

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

Revance Therapeutics, Inc.  
Form 10-K  
March 02, 2018

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2017

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 (I.R.S. Employer  
incorporation or organization) 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

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

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

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

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

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer

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

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial statement accounting standards provide pursuant to Section 13(a) of the Exchange Act.

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

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 \$672.0 million, based on the closing price of the registrant's common stock on the Nasdaq Global Market of \$26.40 per share for such date. Number of shares outstanding of the registrant's common stock, par value \$0.001 per share, as of February 23, 2018: 36,684,782

DOCUMENTS INCORPORATED BY REFERENCE

None

---

Table of Contents

## Table of Contents

	Page
<u>PART I</u>	
Item 1 <u>Business</u>	<u>1</u>
Item 1A <u>Risk Factors</u>	<u>21</u>
Item 1B <u>Unresolved Staff Comments</u>	<u>48</u>
Item 2 <u>Properties</u>	<u>49</u>
Item 3 <u>Legal Proceedings</u>	<u>50</u>
Item 4 <u>Mine Safety Disclosures</u>	<u>51</u>
<u>PART II</u>	
Item 5 <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>52</u>
Item 6 <u>Selected Financial Data</u>	<u>55</u>
Item 7 <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>56</u>
Item 7A <u>Quantitative and Qualitative Disclosures about Market Risk</u>	<u>73</u>
Item 8 <u>Financial Statements and Supplementary Data</u>	<u>74</u>
Item 9 <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	<u>75</u>
Item 9A <u>Controls and Procedures</u>	<u>76</u>
Item 9B <u>Other Information</u>	<u>77</u>
<u>PART III</u>	
Item 10 <u>Directors, Executive Officers and Corporate Governance</u>	<u>78</u>
Item 11 <u>Executive Compensation</u>	<u>82</u>
Item 12 <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>87</u>
Item 13 <u>Certain Relationships and Related Party Transactions, and Director Independence</u>	<u>90</u>
Item 14 <u>Principal Accounting Fees and Services</u>	<u>91</u>
<u>PART IV</u>	
Item 15 <u>Exhibits, Financial Statement Schedules</u>	<u>92</u>
Item 16 <u>Form 10-K Summary</u>	<u>92</u>
<u>Signatures</u>	

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

Table of Contents

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

Table of Contents

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.

---

Table of Contents

## 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, formulated with our patented and proprietary peptide technology, to address unmet needs in large and growing neuromodulator markets. Our proprietary peptide technology enables delivery of botulinum toxin type A through two investigational drug product candidates, DaxibotulinumtoxinA for Injection (RT002), or RT002 injectable, and DaxibotulinumtoxinA Topical. We are pursuing clinical development for RT002 injectable in a broad spectrum of aesthetic and therapeutic indications and are planning to conduct additional preclinical development of our topical program. Neither 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 to RT002 injectable and our topical product candidate, and the pharmaceutical uses of our proprietary peptide technology. RT002 injectable is a novel, injectable formulation of botulinum toxin type A designed to be a targeted and long-acting injectable botulinum toxin treatment. We are studying RT002 injectable for aesthetic indications, such as glabellar (frown) lines and therapeutic indications, such as cervical dystonia and plantar fasciitis. We believe RT002 injectable has the potential to expand into additional aesthetic and therapeutic indications in the future.

PIPELINE	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	2018 PLANNED MILESTONES
Glabellar (Frown) Lines (RT002)					Complete Phase 3 open-label - 2H 2018
Cervical Dystonia (RT002)					Initiate Phase 3 program - 2Q 2018
Plantar Fasciitis (RT002)					Complete Phase 2a 16-week study - Q1 2018

## Topical Program

## 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 a long-lasting effect is desired. We believe, and our preclinical and clinical studies using RT002 indicate, that daxibotulinumtoxinA combined with our novel peptide may permit safe administration of higher doses of botulinum toxin and may result in long-lasting effect. We are initially focusing on developing RT002 for the treatment of glabellar lines, cervical dystonia, and plantar fasciitis.

