Revance Therapeutics, Inc.
Form 10-K
March 04, 2016

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

FORM 10-K

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

For the fiscal year ended December 31, 2015

or

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

For the transition period from to

Commission File No. 001-36297

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

Delaware	77-0551645
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

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

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

Title of Each Class	Name of Exchange on Which Registered
Common Stock, par value $0.001 per share	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

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	x (Do not check if a smaller reporting company)	Smaller reporting company	¨

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter was approximately $469.5 million, based on the closing price of the registrant's common stock on the NASDAQ Global Market of $31.98 per share for such date.

Number of shares outstanding of the registrant's common stock, par value $0.001 per share, as of February 26, 2016: 28,433,208

DOCUMENTS INCORPORATED BY REFERENCE

None

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Form 10-K, contains "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by that section. The forward-looking statements in this Form 10-K are contained principally under "Item 1. Business," "Item 1A. Risk Factors" and "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations." In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "c or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-K, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. These forward-looking statements include, but are not limited to, statements concerning the following:

- our expectations regarding the results and the timing of clinical trials in our development of DaxibotulinumtoxinA Topical Gel (RT001), or RT001 topical, for the treatment of crow's feet, hyperhidrosis or other indications;
- our expectations regarding the results and the timing of clinical trials of DaxibotulinumtoxinA for Injection (RT002), or RT002 injectable, for the treatment of glabellar lines, cervical dystonia or other indications;
- our expectations regarding our future development of RT001 topical and RT002 injectable for other indications, including therapeutic indications;
- our expectation regarding the timing of our regulatory submissions for approval of RT001 topical for the treatment of crow's feet, hyperhidrosis, and other indications in the United States, Europe and other countries;
- our expectation regarding the timing of our regulatory submissions for approval of RT002 injectable for the treatment of glabellar lines, cervical dystonia, and other indications in the United States, Europe and other countries;
- the potential for commercialization of RT001 topical and RT002 injectable, if approved, by us;
- our expectations regarding the potential market size, opportunity and growth potential for RT001 topical and RT002 injectable, if approved for commercial use;
- our belief that RT001 topical and RT002 injectable can expand the overall botulinum toxin market;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners including distributors, to commercialize our product candidates, if approved;
- our ability to transfer manufacturing from third parties to our facility and to scale up our manufacturing capabilities;
- estimates of our expenses, future revenue, capital requirements and our needs for additional financing;
- the timing or likelihood of regulatory filings and approvals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the initiation, timing, progress and results of future preclinical studies and clinical trials, and our research and development programs;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our ability to establish collaborations or obtain additional funding on acceptable terms, if at all;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act;
- our financial performance; and
- developments and projections relating to our competitors and our industry.

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In addition, you should refer to “Item 1A. Risk Factors” in this Form 10-K for a discussion of these and other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Form 10-K will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Also, forward-looking statements represent our estimates and assumptions only as of the date of this Form 10-K. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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PART I

ITEM 1. BUSINESS

Overview

Revance Therapeutics, Inc. is a clinical-stage biotechnology company focused on the development, manufacturing, and commercialization of novel botulinum toxin products for multiple aesthetic and therapeutic indications. We are leveraging our proprietary portfolio of botulinum toxin type A compounds, combined with our patented TransMTS® peptide delivery system, to address unmet needs in large and growing neurotoxin markets. Our proprietary TransMTS technology enables delivery of botulinum toxin type A through two investigational drug product candidates, DaxibotulinumtoxinA Topical Gel (RT001), or RT001 topical, and DaxibotulinumtoxinA for Injection (RT002), or RT002 injectable. We are pursuing clinical development for RT001 topical and RT002 injectable in a broad spectrum of aesthetic and therapeutic indications. Neither formulation of our product candidates contains albumin or any other animal or human-derived materials. We believe this reduces the risk of the transmission of certain viral diseases. We hold worldwide rights for all indications of RT001 topical, RT002 injectable, and our TransMTS technology platform. RT001 topical has the potential to be the first commercially available non-injectable formulation of botulinum toxin type A. We are studying RT001 topical for aesthetic indications, such as crow's feet (wrinkles around the eyes, also known as lateral canthal lines), and therapeutic indications, such as axillary hyperhidrosis (underarm excessive sweating). RT002 injectable is a novel, injectable formulation of botulinum toxin type A designed to be a targeted and long-lasting injectable botulinum toxin treatment. We are studying RT002 injectable for aesthetic indications, such as glabellar (frown) lines and therapeutic indications, such as cervical dystonia. We believe both product candidates have the potential to expand into additional aesthetic and therapeutic indications in the future.

PIPELINE	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	2016 PLANNED MILESTONES
RT001 TOPICAL PRODUCT CANDIDATE					
Lateral Canthal Lines (Crow’s Feet)					Report US Phase 3 pivotal study efficacy results -1H 2016.
Hyperhidrosis (Excessive Sweating)					Complete current Phase 2 study - 1H 2016. Initiate additional Phase 2 study.
Other Therapeutic Indications					
RT002 INJECTABLE PRODUCT CANDIDATE					
Glabellar (Frown) Lines					Conduct End-of-Phase 2 Meeting with FDA - 1H 2016. Initiate Phase 3 program - 2H 2016.
Cervical Dystonia					Report interim Phase 2 study results - 1H 2016.
Other Therapeutic Indications					

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Our Product Candidates

DaxibotulinumtoxinA for Injection (RT002) or RT002 Injectable

We are developing an injectable formulation of botulinum toxin type A, which we refer to as RT002 injectable, for indications where deep delivery of the botulinum toxin is required and a long-lasting effect is desired. We believe RT002 injectable may provide a targeted delivery of botulinum toxin to intended treatment sites while potentially reducing the unwanted spread of botulinum toxin to adjacent areas. We believe, and our preclinical and clinical studies indicate, that this targeted delivery, enabled by our proprietary peptide technology, may permit safe administration of higher doses of botulinum toxin and may result in long-lasting effect. We are initially focused on developing RT002 for the treatment of glabellar lines and cervical dystonia.

Glabellar Lines

Glabellar lines are the result of gathering the tissue between the eyebrows into a fold. They are caused by the repeated action of underlying muscles associated with facial expression. Years of squinting and frowning tend to leave deep wrinkles in the skin between the eyebrows and on the bridge of the nose, across the forehead and at the corners of the eyes. On many people, frown lines produce an angry or sad look that detracts from a pleasant facial appearance. Physical, emotional and social reasons for treating frown lines and forehead furrows include improved appearance and enhanced self-esteem. The most common cosmetic use of the market leader, BOTOX® Cosmetic is for the treatment of glabellar lines. In general, consumers enjoy the benefits of botulinum toxin injections and there is a high rate of satisfaction. Longevity, or duration of effect, is the one area where consumers are less satisfied and desire longer duration.

Botulinum toxin treatment of glabellar lines is the largest proportion of cosmetic neurotoxin sales in the United States and, according to the American Society for Aesthetic Plastic Surgery, botulinum toxin treatment is the number one nonsurgical cosmetic procedure in the United States. We believe RT002 injectable has the potential to satisfy significant unmet needs in this market. According to market research we conducted in April 2015, which involved a quantitative study with eighty dermatologists and plastic surgeons, 60% of the physicians surveyed stated that longer duration is a significant unmet need in the market for the botulinum toxin treatment of glabellar lines and 75% stated that they are likely or very likely to use RT002 injectable based on both injectable data available during the study and the RT002 injectable product concept.

Also, primary market research among over 30 leading aesthetic physicians indicated that they were very impressed by the clinical data generated in the RT002 Phase 1/2 study. In fact, those physicians reported that if RT002 injectable demonstrated similar results in larger trials the increased duration of effect would cause them to change their treatment habits from currently available botulinum toxins to RT002 injectable. While potentially increased safety due to decreased spread to adjacent muscles was an appealing benefit in cosmetic indications, duration of effect was reported to be the primary driver of adoption.

We believe that a product that still shows meaningful consumer benefit at six months would fit very nicely into the current treatment regimen and consumer habits. Most consumers only visit their physicians twice per year for treatments and the longer duration would mean that they would remain satisfied between treatments. Additionally, a longer lasting botulinum toxin product may align more closely with the duration of dermal filler treatments, which often are administered at the same time as botulinum toxin treatments.

We believe that RT002 injectable may provide the following benefits to patients and physicians for treatment of glabellar lines, as compared to the market leader, BOTOX® Cosmetic:

- RT002 injectable may permit longer lasting effect of 6 months.
- RT002 injectable may provide targeted delivery of botulinum toxin to intended treatment sites while potentially reducing the unwanted spread of botulinum toxin to adjacent areas. This could potentially decrease unwanted side effects like eyelid ptosis (droopy eyelids) and patient dissatisfaction.

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We believe that RT002 injectable may provide the following benefits to physicians:

- RT002 injectable may be simple to use and consistent with administration of currently available marketed products. Minimal training is required because administration would be similar to currently available marketed products.
- RT002 injectable may lead to more sustained patient satisfaction between treatments, which is critical for self-pay procedures.
- RT002 injectable could potentially expand their practices by appealing to consumers (particularly men) who are not willing to come in multiple times per year to sustain the benefits of treatment.
- Physicians may be willing to pay more for RT002 injectable compared to currently available neurotoxins as they believe that they could easily pass that cost along to their patients, who would be willing to pay for increased duration of effect.
- In phase 2 studies, RT002 injectable appeared to be well-tolerated with no significant safety concerns.

Development of RT002 Injectable for Treatment of Glabellar Lines

Phase 1 and 2 Clinical Trials. We believe RT002 injectable may provide targeted delivery of botulinum toxin to intended treatment sites while reducing the unwanted spread of botulinum toxin to adjacent areas. We believe this could permit long-lasting effect and safe administration of botulinum toxin, even with higher targeted doses. These properties, longer lasting effect and reduced spread of botulinum toxin, have been demonstrated in a four-cohort Phase 1/2 clinical dose escalation trial outside the United States for improvement of glabellar lines. In the study, RT002 injectable met its primary efficacy and safety endpoints. The open-label, dose escalating, Phase 1/2 study enrolled 48 adults in four cohorts. All subjects had Severe or Moderate wrinkles at baseline, measured using the 4-point Global Line Severity Scale (GLSS). In summary, the data showed:

- 96% of subjects were rated with None or Mild wrinkle severity at maximum frown 4 weeks post-treatment using the GLSS as assessed by the clinical investigator.
- 83% of subjects assessed themselves as achieving None or Mild wrinkles at maximum frown at the same time point.
- In the final cohort, the only one where duration of effect was measured, RT002 injectable achieved a median duration of 29.4 weeks or seven months based on both investigator and subject assessments.
- In this final cohort, 60% of subjects maintained None or Mild wrinkle severity at 6 months.
- RT002 injectable was well-tolerated, and there was no evidence of spread beyond the treatment site at any dose; additionally, adverse event rates did not change in frequency, severity, or type with increasing doses.

RT002 appeared to be generally safe and well-tolerated with minimal adverse events in our Phase 1/2 trial. Adverse events were generally mild, localized and transient. The most common adverse events observed were headache and injection site reactions. There was no evidence of spread beyond the treatment site at any dose. There were no serious adverse events or evidence of any systemic exposure based on clinical laboratory results and related evaluations. Adverse event rates did not change in frequency, severity, or type with increasing doses.

Based on the results of this study, Revance initiated BELMONT, a Phase 2, Randomized, Double-Blind, DosE Ranging, Active and PLacebo Controlled, Multi-Center Study to Evaluate the Safety, Efficacy, and Duration of Effect Of RT002, a BotuliNum Toxin Type A for Injection, injectable to treat glabellar lines. The primary endpoints for the study are the investigator's assessment of glabellar line severity at maximum frown at Week 24 and median duration of effect from the date of treatment back to baseline severity. The BELMONT trial evaluated treatment for glabellar lines in 268 subjects with moderate to severe glabellar lines at nine investigational sites in Canada. The trial compares the safety, efficacy and duration of three doses of RT002 injectable, the labeled dose of the current market leader BOTOX Cosmetic/VISTABEL® and a placebo control in a randomized 1:1:1:1:1 trial design. In October 2015, we reported topline interim data from the trial that showed RT002 injectable achieved its primary efficacy measurement at four weeks for all doses of RT002 injectable and that such efficacy was highly statistically significant as compared to placebo. In addition, the 40 unit dose of RT002 injectable demonstrated a 23.6-week median duration versus BOTOX® Cosmetic with an 18.8-week median duration. Across all cohorts, RT002 injectable appeared to be generally safe and well-tolerated. We plan to conduct an End-of-Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, in the first half of 2016. We then expect to begin Phase 3 clinical studies of RT002 injectable for the treatment of glabellar lines in the second half of 2016. If approved, we believe RT002 injectable has the

potential to satisfy significant unmet needs.

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Cervical Dystonia and Other Muscle Movement Disorders

We have also been developing RT002 for the treatment of cervical dystonia, a muscle movement disorder. We will continue to evaluate development for other therapeutic indications, such as neurological movement and other disorders, based on the results of our current preclinical studies and clinical trials. Muscle movement disorders, such as cervical dystonia, are neurological conditions that affect a person's ability to control muscle activity in one or more areas of the body. Muscle spasticity happens after the body's nervous system has been damaged, most commonly by a stroke, disease, or trauma. While not life-threatening, spasticity can be painful and may have a significant effect on a person's quality of life. Some tasks, like getting dressed or bathing, become difficult, and a person's self-esteem may be affected by their abnormal posture. Common muscle movement disorders include cervical dystonia (excessive pulling of the muscles in the neck and shoulder), upper or lower limb spasticity (stiffness in muscles), and blepharospasm (involuntary closing of the eyelids). Botulinum toxin type A has proven safe and effective for such uses, as the most common treatment for muscle movement disorders is to relax the muscle by injecting it with botulinum toxin. Spasticity was the first approved indication for BOTOX®. We believe muscle movement disorders accounted for approximately $900 million of therapeutic neurotoxin sales globally in 2014.

