

Revance Therapeutics, Inc.  
Form S-1/A  
February 03, 2014  
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As filed with the Securities and Exchange Commission on February 3, 2014

Registration No. 333-193154

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

**Amendment No. 2**  
**to**  
**Form S-1**  
**REGISTRATION STATEMENT**  
*UNDER*  
*THE SECURITIES ACT OF 1933*

**Revance Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**2834**  
(Primary Standard Industrial  
Classification Code Number)  
7555 Gateway Boulevard

**77-0551645**  
(I.R.S. Employer  
Identification Number)

**Newark, California 94560**

**(510) 742-3400**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**L. Daniel Browne**

**President and Chief Executive Officer**

**Revance Therapeutics, Inc.**

**7555 Gateway Boulevard**

**Newark, California 94560**

**(510) 742-3400**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

*Copies to:*

<b>Mark B. Weeks</b>	<b>L. Daniel Browne</b>	<b>Bruce K. Dallas</b>
<b>Gordon K. Ho</b>	<b>President and Chief Executive Officer</b>	<b>Davis Polk &amp; Wardwell LLP</b>
<b>Cooley LLP</b>	<b>Revance Therapeutics, Inc.</b>	<b>1600 El Camino Real</b>
<b>3175 Hanover Street</b>	<b>7555 Gateway Boulevard</b>	<b>Menlo Park, California 94025</b>
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<b>(650) 843-5000</b>	<b>(510) 742-3400</b>	

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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. (Check one):

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

Title of Each Class of Securities to be Registered	Number of Shares to be Registered(1)	Proposed Maximum Offering Price Per Share(2)	Proposed Maximum Aggregate Offering Price(2)	Amount of Registration Fee(3)
Common Stock, \$0.001 par value per share	5,750,000	\$16.00	\$92,000,000	\$11,849.60

(1) Includes an additional 750,000 shares that the underwriters have the option to purchase.

(2) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(a) under the Securities Act of 1933, as amended.

(3) \$11,109 was previously paid.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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**The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.**

**SUBJECT TO COMPLETION, DATED FEBRUARY 3, 2014**

**PRELIMINARY PROSPECTUS**

**5,000,000 Shares**  
**Revance Therapeutics, Inc.**  
**Common Stock**

This is the initial public offering of our common stock. We are selling 5,000,000 shares of common stock in this offering. We currently expect the initial public offering price to be between \$14.00 and \$16.00 per share of common stock.

We have granted the underwriters an option to purchase up to 750,000 additional shares of common stock to cover over-allotments.

Our common stock has been approved for listing on The NASDAQ Global Market under the symbol RVNC.

**Investing in our common stock involves risk. See Risk Factors beginning on page 14.**

We are an emerging growth company under applicable Securities and Exchange Commission rules and will be eligible for reduced public company disclosure requirements.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	<b>Per Share</b>	<b>Total</b>
Public Offering Price	\$	\$
Underwriting Discount <sup>(1)</sup>	\$	\$
Proceeds to Revance (before expenses)	\$	\$

(1) See Underwriting for additional disclosure regarding underwriting commissions and expenses.

Entities and individuals affiliated with certain of our current stockholders have indicated an interest in purchasing an aggregate of up to \$16.25 million of shares of common stock in this offering at the price offered to the public. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these entities or individuals, or any of these entities or individuals may determine to purchase more, less or no shares in this offering.

The underwriters expect to deliver the shares to purchasers on or about \_\_\_\_\_, 2014, through the book-entry facilities of The Depository Trust Company.

**Cowen and Company**

**BMO Capital Markets**

**Piper Jaffray**

The date of this prospectus is \_\_\_\_\_, 2014.

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We have not, and the underwriters have not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospectus may have changed since that date.

Neither we nor the underwriters have done anything that would permit this offering, or possession or distribution of this prospectus, in any jurisdiction where action for that purpose is required, other than in the United States. Persons who come into possession of this prospectus and any applicable free writing prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this prospectus and any such free writing prospectus applicable to that jurisdiction.

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**PROSPECTUS SUMMARY**

*This summary highlights selected information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes thereto and the information set forth under the sections "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case included in this prospectus. Unless the context otherwise requires, we use the terms "Revance," "company," "we," "us" and "our" in this prospectus to refer to Revance Therapeutics, Inc. and, where appropriate, our consolidated subsidiary.*

**Our Company**

We are a clinical stage specialty biopharmaceutical company focused on the development, manufacturing and commercialization of novel botulinum toxin products for multiple aesthetic and therapeutic applications. Botulinum toxin is a well-characterized protein currently used in numerous aesthetic and therapeutic indications and represents a multi-billion dollar market in the United States and other countries. All currently approved and commercially available botulinum toxin products are administered by injection. Our lead product candidate, RT001, is a topical formulation of botulinum toxin type A, which we believe has significant advantages over existing injectable products and could significantly expand the botulinum toxin market beyond existing users. Our second product candidate, RT002, is a novel injectable formulation of botulinum toxin type A designed to be more targeted and longer lasting than currently available botulinum toxin injectable products. Both of our product candidates combine our purified botulinum toxin with our proprietary TransMTS<sup>®</sup> peptide delivery system. We own the worldwide rights to both of our product candidates.

We are evaluating RT001 in a broad clinical program that includes aesthetic indications such as lateral canthal lines, the wrinkles around the eyes which are commonly referred to as crow's feet lines, and therapeutic indications such as hyperhidrosis, or excessive sweating, migraine headache and allergic rhinitis, or inflammation of the mucous membrane inside the nose. RT001 is currently in a Phase 3 clinical development program in the United States for the treatment of crow's feet lines and has the potential to be the first approved non-injectable botulinum toxin product. RT001's primary advantages include painless topical administration, ease of use and limited dependence on administration technique by physicians and medical staff. These advantages should improve the experience of patients undergoing botulinum toxin procedures and make RT001 more suitable for many more indications than currently approved injectable botulinum toxin products.

We are in a Phase 3 clinical development program of RT001 in North America for the treatment of crow's feet lines, and we plan to initiate an additional Phase 3 clinical trial in Europe by early 2015. We expect to receive primary efficacy data from a pivotal Phase 3 clinical trial of RT001 in mid-2014 and duration data in the second half of 2014. We plan to complete the Phase 3 program for the treatment of crow's feet lines and file for regulatory approvals in the United States and Europe in 2016. To date, we have conducted thirteen clinical trials for RT001, with a total of over 1,400 subjects, for the treatment of crow's feet lines.

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 successfully completed initial Phase 2 clinical trials for the treatment of primary axillary, or underarm, hyperhidrosis, and for the prevention of migraine headache. We expect to initiate additional clinical trials for the development of RT001 for these and other indications.

In addition to our topical product candidate, we are developing an injectable formulation of botulinum toxin type A, which we refer to as RT002, for indications where deeper delivery of the botulinum toxin is required and a longer lasting effect is desired. We believe RT002 can provide more targeted delivery of botulinum toxin to intended treatment sites while reducing the unwanted spread of botulinum toxin to adjacent areas.

In October 2012, we terminated a license agreement with Medicis Pharmaceutical Corporation, or Medicis, and reacquired from Medicis rights in all territories for RT001 and RT002 as part of a settlement and termination agreement with Medicis. The agreement requires that we make payments to Medicis from a portion of specified

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types of cash proceeds received by us, including from this offering. Upon the closing of this offering, we will make a payment of approximately \$7 million to Medicis under this agreement. This payment will satisfy our remaining payment obligations under the agreement, other than an additional \$4.0 million due upon receipt of specified marketing approvals for RT001 or RT002.