## Glabellar Lines

Glabellar (frown) lines are the result of the gathering of the tissue between the eyebrows into a fold. They are caused by the repeated action of underlying muscles associated with facial expression. Years of squinting and frowning tend to leave deep wrinkles in the skin between the eyebrows and on the bridge of the nose, across the forehead and at the corners of the eyes. On many people, frown lines produce an angry or sad look that detracts from a pleasant facial appearance. Physical, emotional, and social reasons for treating frown lines and forehead furrows include improved appearance and enhanced self-esteem. The most common cosmetic use of BOTOX® Cosmetic is for the treatment of glabellar lines, which we believe represent a global opportunity of nearly \$1 billion in 2016. In general, consumers enjoy the benefits of currently available botulinum toxin



Table of Contents

injections and express a high rate of satisfaction. However, consumers are less satisfied with the duration and longevity of currently available botulinum toxin injections.

Botulinum toxin treatment of glabellar lines is the largest proportion of cosmetic neuromodulator 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. According to market research Revance conducted in October 2017, which involved a quantitative study with 80 dermatologists and plastic surgeons, 80% of the physicians surveyed stated that longer duration is extremely important in their selection of which botulinum toxin to use for the treatment of glabellar lines, and 59% stated duration is the most important unmet need not addressed by currently available botulinum toxin products. When asked why their patients request to change from one approved botulinum toxin to another, 68% said it is because the treatment did not last as long as the patient expected. The quantitative survey also included eighty patients. When asked what attributes an ideal wrinkle treatment would include, duration was cited as the number one reason by 56% of patients.

Also, in Revance's primary qualitative market research among aesthetic physicians, patients, and office practice managers indicated that they were very impressed by the clinical data generated in the RT002 Phase 2 BELMONT study. In fact, a majority of those physicians interviewed reported that if RT002 injectable demonstrated similar results in Phase 3 trials the increased duration of effect would cause them to change their treatment or purchase habits from currently available botulinum toxins to include RT002 injectable. Duration of effect was reported in the qualitative market research to be the greatest unmet need and the primary driver of adoption amongst physicians, patients, and office managers.

We believe that a product that shows increased persistence of effect over time, with a slower return to baseline and a meaningful consumer benefit up to six months would better fit the current treatment regimen and consumer habits. Quantitative market research shows that the majority of consumers only visit their physicians twice per year for treatments and the longer duration would mean that they would enable patients to remain more satisfied between treatments.

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

• RT002 injectable may permit longer lasting effect up to 6 months and increase response rates.

• RT002 injectable may also provide the ability to administer higher doses without associated adverse events. This could potentially decrease unwanted side effects like eyelid ptosis (droopy eyelids), which leads to patient dissatisfaction.

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

• RT002 injectable may be simple to use and consistent with the method of administration of current treatments.

• RT002 injectable may lead to more sustained patient satisfaction between treatments, which is critical for self-pay procedures.

• RT002 injectable could potentially enable physicians to expand their practices by appealing to consumers who are unwilling 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 neuromodulators with the belief 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 and Phase 3 studies, RT002 injectable appeared to be well-tolerated with no significant safety concerns.

#### Development of RT002 Injectable for Treatment of Glabellar Lines

Phase 3 Clinical Trials. We are in Phase 3 clinical development for RT002 injectable in North America for the treatment of glabellar lines. In December 2017, we announced positive top-line results from our SAKURA Phase 3 program.