RT002 Injectable for Treatment of Cervical Dystonia

We have initiated a Phase 2 dose-escalating, open-label clinical study of RT002 injectable for the treatment of cervical dystonia. The Phase 2 study will evaluate safety, preliminary efficacy, and duration of effect of RT002 in subjects with moderate-to-severe isolated cervical dystonia symptoms of the neck. We completed enrollment in the first cohort and expect to release interim results in the first half of 2016.

DaxibotulinumtoxinA Topical Gel (RT001) or RT001 Topical

RT001 topical is a topical gel formulation of botulinum toxin type A in a proprietary single-use applicator. The botulinum toxin in RT001 topical blocks neuromuscular transmission by binding to receptor sites on motor or sympathetic nerve terminals, entering the nerve terminals and inhibiting the release of specific neurotransmitters. For example, when applied topically around the eye, RT001 topical produces partial interruption of the nerve signaling to the orbicularis oculi muscle, resulting in a localized reduction in muscle activity and improvement in crow’s feet and may offer improvement in skin texture and luminosity of the skin. When applied topically for the treatment of hyperhidrosis, RT001 topical produces temporary interruption of the nerve signaling to the sweat glands, resulting in local reduction in axillary sweating.

RT001 topical is applied to the skin and uses our proprietary TransMTS® technology, consisting of a proprietary peptide, to enable delivery of botulinum toxin across the skin, eliminating the need for injections. We plan to supply RT001 topical in a single-use applicator for reconstitution and administration that contains a vial of lyophilized, or freeze-dried, drug product and a vial of diluent for reconstitution. When the contents of these vials are combined, all within the single-use applicator, the diluent reconstitutes the freeze-dried drug product back to its original form to allow administration. In our crow's feet clinical trials, RT001 topical is administered as a gel and spread over the treatment area with a gloved finger, where it remains for 30 minutes. The application process is a simple procedure that requires minimal time to prepare and can be applied by either physician or medical staff. The gel is then removed by a series of gentle cleansing wipes, deactivated and disposed.

We are developing and plan to commercialize RT001 topical for indications where topical application provides a meaningful advantage over injectable administration. RT001 is designed to have several such advantages, including painless topical administration, no bruising, ease of use and limited dependence on administration technique by physicians and medical staff. We believe these potential advantages may improve the experience of patients undergoing botulinum toxin procedures and make RT001 topical suitable for multiple indications.

The first indications we are pursuing are in the fields of dermatology and plastic surgery. If approved, we believe RT001 topical can expand the overall botulinum toxin aesthetic market by appealing to new patients who would prefer a needle-free approach to treatment. The aesthetic dermatology market is attractive because we believe that patients in this market tend to be open to trying new products and paying for aesthetic procedures out of pocket, reducing our 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 accessed by a specialty sales force and distributor network. We are also developing RT001 topical for therapeutic applications where botulinum toxin has shown

efficacy and that are particularly well suited for needle-free treatments.

Lateral Canthal Lines, or Crow’s Feet

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Crow's feet 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. Despite the fact that prior to September 2013 there were no botulinum toxin products approved for crow's feet, we believe that there has been significant use of botulinum toxin for this indication given the desire of consumers to address the condition.

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

- The RT001 topical procedure is painless and has not shown any evidence of bruising, swelling or any of the other adverse events associated with injections. The RT001 topical procedure consists of a clear gel applied to the skin, remaining on the skin for 30 minutes and then removed with a series of gentle cleansing wipes.
- RT001 topical relaxes the crow's feet wrinkles appearance at "rest," when the face is in a neutral expression, while still allowing a natural smile. Data from our Phase 2b clinical trials indicate that RT001 topical improves the appearance of crow's feet at rest. This improvement is visible to both the consumer and the physician. By targeting only the muscles necessary to achieve this effect, treatment with RT001 topical allows for natural expression at smile. In comparison, injection involves a broader array of muscles, which can lead to an unwanted frozen face appearance even at smile.
- Consumers distinguish between products that are injected into the body and those that are placed on the skin. Of the participants surveyed in consumer market research performed by a third party on our behalf in 2012, a majority of those who responded that they have not received injectable botulinum toxin treatments in the past but who did find the RT001 topical product concept appealing, listed their aversion to needles as the reason why they have not previously tried the injectable botulinum toxin treatments. The responses in this survey, including open-ended questions, suggest that 63% of consumers in the group surveyed are more likely to use RT001 topical over injectable options.

We believe that RT001 topical may provide the following benefits to physicians:

- RT001 topical has been shown to be well-tolerated with no significant safety concerns. There has been no report of the spread of botulinum toxin away from treatment site.
- RT001 topical is simple to use and results are not technique dependent. RT001 topical comes in a pre-filled applicator that contains the proper dose for the treatment of crow's feet. A physician or medical staff applies droplets of the gel from our pre-filled applicator to the treatment area and uses a gloved finger to ensure that the entire area is covered. In contrast, a great deal of physician skill is required to accurately and precisely inject current needle-based botulinum toxin products into smaller, more superficial muscles to achieve a natural looking appearance in the crow's feet area.
- According to our market research data collected by a third-party research organization in 2009 through internet-based surveys and interviews: 82% of the 204 physicians surveyed with existing cosmetic revenues said that they were either "extremely interested" or "very interested" in purchasing the RT001 topical product concept for use in their patients; and 76% of the 204 physicians surveyed mentioned the benefits of topical administration, including no need for needles and easy and convenient administration, as why they liked the RT001 topical product concept.
- RT001 topical 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 believe that RT001 topical can 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. RT001 topical can also improve the profitability of practices by increasing the number of procedures a given patient receives per visit. Importantly, this expansion can come without any increase in the number of patients that the physician has in their practice. In addition, because the RT001 topical procedure for the treatment of crow's feet would be paid for directly by patients, consistent with current aesthetic treatments, physicians would not be encumbered by managed care and government payor reimbursement restrictions applicable in the United States and similar reimbursement-related constraints outside the United States.

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Development of RT001 Topical for Treatment of Crow’s Feet

We have conducted seventeen clinical trials, with a total of over 1,600 subjects, for the treatment of crow’s feet. In two of our Phase 2 clinical trials, RT001 topical demonstrated a statistically significant and clinically meaningful reduction in crow’s feet visible to both physicians and patients. After completing our Phase 2b clinical trials, we modified the formulation of the RT001 topical diluent by adding two ingredients to improve its stability. We then conducted a Phase 3 clinical trial with this new diluent formulation to evaluate efficacy and safety of RT001 topical. Data generated from this clinical trial were inconsistent with the data from our previous three Phase 2b clinical trials for the treatment of crow’s feet. Specifically, we observed no improvement from baseline in either the placebo or RT001 topical group. We initiated two open-label studies to further assess our RT001 topical drug product candidate. Following analysis of the data available from these open-label studies, taken together with our analysis of prior studies and early data from newly developed clinical methods, we decided to proceed with a RT001 topical U.S. Phase 3 clinical trial for the treatment of crow's feet. Our clinical and other studies have consistently indicated that RT001 topical appears to be well-tolerated with no serious adverse events related to the study drug or study treatment procedures or other safety concerns.

Phase 3 Clinical Trials. We are in a Phase 3 development program of RT001 topical in North America for the treatment of crow’s feet. During the third quarter of 2015, we initiated REALISE 1, a pivotal Phase 3 clinical trial designed to evaluate the safety and efficacy of a single, bilateral administration of RT001 topical compared to placebo in approximately 450 subjects with moderate to severe crow's feet. We expect to report efficacy data from this study in the first half of 2016, and if successful, will need to conduct additional Phase 3 studies in order to submit our Biologics License Application, BLA, to the FDA.

REALISE 1 and a second U.S. Phase 3 pivotal trial will utilize the same basic study design and evaluate efficacy and safety of RT001 topical after single administration compared to placebo. Our second U.S. Phase 3 pivotal trial will also measure duration of effect. We plan to conduct a third Phase 3 pivotal clinical trial in the European Union to support European Union marketing applications. The European trial will evaluate efficacy and safety of RT001 topical after single administration compared to placebo with a follow-up for safety.

We have designed the long-term clinical trials to support a safety database adequate for both domestic and international marketing applications, and will continue to conduct clinical trials with periodic, thorough analyses of benefits and risks.

Assuming successful completion of our Phase 3 clinical trials, we plan to file marketing applications in the United States, European Union and Canada. We anticipate that approval in the United States and the European Union would then support approvals in Latin America, such as Brazil and certain other territories in Asia.

European Union Agency Interactions. We requested scientific guidance from the European Medicines Agency, or EMA, on the development of RT001 topical for the treatment of crow’s feet and the proposed Phase 3 program in March 2012. The EMA scientific guidance for the crow’s feet Phase 3 program was completed following a meeting with the EMA in August 2012. The EMA provided comments on Quality, Nonclinical and Clinical programs. Overall, the EMA agreed with the proposed programs and provided details and suggestions to be considered for our marketing application. We have taken the EMA comments into consideration in the Phase 3 program and will provide data to support the various requests in the marketing application.

End-of-Phase 2. After our Phase 2 clinical trials, we used the FDA’s Formal Dispute Resolution process and obtained written confirmation in May 2012 from the FDA that we had achieved End-of-Phase 2 and that our proposed indication, primary endpoint assessment and primary endpoint measurement were acceptable for Phase 3 clinical trials. Specifically, the primary efficacy assessments are being conducted at rest and additional assessments are being

obtained at smile.

RT001 Topical Safety

Clinical Program. Subjects have received doses of RT001 topical containing 1.1 to 25 ng/mL of botulinum toxin per subject and peptide exposures up to 23 mcg/mL per subject for the treatment of crow's feet. Repeat doses of RT001 topical have been administered in the Phase 2 trials and the Phase 1 trial with cumulative exposures up to 50 ng/mL per subject. In all concentrations of peptide and botulinum toxin studied, RT001 topical appeared to be well-tolerated with no serious adverse events related to study drug or study treatment procedures or safety concerns. In particular, there were no systemic or local safety concerns at the site of application or evidence of spread and no significant differences in the incidence of treatment-related adverse events.

Nonclinical Program. In accordance with international guidelines and in consultation with the FDA, we have also conducted a broad nonclinical development program for RT001 topical. The program included preclinical efficacy, safety

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bioavailability and single and repeat dose toxicity studies of RT001 topical, including chronic studies of up to nine months duration. Genotoxicity, local tolerance and formulation bridging studies were also conducted, along with reproductive toxicity testing. Together, these studies supported the clinical development and anticipated future safety labeling of RT001 topical for the treatment of crow's feet.

Hyperhidrosis

We are also developing RT001 topical for therapeutic applications where botulinum toxin is particularly well suited for needle-free treatments. According to published medical articles, hyperhidrosis affects approximately nine million people in the United States (or 2.8% of the current population), with approximately half experiencing axillary hyperhidrosis, or underarm excessive sweating. 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. In 2014, the International Hyperhidrosis Society or IHHS fielded a survey among its email subscribers. While it is recognized that consumers who regularly read newsletters from the IHHS are likely to be more severe sufferers and those who are more likely to treat their disease, this survey does provide up to date information on this population. Additionally, we believe that these consumers may likely be early adopters of new treatments. In this population, hyperhidrosis is a multi-focal disease where the majority of people (81%) suffer in more than one focal area in addition to their underarms, most commonly the hands and feet. Among this group of consumers, 90% have sought assistance from a medical professional (compared to 38% cited in medical literature that describes the general population of hyperhidrosis sufferers). Of the 90% who seek medical assistance, 79% receive a diagnosis of hyperhidrosis, and of those, 87% seek some type of treatment. The most commonly used treatments and percentage of respondents that use each are:

- Over-the-counter antiperspirants (78%)
- Prescription antiperspirants (77%)
- Oral medication (53%)
- Botulinum Toxin Injections (41%)
- Iontophoresis, or the use of electrical current on skin (38%)
- Surgery (13%)
- Other (10%)

Most of these treatments have low levels of satisfaction. Specifically, OTC antiperspirants, prescription antiperspirants and oral medications have satisfaction rates of 5%, 11% and 26% respectively. Only botulinum toxin injections have a higher satisfaction rate versus dissatisfaction (53% versus 35%). Allergan's Botox® was approved in 2004 for axillary hyperhidrosis and remains the only botulinum toxin approved for the treatment of hyperhidrosis. However, the treatment requires up to 30 injections in the underarms. Additionally, in qualitative research consumers who have tried botulinum toxin say that often the injections will "stop working" or cause compensatory sweating in other focal areas.

Severe primary axillary hyperhidrosis affects approximately 1.5 million individuals in the United States and similar proportions globally. This condition has a negative impact on the overall quality of life of patients due to the debilitating psychosocial and emotional consequences of excessive sweating as well as significant medical dermatologic impact. Despite this dramatic impact on quality of life there is a large unmet need for effective treatment given the low levels of treatment satisfaction. In fact, even among the most involved consumers survey by the IHHS almost 40% of them either don't treat or had stopped treating their disease and were coping with lifestyle adjustments (e.g. clothing choices, limited physical activity and avoiding social contact).

Injected delivery of botulinum toxin has been validated as a therapeutically effective pharmaceutical agent for the treatment of hyperhidrosis. However, the injected treatment has not been widely embraced by hyperhidrosis patients because of significant pain and trauma associated with the large number of required injections.