### **Our Product Candidates**

We plan to develop RT001 and RT002 for multiple aesthetic and therapeutic applications. The table below summarizes the phases of development for the indications we are currently pursuing for our two product candidates:

#### ***RT001 Our Topical Formulation of Botulinum Toxin***

RT001, our lead product candidate, is a topical gel formulation of botulinum toxin type A in a proprietary single-use administration apparatus. RT001 is applied to the skin and uses our proprietary TransMTS<sup>®</sup> peptide technology to enable delivery of botulinum toxin across the skin, eliminating the need for injections. Our initial focus is to develop and commercialize RT001 for indications where topical application provides a meaningful advantage over injectable administration. In our Phase 2 clinical trials, RT001 has demonstrated a statistically significant and clinically meaningful reduction in crow's feet lines that is visible to both physicians and patients. These and other studies have also indicated that RT001 is well tolerated with no serious adverse events related to study drug or study treatment procedures or other safety concerns.

#### ***The Opportunity for Botulinum Toxins for Aesthetic Indications***

Today's culture places significant value on physical appearance, leading to widespread adoption of anti-aging and aesthetic treatments. The aesthetic market has grown dramatically in the United States where consumers spent almost \$11.0 billion in 2012 on over 10.1 million physician-administered surgical and non-surgical aesthetic procedures, according to American Society for Aesthetic Plastic Surgery annual statistics. A strong consumer preference for non-surgical options and the increasing availability of effective alternatives has prompted adoption of non-surgical aesthetic procedures by a broader patient population. These trends have made non-surgical procedures the primary driver of growth in the aesthetic medicine market, accounting for 83% of the total number of procedures performed in 2012.

Injectable botulinum toxin treatments are the single largest cosmetic procedure in the United States and the rest of the world. According to GlobalData, in 2012 clinicians spent an estimated \$1.3 billion globally on injectable botulinum toxin for aesthetic procedures and such spending is expected to grow at a compounded annual growth rate of 14% from 2011 through 2018.



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We believe the botulinum toxin market could expand further with the introduction of a topical formulation such as RT001. Based on our market research, a topical treatment would address key consumer barriers for injectable botulinum toxin products such as fear of frozen face, needle aversion and aversion to injecting a toxin in their bodies. We believe that a topical treatment could expand the use of botulinum toxin to a wider range of physicians and allow those physicians who currently perform botulinum toxin procedures to do so on a larger number of patients. Additionally, our research indicates that a topical treatment can improve the profitability of physicians' practices by increasing the number of procedures per patient.

### *Crow's Feet Lines - Our Lead Indication for RT001*

The first indication we are pursuing for RT001 is in the field of aesthetic dermatology. According to GlobalData, the largest use for botulinum toxins is in aesthetic dermatology, which is estimated to generate approximately \$1.4 billion in worldwide sales in 2013. If approved, we believe RT001 can expand the overall botulinum toxin aesthetic market by adding 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 small specialty sales force and distributor network.

Crow's feet lines are skin wrinkles in the outer corner of the eye area, which are commonly caused by aging. Consumers in general, and women in particular, believe that the eye area is the first place where they notice the signs of aging. Consumers also believe that the perception of aging is affected by the quality of the skin. A large segment of the anti-aging topical cosmeceutical market is targeted towards improvement in skin texture and luminosity of the skin in the eye area. We believe that there is currently significant use of botulinum toxin for this indication given the desire of consumers to address the condition.

We believe that RT001 provides the following benefits to patients and physicians for treatment of crow's feet lines, as compared to traditional botulinum toxin treatments that are administered by injection:

The RT001 procedure is painless and has not shown any evidence of bruising, swelling or any of the other adverse events associated with injections. RT001 has been shown to be well tolerated with no significant safety concerns;

RT001 relaxes the crow's feet wrinkles appearance at rest, when the face is in a neutral expression, while still allowing a natural smile;

Consumers who indicated that they were averse to injecting toxin into their bodies found the concept of a topical treatment appealing;

RT001 is simple to use and results are not technique dependent. RT001 comes in a pre-filled applicator that contains the proper dose for the treatment of crow's feet lines; and

RT001 is very appealing to both key physicians and practice groups who perform the majority of cosmetic procedures in the United States and physicians who have less injectable botulinum toxin experience.

We have conducted thirteen clinical trials, with a total of over 1,400 subjects, for the treatment of crow's feet lines and are currently in Phase 3 clinical development in the United States. RT001 was shown to be safe, with statistically significant and clinically meaningful results in our Phase 2 clinical trials. In all concentrations of peptide and botulinum toxin studied, RT001 was well tolerated with no serious adverse events related to study drug or study treatment procedures or safety concerns.

We have completed three Phase 2b clinical trials of RT001 to evaluate a 25 ng/mL dose of botulinum toxin for the treatment of moderate to severe crow's feet lines. Two of these trials were double-blind, randomized, placebo-controlled clinical trials. RT001 met the primary efficacy and all secondary endpoints in both trials.



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After completing these Phase 2b clinical trials, we modified the diluent formulation to improve stability. We then conducted a Phase 3 clinical trial of RT001, but saw no improvement from baseline in either the placebo or RT001 group using the new diluent formulation. Subsequently, we obtained stability data to confirm that the original Phase 2b formulation has adequate commercial stability. We have since returned to the original Phase 2b diluent formulation and have conducted a two-cohort Phase 2 double-blind, randomized, placebo-controlled clinical trial. The combined data for the first and second cohorts showed statistical significance in wrinkle severity from baseline comparable to that observed in our previous Phase 2b clinical trials. Additionally, we plan to initiate a long-term open label Phase 3 safety clinical trial in 2014.

Based on our discussions with the United States Food and Drug Administration, or the FDA, the European Medicines Agency and other regulatory authorities, we believe that three Phase 3 pivotal clinical trials and the Phase 3 open label safety clinical trial, if successful, will provide the efficacy data to support our regulatory filing for approval of crow's feet lines in the United States, Europe and other countries.

### *The Opportunity for Botulinum Toxins for Therapeutic Indications*

While currently approved botulinum toxin products may be better known for their aesthetic applications, according to the market research firm Global Industry Analysts, Inc. or GIA, the worldwide injectable botulinum toxin market has grown from \$1.1 billion in 2004 to over \$2.4 billion in 2012 and the fastest growing segment of that market in the United States and Europe is for therapeutic indications. This growth for therapeutic indications has been driven largely by the approval of injectable botulinum toxin products in new indications such as preventive treatment of migraine headache in 2010 and overactive bladder in 2011, in addition to other therapeutic indications including hyperhidrosis, movement disorders, such as cervical dystonia and upper limb spasticity, and uncontrolled blinking. This therapeutic usage has been enabled by botulinum toxin's ability to affect neuromuscular junctions, muscle activity or the release of neuropeptides, neurotransmitters and neuromediators in a controlled manner.

While botulinum toxin products have been very effective in the treatment of many conditions, there are limitations to the use of the currently approved products in their injectable form. For example, in the case of hyperhidrosis, injectable botulinum toxin products require up to 30 injections in the underarms, and the procedure is reimbursed to physicians at a low rate relative to the time required. As a result, the use of Botox®, the only injectable botulinum toxin product currently approved for hyperhidrosis, has been limited. In the case of chronic migraine headache, injectable botulinum toxin products require as many as 31 injections in different parts of the head and neck.

We believe this leads to a significant need for a painless, topically administered and highly effective botulinum toxin. We also believe that there is an opportunity to develop and seek approval for a botulinum toxin product in therapeutic indications, such as allergic rhinitis, where there are currently no approved botulinum toxin products.

### *Development of RT001 for Treatment of Hyperhidrosis*

According to published medical articles, hyperhidrosis affects an estimated eight million people in the United States, one million of whom have severe hyperhidrosis. Prevalence in the United States is slightly higher among men than women, but women are more likely to take action to have the condition treated. Only 38% of those affected by hyperhidrosis seek treatment. We also believe that the appeal of RT001 may go beyond sufferers of hyperhidrosis and appeal to the one-third of all U.S. adults who believe they have too much underarm sweat. According to a 2008 survey by the International Hyperhidrosis Society, 60% of all U.S. adults reported that they would be embarrassed or very embarrassed by visible underarm sweat stains, and 70% of those U.S. adults who believe they have too much underarm sweat took steps to hide their condition.