The Phase 3 clinical program includes two randomized, double-blind, placebo-controlled pivotal trials (named SAKURA 1 and SAKURA 2) to evaluate the safety and efficacy of a single administration of RT002 for the treatment of moderate to severe glabellar lines in adults. The SAKURA 1 and SAKURA 2 trials enrolled more than 600 subjects



at 30 sites in the United States and Canada. In both trials, subjects were randomized in a 2:1 ratio to either the RT002 or placebo treatment groups,

2

---

## Table of Contents

respectively. Post-treatment, subjects were followed for at least 24 weeks and up to 36 weeks. The primary efficacy endpoint of the pivotal trials was a composite of the proportion of subjects who achieve a score of 0 or 1 (none or mild) and a two-point improvement from baseline in glabellar line severity on the Investigator Global Assessment-Facial Wrinkle Severity (IGA-FWS) and Patient Facial Wrinkle Severity (PFWS) scales, at maximum contraction (frown), at Week 4. Duration of the reduction of severity of the glabellar lines was assessed as a secondary efficacy endpoint in the Phase 3 pivotal trials.

In December 2017, we announced top-line results for the SAKURA 1 and SAKURA 2 pivotal trials:

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

**Secondary Duration Endpoints.** There were several secondary endpoints used to evaluate duration of effect, including the proportion of patients achieving none or mild response on IGA-FWS compared to placebo, median duration for time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS, and median duration for time to return to baseline on both IGA-FWS and PFWS. The percentage of RT002-treated patients who achieved a none or mild response on IGA-FWS was 35.3 percent in SAKURA 1 and 29.4 percent at SAKURA 2 compared to placebo ( $p < 0.0001$ ) at Week 24. The median duration for time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS for RT002-treated patients was 24.0 weeks for SAKURA 1 and 23.9 weeks for SAKURA 2. The median duration for time to return to baseline wrinkle severity on both IGA-FWS and PFWS for RT002-treated patients was 27.7 weeks for SAKURA 1 and 26.0 weeks for SAKURA 2. For comparison, an additional exploratory duration endpoint was evaluated, which mirrors the duration measure used in the BELMONT Phase 2 study. This endpoint, was the median duration of greater or equal to 1 point improvement from baseline on IGA-FWS for RT002-treated patients, and the results were 24.1 weeks for both SAKURA 1 and SAKURA 2, and 23.6 weeks for BELMONT.

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

**European Union Agency Interactions.** We requested scientific guidance from the European Medicines Agency, or EMA, on the development of RT002 injectable for the treatment of glabellar lines and the proposed Phase 3 program in 2016. 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.

Pre-Phase 3 FDA Interactions. In 2016, we completed a pre-Phase 3 meeting with the U.S. Food and Drug Administration, or FDA, regarding RT002 injectable for the treatment of glabellar lines. Based upon the discussion with the FDA and the minutes received following the meeting, we submitted an Investigational New Drug Application (IND) for the SAKURA Phase 3 clinical program for RT002 in glabellar lines and other supportive studies required for a Biologics License Application (BLA) submission.

Phase 1 and 2 Clinical Trials. RT002 has demonstrated long-lasting effect and appeared to provide safe administration of botulinum toxin in Phase 1 and 2 clinical trials, even at high targeted doses. Long-lasting effect was first demonstrated in 2014 in the final cohort of a four-cohort Phase 1/2 clinical dose escalation trial conducted outside the United States for improvement of glabellar lines. In the trial, RT002 injectable met its primary efficacy and safety endpoints. The open-label, dose escalating, Phase 1/2 trial enrolled 48 adults. All subjects had moderate to severe 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.

## Table of Contents

83% of subjects assessed themselves as achieving None or Mild wrinkles at maximum frown at the same time point. In the final cohort, which was the only cohort 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 Glabellar Line Severity Scale scores better than baseline.

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, in 2015 we conducted 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 were the investigator's assessment of glabellar line severity at maximum frown at Week 24 based upon the subject response definition of at least a 1 point improvement from baseline on the IGA-FWS scale 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 compared the safety, efficacy and duration of three doses of RT002 injectable, the labeled dose of BOTOX® Cosmetic/VISTABEL® and a placebo control in a randomized 1:1:1:1 trial design. In 2015, we reported positive 24-week results from the trial that showed RT002 injectable achieved its primary efficacy measurement with high statistical significance. In addition, the 40 Unit dose of RT002 injectable demonstrated a 23.6-week median duration, compared to BOTOX® Cosmetic with an 18.8-week median duration. Across all cohorts, RT002 injectable appeared to be generally safe and well-tolerated.