Having a topical solution could encourage more patients to seek treatment without having to suffer the pain of numerous injections. Additionally, a topical solution may more readily lend itself to treatment of other focal areas such as the palms or feet. From the physicians' standpoint, injections are very time-consuming and reimbursement for the procedure is low. RT001 topical could significantly decrease the physician time and effort necessary for the procedure and potentially make the procedure more profitable for a physician's practice.

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We also believe that the appeal of RT001 topical may go beyond the sufferers of hyperhidrosis and appeal to the one-third of all U.S. adults who simply 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.

Development of RT001 Topical for Treatment of Hyperhidrosis

Data from our initial Phase 2 dose escalation hyperhidrosis clinical trial suggest the feasibility of treating primary axillary hyperhidrosis with RT001 topical. As the dose of RT001 topical increased, patients showed reduced sweating and improvement in their self-assessed sweating severity. To test for sweat production, the skin was first treated with iodine solution that is allowed to dry, and then followed by dusting of corn starch and sweat assessment period of ten minutes. The occurrence of sweat causes the starch and iodine to dissolve permitting their reaction to form the dark staining pattern observed. Reduction in the dark staining intensity signals a reduction in sweat.

This initial Phase 2 clinical trial was a double-blind, randomized, placebo-controlled multi-center study evaluating the safety, tolerability and efficacy of using RT001 topical to treat primary axillary hyperhidrosis in adults. This clinical trial was designed to enroll 36 subjects, with twelve subjects in each dosing group, or cohort. The safety of each cohort was evaluated by an independent data safety committee prior to escalating the dose to the next level. Subjects were randomized to receive a single treatment of RT001 topical or placebo in each cohort. After receiving the treatment, the patients were followed for 28 days in the clinical trial.

In September 2015, we initiated an additional randomized, double-blinded, dose-ranging, placebo-controlled Phase 2 clinical trial designed to evaluate the safety and efficacy of a single, bilateral application of RT001 topical for the treatment of primary axillary hyperhidrosis. This trial evaluated the efficacy of two different doses of RT001 as compared to placebo. In December 2015, we reported positive interim results and, although the trial sample size was not chosen to meet statistical significance, using quantitative gravimetric measurements, the data was positive and showed that a single treatment of RT001 topical gel achieved clinically meaningful efficacy at Week 4. On the primary quantitative assessment of average reduction from baseline in gravimetrically-measured sweat production at Week 4, the results ranged from 214.2 mg to 165.7 mg ($p=0.003$ for the higher dose) per five minutes for RT001, compared to 66.3 mg per five minutes in patients who received placebo. These ranges corresponded to 81.1% to 79.6% change for RT001, compared to 54.6% for placebo. On the primary qualitative efficacy assessment of a 2-point or greater response from baseline using the Hyperhidrosis Disease Severity Scale, or HDSS, at Weeks 1 and 2 the results ranged from a 23.8% to 13.3 % improvement for RT001 compared to 11.8% at Week 1 and 17.6% at Week 2 for placebo. By Week 4, there was a 14.3% to 13.3% improvement for RT001, compared to a 29.4% improvement in patients who received placebo. The clinical study indicated that RT001 topical appeared to be well-tolerated with no serious adverse events related to the study drug or study treatment procedures or other safety concerns. Adverse events were generally mild, localized and transient. The most common treatment-related events reported were application site erythema (redness), folliculitis (razor bumps) and application site pain. We plan to advance RT001 topical into a larger Phase 2 study for the treatment of hyperhidrosis in 2016, which will be designed to confirm a final dose. Upon successful completion of this study, we plan to meet with the FDA to discuss moving forward into Phase 3 studies.

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. Migraine headache affects 36 million people in the United States, 14 million of whom suffer from chronic migraine headache. In the United States, this debilitating condition results in 113 million lost workdays and costs employers $13.0 billion each year, according to the Migraine Research Foundation. Injected

delivery of botulinum toxin has been validated as a therapeutically effective pharmaceutical agent for the preventive treatment of migraine headache. Botox® was approved for the treatment of chronic migraine headache in 2010. However, the treatment requires up to 31 injections in a patient's head and neck and may have significant side effects, including the potential for injected botulinum toxin to diffuse to neighboring sites causing muscle weakness and pain, sometimes even triggering migraine headache attacks.

Development of RT001 Topical for Prevention of Migraine Headache

We have generated preliminary data that support the feasibility of treating chronic migraine headache with topical application of RT001 topical. In our initial Phase 2 clinical trial, RT001 topical was shown to be effective for the preventive treatment of chronic migraine headache. In this trial, RT001 topical was applied topically to five areas on the head, left on for 30 minutes and removed by a series of cleansing wipes. This trial, which used a 25 ng/mL dose, demonstrated statistically

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significant improvement (43.8% for RT001 topical versus 10.5% for placebo) of the composite endpoint of a Headache Impact Test-6, or HIT-6, score, number of migraines and migraine intensity.

RT001 Topical for Treatment of Other Indications

Based on the results of our future preclinical studies and clinical trials, we will determine further development of other indications for RT001 topical, such as:

Neuropsychiatric disorders:

Chronic daily headache, which is defined as an idiopathic headache occurring on more than 15 days per month for at least 3 months and a daily duration of at least 4 hours, is considered as a headache disorder that may benefit from treatment with botulinum toxin A. It is likely that those patients with chronic daily headache (with or without medication overuse) who are severely impaired (i.e., highest loss of productivity) and who are not receiving any other prophylactic treatment are the appropriate group of patients with a benefit from botulinum toxin. Since this total patient group shows a prevalence of up to 4% in population based epidemiological studies, it is warranted to further elucidate the clinical efficacy of botulinum toxin in this subgroup.

Major depressive disorder is a common and serious disease that may be resistant to routine pharmacologic and psychotherapeutic treatment approaches. Preliminary studies have shown a single treatment of botulinum toxin in the forehead region can improve symptoms of depression in patients with major depressive disorder, or MDD, as defined by DSM-IV criteria. Positive effects on mood have been observed in subjects who underwent treatment of glabellar lines with botulinum toxin and, in an open case series, depression remitted or improved after such treatment.
Neuropathic pain is a condition that may arise as a result of a lesion or disease affecting the nervous system and, as a collection of syndromes, is often chronic in nature causing significant negative impact to quality of life. Existing treatments include antidepressants, serotonin inhibitors and calcium channel agonists, each of which require daily dosing and are often accompanied by side effects and modest efficacy. More recently, injected botulinum toxin has been shown to address many forms of neuropathic pain and provide extended relief, of approximately three months, in line with the known duration profile for botulinum toxin treatment of other targets. RT001 topical represents an appealing alternative with its topical delivery, allowing relatively large areas to be treated without injection pain while maintaining the potential benefit of extended duration from a single treatment of botulinum toxin. RT001 topical is currently in preclinical development for neuropathic pain.

Chronic inflammatory diseases:
Psoriasis is a chronic skin condition that affects an estimated 125 million people worldwide, 2 to 3 percent of the total population, and is the most prevalent autoimmune disease according to the World Psoriasis Day consortium. Animal-model studies have shown the potential role of botulinum toxin in inflammatory skin conditions, specifically demonstrating that botulinum toxin injections improved the clinical appearance of psoriasis.
Eczema is another chronic inflammatory skin condition marked by dry, itchy skin. Atopic dermatitis - the most common form of eczema - affects millions of people, including an estimated six to 10 percent of children. Early research suggests that there could be a role for botulinum toxin in combating itch by better understanding the interaction of the vascular system in inflammatory skin conditions. While there are available therapies to treat eczema and psoriasis, not all therapies are equally effective.
In inflammatory conditions such as these, a topical botulinum toxin could potentially provide a viable treatment alternative to the current standard treatment, topical steroids, which have side effects, such as rosacea, perioral dermatitis, and acne.
Rheumatic conditions: In rheumatology, botulinum toxin may be able to help treat painful blood vessel conditions, such as Raynaud’s disease and Scleroderma. In initial studies, botulinum toxin injections have shown overall improvement in patient pain as well as a reduction in soft tissue ulceration.

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Our Technology

Our Proprietary TransMTS® Technology Platform

Our TransMTS® peptide technology serves different purposes depending on whether it is used in a topical formulation, such as in RT001 topical, or in an injectable formulation, such as in RT002 injectable. In a topical formulation, the TransMTS® peptide technology enables transmembrane delivery of large macromolecules, such as our botulinum toxin type A, to the targeted tissue and eliminates the need for injections or other invasive procedures. In an injectable formulation, the TransMTS® peptide technology may restrict the active macromolecule to the target site and reduce unwanted spread to other neighboring tissues.

The TransMTS® proprietary peptides are single, straight-chain, peptides which have two distinct types of domains:

- The peptide backbone core is a sequence of consecutive lysine residues that are positively charged under physiologic conditions. The purpose of this positively charged core is to form a non-covalent (electrostatic) bond with the negatively charged macromolecule to be transported across the skin.
- The second part of the peptide is a Protein Transduction Domain, or PTD, which is responsible for delivering the macromolecule to the target site. There are two identical PTDs at each end of the peptide.

We believe our TransMTS® peptide technology could be applied to a range of active ingredient molecules. We have begun to leverage our TransMTS® platform to develop additional products through partnering arrangements and may use our technology platform to develop additional proprietary products.

Our Proprietary Botulinum Toxin-Peptide Complex

Our proprietary botulinum toxin-peptide complex has two components that contribute to the performance of RT001 and RT002. First, our TransMTS® peptide provides the delivery across the skin and restricts the toxin molecule to the target site. Second, the botulinum toxin type A provides the mechanism of pharmacologic action and is responsible for the drug effects demonstrated in our clinical trials.

RT002 Injectable Delivery of Botulinum Toxin

RT002 injectable utilizes our proprietary botulinum toxin-peptide complex in a saline-based formulation. In RT002 injectable, the peptide interacts with both extracellular structures and cell surface receptors in the targeted muscle. This interaction restricts the toxin molecule to the target site and potentially reduces unwanted spread to other neighboring muscles. We believe that by limiting the spread of RT002 injectable to neighboring muscles, RT002 injectable is likely to be tolerated at higher doses than Botox® Cosmetic. Additionally, at doses where the spread of BOTOX® Cosmetic and RT002 injectable were compared, RT002 injectable appeared to be more targeted with longer duration in our preclinical studies. Nonclinical and clinical data taken together suggest that RT002 injectable may provide longer duration of effect at the target muscle and reduce spread to untargeted muscles.

RT001 Topical Botulinum Toxin-Peptide Complex

In RT001 topical, our proprietary peptide carries and releases botulinum toxin to a defined depth of penetration targeting the mid-dermis, which is an appropriate depth of skin penetration for the treatment of crow’s feet, hyperhidrosis, migraine headache, pain syndromes and other conditions.

Our nonclinical and clinical data show that the absorption enhancer peptide is necessary for the botulinum toxin to cross the skin and have pharmacologic effect. Our data also show that the peptide alone does not have pharmacologic action and that the botulinum toxin molecule without the peptide cannot cross the skin to achieve its effect.

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RT001 topical is applied to the skin as a clear gel. The gel is temperature-triggered so that it is liquid at ambient temperature and forms a gel as it warms upon contact with the skin. RT001 topical quickly reaches a viscosity sufficient to remain in place in the defined treatment area

RT001 Topical Delivery of Botulinum Toxin

The absorption enhancer peptide has two pathways for the delivery of the botulinum toxin. The first pathway is energy independent and can occur in non-living cells, such as the stratum corneum, which is the outermost layer of the skin. This pathway allows the molecule to bind and traverse the stratum corneum where the molecule “shuttles” across the surface of the lipid layers in a process called “lipid rafting.”

The second pathway is energy dependent and can only occur across living cells. It is an active process where transcytosis, the process by which molecules are transported across the interior of a cell, takes the molecule from one side of the cell to another. The peptide triggers the cell to fold around the peptide, carrying the target molecule with it. This pathway releases RT001 topical on either side of the cell. When returned to the original side, no net change occurs; but when returned to the opposite side, the contents have crossed the cell. The result is a net flow of RT001 topical from high to low concentration across the cells.

Administration of RT001 Topical on the Skin

The proprietary applicator for delivering RT001 topical to multiple locations was developed to provide for simple storage, reconstitution and ease of applying RT001 topical to the skin with minimal training.

Botulinum toxin is not stable in liquid form. It must be lyophilized, or freeze-dried, for refrigerated storage and distribution. Injectable botulinum toxin products are distributed as lyophilized powders in sealed vials. Before they can be injected into a patient, the products must be reconstituted by a trained healthcare provider by drawing a precisely measured volume of saline solution into a syringe through a needle, and then transferring it into the botulinum toxin vial through the needle.

We designed our proprietary applicator in collaboration with Duoject, a supplier of medical devices and provider of design and development services, with over 25 years of developing medical devices for drug reconstitution and delivery. The design of our applicator has several features focused on safety and ease-of-use, and is covered by pending patents.

We plan to supply RT001 topical in a single-use administration applicator containing a vial of our lyophilized drug product and a vial of diluent for reconstitution. The vial of drug product is protected within our device to reduce potential for misuse as an injectable, and to eliminate the potential for needle stick injuries as could occur when reconstituting currently available injectable botulinum toxin products. The pre-filled amounts of drug product and diluent ensure accurate preparation of the intended concentration and dosage for treatment.

Once reconstituted, our device allows for storage of the dose within our device for up to eight hours, and then provides a means to easily administer the dose of RT001 topical. RT001 topical is spread over the treatment area with a gloved finger, where it remains in place for 30 minutes and is then removed by a series of gentle cleansing wipes, deactivated and disposed. The entire application process is a simple procedure which requires minimal time to prepare and apply by physician or medical staff.