Injectable botulinum toxin is among the currently available treatments for hyperhidrosis. Allergan's Botox® was approved in 2004 for underarm hyperhidrosis and remains the only botulinum toxin approved for the treatment of hyperhidrosis. However, the treatment requires up to 30 injections in the underarms. Having a

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topical solution could encourage more patients to seek treatment without having to suffer the pain of numerous injections. From the physicians standpoint, injections are very time-consuming and reimbursement for the procedure is relatively low. RT001 could significantly decrease the physician time and effort necessary for the procedure and potentially make the procedure more profitable for a physician's practice.

Data from our initial dose escalation hyperhidrosis Phase 2 clinical trial suggest the feasibility of treating primary underarm hyperhidrosis with RT001.

Based on data generated from current studies to date, we plan to initiate additional Phase 2 clinical trials for the treatment of hyperhidrosis with RT001. In these future trials, we plan to evaluate the efficacy of a higher dose compared to placebo and permit evaluation of the RT001 dose response to treatment of signs and symptoms of primary underarm hyperhidrosis. This data should help to establish whether this new botulinum toxin dose is adequate or whether further dose escalation in this clinical indication is needed prior to definitive safety and efficacy testing.

### *Development of RT001 for Prevention of Migraine Headache*

Migraine headache is a central nervous system disorder characterized by moderate-to-severe headache and often includes additional symptoms such as nausea and vomiting. The global market for treatment of migraine headache was estimated to be \$3.8 billion in 2009. Injected delivery of botulinum toxin has been validated as a therapeutically effective pharmaceutical agent for the preventive treatment of migraine headache. However, the treatment requires up to 31 injections in a patient's head and neck and may have significant side effects.

We have generated preliminary data that supports the feasibility of treating chronic migraine headache with topical application of RT001. In our initial Phase 2 clinical trial, RT001 was shown to be effective for the preventive treatment of chronic migraine headache, when applied topically to six areas on the head. This trial demonstrated statistically significant improvement of a composite endpoint.

For our next Phase 2 clinical trial, we plan to enroll and treat subjects with migraine headache using RT001 in a randomized double-blind placebo-controlled dose-ranging clinical trial design. This trial will provide new information on the treatment of subjects suffering migraine headache with RT001 and further characterize the dose-response relationship of RT001 in migraine headache to identify the optimal dose to be carried forward into later stage clinical trials.

### *RT001 for Treatment of Other Indications*

Based on the results of our preclinical studies and clinical trials, we will determine further development of other indications for RT001, such as neuropathic pain and rhinitis.

### ***RT002 Our Injectable Formulation of Botulinum Toxin***

We are developing RT002 as a new injectable botulinum toxin option that is designed to offer more targeted delivery of botulinum toxin to intended treatment sites while reducing the spread beyond the site of local injection. We believe this delivery permits safe administration of higher targeted doses of botulinum toxin and can result in longer lasting effect. These properties of RT002 have been demonstrated in preclinical studies and we are currently testing RT002 in a four-cohort, dose escalating, open label Phase 1/2 clinical trial outside of the United States for improvement of glabellar lines, the vertical lines between the eyebrows and above the nose. Initial data from this clinical trial indicated that RT002 is safe and efficacious at all four doses. Based upon the data analyzed, we plan to further develop RT002 for the treatment of glabellar lines by initiating a Phase 2 clinical trial in 2014. In addition, we plan to study RT002 in therapeutic indications already approved for botulinum toxin, such as movement disorders and overactive bladder. These indications require deeper delivery of the botulinum toxin, and are likely to be better served by injectable delivery of RT002.

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### **Intellectual Property and Manufacturing**

As of January 21, 2014, we held approximately 86 issued patents and approximately 150 pending patent applications in several countries and we expect to continue to expand this patent portfolio.

We have the ability to manufacture our own botulinum toxin type A product to support our clinical trials and eventually our commercial products. We manufacture and perform testing for both bulk drug substance and finished dose forms of drug product to support our topical RT001 product candidate and our injectable RT002 product candidate. The additional components required for our topical RT001 dose form, the peptide, diluent and delivery apparatus, are all manufactured by third parties. 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. We believe that having direct control over our manufacturing processes, from initial drug substance to finished product, will enable us to develop additional pharmaceutical product configurations effectively and with a competitive cost structure.

### **Our Strategy**

Our objective is to be a leading provider of botulinum toxin products across multiple aesthetic and therapeutic indications in both topical and injectable dose forms and to expand the market for botulinum toxin products. To achieve this objective, we plan to develop and commercialize two proprietary, patent-protected product candidates: RT001, our topical botulinum toxin, and RT002, our injectable botulinum toxin.

Key elements of our strategy are:

Complete development and seek regulatory approval for RT001;

Assess and prioritize future therapeutic indications for RT001;

Advance RT002 into clinical development;

Build our own sales and marketing capabilities to commercialize RT001 and RT002 in North America to support commercial launches starting in 2017, assuming successful and timely completion of our clinical trials and approval of our Biologic License Applications;

Expand the global market for botulinum toxin products;

Establish selective strategic partnerships to maximize the commercial potential of our product candidates and TransMTS<sup>®</sup> delivery technology platform; and

Maximize the value of our botulinum toxin cell line and manufacturing assets.

### **Risks That We Face**

Our business is subject to numerous risks and uncertainties, including those highlighted in the section entitled "Risk Factors" immediately following this prospectus summary. These risks include, among others, the following:

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We are substantially dependent on the clinical and commercial success of our product candidates, primarily our lead product candidate RT001, which is in Phase 3 clinical development, and our second product candidate, RT002, which is expected to enter into Phase 2 clinical development;

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;

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;

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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;

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 currently make our clinical drug products exclusively in one manufacturing facility and plan to utilize this facility in the future to support commercial production if our product candidates are approved. If this 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 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;

Even if RT001, RT002 or any future product candidates obtain regulatory approval, they may never achieve market acceptance or commercial success; and

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.

## **Our Corporate Information**

We were incorporated in Delaware in August 1999 under the name Essentia Biosystems, Inc. We commenced operations in June 2002 and, in April 2005, changed our name to Revance Therapeutics, Inc. Our principal executive offices are located at 7555 Gateway Boulevard, Newark, California 94560, and our telephone number is (510) 742-3400. Our website address is <http://www.revance.com>. The information contained in, or that can be accessed through, our website is not part of this prospectus.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012. As an emerging growth company we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 and reduced disclosure obligations regarding executive compensation. 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 this offering, (b) in which we have total annual gross revenue of at least \$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 that is 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 refer to the Jumpstart Our Business Startups Act of 2012 herein as the JOBS Act, and references herein to emerging growth company shall have the meaning associated with it in the JOBS Act.

Revance Therapeutics, the Revance logos and other trademarks or service marks of Revance appearing in this prospectus are the property of Revance. This prospectus contains additional trade names, trademarks and service marks of others, which are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

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**THE OFFERING**

Common stock offered by us	5,000,000 shares
Common stock to be outstanding after this offering	16,879,893 shares
Over-allotment option	The underwriters have an option to purchase up to 750,000 additional shares of our common stock to cover over-allotments, if any.
Use of proceeds	We estimate the net proceeds from this offering will be approximately \$65.8 million (or \$76.2 million if the underwriters exercise their over-allotment option in full), assuming an initial public offering price of \$15.00 per share, which is the midpoint of the range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently expect to use the net proceeds from the offering as follows:

Approximately \$18 million to \$23 million to fund research and development expenses associated with our RT001 and RT002 manufacturing, quality and regulatory efforts.

Approximately \$10 million to \$15 million to complete one Phase 3 clinical pivotal trial in the United States, to continue a long term safety clinical trial and other associated programs relating to RT001 for the treatment of crow's feet lines, and to initiate our first Phase 2 clinical trial and associated programs relating to RT002 for the treatment of glabellar lines.

Approximately \$11 million to make payments through 2014 under our September 2011 term loan agreement with Hercules Technology Growth Capital, Inc.

Approximately \$7 million to make payments under our settlement agreement with Medicis Pharmaceutical Corporation (acquired by Valeant Pharmaceuticals International, Inc.).