### 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. Certain tasks, like getting dressed or bathing, become difficult, and a person's self-esteem may be affected by an 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. We believe that muscle movement disorders have accounted for over \$1 billion of therapeutic neuromodulator sales globally in 2016.

### RT002 Injectable for Treatment of Cervical Dystonia

In 2015, we initiated a Phase 2 dose-escalating, open-label clinical study of RT002 injectable to evaluate safety, preliminary efficacy, and duration of effect of RT002 injectable in subjects with moderate to severe isolated cervical dystonia symptoms of the neck. In December 2016, we announced positive interim results from the Phase 2 clinical trial. The interim data showed that RT002 injectable appeared to be generally safe and well-tolerated, demonstrated a median duration of at least 24 weeks for the first cohort of the study, and displayed a clinically significant impact on cervical dystonia signs and symptoms. The trial enrolled 37 subjects and follows three sequential treatment cohorts for up to a total of 24 weeks after treatment for each cohort. The trial's first cohort of 12 subjects received a single dose of up to 200 units of RT002 injectable, the second cohort of 12 subjects received between 200 and 300 units, and the

third cohort of 13 subjects received from 300 to 450 units. In May 2017, we announced positive 24-week topline results in all three cohorts from the Phase 2 trial. The topline data demonstrated a median duration of at least 24 weeks for all three cohorts.

## Table of Contents

Key results of the cervical dystonia trial are as follows:

**Safety.** In all three cohorts, RT002 injectable appeared to be generally safe and well-tolerated through Week 24. There were no serious adverse events and no dose-dependent increase in adverse events. The treatment-related adverse events were transient and mild to moderate in severity, except for one case of neck pain reported as severe, with a duration of 2 days. The most common adverse events were dysphagia, or difficulty in swallowing (14%), of which all cases were mild in severity, injection site redness (8%), bruising (5%), injection site pain (5%), muscle tightness (5%) and muscle weakness (5%). For reference, trials for botulinum type A products approved to treat cervical dystonia have reported adverse events for dysphagia ranging from 13% to 39%.

**Efficacy.** The trial's 4-week primary efficacy measurement was the improvement in dystonia symptoms as determined by reduction from baseline on the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS)-Total score. RT002 injectable showed a clinically significant mean reduction of 16.8 from baseline, or 38%, across all three cohorts at Week 4. This reduction continued to increase to 50% at Week 6 for all subjects, was 42% at Week 12 and was maintained at or above 30% through Week 24. Clinically meaningful mean reductions in the TWSTRS Severity, Disability and Pain subscales were consistent and observed at all follow-up visits across all subjects. For reference, placebo-controlled trials for botulinum toxin type A products approved to treat cervical dystonia had a reduction in the TWSTRS-Total score from baseline of 21% to 26% at Week 4 and 13% to 16% at Week 12.

**Duration of Effect.** The median duration of effect was at least 24 weeks for each of the three dose cohorts studied. Duration of effect was defined as the number of weeks from treatment until the return of signs and symptoms that warrant retreatment, based on subjects reaching their target Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) score. For reference, treatment with currently approved neuromodulators for cervical dystonia calls for injection of botulinum toxin approximately every 3 months (12 weeks), or 4 times per year.

**FDA and EMA Interactions.** In November 2017, we completed our End-of-Phase 2 meeting with the FDA and received Scientific Advice from the EMA regarding RT002 for the treatment of cervical dystonia. Based on the Phase 2 safety and efficacy results and guidance from the FDA and EMA, we plan to initiate our Phase 3 program for cervical dystonia in the second quarter of 2018. In November 2017, the FDA also granted orphan drug status to DaxibotulinumtoxinA for Injection for the treatment of cervical dystonia in adults.