The Botulinum Toxin Market

Botulinum toxin is a protein and neurotoxin produced by Clostridium botulinum. Since 1989 botulinum toxin in an injectable dose form has been used to treat a variety of aesthetic and therapeutic indications in the United States. Botulinum toxin has been approved for a variety of therapeutic indications including cervical dystonia, upper limb spasticity, blepharospasm, strabismus associated with neurological movement disorders, hyperhidrosis, migraine headache, overactive bladder conditions and, most recently, lower limb spasticity. In the United States, botulinum toxin has been approved to treat two aesthetic indications, glabellar lines and lateral canthal lines, although we believe that botulinum toxin is widely used for other aesthetic indications. Only three products, Allergan’s Botox® Cosmetic, Ipsen and Galderma’s Dysport®, and Merz’s

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Xeomin®, each of which is delivered in an injectable form, have been approved for the treatment of glabellar lines in the United States.

According to UBS, the global market for botulinum toxin was estimated to be $3.4 billion in 2014 and has an estimated compound growth rate of 8.8% from 2015 to 2020, reaching $5.3 billion by the end of this decade. The market is split into aesthetic ($1.4 billion in 2015) and therapeutic indications ($2.0 billion in 2015). We expect continued growth of the botulinum toxin market to be driven by new indications and product launches in new geographies. According to the National Library of Medicine, there are over 200 active clinical trials for a wide range of uses of botulinum toxin, with more than one-fifth of these identified as being in Phase 3 clinical development. While we are unaware of any clinical trials for potentially competitive topical products that may reach the market before RT001 topical, it is possible that clinical trials for such potentially competitive topical products have occurred or are occurring.

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, driven by a large population of consumers who are looking to delay signs of aging and improve general appearance.

Injectable botulinum toxin treatments are the single largest cosmetic procedure in the United States and the rest of the world. According to the American Society for Aesthetic Plastic Surgery, or ASAPS, a strong consumer preference for non-surgical options and the increasing availability of effective alternatives have 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 83.5% of the total number of procedures performed in 2013, according to the ASAPS annual statistics. Injectable botulinum toxin was the most frequently performed non-surgical procedure in 2013, with 3.8 million procedures in the US, a 16% increase over 2012.

Injectable botulinum toxin treatments have almost doubled in the past ten years according to ASAPS annual statistics. Global Industry Analysts, Inc., or GIA, further estimates that in 2014, 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 10% from 2013 through 2020.

The Opportunity for Botulinum Toxins for Therapeutic Indications

While currently approved botulinum toxin products may be better known for their aesthetic applications, according to GIA, the fastest-growing segment of the botulinum toxin market in the United States and Europe is actually for therapeutic indications. This growth has been driven largely by the approval of botulinum toxin products in new indications such as preventive treatment of migraine headache and upper limb spasticity in 2010, urinary incontinence in 2011, overactive bladder in 2013, and lower limb spasticity in 2016. Botulinum toxin's ability to affect neuromuscular junctions, muscle activity or the release of neuropeptides, neurotransmitters and neuromediators in a controlled manner has enabled it to be developed and used in a wide range of therapeutic indications. Botulinum toxin products in their injectable form have been approved for multiple therapeutic indications including:

- hyperhidrosis;
- chronic migraine headache;
- urinary incontinence and overactive bladder;
- movement disorders, such as cervical dystonia and upper and lower limb spasticity; and
- uncontrolled blinking.

In addition to these approved therapeutic indications, botulinum toxin products are being evaluated in clinical trials in multiple other therapeutic indications including acne, rosacea, skin and wound healing, scar reduction, hair loss treatments, plantar fasciitis and several muscular-skeletal conditions.

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, an area that is particularly sensitive to pain, and a procedure that is reimbursed to physicians at a low rate relative to the time required to perform the procedure. As a result, the use of Botox®, which is 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

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and neck. Due to the pain associated with injections and other limitations associated with injectable botulinum toxin products, we believe that there is a significant need for a painless, topically administered and effective botulinum toxin.

We also believe there is opportunity to improve injectable botulinum toxin use in neurological movement and other disorders. Muscle movement disorders are neurological conditions that affect a person's ability to control muscle activity in one or more areas of the body. Muscle spasticity happens after the body's nervous system has been damaged, most commonly by a stroke, disease, or trauma. Muscle spasticity can be painful and may have a significant effect on a person's quality of life. Some tasks, like getting dressed or bathing, become difficult, and a person's self-esteem may be affected by their abnormal posture. Common muscle movement disorders include cervical dystonia (excessive pulling of the muscles in the neck and shoulder), and upper or lower limb spasticity (stiffness in arm or leg muscles). Botulinum toxin type A has proven safe and effective for such uses, as the most common treatment for muscle movement disorders is to relax the muscle by injecting it with botulinum toxin. However, such injections must be repeated every 3-4 months and require large doses, typically more than 200 BOTOX® units each treatment. As a result of the discomfort associated with muscle movement disorders and the associated demand for treatment that currently requires up to four visits per year, we believe that there is a significant need for a longer-lasting and more targeted injectable botulinum toxin.

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: RT002 injectable, our injectable botulinum toxin, and RT001 topical, our topical botulinum toxin.

Key elements of our strategy are:

- Advance RT002 Injectable Clinical Development. In the first half of 2016, we plan to complete the BELMONT Phase 2 active comparator against the market leader, BOTOX® Cosmetic, for the treatment of glabellar lines and have an End of Phase 2 meeting with the FDA. Following the End of Phase 2 meeting with the FDA, we plan to initiate a Phase 3 program in the second half of 2016. In muscle movement disorders, we plan to continue our Phase 2 trial for the treatment of cervical dystonia.
- Complete Development And Seek Regulatory Approval for RT001 Topical. We are in the advanced stages of our development process of RT001 topical for the treatment of crow's feet. We expect to report results from the first of two U.S. Phase 3 pivotal clinical trials in the first half of 2016 and plan to initiate additional Phase 3 pivotal clinical trials in the United States and Europe subsequently. We expect to file for regulatory approvals for the treatment of crow's feet in the United States and Europe. We chose to focus on these markets not only because of their size and growth potential but also because, in the United States and Europe, the market can be easily accessed by a specialty sales force.
- Advance Future Therapeutic Indication for RT001 Topical. We expect to initiate a second Phase 2 clinical study using RT001 topical for the treatment of axillary hyperhidrosis in the second half of 2016. In the future, we expect to continue developing RT001 topical for therapeutic indications where injection-based botulinum toxin dose forms are poorly tolerated, or have higher risk of adverse events. We believe that the commercial potential of RT001 topical in therapeutic indications could be substantial given the number of indications that we could pursue and the significant advantages of a painless, topical approach.
- Build Our Own Sales And Marketing Capabilities To Commercialize RT001 Topical and RT002 Injectable in North America. If RT001 topical is approved for the treatment of crow's feet or RT002 injectable is approved for the treatment of glabellar lines by the FDA, we intend to build our own sales force and commercial organization to launch in North America. Specifically, we plan to build a specialty sales force to target key physicians who perform the majority of aesthetic procedures, including dermatologists, plastic surgeons, facial plastic surgeons, and oculo-plastic surgeons.
- Expand The Global Market For Botulinum Toxin Products. We believe RT001 topical can expand the overall botulinum toxin market beyond the current patient base by bringing in new patients who would prefer a needle-free

approach to treatment and a more tolerable procedure. RT001 topical's profile may also make it preferable for aesthetic indications where the risk of toxin spreading to adjacent muscles can cause undesired outcomes such as bruising, droopy eye and unwanted frozen face. We believe RT002 injectable also has the ability to expand the botulinum toxin market by appealing to patients who seek a longer lasting effect.

- Establish Selective Strategic Partnerships To Maximize The Commercial Potential Of Our Product Candidates and TransMTS® Delivery Technology Platform. Outside of North America, we plan to evaluate whether to

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commercialize our product candidates on our own or in collaboration with potential partners and distributors. Specifically, assuming regulatory approval of RT001 topical and RT002 injectable outside of the United States, we will evaluate whether to build in-house commercial capabilities in one or more foreign countries or to seek commercialization partners to maximize the profitability of RT001 topical and RT002 injectable. Additionally, the TransMTS® peptide delivery technology platform can be used for molecules other than botulinum toxin. We plan on opportunistically partnering or licensing the technology to develop this capability.

- Maximize The Value Of Our Botulinum Toxin Cell Line And Manufacturing Assets. We have developed an integrated manufacturing, analytics, research and development facility that is capable of producing proprietary forms of botulinum toxin combined with TransMTS® peptide for Revance and any future partners.

Manufacturing and Operations

We have established capabilities for the production of botulinum toxin type A, including bulk drug substance and both topical and injectable finished drug product. Botulinum toxin is regulated as a Select Agent under authority of the Centers for Disease Control and Detection, or CDC, and as such requires that we perform our operations in compliance with CDC regulations. We are in good standing under our Select Agent license with the CDC. We have assembled a team of experienced individuals in the technical disciplines of chemistry, biology and engineering and have appropriately equipped laboratory space to support ongoing research and development efforts in our botulinum toxin product development platform. We have the ability to manufacture our own botulinum toxin to support our clinical trial programs and eventually, our commercial production. We believe that having direct control over our manufacturing processes will enable us to develop additional pharmaceutical product configurations effectively and with a competitive cost structure.

We manufacture and perform testing for both bulk drug substance and finished dosage forms of drug product to support our RT001 topical and our RT002 injectable product candidates. The additional components required for our RT001 topical dose form, the peptide, diluent and delivery applicator, are all manufactured by third parties under contract with us. See the section entitled “Outsourced Components” below for additional information.

Drug Substance

The manufacture of the drug substance for RT001 topical and RT002 injectable is based on microbial fermentation followed by product recovery and purification steps. The process is entirely free of animal and human-derived materials and depends on standard raw materials available commercially. The process is already scaled to support all future commercial demands. Bulk drug substance is stable when stored for extended periods, which allows us to establish reserves of drug substance and allows periodic drug substance production to replenish inventories as needed.

Drug Product

Manufacture of topical and injectable dose forms to support RT001 topical and RT002 injectable is currently performed at our pilot fill-finish facility and third-party manufacturer. The manufacturing process consists of bulk compounding, liquid fill and freeze-drying to support acceptable shelf-life duration. We have constructed a larger capacity fill-finish line dedicated to RT001 topical that we plan to validate to support our regulatory license applications and future commercial demand. RT001 topical botulinum toxin and diluent has shown stability to date to support commercial launch. We plan to perform further scale-up of RT002 injectable drug product manufacturing to meet anticipated commercial demand.

Outsourced Components

We contract with third parties for the manufacture of the additional components required for RT001 topical dose form, which includes the manufacture of bulk peptide through American Peptide Company, Inc., or American Peptide, diluent through Hospira Worldwide, Inc., or Hospira, and our delivery applicator through Duoject. American Peptide, Hospira, and Duoject have been or were recently acquired by Bachem, Pfizer, Inc., and Novocol Healthcare, Inc., respectively.

Our agreement with List Biological Laboratories, Inc., or List Laboratories, a developer of botulinum toxin, includes certain milestone payments related to the clinical development of our botulinum toxin products and the toxin manufacturing process. There is a royalty with an effective rate ranging from low-to-mid single-digit percentages of future sales of botulinum toxin. Our agreement with List Laboratories will remain in effect until expiration of our royalty obligations and may be terminated earlier on mutual agreement or because of a material breach by either party.

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Our agreement with Hospira includes product development services and manufacture and supply services and requires that we provide Hospira with advance forecasts of our product needs. This agreement also includes minimum purchase requirements once we have commercialized our products. Our agreement with Hospira will remain in effect for seven years, subject to extensions, after we commercialize our products and may be terminated earlier by either party following advance notice and good faith consultation.

Our agreement with Duoject includes development work and manufacture and supply services. This agreement also includes a royalty of less than one percent of future sales of products which include the delivery applicator, in the event we do not use Duoject to manufacture the delivery applicator. Our agreement with Duoject will remain in effect until the later of April 30, 2020 or the expiration of the last patent issued to us for the delivery applicator and may be terminated earlier because of a material breach by either party.

Our agreement with American Peptide includes development, manufacture and supply of peptide in accordance with certain specifications. This agreement also includes certain quality control and inspection provisions through which we can ensure the satisfactory quality of our peptide. Our agreement with American Peptide will remain in effect until May 20, 2020 and may be terminated earlier by either party following advance notice or a material breach by either party.

Competition

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, 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, manufacture and marketing of healthcare products competitive with those that we are developing.

Many of our competitors have substantially greater manufacturing, financial, research and development, personnel and marketing resources than we do. Our competitors may also have more experience and expertise in obtaining marketing approvals from the FDA and other regulatory authorities. In addition to product development, testing, approval and promotion, other competitive factors in the pharmaceutical and medical device industries include industry consolidation, product quality and price, product technology, reputation, customer service and access to technical information. As a result, our competitors may be able to develop competing or superior technologies and processes, and compete more aggressively and sustain that competition over a longer period of time than we could. Our technologies and products may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by one or more of our competitors. As more companies develop new intellectual property in our markets, the possibility of a competitor acquiring patent or other rights that may limit our products or potential products increases, which could lead to litigation.

Upon marketing approval, the first expected use of our products will be to treat crow’s feet, glabellar lines and other indications in aesthetic medicine, followed by potential use to treat excessive sweating, cervical dystonia and other therapeutic conditions. The technologies with which we expect to compete directly are injectable and topical neuromodulators, and to a lesser extent, dermal fillers.