We will use the balance of the proceeds, if any, for the development of RT001 for the treatment of hyperhidrosis and other indications, as well as for working capital and other general corporate purposes.

Pending their use as described above, we plan to invest the net proceeds in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or guaranteed obligations of the U.S. government.



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See Use of Proceeds for additional information.

Risk factors

See the section titled Risk Factors beginning on page 14 and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.

Proposed NASDAQ Global Market trading symbol RVNC

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The number of shares of our common stock to be outstanding after this offering is based on 11,879,893 shares of common stock outstanding as of September 30, 2013, excluding the following shares:

1,045,188 shares of our common stock issuable upon the exercise of options to purchase our common stock outstanding under our 2002 Equity Incentive Plan and 2012 Equity Incentive Plan at a weighted-average exercise price of \$7.37 per share (excluding an additional 233,876 shares issuable upon the exercise of options to purchase our common stock at the weighted-average exercise price of \$9.50 per share and 1,111 shares of common stock issued outside of our 2012 Equity Incentive Plan, all granted after September 2013);

172,141 shares of our common stock issuable upon the exercise of outstanding convertible preferred stock warrants at a weighted-average exercise price of \$20.19 per share;

24,690 shares of our common stock issuable upon the exercise of outstanding convertible preferred stock warrants that were issued to Essex Capital Corporation after September 30, 2013, and 47,736 shares of our common stock issuable upon the exercise of common stock warrants that we expect to issue to Essex Capital Corporation after the closing of this offering, assuming an initial public offering price of \$15.00, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, which we together refer to as the Essex warrants, and which are issuable pursuant to our loan and lease agreement with Essex Capital Corporation, which we refer to as the Essex Capital Facility;

373,100 shares of our common stock reserved for future issuance under our 2012 Equity Incentive Plan (including an additional 233,876 shares issuable upon the exercise of options to purchase our common stock granted after September 2013);

1,000,000 shares of our common stock (which will include the shares then reserved for future issuance under our 2012 Equity Incentive Plan at the time of the execution and delivery of the underwriting agreement for this offering) reserved for future issuance under our 2014 Equity Incentive Plan, plus annual increases thereunder, which will become effective prior to the closing of this offering as more fully described in Executive Compensation Employee Benefit Plans ; and

200,000 shares of our common stock reserved for future issuance under our 2014 Employee Stock Purchase Plan, plus annual increases thereunder, which will become effective prior to the closing of this offering as more fully described in Executive Compensation Employee Benefit Plans.

Unless otherwise indicated, all information in this prospectus reflects and assumes the following:

the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 8,689,999 shares of our common stock, which will occur upon the closing of this offering;

the automatic exercise of our outstanding common stock warrants, assuming net exercise for 752,370 shares of our common stock immediately prior to the closing of this offering, assuming an initial public offering price of \$15.00 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus and assuming cash exercise for 30,769 additional shares of our common stock;

the automatic conversion of the \$23.65 million in aggregate principal amount of convertible promissory notes issued in the fourth quarter of 2013 and January 2014, or the 2013 notes, and accrued interest through October 7, 2014, into 1,747,033 shares of common stock immediately prior to the closing of this offering at a conversion price equal to the initial public offering price, assuming an initial public offering price of \$15.00 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this

prospectus;

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the automatic exercise of outstanding common stock warrants issued in connection with the 2013 notes, or the 2013 warrants, assuming net exercise for 432,363 shares of our common stock immediately prior to the closing of this offering, assuming an initial public offering price of \$15.00 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus;

a reverse stock split of 1-for-15 of our common stock and preferred stock effected on February 3, 2014;

no exercise by the underwriters of their over-allotment option to purchase up to 750,000 additional shares of our common stock from us in this offering; and

the filing and effectiveness of our amended and restated certificate of incorporation and the effectiveness of our amended and restated bylaws immediately prior to the closing of this offering.

Because the number of shares that will be issued upon conversion of the 2013 notes and the exercise of the 2013 warrants depends upon the actual initial public offering price per share in this offering, the actual number of shares issuable upon such conversion and exercise will likely differ from the number of shares set forth above. In this regard, a \$1.00 increase in the assumed initial public offering price of \$15.00 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would decrease the number of shares of our common stock issued on conversion of the 2013 notes and the exercise of the 2013 warrants (and therefore the number of shares to be outstanding after this offering) by 135,942 shares. A \$1.00 decrease in the assumed initial public offering price would increase the number of shares of our common stock issued on conversion of the 2013 notes and the exercise of the 2013 warrants (and therefore the number of shares to be outstanding after this offering) by 155,350 shares.

Entities and individuals affiliated with Essex Woodlands Health Ventures Fund VIII, L.P., or Essex VIII, NovaQuest Pharma Opportunities Fund III, L.P., or NovaQuest, and Biotechnology Development Fund IV, or Vivo Ventures, each of which is a current stockholder, have indicated an interest in purchasing an aggregate of up to \$16.25 million of shares of common stock in this offering, at the price offered to the public. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these entities or individuals, or any of these entities or individuals may determine to purchase more, less or no shares in this offering.

**Table of Contents****SUMMARY CONSOLIDATED FINANCIAL DATA**

The following tables summarize our financial data. We derived the summary consolidated statements of operations data for the years ended December 31, 2011 and 2012 from our audited consolidated financial statements included elsewhere in this prospectus. We derived the summary consolidated statements of operations data for the nine months ended September 30, 2012 and 2013 and the balance sheet data as of September 30, 2013 from our unaudited interim consolidated financial statements included elsewhere in this prospectus. The unaudited interim consolidated financial statements reflect, in the opinion of management, all adjustments, of a normal, recurring nature that are necessary for the fair presentation of the financial statements. Our historical results are not necessarily indicative of the results to be expected in the future and the results for the nine months ended September 30, 2013 are not necessarily indicative of results to be expected for the full year or any other period. You should read the following summary consolidated financial data in conjunction with the sections entitled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements, related notes and other financial information included elsewhere in this prospectus.

Pro forma basic and diluted net loss per share has been calculated assuming the conversion of all outstanding shares of convertible preferred stock into common stock. See Note 16 to our consolidated financial statements for an explanation of the method used to determine the number of shares used in computing historical basic and diluted net income (loss) per share and our pro forma unaudited basic and diluted net loss per share.

	Year Ended December 31,		Nine Months Ended September 30,	
	2011	2012	2012	2013
	(Unaudited)			
	(In thousands, except share and per share amounts)			
<b>Consolidated Statements of Operations Data:</b>				
Revenue	\$ 557	\$ 717	\$ 600	\$ 308
Cost of revenue	5			
Gross profit	552	717	600	308
Operating expenses:				
Research and development(1)	22,735	32,708	15,829	21,592
Sales, general and administrative(1)	5,555	11,195	9,581	8,008
Total operating expenses	28,290	43,903	25,410	29,600
Loss from operations	(27,738)	(43,186)	(24,810)	(29,292)
Interest income	15	7	8	2
Interest expense	(17,790)	(28,959)	(19,250)	(13,466)
Change in fair value of derivative liabilities associated with convertible notes	(356)	13,860	(3,338)	1,800
Change in fair value of derivative liabilities associated with the Medicis settlement				(265)
Change in fair value of convertible preferred stock warrant liability	836	125	117	(1,108)
Other income (expense), net	170	(106)	(85)	(40)
Loss before income taxes	(44,863)	(58,259)	(47,358)	(42,369)
Benefit from income taxes				
Net loss	\$ (44,863)	\$ (58,259)	\$ (47,358)	\$ (42,369)
Net income (loss) attributable to common stockholders(2):				
Basic	\$ (44,863)	\$ (58,259)	\$ (47,358)	\$ 733
Diluted	\$ (44,863)	\$ (58,259)	\$ (47,358)	\$ 2,966
Net income (loss) per share attributable to common stockholders(2):				
Basic	\$ (226.06)	\$ (290.48)	\$ (237.12)	\$ 3.40

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Diluted	\$ (226.06)	\$ (290.48)	\$ (237.12)	\$ 3.05
Weighted-average number of shares used in computing net income (loss) per share attributable to common stockholders(2):				
Basic	198,456	200,560	199,719	215,315
Diluted	198,456	200,560	199,719	971,472

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	Year Ended December 31,		Nine Months Ended September 30,	
	2011	2012	2012	2013
	(Unaudited)			
	(In thousands, except share and per share amounts)			
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(2)	\$	(27.20)	\$	(5.91)
Weighted-average number of shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(2)		2,146,489		7,176,423

(1) Results above include stock-based compensation as follows:

	Year Ended December 31,		Nine Months Ended September 30,	
	2011	2012	2012	2013
	(Unaudited)			
	(In thousands)			
<b>Stock-Based Compensation:</b>				
Research and development	\$ 150	\$ 48	\$ 27	\$ 138
Sales, general and administrative	123	31	39	208
Total stock-based compensation	\$ 273	\$ 79	\$ 66	\$ 346

(2) Please see Note 16 of our consolidated financial statements included elsewhere in this prospectus for an explanation of the calculations of our actual basic and diluted net income (loss) per share and our pro forma unaudited basic and diluted net loss per share.