### Plantar Fasciitis

We are also developing RT002 for the treatment of plantar fasciitis. Plantar fasciitis is a painful affliction caused by inflammation of the ligament running along the bottom of the foot and is the most common cause of heel pain. Heel pain is the most common complaint of patients who visit podiatrists and orthopedic foot and ankle surgeons. Eighty percent of reported heel pain complaints are due to plantar fasciitis. Plantar fasciitis is estimated to affect 10 to 18 million individuals in the United States. Risk factors include age, long distance running, excessive weight, abnormal foot posture, use of poor foot wear, and repetitive trauma.

Symptoms can last six months or more, sometimes requiring surgery. In the United States alone, more than two million patients undergo treatment for plantar fasciitis each year. Treatment options for less severe cases include leg and foot stretching exercises, nonsteroidal anti-inflammatory drugs, shoe inserts, heel pads, and night splints. More severe or refractory cases are currently treated with steroid injections, extracorporeal shock wave therapy, platelet rich plasma injections, and/or surgery. Preclinical and clinical research suggests a neuromodulator candidate such as RT002 injectable may provide patients with sustained relief from chronic heel pain and support healing of the plantar fascia without the risks of plantar fascia rupture or atrophy of the fat pad that can occur with corticosteroid injections, a common treatment.

Botulinum toxin is not currently approved for treating plantar fasciitis; the clinical endpoints, however, are well established. Published estimates place the annual U.S. evaluation and treatment market for plantar fasciitis at more than \$250 million, and we believe the market could grow significantly larger if patients had a compelling

neuromodulator treatment option.

5

---

## Table of Contents

### RT002 Injectable for Treatment of Plantar Fasciitis

In 2016, we initiated a Phase 2 prospective, randomized, double-blinded, placebo-controlled trial of RT002 injectable in the therapeutic indication of plantar fasciitis. This study will evaluate the safety and efficacy of a single administration of RT002 injectable in reducing the signs and symptoms of plantar fasciitis. The study completed enrollment of 59 subjects in the United States in October 2017. The study's primary efficacy endpoint is the improvement in the American Orthopedic Foot and Ankle Score (AOFAS).

In January 2018, we announced the interim 8-week Phase 2a results for the plantar fasciitis trial. The trial's primary endpoint, the reduction in the patient-reported visual analog scale (VAS) for pain at Week 8, showed a robust impact on pain, with a greater than 50% reduction for patients treated with RT002. In the intent-to-treat population, a mean reduction in the VAS score of 54.2% from baseline was achieved with RT002, compared with a 42.6% reduction in the placebo group, which upon further subgroup analysis, was driven primarily by a strong placebo response in the control group at three of the five study sites. While the results are not statistically significant ( $p=0.39$ ), RT002 provided patients with considerable pain relief. Similar numeric trends were seen in the secondary and exploratory endpoints. RT002 appeared to be generally safe and well-tolerated through Week 8. The majority of adverse events in both treatment groups were mild in severity. There were no treatment-related serious adverse events. The most common treatment-related adverse events for RT002 and placebo were injection site pain (10.0 percent and 10.3 percent) and muscle weakness (3.3 percent and 3.4 percent), both respectively, all of which were classified as mild in severity. The Company plans to complete the 16-week trial and then expects to conduct another Phase 2 trial with a modified design to demonstrate the ability of RT002 to treat plantar fasciitis in the second half of 2018.

### DaxibotulinumtoxinA Topical

DaxibotulinumtoxinA Topical is a topical formulation of botulinum toxin type A. The botulinum toxin in our topical product candidate 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. The topical product candidate is designed to provide treatment with no needles, no downtime, no bruising, and no pain.

We previously completed topical clinical trials for the treatment of lateral canthal lines (crow's feet) and primary axillary hyperhidrosis, but discontinued further clinical development in 2016 following the results of our REALISE 1 Phase 3 clinical trial using topical to treat crow's feet. We plan to study our topical in a preclinical setting for therapeutic and aesthetic applications where topical administration of a neuromodulator provides a meaningful advantage over injection.

### Preclinical Program

In accordance with international guidelines and in consultation with the FDA, we previously conducted a nonclinical topical development program. The program included preclinical efficacy, safety bioavailability and single and repeat dose toxicity studies of our topical product candidate, 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 support future clinical development.