Injectable and Topical Neuromodulators

Our primary competitors in the pharmaceutical market are companies offering injectable dose forms of botulinum toxin, including:

- BOTOX® and BOTOX Cosmetic®, marketed by Allergan, Inc., since its original approval by the FDA in 1989, has been approved for multiple indications, including glabellar lines, crow’s feet, hyperhidrosis, upper and lower limb spasticity, cervical dystonia, strabismus, blepharospasm, chronic migraine, incontinence, and overactive bladder. In November 2015, Pfizer Inc. and Allergan entered into a merger agreement set to close in 2016. This creates a leading global pharmaceutical company with significant research, discovery, and delivery capabilities.
- Myobloc®, a neuromodulator currently marketed by US WorldMeds and approved by the FDA in 2000.
- Dysport®, an injectable botulinum toxin for the treatment of cervical dystonia, and glabellar lines and upper limb spasticity, which is marketed by Ipsen Ltd., or Ipsen, and Galderma, a Nestle company. Galderma acquired rights to

market the product in the United States and Canada from Valeant Pharmaceuticals International, Inc. in 2014. Dysport® was approved by the FDA in 2009. Ipsen had previously received marketing authorization for a cosmetic indication for Dysport® in Germany in 2006 and, in 2007, Ipsen granted Galderma an exclusive

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development and marketing license for Dysport® for cosmetic indications in the European Union, Russia, Eastern Europe and the Middle East, and first rights of negotiation for other countries around the world, except the United States, Canada and Japan. In 2008, Galderma became Ipsen's sole distributor for Dysport® in Brazil, Argentina and Paraguay. In 2009, the health authorities of 15 European Union countries approved Dysport® for glabellar lines under the trade name Azzalure®. In 2011, Ipsen and Syntaxin engaged in a research collaboration agreement to develop native and engineered formats of botulinum toxin.

- Xeomin®, marketed by Merz Pharma, or Merz, and approved by the FDA in 2010 for cervical dystonia and blepharospasm in adults previously treated with Botox®. In the third quarter of 2011, Xeomin® was approved by the FDA and in Korea for glabellar lines. In the fourth quarter of 2015, Xeomin® was approved by the FDA for the treatment of upper limb spasticity. Xeomin® is also currently approved for therapeutic indications in most countries in the European Union as well as Canada and certain countries in Latin America and Asia. Bocouture® (rebranded from Xeomin®), marketed by Merz and received approval for glabellar lines in Germany in 2009. In 2010, Bocouture® was approved in significant markets within the European Union. Xeomin® is also approved for glabellar lines in Argentina and Mexico.

We are aware of competing neuromodulators currently being developed and commercialized in Asia, South America and other markets. These lightly regulated markets may not require adherence to the FDA's cGMPs or the regulatory requirements of the European Medicines Agency or other regulatory agencies in countries that are members of the Organization for Economic Cooperation and Development. While these products are unlikely to meet stringent U.S. regulatory standards, the companies operating in these markets may be able to produce products at a lower cost than United States and European manufacturers. In addition to the injectable botulinum toxin dose forms, we are aware that other companies are developing topical neuromodulators for cosmetic and therapeutics indications and are conducting clinical trials for acne and facial aesthetic and hyperhidrosis.

Aesthetic Medicine

We anticipate that the first use of our products will be in the professional facial aesthetic medicine market, which includes neurotoxins and dermal fillers, as well as polymer-based injectables. These and other products experience indirect competition from procedures, such as laser treatments, face lifts, chemical peels, fat injections and cold therapy. In the United States, dermal filler products, including Allergan's Juvéderm family of fillers including Juvéderm VoLUMA® XC, compete with Galderma's products Restylane® and Perlane™. In 2010, the FDA approved Allergan's Juvéderm® Ultra XC and Ultra Plus XC products containing lidocaine as well as new formulations of Galderma's Restylane® and Perlane™, also containing lidocaine and Restylane® without lidocaine for lips. Additional competitors in the filler category include Radiesse®, a calcium hydroxylapatite from BioForm, which was acquired by Merz in 2010, Sculptra® from Galderma, and Belotero Balance® from Merz. Internationally, competitive products include Q-Med's range of Restylane® and Perlane™ products, as well as products from Anteis, Filoraga, Teoxane, Galderma and a large number of other hyaluronic acid, bioceramic, protein and other polymer-based dermal fillers.

Sales and Marketing

We currently have limited marketing capabilities and no sales organization. Assuming successful completion of clinical trials and receipt of marketing approval for RT001 topical for treatment of crow's feet or for RT002 injectable for treatment of glabellar lines by the FDA, we plan to launch in North America with our own sales force and commercial organization. Specifically, we would access the North American market through a focused, specialized sales force that targets the core physicians (dermatologists, plastic surgeons, facial plastic surgeons and oculo-plastic surgeons) who perform the majority of the cosmetic procedures. Assuming approval to market in the United States, we will focus our initial marketing of RT001 topical and RT002 injectable on these core specialties.

After European approval to market, we anticipate marketing RT001 topical and RT002 injectable through either our own commercial infrastructure or a combination of our own infrastructure and that of our possible future partners. For future uses of RT001 topical and RT002 injectable outside of aesthetic medicine, we are evaluating launching on our own or through partner relationships.

Strategic Partnering

We plan to focus our efforts on developing and commercializing RT001 topical and RT002 injectable in North America. We intend to market on our own and seek collaborative relationships outside of North America to maximize

the commercial potential of our product candidates and delivery technology.

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We also plan to leverage our TransMTS® technology platform outside of our core focus in botulinum toxin by partnering with other companies. For example, in June 2013 we entered into an exclusive technology evaluation agreement with the Procter & Gamble Company to co-develop a peptide and explore applications of the TransMTS® delivery technology in two classes of over-the-counter cosmetic compounds. If successful, this partnership would enable us to receive royalty revenue.

Intellectual Property

Our success depends in large part on our ability to obtain and maintain intellectual property protection for our drug candidates, novel biological discoveries, and drug development technology and other know-how, to operate without infringing on the proprietary or intellectual property rights of others and to prevent others from infringing our proprietary and intellectual property rights. We seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on know-how, copyright, trademarks and trade secret laws, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. Such protection is also maintained using confidential disclosure agreements. Protection of our technologies is important for us to offer our customers proprietary services and products unavailable from our competitors, and to exclude our competitors from practicing technology that we have developed. If competitors in our industry have access to the same technology, our competitive position may be adversely affected. It is possible that our current patents, or patents which we may later acquire, may be successfully challenged or invalidated in whole or in part. It is also possible that we may not obtain issued patents from our pending patent applications or other inventions we seek to protect. Due to uncertainties inherent in prosecuting patent applications, sometimes patent applications are rejected and we subsequently abandon them. It is also possible that we may develop proprietary products or technologies in the future that are not patentable or that the patents of others will limit or altogether preclude our ability to do business. In addition, any patent issued to us may provide us with little or no competitive advantage, in which case we may abandon such patent or license it to another entity. For more information, please see “Item 1A. Risk Factors — Risks Related to our Intellectual Property.”

As of February 25, 2016, we held approximately 125 issued patents and approximately 138 pending patent applications, including foreign counterparts of U.S. patents and applications. Eleven of our patents are issued in the United States, with the rest issued in Australia, Canada, China, various countries in Europe, Hong Kong, Israel, Japan, Malaysia, Mexico, New Zealand, Singapore and South Africa. In addition, we have pending patent applications in the United States as well as in Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Korea, Mexico, and Singapore. The earliest that any of our patents will expire is July 20, 2021 for U.S. Patent No. 7,807,780. Because approval for RT001 topical is still pending before the FDA, one of these patents, or a later granted Revance patent, may be eligible for a patent term extension of up to five years, provided the total period of market exclusivity based on the extended patent does not exceed 14 years. For more information, please see “Business - Government Regulation - U.S. Patent Term Restoration and Marketing Exclusivity.”

We will continue to pursue additional patent protection as well as take appropriate measures to obtain and maintain proprietary protection for our innovative technologies.

Our registered and pending U.S. trademarks include REVANCE®, TRANSMTS®, MOTISTE, XOTIKIS and JANTYNG.

Government Regulation

Product Approval Process in the United States

In the United States, the FDA regulates drugs and biologic products under the Federal Food, Drug and Cosmetic Act, or FDCA, its implementing regulations, and other laws, including, in the case of biologics, the Public Health Service Act. Our product candidates, RT001 topical and RT002 injectable, are subject to regulation by the FDA as a biologic. Biologics require the submission of a BLA to the FDA and approval of the BLA by the FDA before marketing in the United States.

The process of obtaining regulatory approvals for commercial sale and distribution and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U. S. requirements at any time during the product

development process, approval process or after approval, may subject an applicant to administrative or judicial civil or criminal sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold on clinical trials, warning letters, product recalls, product seizures, total or partial

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suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies performed in accordance with the FDA's current good laboratory practices, or GLP, regulations;
- submission to the FDA of an IND which must become effective before human clinical trials in the United States may begin;
- approval by an institutional review board, or IRB, at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with the FDA's current good clinical practices, or GCP, regulations to establish the safety and efficacy of the product candidate for its intended use;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA inspection, if the FDA deems it as a requirement, of the manufacturing facility or facilities where the product is produced to assess compliance with the FDA's current good manufacturing practice standards, or cGMP, regulations to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity, as well as compliance with applicable Quality System Regulations, or QSR, for devices;
- potential audits by the FDA of the nonclinical and clinical trial sites that generated the data in support of the BLA;
- potential review of the BLA by an external advisory committee to the FDA, whose recommendations are not binding on the FDA; and
- FDA review and approval of the BLA prior to any commercial marketing or sale.

Preclinical Studies

Before testing any compounds with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, stability and formulation, as well as animal studies to assess the potential toxicity and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance, or for other reasons.

Clinical Trials

Clinical trials involve the administration of the product candidate to human patients under the supervision of qualified investigators, generally physicians not employed by or under the clinical trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and effectiveness. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with GCPs. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of clinical trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The product candidate is initially introduced into a limited population of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for some diseases, or when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial

human testing is often conducted in patients with the disease or condition for which the product candidate is intended to gain an early indication of its effectiveness.

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- Phase 2. The product candidate is evaluated in a limited patient population, but larger than in Phase 1, to identify possible adverse events and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to assess dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, and provide substantial evidence of clinical efficacy and safety in an expanded patient population, such as several hundred to several thousand, at geographically dispersed clinical trial sites. Phase 3 clinical trials are typically conducted when Phase 2 clinical trials demonstrate that a dose range of the product candidate is effective and has an acceptable safety profile. These trials typically have at least 2 groups of patients who, in a blinded fashion, receive either the product or a placebo. Phase 3 clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

IND sponsors may dispute FDA decisions concerning clinical development. For example, we engaged in the Formal Dispute Resolution process with the FDA for the proposed indication, primary endpoint assessment and primary endpoint measurement of RT001 topical for crow's feet. In May 2012, we received a determination that the End-of-Phase 2 had been reached for the indication of lateral canthal lines.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication to further assess the biologic's safety and effectiveness after BLA approval. Phase 4 trials can be initiated by the drug sponsor or as a condition of BLA approval by the FDA.

Annual progress reports detailing the results of the clinical trials must be submitted to the FDA and written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the biologic and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final biologic product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests, proposed labeling and other relevant information are submitted to the FDA in the form of a BLA requesting approval to market the product for one or more specified indications. The submission of a BLA is subject to the payment of substantial user fees.

Once the FDA receives a BLA, it has 60 days to review the BLA to determine if it is substantially complete and the data are readable, before it accepts the BLA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has twelve months from submission in which to complete its initial review of a standard BLA and make a decision on the application, and eight months from submission for a priority BLA, and such deadline is referred to as the PDUFA date. The FDA does not always meet its PDUFA dates for either standard or priority BLAs. The review process and the PDUFA date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA date.

After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug or biological products or drug or biological products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations

carefully when making decisions. During the approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategies, or REMS, is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not

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approve the BLA without an approved REMS, if required. A REMS can substantially increase the costs of obtaining approval and limit commercial opportunity.

Before approving a BLA, the FDA can inspect the facilities at which the product is manufactured. The FDA will not approve the BLA unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with GCP requirements. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional clinical testing or information before a BLA can be approved.

The FDA will issue a complete response letter if the agency decides not to approve the BLA. The complete response letter describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post marketing studies, sometimes referred to as Phase 4 testing, which involves clinical trials designed to further assess drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. After approval, certain changes to the approved biologic, such as adding new indications, manufacturing changes or additional labeling claims, are subject to further FDA review and approval. Depending on the nature of the change proposed, a BLA supplement must be filed and approved before the change may be implemented. For many proposed post-approval changes to a BLA, the FDA has up to 180 days to review the application. As with new BLAs, the review process is often significantly extended by the FDA requests for additional information or clarification.

Post-Approval Requirements

Any biologic products for which we or our collaborators receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements, which include, among others, restrictions on direct-to-consumer advertising, promoting biologics for uses or in patient populations that are not described in the product's approved labeling, known as "off-label use," industry-sponsored scientific and educational activities, and promotional activities involving the internet. The FDA closely regulates the post-approval marketing and promotion of biologics, and although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Failure to comply with these or other FDA requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action, mandated corrective advertising or communications with healthcare professionals, possible civil or criminal penalties or other negative consequences, including adverse publicity.