	As of September 30, 2013		
	Actual	Pro Forma(1) (Unaudited) (In thousands)	Pro Forma as Adjusted(2)
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 1,909	\$ 25,450	\$ 91,200
Restricted cash – current and non-current	585	585	585
Working capital (deficit)	(28,645)	(5,104)	60,646
Total assets	18,920	42,461	108,211
Convertible notes			
Notes payable – current and non-current	12,951	12,951	12,951
Derivative liabilities associated with Medicis settlement – current and non-current	8,606	8,606	8,606
Convertible preferred stock warrant liability	1,459		
Convertible preferred stock	123,982		
Total stockholders' deficit	(147,683)	1,299	67,049

(1) The pro forma column gives effect to (i) the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock immediately upon the closing of this offering, (ii) the resulting reclassification of the convertible preferred stock warrant liability to additional paid-in capital, (iii) the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the closing of this offering, (iv) the issuance and automatic conversion of the principal and accrued interest through October 7, 2014 under the 2013 notes into 1,747,033 shares of common stock immediately prior to the closing of this offering at a conversion price equal to the initial public offering price, assuming an initial public offering price of \$15.00 per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, including charges to retained earnings to reflect the accelerated amortization of debt discounts, issuance costs, and accelerated unaccrued interest to interest expense, as well as changes in fair value of the related warrant and embedded derivative liabilities, and (v) the issuance and automatic exercise of the 2013 warrants and the automatic exercise of the other

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outstanding common stock warrants into 1,215,502 shares of common stock upon the closing of this offering, assuming net share exercise and an initial public offering price of \$15.00 per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, but does not give effect to the issuance and exercise of the Essex warrants.

Because the number of shares of common stock that will be issued upon the conversion of the 2013 notes and the exercise of the 2013 warrants depends upon the actual initial public offering price per share in this offering, the actual number of shares issuable



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upon such exercise and conversion will likely differ from the respective number of shares set forth above. See Prospectus Summary The Offering.

- (2) The pro forma as adjusted column gives further effect to the sale of 5,000,000 shares of common stock in this offering at an assumed initial public offering price of \$15.00 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A \$1.00 increase or decrease in the assumed initial public offering price of \$15.00 per share would increase or decrease our pro forma as adjusted cash and cash equivalents, working capital, total assets and total stockholders deficit by \$4.7 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of one million in the number of shares of common stock offered by us would increase or decrease our pro forma as adjusted cash and cash equivalents, working capital, total assets and total stockholders deficit by \$14.0 million, assuming that the assumed initial public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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**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 prospectus, including our 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.*

**Risks Related to Our Business and Strategy**

**We are substantially dependent on the clinical and commercial success of our product candidates, primarily our lead product candidate RT001, which is in Phase 3 clinical development, and our second product candidate RT002, which is expected to enter into Phase 2 clinical development.**

To date, we have invested most of our efforts and financial resources in the research and development of RT001, a topical formulation of botulinum toxin, which is currently our lead product candidate. In particular, we have completed thirteen clinical trials and are in Phase 3 clinical development in the United States for RT001. We have also invested, to a lesser extent, in the research and development of an injectable form of botulinum toxin, RT002, which is expected to enter into Phase 2 clinical development in 2014. 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, to a lesser extent, 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 U.S. Phase 3 clinical trials for RT001, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the accurate and satisfactory performance of third party contractors;

our ability to demonstrate to the satisfaction of the United States Food and Drug Administration, or 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 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;

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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

a 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 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 clinical 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 filing. 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 three positive Phase 2b clinical trials of RT001, in which RT001 met the primary efficacy and all secondary endpoints. 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.

Our lead product candidate, RT001, is currently in Phase 3 clinical development, and our business currently depends substantially on its 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. 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 in the United States until we receive approval of a BLA from the FDA. We are also not permitted to market RT001 in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries.

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The FDA or any foreign regulatory bodies can delay, limit or deny approval of our product candidates, including RT001, 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;

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 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 our Phase 3 clinical trial protocol.

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. 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.

**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.**

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Since our inception, most of our resources have been dedicated to the preclinical and clinical development of our lead product candidate, RT001. In particular, our U.S. Phase 3 clinical program for RT001 will require substantial funds to complete. We have recorded net losses of \$44.9 million, \$58.3 million and \$42.4 million for the years ended December 31, 2011 and 2012 and for the nine months ended September 30, 2013, respectively, had an accumulated deficit during our development stage through September 30, 2013 of \$185.8 million and had

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a net working capital deficit of \$28.6 million as of September 30, 2013. We have funded our operations primarily through the sale and issuance of convertible preferred stock, notes payable and convertible notes. As of September 30, 2013, we had capital resources consisting of cash and cash equivalents of \$1.9 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 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 the net proceeds from this offering, together with our existing cash and cash equivalents and existing credit facility will allow us to fund our operating plan through 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 we have sufficient funds for our current or future operating plans.

Our future capital requirements depend on many factors, including:

the results of our Phase 3 clinical trials for RT001 in the United States and Europe;

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;

the costs associated with being a public company;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and

the timing, receipt and amount of sales of, or royalties on, future approved products, if any.

Additional capital may not be available when we need them, 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 or other development activities for RT001, RT002 or any future product candidate;



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delay, limit, reduce or terminate our research and development activities; or

delay, limit, reduce or terminate our establishment of manufacturing, sales and marketing or distribution capabilities or other activities that may be necessary to commercialize RT001, RT002 or any future product candidates.

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 lateral canthal lines, or crow's feet lines, hyperhidrosis 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 of our product as compared to existing therapies;

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

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

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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

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characterized by rapid and substantial technological development and product innovations. This market is also characterized by competitors obtaining patents to protect what they consider to be their intellectual property. We are seeking regulatory approval of RT001 for the treatment of crow's feet lines. We anticipate that RT001, if approved, 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. To compete successfully in the aesthetic market, we will have to demonstrate that the reduction of crow's feet lines with RT001 is a worthwhile aesthetic treatment and is a superior alternative to 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 clinical drug products exclusively in one manufacturing facility and plan to utilize this facility in the future to support commercial production if our product candidates are approved. If this 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 products to support both RT001 and RT002 exclusively in a single manufacturing and laboratory facility and plan to utilize this facility in the future to support commercial production if our product candidates are approved. If this 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 facility 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 \$13.7 million against damage to our property and equipment, \$2.0 million in general liability coverage, a \$9.0 million umbrella policy, and an additional \$30.0 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.

**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 \$44.9 million, \$58.3 million and \$42.4 million for the years ended December 31,

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2011 and 2012 and for the nine months ended September 30, 2013, respectively, had an accumulated deficit during our development stage through September 30, 2013 of \$185.8 million and had a net working capital deficit of \$28.6 million as of September 30, 2013. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue our development of, and seek regulatory approvals for, RT001 and RT002, and begin to commercialize RT001. 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 successfully manufacture, market and commercialize our products. 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;

relative convenience and ease of administration;

the prevalence and severity of adverse events; and

the effectiveness of our sales and marketing efforts.