Based on the results of additional preclinical studies, we plan to evaluate further development of indications for our topical candidate, such as axillary hyperhidrosis, neuropsychiatric disorders, and chronic inflammatory diseases.

### Our Technology

#### Our Proprietary Peptide Technology

Combining our proprietary peptide technology with active drug macromolecules such as daxibotulinumtoxinA may help address currently unfulfilled needs in aesthetic medicine and therapeutic categories. Employing our proprietary peptide technology may ensure overall formulation performance of the RT002 injectable where the focus is on delivering the first potentially long-acting neuromodulator. Our daxibotulinumtoxinA compound is often referred to as "a pipeline within a product," as there are multiple indications that may potentially be treated by our daxibotulinumtoxinA compound.





## Table of Contents

### 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 better 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 long duration of effect at the target muscle and reduce spread to untargeted muscles.

### The Botulinum Toxin Opportunity

Botulinum toxin is a protein and neuromodulator 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 and globally. 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 and, most recently, lower limb spasticity. In the United States, botulinum toxin has been approved to treat three aesthetic indications, glabellar lines, forehead lines and lateral canthal lines, although we believe botulinum toxin to be widely used for other aesthetic indications. Three products, Allergan's BOTOX® Cosmetic, Ipsen and Galderma's Dysport®, and Merz's 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 Global Industry Analysts, Inc. or GIA, the global opportunity for botulinum toxin was estimated to be \$4.0 billion in 2017 compared to \$3.6 billion in 2016. The market is projected to reach \$7.4 billion by 2024, registering a compounded annual growth rate of 9.6% over the analysis period of 2016 to 2024. In 2017, the aesthetic segment amounted to \$1.6 billion while therapeutic indications totaled \$2.4 billion. We expect continued growth to be driven by new indications and product launches in new geographies. According to clinicaltrials.gov, as of December 31, 2017 there were more than 170 active clinical trials for a wide range of uses of botulinum toxin, with approximately one-fourth of these identified as being in Phase 3 clinical development. While we are unaware of any clinical trials for potentially competitive long-lasting products that may be commercialized before RT002 injectable, it is possible that clinical trials for such potentially competitive 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. Aesthetic treatments have 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 aesthetic medicine, accounting for 85% of the total number of procedures performed in 2016, according to the ASAPS annual statistics. Injectable botulinum toxin was the most frequently performed non-surgical procedure in 2016, with 4.6 million procedures in the US, a 7.8% increase over 2015. Injectable treatments overall, botulinum toxins and dermal fillers, increased 10.1% in 2016, according to ASAPS. Injectable botulinum toxin treatments have been the number one nonsurgical procedure since 2000, according to ASAPS. The number of procedures surpassed 4.5 million annually for the first time in 2016.

### 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 for botulinum toxin treatments 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 chronic 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.

7

---

## Table of Contents

In addition to the approved therapeutic indications mentioned above, 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 musculoskeletal conditions.

We 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. Certain tasks, like getting dressed or bathing, become difficult, and a person's self-esteem may be affected by an 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 long-lasting and targeted injectable botulinum toxin.

### Hyperhidrosis

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. GIA estimates the global market for treatment of axillary hyperhidrosis with botulinum toxin to be \$98 million in 2016. 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 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%)

### Neuropsychiatric Disorders

Migraine Headache. Migraine headache is a central nervous system disorder characterized as 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 \$3.2 billion in 2015 according to a report published by Decision Resource Group. Migraine headache affects more than 38 million people in the United States, of which more than 3 million of whom suffer from chronic migraine headache. In the United States, this debilitating condition results in \$36 billion

each year in healthcare and lost productivity costs, 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. In 2017, BOTOX® sales for migraine were estimated to be more than \$550 million. 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.

## Table of Contents

**Chronic Daily Headache.** Chronic daily headache, which is defined as an idiopathic headache occurring on more than 15 days per month for at least 3 months and for a daily duration of at least 4 hours, is considered 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 that may benefit from treatment with 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.** 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.** 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.