We currently manufacture clinical drug supplies using a combination of third-party manufacturers and our own manufacturing facility in order to support both of our product candidates and plan to do so on a commercial scale if our product candidates are approved. We contract with third-party manufacturers for certain components necessary to produce RT001 topical in clinical quantities and expect to continue to do so to support commercial scale production if RT001 topical is approved. Our future collaborators may also utilize third parties for some or all of a product we are developing with such collaborator. We and our third-party manufacturers are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation. Drug

manufacturers and other entities involved in the manufacture and distribution of approved biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

U.S. Patent Term Restoration and Marketing Exclusivity

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Depending upon the timing, duration and specifics of the FDA approval of our biologic product candidate, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications of other companies seeking to reference another company's BLA. Specifically, the Biologics Price Competition and Innovation Act of 2009, or BPCIA, established an abbreviated pathway for the approval of biosimilar and interchangeable biological products. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until twelve years after the original branded product was approved under a BLA. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator BLA holder. The BPCIA is complex and subject to interpretation as it is presently being implemented.

Product Approval Process Outside the United States

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing manufacturing, clinical trials, commercial sales and distribution of our future products. Whether or not we obtain FDA approval for a product candidate, we must obtain approval of the product by the comparable regulatory authorities of foreign countries before commencing clinical trials or marketing in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized, decentralized or mutual recognition procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure includes selecting one "reference member state," or RMS, and submitting to more than one member state at the same time. The RMS National Competent Authority conducts a detailed review and prepares an assessment report, to which concerned member states provide comment. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states post-initial approval. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

Federal and State Fraud and Abuse and Data Privacy and Security Laws and Regulations

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state fraud and abuse laws restrict certain business practices in the biotechnology industry. These laws include anti-kickback and false claims statutes. We will be subject to these laws and regulations once we begin to directly commercialize our products.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand prescribers, purchasers and formulary managers on

the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and our practices may not in all cases meet all of the criteria for statutory exemptions or safe harbor protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to

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induce referrals of federal healthcare covered business, the statute has been violated. The reach of the Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. The federal transparency requirements under ACA require certain manufacturers of drugs, devices, biologics and medical supplies to annually report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests.

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. Pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," those independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities now and in the future could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion of products from reimbursement under government programs and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

Environment, Health and Safety

We are voluntarily assessing and publicly reporting our greenhouse gas emissions and water usage, and have begun to take action to reduce such emissions and usage. For example we have established employee commuter programs, evaluated the energy efficiency of our buildings and installed low-flow water fixtures. Various laws and regulations have been implemented or are under consideration to mitigate the effects of climate change caused by greenhouse gas emissions. For example, the California Air Resources Board is in the process of drafting regulations to meet state

emissions targets. Based on current information and subject to the finalization of the proposed regulations, we believe that our primary risk related to climate change is the risk of increased energy costs. However, because we are not an energy-intensive business, we do not anticipate being subject to a cap and trade system or any other mitigation measures that would likely be material to our capital expenditures, results of operations or competitive position.

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We are also subject to other federal, state and local regulations regarding workplace safety and protection of the environment. We use hazardous materials, chemicals, viruses and various radioactive compounds in our research and development activities and cannot eliminate the risk of accidental contamination or injury from these materials. Certain misuse or accidents involving these materials could lead to significant litigation, fines and penalties. We have implemented proactive programs to reduce and minimize the risk of hazardous materials incidents.

Research and Development

Conducting research and development is central to our business model. We have invested and expect to continue to invest significant time and capital in our research and development operations. Our research and development expenses were $47.5 million, $33.4 million, and $27.8 million during the years ended December 31, 2015, 2014, and 2013, respectively. We plan to increase our research and development expenses for the foreseeable future to initiate and complete clinical trials and other associated programs relating to RT001 topical for the treatment of crow’s feet and therapeutic indications such as hyperhidrosis, and to initiate and complete additional clinical trials and associated programs related to RT002 injectable for the treatment of glabellar lines and therapeutic indications in areas such as muscle movement disorders.

Employees

As of December 31, 2015, we had 103 full-time employees. Of these employees, 82 employees were engaged in research and development and 21 employees were engaged in finance, marketing, human resources, facilities, information technology, general management, and administrative activities. We plan to continue to expand our research and development activities. To support this growth, we will need to expand managerial, research and development, operations, commercial, finance and other functions. None of our employees are represented by a labor union, and we consider our employee relations to be good.

Other Information

We were incorporated in Delaware on August 10, 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 Form 10-K.

We file electronically with the SEC, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act . We make available on our website at www.revance.com (under “Investors-Financials & Filings”), free of charge, copies of these reports as soon as reasonably practicable after filing these reports with, or furnishing them to, the SEC.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. 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 our initial public offering in February 2014, (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, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. References herein to "emerging growth company" shall have the meaning associated with it in the JOBS Act.

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ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as all other information included in this Form 10-K, 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 topical product candidate RT001 topical and our injectable product candidate RT002 injectable.

To date, we have invested substantial efforts and financial resources in the research and development of RT001 topical, our topical formulation of botulinum toxin. We are in a Phase 3 development program for RT001 topical for the treatment of crow's feet. In October 2014, we initiated an open-label study designed to confirm successful transfer of the production of our RT001 topical drug product to our manufacturing facility. Following a comprehensive analysis of the data obtained in such study, we subsequently commenced and completed a second open-label study using RT001 topical in the first half of 2015. Following analysis of the data obtained from these open-label studies, taken together with our analysis of prior studies and early data from newly developed clinical methods, we decided to proceed with a RT001 topical U.S. pivotal Phase 3 clinical trial for the treatment of crow's feet, which commenced during the third quarter of 2015. To date, we have conducted 17 clinical trials for RT001 topical, with a total of over 1,600 subjects, for the treatment of crow's feet. In September 2015, we initiated an additional randomized, double-blinded, dose-ranging, placebo-controlled Phase 2 clinical trial designed to evaluate the safety and efficacy of a single, bilateral application of RT001 topical for the treatment of primary axillary hyperhidrosis. This trial evaluated efficacy of two different doses of RT001 as compared to placebo. In December 2015, we reported positive interim results and, although the trial sample size was not chosen to meet statistical significance, using quantitative gravimetric measurements, the data was positive and showed that a single treatment of RT001 topical gel achieved clinically meaningful efficacy at Week 4. On the primary quantitative assessment of average reduction from baseline in gravimetrically-measured sweat production at Week 4, the results ranged from 214.2 mg to 165.7 mg ($p=0.003$ for the higher dose) per five minutes for RT001, compared to 66.3 mg per five minutes in patients who received placebo. These ranges corresponded to 81.1% to 79.6% change for RT001, compared to 54.6% for placebo. On the primary qualitative efficacy assessment of a 2-point or greater responders from baseline using the Hyperhidrosis Disease Severity Scale, or HDSS, at Weeks 1 and 2 the results ranged from a 23.8% to 13.3% improvement for RT001, compared to 11.8% at Week 1 and 17.6% at Week 2 for placebo. By Week 4, there was a 14.3% to 13.3% improvement for RT001, compared to a 29.4% improvement in patients who received placebo. The clinical study indicated that RT001 topical appeared to be well-tolerated with no serious adverse events related to the study drug or study treatment procedures or other safety concerns. We plan to advance RT001 topical into a larger Phase 2 study for the treatment of hyperhidrosis in 2016, which will be designed to confirm a final dose. Upon successful completion of this study, we plan to meet with the FDA to discuss moving forward into Phase 3 studies.

We have also invested substantial efforts and financial resources in the research and development of an injectable form of botulinum toxin, RT002 injectable. Based upon the results to date, we are further developing RT002 injectable for the treatment of glabellar lines and reported interim results from BELMONT, a Phase 2 active comparator clinical trial against the market leader BOTOX® Cosmetic. The topline interim data from the trial showed that RT002 injectable achieved its primary efficacy measurement at four weeks for all doses of RT002 injectable and that such efficacy was highly statistically significant as compared to placebo. In addition, RT002 injectable demonstrated a 23.6-week median duration versus BOTOX® Cosmetic with an 18.8-week median duration. Across all cohorts, RT002 injectable appeared to be generally safe and well-tolerated. Final results may differ from interim

results. We plan to conduct an End-of-Phase 2 meeting with the FDA in the first half of 2016. We then expect to begin Phase 3 clinical studies of RT002 injectable for the treatment of glabellar lines in the second half of 2016.

We continue to explore therapeutic indications for muscle movement disorders such as cervical dystonia. In September 2015, we initiated a Phase 2 dose-escalating, open-label clinical study of RT002 for the treatment of cervical dystonia. The Phase 2 study is evaluating the safety, preliminary efficacy, and duration of effect of RT002 injectable in subjects with moderate-to-severe isolated cervical dystonia. We completed enrollment in the first cohort and expect to release interim results in 2016.

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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 topical and RT002 injectable, as well as any future product candidates. The clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- timely completion of, or need to conduct additional, clinical trials, including our clinical trials for RT001 topical, RT002 injectable and any future product candidates, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the number and design of such trials and the accurate and satisfactory performance of third-party contractors;
- our ability to demonstrate the effectiveness and duration of effect of our products on a consistent basis as compared to existing or future therapies;
- our ability to demonstrate to the satisfaction of the FDA, the safety and efficacy of RT001 topical, RT002 injectable 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 topical, RT002 injectable 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 topical;
- our success in educating physicians and patients about the benefits, administration and use of RT001 topical, RT002 injectable or any future product candidates, if approved;
- the prevalence and severity of adverse events experienced with our product candidates or future approved products;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- the ability to raise additional capital on acceptable terms and in the time frames necessary to achieve our goals;
- achieving and maintaining compliance with all regulatory requirements applicable to RT001 topical, RT002 injectable or any future product candidates or approved products;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- the effectiveness of our own or our future potential strategic collaborators' marketing, sales and distribution strategy and operations;
- our ability to manufacture clinical trial supplies of RT001 topical, RT002 injectable 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 topical, RT002 injectable 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 topical, RT002 injectable or any future product candidates;
- our ability to avoid third-party patent interference or intellectual property infringement claims;
- acceptance of RT001 topical, RT002 injectable or any future product candidates, if approved, as safe and effective by patients and the medical community; and
- the continued acceptable safety profile of RT001 topical, RT002 injectable 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 topical, RT002 injectable or any future product candidate to continue our business.

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We may be unable to obtain regulatory approval for RT001 topical, RT002 injectable 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 topical and RT002 injectable, we must provide the FDA and foreign regulatory authorities with data that adequately demonstrate the safety, purity and potency of the product for the intended indication applied for in a Biologics License Application, or BLA, or other respective regulatory filings. The development of biologic products is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, including in Phase 3 development, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and the results of clinical trials by other parties may not be indicative of the results in trials we may conduct. In particular, we have conducted two Phase 2b controlled clinical trials of RT001 topical, in which RT001 topical met the primary efficacy and all secondary endpoints. We have also conducted one open-label, Phase 2b safety trial, which demonstrated that sequential applications of RT001 topical appear to be safe and well-tolerated, even at an accelerated frequency. However, we have conducted one Phase 3 clinical efficacy trial using a modified diluent formulation, the results of which were inconsistent with our previous Phase 2b clinical trials and which did not show improvement from baseline in either the placebo or RT001 topical group. In October 2014, we conducted an open-label clinical trial of our RT001 topical drug product. The safety analysis from the 43 subjects enrolled in the open-label trial indicated that RT001 topical appeared to be well-tolerated. The efficacy analysis showed clinically meaningful efficacy measured by the one-point investigator’s global assessment, or IGA, and the one-point patient severity assessment, or PSA, as well as in the aggregate for the composite one-point assessment. The two-point response rates for the individual IGA and composite IGA and PSA assessments, however, did not meet the endpoints for the subjects enrolled in the trial. Following a comprehensive analysis of the data obtained in this trial, we determined that the preliminary composite results were not adequate to move forward with our Phase 3 pivotal trial at such time.

In the first half of 2015, we then commenced and completed an additional open-label clinical trial using RT001 topical. We designed this study to evaluate the attributes of different RT001 topical drug products aimed at improving the interaction between our peptide and toxin. The safety analysis from the 69 subjects enrolled in this study indicated that RT001 topical appeared to be well-tolerated. The efficacy analysis for two of the RT001 topical drug products evaluated in this open-label trial showed clinically meaningful efficacy measured by the one-point IGA and the one-point PSA as well as in the aggregate for the composite one-point assessment. In the same two RT001 topical drug products evaluated, we observed some two-point composite response but given the small number of subjects enrolled in this trial, the patient response and other results observed are not necessarily predictive of future clinical trial results. Following analysis of the data available from these open-label studies, taken together with our analysis of prior studies and early data from newly developed clinical methods, we decided to proceed with a RT001 topical U.S. Phase 3 clinical trial for the treatment of crow's feet using a drug product that incorporates attributes of the drug products evaluated in the 2015 open-label trial.

If this RT001 topical drug product, Phase 3 clinical trial or any of our clinical trials do not demonstrate the safety and efficacy to our satisfaction, or to the satisfaction of the FDA, we may be required to conduct additional clinical trials and the timing and our ability to obtain regulatory approval for RT001 topical could be materially and adversely affected.

RT001 topical is currently in Phase 3 development and RT002 injectable is in Phase 2 development. Our business currently depends substantially on their successful development, regulatory approval and commercialization. We currently have no drug or biologic products approved for sale, and we may never obtain regulatory approval to commercialize RT001 topical or RT002 injectable. 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 topical or RT002 injectable in the United States until we receive approval of a BLA from the FDA. We are also not permitted to market RT001 topical or RT002 injectable in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries.

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

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that RT001 topical, RT002 injectable 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;

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- our inability to demonstrate that clinical and other benefits of RT001 topical, RT002 injectable 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 topical, RT002 injectable or any future product candidates;
- the FDA's or the applicable foreign regulatory agency's failure to approve our manufacturing processes or facilities, or the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs, including biologics, in development, only a small percentage successfully complete the FDA or other regulatory approval processes and are commercialized. We are not conducting and do not plan to conduct our U.S. Phase 3 clinical trials for RT001 topical 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 the protocols used in REALISE 1, our Phase 3 pivotal clinical trial protocol, or our planned additional Phase 3 pivotal clinical trial in the United States and subsequent European Phase 3 pivotal clinical trial.