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

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Furthermore, we rely on contract research organizations, or CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing the committed activities of our CROs, we have limited influence over their actual performance. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. For example, the positive results generated to date in clinical trials for RT001 do not ensure that later clinical trials, including our ongoing Phase 3 clinical trials for the treatment of crow's feet lines, will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through

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preclinical studies and initial clinical trials. In particular, we have conducted three positive Phase 2b clinical trials of RT001, in which RT001 met the primary efficacy and all secondary endpoints. 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. 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.

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 patients 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 patients to participate in a trial;

have patients 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.

Patient 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.

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**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, which contemplate internally manufacturing a significant portion of our drug substance and finished dose form at full commercial scale if our product candidates are approved, we may need to expand our manufacturing facilities, add manufacturing personnel and ensure that validated processes are consistently implemented in our facilities. For example, plans are underway to fabricate and install a larger capacity fill-finish line dedicated to our topical non-aseptic dose form, which we expect will be installed in 2014 and validated in 2015 to support our regulatory license applications and future commercial demand for RT001, if approved. In addition, we expect to further scale up our RT002 drug product manufacture according to established demand. 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.

**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 or any other product candidates or products that we may develop. Any failure or refusal to supply the components for RT001 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,



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and if approved, ultimately for commercial sale. In particular, we outsource the manufacture of bulk peptide through American Peptide Company, Inc., the diluent through Hospira Worldwide, Inc. and our delivery apparatus through Duoject 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 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.

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 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

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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 current good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We also rely on consultants to assist in the execution, including data collection and analysis, of our clinical trials.

In addition, the execution of preclinical studies and clinical trials, and the subsequent compilation and analysis of the data produced, requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties communicate and coordinate with one another. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. These third parties may terminate their agreements with us upon as little as 30 days' prior written notice of a material breach by us that is not cured within 30 days. Many of these agreements may also be terminated by such third parties under certain other circumstances, including our insolvency or our failure to comply with applicable laws. In general, these agreements require such third parties to reasonably cooperate with us at our expense for an orderly winding down of services of such third parties under the agreements. If the third parties or consultants conducting our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols or GCPs, 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.

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

We are currently seeking regulatory approval for RT001 in the United States and Europe for the treatment of crow's feet lines. 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 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 lines, 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

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become subject to significant liability, which would materially harm our business. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry.

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

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

### **Even if RT001 is approved for commercialization, if there is not sufficient patient demand for RT001 procedures, our financial results and future prospects will be harmed.**

Treatment of crow's feet lines with RT001, our lead product candidate, is an elective procedure, the cost of which must be borne by the patient, and we do not expect it to be reimbursable through government or private health insurance. The decision by a patient to elect to undergo treatment with RT001 for the treatment of crow's feet lines or 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 to their patients;

the extent to which RT001 satisfies patient expectations;

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

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

consumer sentiment about the benefits and risks of aesthetic procedures generally and RT001 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 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

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capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If RT001 receives regulatory approval, we expect to market RT001 in the United States through an internal specialized sales force and in Europe through either our internal sales force or a combination of our internal sales force and distributors, which will 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 January 21, 2014, we had 64 full-time employees. We will need to continue to expand our managerial, operational, finance and other resources to manage our operations and clinical trials, continue our development activities and commercialize RT001 or any other product candidates, if approved. Our management and 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 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.

### **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;

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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 or any future products we develop. We currently carry product liability insurance covering our clinical trials in the amount of \$1.0 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, we intend to expand our insurance coverage to include the sale of RT001; however, we may be unable to obtain this liability insurance on commercially reasonable terms.

**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.

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

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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

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our other potential product candidates remain in the discovery 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.

**We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm our business.**

As a public company in the United States, we will be required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. We expect that our first report on compliance with Section 404 will be in connection with our consolidated financial statements for the year ending December 31, 2014.

The controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the Securities and Exchange Commission, or SEC, is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We are in the early stages of conforming our internal control procedures to the requirements of Section 404 and we may not be able to complete our evaluation, testing and any required remediation needed to comply with Section 404 in a timely fashion. Our independent registered public accounting firm was not engaged to perform an audit of our internal control over financial reporting for the year ended December 31, 2012 or for any other period. Accordingly, no such opinion was expressed. Even if we develop effective controls, these new controls may become inadequate because of changes in conditions or the degree of compliance with these policies or procedures may deteriorate.

Even after we develop these new procedures, material weaknesses in our internal control over financial reporting may be discovered. To fully comply with Section 404, we will need to retain additional employees to supplement our current finance staff, and we may not be able to do so in a timely manner, or at all. In addition, in the process of evaluating our internal control over financial reporting, we expect that certain of our internal control practices will need to be updated to comply with the requirements of Section 404 and the regulations promulgated thereunder,



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and we may not be able to do so on a timely basis, or at all. In the event that we are not able to demonstrate compliance with Section 404 in a timely manner, or are unable to produce timely or accurate consolidated financial statements, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or the stock exchange on which our stock is listed, and investors may lose confidence in our operating

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results and the price of our common stock could decline. Furthermore, if we are unable to certify that our internal control over financial reporting is effective and in compliance with Section 404, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or stock exchanges, and we could lose investor confidence in the accuracy and completeness of our financial reports, which could hurt our business, the price of our common stock and our ability to access the capital markets.

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

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

We may license or selectively pursue strategic collaborations for the development, validation and commercialization of 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.

### **If we fail to comply with the covenants and other obligations under our credit facilities, the lenders may be able to accelerate amounts owed under the facilities and may foreclose upon the assets securing our obligations.**

In September 2011, we entered into a credit facility with Hercules Technology Growth Capital, Inc., or Hercules. The facility consists of \$22.0 million in a term loan from Hercules. The balance of the term loan as of September 30, 2013 was \$13.0 million and is payable in monthly installments of principal and interest through

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March 1, 2015. Borrowings under our credit facility are secured by substantially all of our tangible assets. The covenants set forth in the loan and security agreement require, among other things, that we seek consent from Hercules prior to certain corporate changes and provide certain unaudited financial information within 30 days after the end of each month. If we fail to comply with the covenants and our other obligations under the credit facility, Hercules would be able to accelerate the required repayment of amounts due under the loan agreement and, if they are not repaid, could foreclose upon our assets securing our obligations under the credit facility.

In December 2013, we entered into a \$10.8 million loan and lease agreement with Essex Capital Corporation, or the Essex Capital Facility. Borrowings under the Essex Capital Facility are secured by substantially all of our tangible assets, excluding intellectual property. The covenants set forth in the Essex Capital Facility require, among other things, that we seek consent from Essex Capital prior to certain corporate events, including the incurrence of additional secured indebtedness or additional liens. If we fail to comply with the covenants and our other obligations under the Essex Capital Facility, Essex Capital would be able to accelerate the required repayment of amounts due under the Essex Capital Facility and, if they are not repaid, could foreclose upon our assets securing our obligations under the Essex Capital Facility, subject to limitations set forth in a subordination agreement between Essex Capital and Hercules.

### **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 lines to be reimbursed by any government or third party payor and, as a result, demand for this product 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.

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 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.

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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 based on patent applications filed after March 15, 2013. 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 United States Patent and Trademark Office, or 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. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, 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.

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.

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

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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 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.

Interference, derivation or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our 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

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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 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 Centers for Disease Control and Prevention, or 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.

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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 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 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;



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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.

**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.**

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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

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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 necessary approvals to commercialize our products in markets outside of the United States.

**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, 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 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

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obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

### **Legislative or regulatory healthcare reforms in the United States may make it more difficult and costly for us to obtain regulatory clearance or approval of 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. 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 this Offering and Our Common Stock**

#### **An active trading market for our common stock may not develop.**

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations with the underwriters and may bear no relationship to the price at which the common stock will trade upon the closing of this offering. Although our common stock has been approved for listing on The NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop, it may be difficult for you to sell the shares you purchase in this offering without depressing the market price for the common stock or to sell your shares at all.

