ability to market or advertise RT001 for other indications, which could limit physician and patient adoption. We may attempt to develop, promote and commercialize new treatment indications and protocols for RT001, as well as seek regulatory approval for RT002, in the future, but we cannot predict when or if we will receive the clearances required to do so. In addition, we would be required to conduct additional clinical trials or studies to support approvals for additional indications, which would be time consuming and expensive, and may produce results that do not support regulatory approvals. If we do not obtain additional regulatory approvals, our ability to expand our business will be limited.

If RT001 and/or RT002 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 RT001 and RT002, 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. For example, if we receive marketing approval for RT001 for the treatment of crow's feet, the first indication we are pursuing, we cannot prevent physicians from using our RT001 products on their patients in a manner that is inconsistent with the approved label, potentially including for the treatment of other aesthetic or therapeutic indications. 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.

Table of Contents

Even if RT001, RT002 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 crow's feet with RT001 and glabellar lines with RT002, are elective procedures, 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 crow's feet with RT001, the treatment of glabellar lines with RT002 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 RT001 or RT002 to their patients;

- the extent to which RT001 or RT002 satisfies patient expectations;

- our ability to properly train physicians in the use of RT001 or RT002 such that their patients do not experience excessive discomfort during treatment or adverse side effects;

- the cost, safety and effectiveness of RT001 or RT002 versus other aesthetic treatments;

- consumer sentiment about the benefits and risks of aesthetic procedures generally and RT001 or RT002 in particular;

- the success of any direct-to-consumer marketing efforts we may initiate; and

- general consumer confidence, which may be impacted by economic and political conditions.

Our business, financial results and future prospects will be materially harmed if we cannot generate sufficient demand for RT001, or for RT002 or any other future product candidate, once approved.

We are subject to uncertainty relating to reimbursement policies which, if not favorable for RT001, RT002 or any future product candidates, could hinder or prevent their commercial success.

Our ability to commercialize RT001, RT002, or any future product candidates for therapeutic indications such as hyperhidrosis or cervical dystonia 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 RT001, RT002 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 RT001 and RT002 in determining whether to approve reimbursement for RT001 and RT002 and at what level. Obtaining these approvals can be a time-consuming and expensive process. Our business would be materially adversely affected if we do not receive approval for reimbursement of RT001 or RT002 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 RT001 or RT002 will be reimbursed to a smaller 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 RT001 or RT002, 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.

Table of Contents

We currently have limited marketing capabilities and no 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 RT001, RT002 or any other future product candidates, if approved, or generate product revenue. \*

We currently have limited marketing capabilities and no sales organization. To commercialize RT001, RT002 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 RT001 or RT002 receives regulatory approval, we expect to market RT001 or RT002, 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 RT001, RT002 or any future product candidates. If we are not successful in commercializing RT001, RT002 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, 2015, we had 102 full-time 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 RT001, RT002 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.

## Table of Contents

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 as a result of the clinical testing of our product candidates and 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 RT001, RT002 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 RT001, RT002 or any future products we develop. We currently carry product liability insurance covering our clinical trials in the amount of \$5.0 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 RT001 or RT002, we intend to expand our insurance coverage to include the sale of RT001 or RT002, 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 lawsuits and shareholder 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 shareholder 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. This and any such other actions or claims could result in substantial damages and may divert management's time and attention from our business.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop RT001, RT002 or any future product candidates, conduct our clinical trials and commercialize RT001, RT002 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 our President and Chief Executive 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, completion of our planned clinical trials or the commercialization of RT001, RT002 or any future products we develop.



Table of Contents

Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense 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 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 RT001 and RT002, a key element of our strategy is to discover, develop and commercialize a portfolio of botulinum toxin products to serve both the aesthetic and therapeutic markets. 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 our two product candidates, RT001 and RT002, are each in the clinical development stage, 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 markets, 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 any problems that we encounter in developing and commercializing RT001 and RT002.

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.

Table of Contents

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.

Table of Contents

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 RT001, RT002 and any future product candidates. In any third-party collaboration, we would be dependent upon the success of the collaborators in performing their responsibilities and their 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 market for aesthetic medical procedures may be particularly vulnerable to unfavorable economic conditions. We do not expect RT001 for the treatment of crow's feet or RT002 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. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for RT001, RT002 or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, which is undergoing a continued severe economic crisis. 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 economic climate and financial market conditions could adversely impact our business.

**Risks Related to Our Intellectual Property**

If our efforts to protect our intellectual property related to RT001, RT002 or any future product candidates are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to RT001, RT002 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, eroding our competitive position in our market.

Table of Contents

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 United States 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 RT001, RT002 or any future product candidates is challenged, then it could threaten our ability to commercialize RT001, RT002 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 RT001, RT002 or any future product candidates under patent protection would be reduced. 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 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.

52

---

Table of Contents

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, 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 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.

Table of Contents

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, 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 biopharmaceuticals, 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.





## Table of Contents

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, or 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 RT001, RT002 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 is permitted to market RT001, RT002 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 RT001 or RT002 anywhere in the world. Obtaining regulatory approval of a BLA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable United States 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 and our collaborator believe the preclinical or 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 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, pure or potent;
- 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 RT001, RT002 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.



## Table of Contents

Even if we receive regulatory approval for RT001, RT002 or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, limit or delay regulatory approval and subject us to penalties if we fail to comply with applicable regulatory requirements.