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

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

While the FDA provided written confirmation that our proposed indication, primary endpoint assessment and primary endpoint measurement were acceptable for Phase 3 clinical trials, the FDA has not confirmed that our proposed indication, primary endpoint assessment and primary endpoint measurement are acceptable for regulatory approval. Further, while we did obtain written confirmation with respect to these aspects of our Phase 3 clinical trial designs, there is no assurance that the FDA will approve our BLA for RT001 topical, will agree that the benefits of RT001 topical 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 topical, RT002 injectable 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 topical, RT002 injectable 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 topical, in

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particular, would delay or prevent commercialization of RT001 topical and would materially adversely impact our business, results of operations and prospects.

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

Since our inception, most of our resources have been dedicated to the research and preclinical and clinical development of our botulinum toxin product candidates RT001 topical and RT002 injectable. In particular, our U.S. clinical programs for RT001 topical and RT002 injectable will require substantial additional funds to complete. We have recorded net losses of $73.5 million, $62.9 million, and $52.4 million for the years ended December 31, 2015, 2014 and 2013, respectively, had an accumulated deficit as of December 31, 2015 of $332.3 million and had a working capital surplus of $241.9 million as of December 31, 2015, primarily as a result of our IPO, June 2014 and November 2015 follow-on public offerings, and At-The-Market, or ATM offering. We have funded our operations primarily through the sale and issuance of convertible preferred stock, common stock, notes payable and convertible notes. As of December 31, 2015, we had capital resources consisting of cash, cash equivalents, and investments of $254.1 million. On February 6, 2014, we sold 6,900,000 shares of common stock at $16.00 per share for aggregate net proceeds of $98.6 million in our IPO, after underwriting discounts, commissions, and other offering expenses. On June 19, 2014, we sold 4,600,000 shares of common stock at $30.50 per share for aggregate net proceeds of $131.3 million in our follow-on public offering, after underwriting discounts, commissions, and other offering expenses. In the third quarter of 2015, we sold 352,544 shares of our common stock under the ATM agreement at a weighted average price of $30.76 per share resulting in net proceeds of approximately $10.0 million, after underwriting discounts, commissions, and other offering expenses. On November 9, 2015, we completed a follow-on public offering, pursuant to which we issued 3,737,500 shares of common stock at $36.00 per share, including the exercise of the underwriters' option to purchase 487,500 additional shares of common stock, for net proceeds of $126.2 million.

We believe that we will continue to expend substantial resources for the foreseeable future for the clinical development of RT001 topical, RT002 injectable and development of any other indications and product candidates that we may choose to pursue. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, and manufacturing and supply as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of RT001 topical, RT002 injectable and any future product candidates.

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

Our future capital requirements depend on many factors, including:

- the results of our clinical trials for RT001 topical and RT002 injectable;
- the timing of, and the costs involved in, obtaining regulatory approvals for RT001 topical, RT002 injectable 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 topical, RT002 injectable or any future product candidates, and conducting preclinical and clinical trials;
- the cost of commercialization activities if RT001 topical, RT002 injectable or any future product candidates are approved for sale, including marketing, sales and distribution costs;
-

the cost of manufacturing RT001 topical, RT002 injectable 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;

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- any product liability or other lawsuits related to our products;
- the expenses needed to attract and retain skilled personnel;
- any litigation, including litigation costs and the outcome of such litigation;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, future approved products, if any.

Additional capital may not be available when needed, on terms that are acceptable to us or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials, research, development, manufacturing, sales, marketing or other commercial activities for RT001 topical, RT002 injectable or any future product candidate.

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

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

The commercial success of RT001 topical, RT002 injectable 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. The degree and rate of physician adoption of RT001 topical, RT002 injectable and any future product candidates, if approved, will depend on a number of factors, including:

- the effectiveness and duration of effect of our product as compared to existing therapies;
- physician willingness to adopt a new therapy to treat crow’s feet, hyperhidrosis, glabellar lines, cervical dystonia or other aesthetic or therapeutic indications;
- overcoming any biases physicians or patients may have toward injectable procedures for the treatment of crow’s feet, hyperhidrosis or other indications;
- patient satisfaction with the results and administration of our product and overall treatment experience;
- patient demand for the treatment of crow’s feet, hyperhidrosis, glabellar lines, cervical dystonia or other aesthetic or therapeutic indications; and
- the revenue and profitability that our product will offer a physician as compared to alternative therapies.

If RT001 topical, RT002 injectable or any future product candidates are approved for use but fail to achieve the broad degree of physician adoption necessary for commercial success, our operating results and financial condition will be adversely affected.

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

We expect to enter highly competitive pharmaceutical and medical device markets. Successful competitors in the pharmaceutical and medical device markets have the ability to effectively discover, 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 healthcare 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 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 plan to seek regulatory approval of RT001 topical for the treatment of crow's feet and RT002 injectable for the treatment of glabellar lines.

We anticipate that RT001 topical, if approved for the treatment of crow's feet, will face significant competition from other facial aesthetic products, including injectable botulinum toxins and dermal fillers. If approved, RT001 topical may also compete with unapproved and off-label treatments. We anticipate that RT002 injectable, if approved, will also face significant competition from existing injectable botulinum toxins and dermal fillers, as well as unapproved and off-label treatments. Further, if approved, in the future we may face competition for both RT001 topical and RT002 injectable from biosimilar products and products based upon botulinum toxin. To compete successfully in the aesthetic market, we will have to demonstrate that the reduction of crow's feet with RT001 topical or the treatment of glabellar lines with RT002 injectable is a worthwhile aesthetic treatment and has advantages over existing therapies. Competing in the aesthetic market could result in price-cutting, reduced profit margins and limited market share, any of which would harm our business, financial condition and results of operations.

Due to less stringent regulatory requirements, there are many more aesthetic products and procedures available for use in international markets than are approved for use in the United States. There are also fewer limitations on the claims that our competitors in international markets can make about the effectiveness of their products and the manner in which they can market them. As a result, we face more competition in these markets than in the United States.

We currently make our RT001 topical clinical drug product exclusively in one manufacturing facility and our RT002 injectable clinical drug product in the same and one other external facility. We plan to utilize certain of these facilities in the future to support commercial production if our product candidates are approved. If these or any future facility or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business would be materially harmed.

We currently manufacture our own clinical drug product to support RT001 topical exclusively in a single facility and plan to utilize this facility in the future to support commercial production if RT001 topical is approved. The drug product to support RT002 injectable clinical trials is manufactured in the same facility, as well as in an external manufacturing facility. We expect that additional manufacturing capacity would need to be established in the future to support commercial production of RT002 injectable if this product candidate is approved. If these or any future facility were to be damaged, destroyed or otherwise unable to operate, whether due to earthquakes, fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages or otherwise, or if performance of our manufacturing facilities is disrupted for any other reason, such an event could delay our clinical trials or, if our product candidates are approved, jeopardize our ability to manufacture our products as promptly as our customers expect or possibly at all. If we experience delays in achieving our development objectives, or if we are unable to manufacture an approved product within a timeframe that meets our customers' expectations, our business, prospects, financial results and reputation could be materially harmed.

Currently, we maintain insurance coverage totaling $27.7 million against damage to our property and equipment, $2.0 million in general liability coverage, a $9.0 million umbrella policy, and an additional $35.0 million to cover business interruption and research and development restoration expenses, subject to deductibles and other limitations. If we have underestimated our insurance needs with respect to an interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses.

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

We have constructed, and are continuing to invest capital to validate a larger capacity fill-finish line dedicated to the manufacture of our product candidate RT001 topical and to support our regulatory license applications. Under generally accepted accounting principles in the United States, long-lived assets, such as our fill-finish line, are required to be reviewed for impairment whenever adverse events or changes in circumstances indicate a possible impairment. If business conditions or other factors indicate that the carrying value of the asset may not be recoverable, we may be required to record non-cash impairment charges. Additionally, if the carrying value of our capital equipment exceeds current fair value as determined based on the discounted future cash flows of the related product,

the capital equipment would be considered impaired and would be reduced to fair value by a non-cash charge to earnings, which could negatively affect our operating results. Events and conditions that could result in impairment in the value of our long-lived assets include adverse clinical trial results, unfavorable changes in competitive landscape, adverse changes in the regulatory environment, or other factors leading to reduction in

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expected long-term sales or profitability. During the years ended December 31, 2015, 2014, and 2013, we did not record any impairment 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 biotechnology company with a limited operating history. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We are not profitable and have incurred losses in each year since we commenced operations in 2002. 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 biotechnology industry. To date, we have not obtained any regulatory approvals for any of our product candidates or generated any revenue from product sales relating to RT001 topical or RT002 injectable. 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 $73.5 million, $62.9 million, and $52.4 million for the years ended December 31, 2015, 2014, and 2013 , respectively, had an accumulated deficit through December 31, 2015 of $332.3 million and had a working capital surplus of $241.9 million as of December 31, 2015, primarily as a result of our IPO, June 2014 and November 2015 follow-on public offerings, and ATM offering. In February 2014, we closed our IPO. The net proceeds from the sale of the shares in our IPO and our June 2014 follow-on public offering, after deducting the underwriters' discount, commissions, and other offering expenses related to the IPO and follow-on offering were approximately $98.6 million and $131.3 million, respectively. In November 2015, the Company also completed a public offering for net proceeds of $126.2 million. Our capital requirements to implement our business strategy are substantial, including our capital requirements to develop and commercialize RT001 topical and RT002 injectable. We believe that our currently available capital is sufficient to fund our operations through at least the next 12 months.

We expect to continue to incur losses for the foreseeable future, and we anticipate that these losses will increase as we continue our development of, and seek regulatory approvals for, RT001 topical and RT002 injectable, and begin to commercialize RT001 topical and RT002 injectable. Our ability to achieve revenue and profitability is dependent on our ability to complete the development of our product candidates, obtain necessary regulatory approvals and manufacture, market and commercialize our products successfully. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

Even if RT001 topical, RT002 injectable 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 topical, RT002 injectable 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 topical, RT002 injectable 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 topical, RT002 injectable and other aesthetic treatments in general, relative to other discretionary items, especially during economically challenging times;
- the willingness of third-party payors to reimburse physicians for RT001 topical, RT002 injectable and any future products we may commercialize;

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

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

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Furthermore, we rely on contract research organizations, or CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing the committed activities of our CROs, we have limited influence over their actual performance. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Furthermore, final results may differ from interim results. For example, any positive results generated to date in clinical trials for RT001 topical or RT002 injectable do not ensure that later clinical trials, including our RT001 topical Phase 3 clinical trials for the treatment of crow’s feet or any RT002 injectable clinical trials for the treatment of glabellar lines, will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety profile and efficacy despite having progressed through preclinical studies and initial clinical trials. In particular, we have conducted two Phase 2b controlled clinical trials of RT001 topical, in which RT001 topical met the primary efficacy and all secondary endpoints. We have also conducted one open-label, Phase 2b safety trial, which demonstrated that sequential applications of RT001 topical appear to be safe and well-tolerated, even at an accelerated frequency. However, we have conducted one Phase 3 clinical efficacy trial using a modified diluent formulation, the results of which were inconsistent with our previous Phase 2b clinical trials and which did not show improvement from baseline in either the placebo or RT001 topical group. In October 2014, we conducted an open-label clinical trial of our RT001 topical drug product. The safety analysis from the 43 subjects enrolled in the open-label trial indicated that RT001 topical appeared to be well-tolerated. The efficacy analysis showed clinically meaningful efficacy measured by the one-point investigator’s global assessment, or IGA, and the one-point patient severity assessment, or PSA, as well as in the aggregate for the composite one-point assessment. The two-point response rates for the individual IGA and composite IGA and PSA assessments, however, did not meet the endpoints for the subjects enrolled in the trial. Following a comprehensive analysis of the data obtained in this trial, we determined that the preliminary composite results were not adequate to move forward with our Phase 3 pivotal trial at such time.

In the first half of 2015, we then commenced and completed an additional open-label clinical trial using RT001 topical. We designed this study to evaluate the attributes of different RT001 topical drug products aimed at improving the interaction between our peptide and toxin. The safety analysis from the 69 subjects enrolled in this study indicated that RT001 topical appeared to be well-tolerated. The efficacy analysis for two of the RT001 topical drug products evaluated in this open-label trial showed clinically meaningful efficacy measured by the one-point IGA and the one-point PSA as well as in the aggregate for the composite one-point assessment. In the same two RT001 topical drug products evaluated, we observed some two-point composite response but given the small number of subjects enrolled in this trial, the patient response and other results observed are not necessarily predictive of future clinical trial results. Following analysis of the data available from these open-label studies, taken together with our analysis of prior studies and early data from newly developed clinical methods, we decided to proceed with a RT001 topical U.S. Phase 3 clinical trial for the treatment of crow's feet using a drug product that incorporates attributes of the drug products evaluated in the 2015 open-label trial.

A number of companies in the biotechnology 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.