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

Our stock price is likely to be volatile. The stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the initial public offering price. 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;

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announcements of regulatory approval or disapproval of RT001, RT002 or any future product candidates;

FDA or other U.S. or foreign regulatory actions affecting us or our industry;

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introductions and announcements of new products by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;

variations in our financial results or those of companies that are perceived to be similar to us;

changes in the structure of healthcare payment systems;

announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;

market conditions in the pharmaceutical and 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

the other factors described in this "Risk Factors" section.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if 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.**

Equity research analysts do not currently provide research coverage of our common stock, and we cannot assure you that any equity research analysts will provide research coverage of our common stock after the closing of this offering. In particular, as a smaller company, it may be difficult for us to attract the interest of equity research analysts. A lack of research coverage may adversely affect the liquidity of and market price of our common stock. To the extent we obtain equity research analyst coverage, we will not have any control of the 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. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market following this offering, the market price of our common stock could decline significantly.

Substantially all of our existing stockholders are subject to lock-up agreements with the underwriters of this offering that restrict the stockholders' ability to transfer shares of our common stock for at least 180 days from the date of this prospectus. The lock-up agreements limit the number of shares of common stock that may be sold immediately following the public offering. Subject to certain limitations, approximately 11,879,893 shares will become eligible for sale upon expiration of the lock-up period, as calculated and described in more detail in the section entitled "Shares Eligible for Future Sale". In addition, shares issued or issuable upon exercise of options

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and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

Following the closing of this offering, certain holders of approximately 10,127,046 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, subject to the 180-day lock-up arrangement described above. 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.

### **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 certificate of incorporation and bylaws as they will be in effect upon the closing of this offering 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 will have 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 will also contain other provisions that could have an anti-takeover effect, including:

only one of our three classes of directors will be elected each year;

no cumulative voting in the election of directors;

the ability of our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;

the exclusive right of our board of directors to elect a director to fill a vacancy or newly created directorship;

stockholders will not be permitted to take actions by written consent;

stockholders cannot call a special meeting of stockholders;

stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;

the ability of our board of directors, by a majority vote, to amend the bylaws; and

the requirement for the affirmative vote of at least  $66\frac{2}{3}\%$  or more of the outstanding common stock to amend many of the provisions described above.



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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 will also provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders.

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**Concentration of ownership of our common stock among our existing principal stockholders after this offering may effectively limit the voting power of other stockholders, including purchasers in this offering.**

Upon the closing of this offering, our executive officers, directors and current beneficial owners of 5% or more of our common stock will, in aggregate, beneficially own approximately 56% of our outstanding common stock, assuming an initial public offering price of \$15.00 per share, and assuming such persons do not purchase any shares of our common stock in this offering. However, certain of our current stockholders have indicated an interest in purchasing an aggregate of \$16.25 million of shares of common stock in this offering. If such current stockholders purchase \$16.25 million of shares of common stock in this offering at the assumed initial public offering price of \$15.00 per share, our executive officers, directors and stockholders who beneficially owned more than 5% of our outstanding common stock before this offering would beneficially own shares representing approximately 62% of our common stock after this offering. These stockholders, acting together, will continue to be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. The interests of this group of stockholders may not coincide with the interests of other stockholders.

**We will have broad discretion in the use of proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not yield a return.**

We will have broad discretion over the use of proceeds from this offering. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment in us. Our failure to apply the net proceeds of this offering effectively could result in financial losses that could materially impair our ability to pursue our growth strategy, cause the price of our common stock to decline, delay development of our product candidates or require us to raise additional capital.

**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 as they will be in effect following this offering 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 as they will be in effect following this offering 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.



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We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

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

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

**We will incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the United States, which may adversely affect our operating results.**

As a public company listed in the United States, we will incur significant additional legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the NASDAQ Stock Market, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. 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 notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

**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 Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012, 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 this offering, (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 following the closing of this offering and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus, particularly in the sections titled Prospectus Summary, Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and Business, contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as believe, will, may, estimate, continue, anticipate, intend, should, plan, expect, potentially or the negative of these terms or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include, but are not limited to, statements concerning the following:

our expectations regarding the results and the timing of results in our Phase 3 clinical trials of RT001 for the treatment of crow's feet lines;

our expectations regarding the results and the timing of clinical trials of RT001 for the treatment of hyperhidrosis or other indications;

our expectations regarding the results and the timing of clinical trials of RT002 for the treatment of glabellar lines;

our expectations regarding our future development of RT001 for other indications, including therapeutic indications;

our expectation regarding the timing of our regulatory submissions for approval of RT001 for the treatment of crow's feet lines in the United States, Europe and other countries or for 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, to commercialize our product candidates, if approved;

our ability 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;

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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 JOBS Act;

our use of proceeds from this offering;

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our financial performance; and

developments and projections relating to our competitors and our industry.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions described under the section titled Risk Factors and elsewhere in this prospectus. We also operate in a very competitive and rapidly changing environment. New risks emerge from time to time and 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, or implied by, any forward-looking statements. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances described in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements contained in this prospectus.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, events, circumstances or achievements reflected in the forward-looking statements will ever be achieved or occur. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement on Form S-1, of which this prospectus is a part, with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

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**USE OF PROCEEDS**

We estimate that the net proceeds from the sale of shares of our common stock in this offering will be \$65.8 million, based on an assumed initial public offering price of \$15.00 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' over-allotment option to purchase additional shares in this offering is exercised in full, we estimate that our net proceeds would be \$76.2 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A \$1.00 increase or decrease in the assumed initial public offering price of \$15.00 per share would increase or decrease the net proceeds that we receive from this offering by \$4.7 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of one million in the number of shares of common stock offered by us would increase or decrease the net proceeds that we receive from this offering by \$14.0 million, assuming that the assumed initial public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We currently expect to use the net proceeds from the offering as follows:

Approximately \$18 million to \$23 million to fund research and development expenses associated with our RT001 and RT002 manufacturing, quality and regulatory efforts.

Approximately \$10 million to \$15 million to complete one Phase 3 clinical pivotal trial in the United States, to continue a long term safety clinical trial and other associated programs relating to RT001 for the treatment of crow's feet lines, and to initiate our first Phase 2 clinical trial and associated programs relating to RT002 for the treatment of glabellar lines.

Approximately \$11 million to make payments through 2014 under our September 2011 term loan agreement with Hercules Technology Growth Capital, Inc., which bears interest at a rate equal to the greater of 9.85% or the prime rate plus 6.60%, and requires the principal balance to be repaid in thirty-three equal monthly installments beginning in July 2012.

Approximately \$7 million to make payments under our settlement agreement with Medicis Pharmaceutical Corporation (acquired by Valeant Pharmaceuticals International, Inc.).

We will use the balance of the proceeds, if any, for the development of RT001 for the treatment of hyperhidrosis and other indications, as well as for working capital and other general corporate purposes.

This expected use of the net proceeds from the offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with any certainty all of the particular uses for the net proceeds or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the status, results and timing of our current preclinical studies and ongoing clinical trials or clinical trials we may commence in the future, product approval process with the FDA, as well as any collaborations that we may enter into with third parties and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Pending their use as described above, we plan to invest the net proceeds in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or guaranteed obligations of the U.S. government.

**DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain any future earnings and do not expect to pay any cash dividends on our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will be dependent on a number of factors, including our earnings, capital requirements, overall financial conditions, business prospects, contractual restrictions and other factors our board of directors may deem relevant. Our loan and security



agreement with Hercules Technology Growth Capital, Inc. prohibits the payment of dividends.