Once regulatory approval has been granted, RT001, RT002, 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 RT001, RT002 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 RT001, RT002 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 GCP for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with RT001, RT002 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 filed 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 RT001, RT002 or any future product candidates, 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, and 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

markets outside of the United States.

56

---

Table of Contents

If approved, RT001, RT002 or any future 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 RT001. If we are successful in commercializing RT001 or any other products, 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 health care 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 RT001, if approved for the treatment of crow's feet, or RT002, if approved for the treatment of glabellar lines, will subject us to the various U.S. federal and state laws intended to prevent health care fraud and abuse, we may in the future become subject to such laws. 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 health care 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 health care programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal health care programs and 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 health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are 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 their 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.



Table of Contents

Legislative or regulatory health care reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of RT001, RT002 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, as discussed in more detail in the risk factors in Part II, Item 1A of our Form 10-Q entitled "We may be unable to obtain regulatory approval for RT001, RT002 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 and our results of operations." Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of RT001, RT002 or any future product candidates. 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, among other things, require:

- 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 Phase 3 clinical program for RT001 and our Phase 2 clinical program for RT002;
- announcements of regulatory approval or disapproval of RT001, RT002 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 health care 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 biopharmaceutical 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

58

---

Table of Contents

• 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 action lawsuits 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.

As a smaller company, it may be difficult for us to attract or retain the interest of equity research analysts. A lack of research coverage may adversely affect the liquidity of 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. On March 4, 2015, we entered into the ATM agreement, with Cowen , under which we may offer and sell our common stock having aggregate sales proceeds of up to \$50 million from time to time through our sales agent. As of September 30, 2015, common stock for aggregate gross proceeds of \$39.2 million remained available to be sold under this facility, subject to certain conditions as specified in the ATM agreement.

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.

As of September 30, 2015, certain holders of approximately 6,765,042 shares of our common stock, including shares issuable upon the exercise of outstanding warrants, are entitled to certain rights with respect to the registration of their shares under the Securities Act of 1933, as amended, or the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. On October 16, 2015, we filed a shelf registration statement on Form 3, registering the resale of the 8,414,711 shares held by certain selling stockholders identified therein. The shares covered thereby may be offered from time to time by the selling stockholders.

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;

59

---

Table of Contents

• 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.

Insiders 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, 2015, 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 46.9% 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.



Table of Contents

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 shareholder approval of any golden parachute payments not previously approved. We will remain an “emerging growth company” until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenues of over \$1.0 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. 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 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.

Period	Total Number of Shares Purchased (i)	Weighted-Average Price Paid per Share (ii)	Total Number of Share Purchased as Part of Publicly Announced Plan or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plan or Programs (in thousands)
July 1 through July 31, 2015	120	\$ 31.03	—	—
August 1 through August 31, 2015	504	29.98	—	—
September 1 through September 30, 2015	4,071	30.27	—	—
Total	4,695	\$ 30.26	—	—

- (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.

Table of Contents

Use of Proceeds

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC pursuant to Rule 424(b) on February 6, 2014. As of September 30, 2015, we have used all of the proceeds from our IPO for working capital and general corporate purposes.

ITEM 3.      DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4.      MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5.      OTHER INFORMATION

None.

ITEM 6.      EXHIBITS

The documents listed in the Exhibit Index of this Quarterly Report on Form 10-Q are herein incorporated by reference.



Table of Contents

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 10, 2015

By: /s/ L. Daniel Browne  
L. Daniel Browne  
President and Chief Executive Officer  
(Duly Authorized Principal Executive Officer)

Date: November 10, 2015

By: /s/ Lauren P. Silvernail  
Lauren P. Silvernail  
Chief Financial Officer and Executive Vice  
President of Corporate Development  
(Duly Authorized Principal Financial Officer)



Table of Contents

## EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference to the Company's				Filed Herewith
		Form	File No.	Exhibit No.	Filed On	
3.1	Amended and Restated Certificate of Incorporation	8-K	001-36297	3.1	February 11, 2014	
3.2	Amended and Restated Bylaws	S-1	333-193154	3.4	December 31, 2013	
4.1	Amended and Restated Investor Rights Agreement, effective as of February 5, 2014, among Revance Therapeutics, Inc. and certain of its stockholders	S-1/A	333-193154	4.3	January 27, 2014	
4.2	Form of Common Stock Certificate Second Amendment to Development and Supply Agreement, dated August 31, 2015, between Revance Therapeutics, Inc and Hospira Worldwide, Inc.	S-1/A	333-193154	4.4	February 3, 2014	
10.1+						X
10.2*	Form of Restricted Stock Unit Award Agreement and Grant Notice for Revance Therapeutics, Inc. 2014 Equity Incentive Plan					X
10.3*	Form of Stock Option Agreement and Grant Notice for Revance Therapeutics, Inc. 2014 Equity Incentive Plan					X
10.4*	Form of Restricted Stock Bonus Agreement and Grant Notice for Revance Therapeutics, Inc. 2014 Equity Incentive Plan					X
10.5*	Form of Stock Option Agreement and Grant Notice under Revance Therapeutics, Inc. 2014 Inducement Plan					X
10.6*	Form of Restricted Stock Agreement and Grant Notice under Revance Therapeutics, Inc. 2014 Inducement Plan					X
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) promulgated under the Exchange Act					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) promulgated under the Exchange Act					X

Edgar Filing: Revance Therapeutics, Inc. - Form 10-Q

32.1†	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.	X
32.2†	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	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

---

Table of Contents

\*Indicates a management contract or compensatory plan or arrangement.

+ Confidential treatment has been requested for certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

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.