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

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

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

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

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

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

We have developed an integrated manufacturing, research and development facility located at our corporate headquarters. We manufacture drug substance and finished dose forms of drug product at this facility that we use for research and development purposes and for clinical trials of our product candidates. We do not have experience in manufacturing our product candidates at commercial scale. If our product candidates are approved, we may need to expand our manufacturing facilities, add manufacturing personnel and ensure that validated processes are consistently implemented in our facilities. For example, we are building a larger capacity fill-finish line dedicated to our product candidate RT001 topical and to support our regulatory license applications, if approved. In addition, we expect to further scale up our RT002 injectable drug product manufacturing. The upgrade and expansion of our facilities will require additional regulatory approvals. In addition, it will be costly and time-consuming to expand our facilities and recruit necessary additional personnel. If we are unable to expand our manufacturing facilities in compliance with

regulatory requirements or to hire additional necessary manufacturing personnel, we may encounter delays or additional costs in achieving our research, development and commercialization objectives, including in obtaining regulatory approvals of our product candidates, which could materially damage our business and financial position.

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We currently contract with third-party manufacturers for certain components necessary to produce RT001 topical for clinical trials and expect to continue to do so to support commercial scale production if RT001 topical is approved. This increases the risk that we will not have sufficient quantities of RT001 topical 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 topical for our clinical trials, including the bulk peptide, diluent and the delivery applicator and expect to continue to rely on these or other manufacturers to support our commercial requirements if RT001 topical 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 topical, RT002 injectable or any other product candidates or products that we may develop. Any failure or refusal to supply the components for RT001 topical, RT002 injectable or any other product candidates or products that we may develop could delay, prevent or impair our clinical development or commercialization efforts.

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

We and our manufacturers purchase the materials necessary to produce RT001 topical and RT002 injectable for our clinical trials from single-source third-party suppliers. There are a limited number of suppliers for the raw materials that we use to manufacture our product candidates and we may need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. In particular, we outsource the manufacture of bulk peptide through American Peptide Company, Inc., the RT001 topical diluent through Hospira Worldwide, Inc. and our RT001 topical delivery applicator through Duoject. American Peptide, Hospira, and Duoject were recently or have been acquired by Bachem, Pfizer, Inc., and Novocol Healthcare, Inc., respectively. We do not have any control over the process or timing of the acquisition of raw materials by our manufacturers. Although we generally do not begin a clinical trial unless we believe that we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of RT001 topical, RT002 injectable or any future product candidates, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party supplier could considerably delay completion of our clinical trials, product testing and potential regulatory approval of RT001 topical, RT002 injectable 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 topical, RT002 injectable and any future product candidates, or the commercial launch of any approved products, would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of any approved products.

Furthermore, if there is a disruption to our or our third-party suppliers' relevant operations, we will have no other means of producing RT001 topical, RT002 injectable or any future product candidates until they restore the affected facilities or we or they procure alternative facilities. Additionally, any damage to or destruction of our or our third party or suppliers' facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

We 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.

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

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

We currently rely on third parties and consultants to conduct all our preclinical studies and clinical trials. If these third parties or consultants do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize RT001 topical, RT002 injectable or any future product candidates.

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

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

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

We plan to seek regulatory approval for RT001 topical in the United States and Europe for the treatment of crow's feet. If RT001 topical is approved, the applicable regulatory agency will restrict our ability to market or advertise RT001 topical 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 topical, as well as seek regulatory approval for RT002 injectable, 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 topical and/or RT002 injectable is approved for marketing, and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, significant fines, penalties, and sanctions, product liability claims, and our image and reputation within the industry and marketplace could be harmed.

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug products, such as RT001 topical and RT002 injectable, if approved. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. For example, if we receive marketing approval for RT001 topical for the treatment of crow's feet, the first indication we are pursuing, we cannot prevent physicians from using our RT001 topical products on their patients in a manner that is inconsistent with the approved label, potentially including for the treatment of other aesthetic or therapeutic indications. If we are found to have promoted such off-label uses, we may receive warning letters and become subject to significant liability, which would materially harm our business. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred, and our reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry.

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

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

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Even if RT001 topical, RT002 injectable or any future product candidate is approved for commercialization, if there is not sufficient patient demand for such procedures, our financial results and future prospects will be harmed.

Treatment of crow's feet with RT001 topical and glabellar lines with RT002 injectable, are elective procedures, the cost of which must be borne by the patient, and we do not expect it to be reimbursable through government or private health insurance. The decision by a patient to elect to undergo the treatment of crow's feet with RT001 topical, the treatment of glabellar lines with RT002 injectable or the treatment of other aesthetic indications we may pursue may be influenced by a number of factors, including:

- the success of any sales and marketing programs that we, or any third parties we engage, undertake, and as to which we have limited experience;
- the extent to which physicians recommend RT001 topical or RT002 injectable to their patients;
- the extent to which RT001 topical or RT002 injectable satisfies patient expectations;
- our ability to properly train physicians in the use of RT001 topical or RT002 injectable such that their patients do not experience excessive discomfort during treatment or adverse side effects;
- the cost, safety and effectiveness of RT001 topical or RT002 injectable versus other aesthetic treatments;
- consumer sentiment about the benefits and risks of aesthetic procedures generally and RT001 topical or RT002 injectable in particular;
- the success of any direct-to-consumer marketing efforts we may initiate; and
- general consumer confidence, which may be impacted by economic and political conditions.

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

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

Our ability to commercialize RT001 topical, RT002 injectable, or any future product candidates for therapeutic indications such as hyperhidrosis or cervical dystonia will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not obtain adequate third-party coverage or reimbursement for RT001 topical, RT002 injectable or any future product candidates, or we may be required to sell them at a discount.

We expect that private insurers will consider the efficacy, cost effectiveness and safety of RT001 topical and RT002 injectable in determining whether to approve reimbursement for RT001 topical and RT002 injectable and at what level. Obtaining these approvals can be a time-consuming and expensive process. Our business would be materially adversely affected if we do not receive approval for reimbursement of RT001 topical or RT002 injectable from private insurers on a timely or satisfactory basis. Our business could also be adversely affected if private insurers, including managed care organizations, the Medicare program or other reimbursing bodies or payors limit the indications for which RT001 topical or RT002 injectable will be reimbursed to a smaller set than we believe they are effective in treating.

In some foreign countries, particularly Canada and European countries, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. To obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our products, including RT001 topical or RT002 injectable, to other available therapies. If reimbursement for our product is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

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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 topical, RT002 injectable 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 topical, RT002 injectable or any other future product candidates, if approved, in the United States, Europe and other jurisdictions we seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If RT001 topical or RT002 injectable receives regulatory approval, we expect to market RT001 topical or RT002 injectable, as applicable, through our own sales force in North America, and in Europe and other countries through either our own sales force or a combination of our internal sales force and distributors or partners, which may be expensive and time-consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize RT001 topical, RT002 injectable or any future product candidates. If we are not successful in commercializing RT001 topical, RT002 injectable or any future product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

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

As of December 31, 2015, we had 103 full-time employees. We will need to continue to expand our managerial, operational, and other resources to manage our operations and clinical trials, continue our development activities and commercialize RT001 topical, RT002 injectable or any other product candidates, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

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

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

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

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of RT001 topical, RT002 injectable or any future products we develop. We currently carry product liability insurance covering our clinical trials in the amount of $5.0 million in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing RT001 topical or RT002 injectable, we intend to expand our insurance coverage to include the sale of RT001 topical or RT002 injectable, as applicable; however, we may be unable to obtain this liability insurance on commercially reasonable terms.

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

We have been, and may in the future be, the target of securities class actions or shareholder derivative claims. On May 1, 2015, a securities class action complaint was filed on behalf of City of Warren Police and Fire Retirement System against us and certain of our directors and executive officers at the time of our follow-on public offering, and the investment banking firms that acted as the underwriters in our follow-on public offering. This and any such other actions or claims could result in substantial damages and may divert management's time and attention from our business.

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop RT001 topical, RT002 injectable or any future product candidates, conduct our clinical trials and commercialize RT001 topical, RT002 injectable 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, Chief Operating Officer, and Chief Financial Officer and Chief Business 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 topical, RT002 injectable or any future products we develop.

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

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 and the turnover rate can be high due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their 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 topical and RT002 injectable, a key element of our strategy is to discover, develop and commercialize a portfolio of botulinum toxin products to serve both the aesthetic and therapeutic markets. We are seeking to do so through our internal research programs and may explore strategic collaborations for the development or acquisition of new products. While our two product candidates, RT001 topical and RT002 injectable, are each in the clinical development stage, all of our other potential product candidates remain in the discovery or preclinical stage. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

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

If we fail to develop and successfully commercialize other product candidates, our business and future prospects may be harmed and our business will be more vulnerable to any problems that we encounter in developing and commercializing RT001 topical and RT002 injectable.

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

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

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

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

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

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

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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 topical, RT002 injectable and any future product candidates. In any third-party collaboration, we would be dependent upon the success of the collaborators in performing their responsibilities and their continued cooperation. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to performing their responsibilities under our agreements with them. Our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us. The development, validation and commercialization of our product candidates will be delayed if collaborators fail to conduct their responsibilities in a timely manner or in accordance with applicable regulatory requirements or if they breach or terminate their collaboration agreements with us. Disputes with our collaborators could also impair our reputation or result in development delays, decreased revenues and litigation expenses.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Furthermore, the market for aesthetic medical procedures may be particularly vulnerable to unfavorable economic conditions. We do not expect RT001 topical for the treatment of crow's feet or RT002 injectable for the treatment of glabellar lines to be reimbursed by any government or third-party payor and, as a result, demand for the first indications of each of our product candidates will be tied to discretionary spending levels of our targeted patient population. 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 topical, RT002 injectable 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 topical, RT002 injectable 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 topical, RT002 injectable 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.

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The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of issued patents. The patent applications that we own or license may fail to result in issued patents in the United States or foreign countries. Competitors in the field of cosmetics, pharmaceuticals, and botulinum toxin have created a substantial amount of prior art, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. In addition, recent changes to the patent laws of the United States provide additional procedures for third parties to challenge the validity of issued patents. Patents issued from applications filed after March 15, 2013 may be challenged by third parties using the post-grant review procedure which allows challenges for a number of reasons, including prior art, sufficiency of disclosure, and subject matter eligibility. Under the inter partes review procedure, any third party may challenge the validity of any issued U.S. Patent in the USPTO on the basis of prior art. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings as compared to the evidentiary standard relied on in U.S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to RT001 topical, RT002 injectable or any future product candidates is challenged, then it could threaten our ability to commercialize RT001 topical, RT002 injectable 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 topical, RT002 injectable or any future product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act signed into law on September 16, 2011. Among some of the other changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO.

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

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

development processes that involve proprietary know-how, information or technology that is not covered by patents.

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

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

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

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

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

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

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

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

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

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

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

Risks Related to Government Regulation

Our business and products are subject to extensive government regulation.

We are subject to extensive, complex, costly and evolving regulation by federal and state governmental authorities in the United States, principally by the FDA, the U.S. Drug Enforcement Administration, or DEA, the CDC, and foreign regulatory authorities. Failure to comply with all applicable regulatory requirements, including those promulgated under the Federal Food, Drug, and Cosmetic Act, or FFDCA, 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 topical, RT002 injectable or any future product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug and biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor any collaboration partner is permitted to market RT001 topical, RT002 injectable or any future product candidates in the United States until we receive approval of a BLA from the FDA. We have not submitted an application or obtained marketing approval for RT001 topical or RT002 injectable 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 U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

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

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

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

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

If RT001 topical, RT002 injectable or any future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain approval, our business and results of operations will be materially and adversely harmed.

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Even if we receive regulatory approval for RT001 topical, RT002 injectable or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, 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 topical, RT002 injectable, or any approved product will be subject to continual regulatory review by the FDA and/or non-U.S. regulatory authorities. Additionally, any product candidates, if approved, will be subject to extensive and ongoing regulatory requirements, including labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we or our collaborators receive for RT001 topical, RT002 injectable or any future product candidates may also be subject to limitations on the approved indications for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the applicable regulatory agency approves RT001 topical, RT002 injectable or any future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with RT001 topical, RT002 injectable or any future product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications 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 topical, RT002 injectable or any future product candidates, we will be unable to market our products outside of the United States.

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

timely basis, and even if we do file, we may not receive the necessary approvals to commercialize our products in markets outside of the United States.

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If approved, RT001 topical, RT002 injectable 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 topical or RT002 injectable. If we are successful in commercializing RT001 topical, RT002 injectable, or any other products, the FDA and foreign regulatory agency regulations require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or a foreign regulatory agency could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

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

While we do not expect that RT001 topical, if approved for the treatment of crow’s feet, or RT002 injectable, if approved for the treatment of glabellar lines, will subject us to the various U.S. federal and state laws intended to prevent healthcare fraud and abuse, we may in the future become subject to such laws. The federal anti-kickback statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal healthcare programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state healthcare programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal healthcare programs and substantial civil and criminal penalties.

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

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

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

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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 topical, RT002 injectable or any future product candidates and to produce, market, and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products, as discussed in more detail in the risk factors in Part II, Item 1A of our Form 10-Q entitled "We may be unable to obtain regulatory approval for RT001 topical, RT002 injectable or future product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations." Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of RT001 topical, RT002 injectable or any future product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

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

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

Risks Related to the Ownership of Our Common Stock

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

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

- regulatory or legal developments in the United States and foreign countries;
- results from or delays in clinical trials of our product candidates, including our Phase 3 clinical program for RT001 topical and our Phase 2 clinical program for RT002 injectable;
- announcements of regulatory approval or disapproval of RT001 topical, RT002 injectable or any future product candidates;
- FDA or other U.S. or foreign regulatory actions or guidance affecting us or our industry;
- introductions and announcements of new products by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts’ reports or recommendations;
- quarterly variations in our results of operations or those of our future competitors;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
-

sales of substantial amounts of our stock by insiders and large stockholders, or the expectation that such sales might occur;

- general economic, industry and market conditions;
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;

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- expiration or termination of our potential relationships with customers and strategic partners; and