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**CAPITALIZATION**

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2013 on:

an actual basis;

a pro forma basis to give effect to (i) the conversion of all outstanding shares of our convertible preferred stock into common stock immediately upon the closing of this offering, (ii) the resulting reclassification of the convertible preferred stock warrant liability to additional paid-in capital, (iii) the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the closing of this offering, (iv) the issuance and automatic conversion of the principal and accrued interest through October 7, 2014 under the 2013 notes into 1,747,033 shares of common stock immediately prior to the closing of this offering at a conversion price equal to the initial public offering price, assuming an initial public offering price of \$15.00 per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, including charges to retained earnings to reflect the accelerated amortization of debt discounts, issuance costs and accelerated unaccrued interest to interest expense, as well as changes in fair value of the related warrant and embedded derivative liabilities, and (v) the issuance and automatic exercise of the 2013 warrants and the automatic exercise of the other outstanding common stock warrants into 1,215,502 shares of common stock upon the closing of this offering, assuming net share exercise and an initial public offering price of \$15.00 per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, but does not give effect to transactions under the Essex Capital Facility; and

a pro forma as adjusted basis to give further effect to the sale of 5,000,000 shares of our common stock offered by us in this offering at an assumed initial public offering price of \$15.00 per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Because the number of shares that will be issued upon conversion of the 2013 notes and the exercise of the 2013 warrants depends upon the actual initial public offering price per share in this offering, the actual number of shares issuable upon such conversion and exercise will likely differ from the number of shares set forth above. In this regard, a \$1.00 increase in the assumed initial public offering price of \$15.00 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would decrease the number of shares of our common stock issued on conversion of the 2013 notes and the exercise of the 2013 warrants (and therefore the number of shares to be outstanding after this offering) by 135,942 shares. A \$1.00 decrease in the assumed initial public offering price would increase the number of shares of our common stock issued on conversion of the 2013 notes and the exercise of the 2013 warrants (and therefore the number of shares to be outstanding after this offering) by 155,350 shares.

Share amounts have been retroactively adjusted to give effect to a reverse stock split of 1-for-15 of our common stock and preferred stock effected on February 3, 2014.

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The information below is illustrative only, and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of the offering determined at the pricing of this offering. You should read this table together with our consolidated financial statements and related notes, Selected Consolidated Financial Data and Management's Discussion and Analysis of Financial Condition and Results of Operations, each included elsewhere in this prospectus.

	As of September 30, 2013		
	Actual	Pro Forma (In thousands, except share and per share amounts) (Unaudited)	Pro Forma as Adjusted
Cash and cash equivalents(1)	\$ 1,909	\$ 25,450	\$ 91,200
Note payable, net of discounts and including current and non-current portion	\$ 12,951	\$ 12,951	\$ 12,951
Capital leases, including current and non-current portion	125	125	125
Convertible notes			
Convertible preferred stock warrant liability	1,459		
Convertible preferred stock, par value of \$0.001 per share: 145,010,269 shares authorized, 8,689,999 shares issued and outstanding, actual; no shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	123,982		
Stockholders' deficit:			
Preferred stock, par value of \$0.001 per share; no shares authorized issued or outstanding, actual; 5,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted		12	17
Common stock, par value of \$0.001 per share: 221,000,000 shares authorized; 227,359 shares issued and outstanding, actual; 95,000,000 shares authorized, 11,879,893 shares issued and outstanding, pro forma; 95,000,000 shares authorized, 16,879,893 shares issued and outstanding, pro forma as adjusted			
Additional paid-in capital	38,118	196,231	261,976
Deficit accumulated during the development stage	(185,801)	(194,944)	(194,944)
Total stockholders' deficit	(147,683)	1,299	67,049
Total capitalization	\$ (9,166)	\$ 14,375	\$ 80,125

(1) Excludes restricted cash of \$585,000. As of January 22, 2014, we had cash and cash equivalents of \$5.2 million.

A \$1.00 increase or decrease in the assumed initial public offering price of \$15.00 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, would increase or decrease our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' deficit and total capitalization by \$4.7 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of one million in the number of shares of common stock offered by us would increase or decrease our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' deficit and total capitalization by \$14.0 million, assuming that the assumed initial public offering price remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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The number of shares of common stock issued and outstanding actual, pro forma and pro forma as adjusted in the table above excludes the following shares as of September 30, 2013:

1,045,188 shares of our common stock issuable upon the exercise of options to purchase our common stock outstanding under our 2002 Equity Incentive Plan and 2012 Equity Incentive Plan, with a weighted-average exercise price of \$7.37 per share (excluding an additional 233,876 shares issuable upon the exercise of options to purchase our common stock at the weighted-average exercise price of \$9.50 per share and 1,111 shares of common stock issued outside of our 2012 Equity Incentive Plan, all granted after September 2013);

172,141 shares of our common stock issuable upon the exercise of outstanding convertible preferred stock warrants at a weighted-average exercise price of \$20.19 per share;

24,690 shares of our common stock issuable upon the exercise of the outstanding Essex warrants that were issued after September 30, 2013 and 47,736 shares of our common stock issuable upon the exercise of the Essex warrants that we expect to issue after the closing of this offering, assuming an initial public offering price of \$15.00, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus;

373,100 shares of our common stock reserved for future issuance under our 2012 Equity Incentive Plan (including an additional 233,876 shares issuable upon the exercise of options to purchase our common stock granted after September 2013);

1,000,000 shares of our common stock (which will include the shares then reserved for future issuance under our 2012 Equity Incentive Plan at the time of the execution and delivery of the underwriting agreement for this offering) reserved for future issuance under our 2014 Equity Incentive Plan, plus annual increases thereunder, which will become effective prior to the closing of this offering as more fully described in Executive Compensation Employee Benefit Plans ; and

200,000 shares of our common stock reserved for future issuance under our 2014 Employee Stock Purchase Plan, plus annual increases thereunder, which will become effective prior to the closing of this offering as more fully described in Executive Compensation Employee Benefit Plans .

The number of shares of common stock issued and outstanding actual in the table above as of September 30, 2013 excludes 790,855 shares of our common stock issuable upon the exercise of outstanding common stock warrants at a weighted-average exercise price of \$0.15 per share.

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If you invest in our common stock in this offering, your interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. Our pro forma negative net tangible book value as of September 30, 2013 was \$0.8 million, or \$0.07 per share. Pro forma net tangible book value per share represents the amount of our total tangible assets less our total liabilities, divided by the number of shares of common stock outstanding as of September 30, 2013, after giving effect to (i) the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock immediately upon the closing of this offering, (ii) the resulting reclassification of the convertible preferred stock warrant liability to additional paid-in capital, (iii) the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the closing of this offering, (iv) the issuance and automatic conversion of the principal and accrued interest through October 7, 2014 under the 2013 notes into 1,747,033 shares of common stock immediately prior to the closing of this offering at a conversion price equal to the initial public offering price, assuming an initial public offering price of \$15.00 per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, including charges to retained earnings to reflect the accelerated amortization of debt discounts, issuance costs and accelerated unaccrued interest to interest expense, as well as changes in fair value of the related warrant and embedded derivative liabilities, and (v) the issuance and automatic exercise of the 2013 warrants and the automatic exercise of the other outstanding common stock warrants into 1,215,502 shares of common stock upon the closing of this offering, assuming net share exercise and an initial public offering price of \$15.00 per share, the midpoint of the estimated offering price range set forth on the cover page of this prospectus, but does not give effect to transactions under the Essex Capital Facility.

After giving further effect to the sale by us of 5,000,000 shares of common stock in this offering at an assumed initial public offering price of \$15.00 per share, which is the midpoint of the estimated offering price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2013 would have been \$65.0 million, or \$3.85 per share. This amount represents an immediate increase in pro forma net tangible book value of \$3.92 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of \$11.15 per share to new investors purchasing shares of common stock in this offering at the assumed initial public offering price.

Because the number of shares of common stock that will be issued upon the conversion of the 2013 notes and the exercise of the 2013 warrants depends upon the actual initial public offering price per share in this offering, the actual number of shares issuable upon such exercise and conversion will likely differ from the respective number of shares set forth above. See Prospectus Summary The Offering.

The following table illustrates this dilution:

Assumed initial public offering price per share	\$ 15.00
Pro forma net tangible book value per share as of September 30, 2013	\$ (0.07)
Increase in pro forma net tangible book value per share attributable to new investors in this offering	3.9