### Chronic Inflammatory Diseases

**Rosacea.** Rosacea is a common skin condition that causes redness, dilated blood vessels and may produce small red pus-filled bumps of the face. It affects an estimated 16 million Americans, yet only a small fraction are being treated. While there is no cure for rosacea and the cause is unknown, medical therapy is available to control or reverse its signs and symptoms.

**Psoriasis.** 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 addressing inflammatory skin conditions, specifically demonstrating that botulinum toxin injections improved the clinical appearance of psoriasis.

**Eczema.** 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 6 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.

### Our Strategy

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

Key elements of our strategy are:

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

Complete RT002 Injectable Clinical Development and File for Marketing Approval in Frown Lines in the U.S. Followed by Europe. We announced positive top-line results for DaxibotulinumtoxinA for Injection (RT002) in alleviating moderate-to-severe glabellar lines in two randomized, double-blind, placebo-controlled pivotal Phase 3

9

---

## Table of Contents

trials that evaluated the safety and efficacy of a single administration of RT002 for the treatment of moderate-to-severe glabellar lines in adults. The SAKURA 1 and SAKURA 2 trials enrolled a total of 609 patients at 30 sites in the United States and Canada. We plan to complete our SAKURA Phase 3 program of RT002 injectable for the treatment of glabellar lines in the second half of 2018. In the first half of 2019, we plan to file a Biologics License Application in the United States to gain marketing approval, followed by filings in other countries.

**Advance RT002 Injectable Clinical Development for Therapeutic Indications.** We reported Phase 2 results for cervical dystonia in November 2017 and Phase 2a results for plantar fasciitis in January 2018. We plan to initiate our Phase 3 program for the treatment of cervical dystonia in the second quarter of 2018. We are evaluating future development of RT002 injectable in other indications where longer-duration, provides enhanced patient care.

**Build Our Own Sales and Marketing Capabilities To Commercialize RT002 Injectable in North America.** We have expanded our pre-commercial activities in anticipation of approval of RT002 in glabellar lines. If RT002 injectable is approved for the treatment of glabellar lines by the FDA, we intend to expand our own commercial organization 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 oculoplastic surgeons.

**Expand the Global Opportunity for Botulinum Toxin Products.** We believe RT002 injectable has the ability to expand the botulinum toxin opportunity by appealing to patients who seek a long-lasting effect. We also believe our topical product candidate and other possible dose forms can expand the overall botulinum toxin opportunity beyond the current patient base by bringing in new patients who would prefer a needle-free approach to treatment and a more tolerable procedure.

**Establish Selective Strategic Partnerships to Maximize the Commercial Potential of our Product Candidates and our Proprietary Peptide Technology.** Outside of North America, we plan to evaluate whether to commercialize our product candidates on our own or in collaboration with potential partners and distributors. Specifically, assuming regulatory approval of RT002 injectable outside of the United States, we will evaluate whether to build in-house commercial capabilities in one or more countries outside of the U.S. and Canada or to seek commercialization partners to maximize the profitability of RT002 injectable. Additionally, our proprietary peptide technology can be used for molecules other than botulinum toxin. We plan to partner or license the peptide technology opportunistically to monetize our technology platform.

**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 for Revance and for potential future partners.

### **Manufacturing and Operations**

We have established capabilities for the production of botulinum toxin type A, including bulk drug substance and injectable finished drug product. Botulinum toxin is regulated as a Select Agent under authority of the Centers for Disease Control and Prevention, 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 bulk drug substance 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. In March 2017, Revance entered into a Technology Transfer, Validation and Commercial Fill/Finish Services Agreement with Ajinomoto Althea, Inc., a contract development and manufacturing organization, to provide us with expanded capacity and a second source for drug product manufacturing to support a global launch of DaxibotulinumtoxinA for Injection (RT002). The Services Agreement also mitigates supply chain risk by giving us a different manufacturing location and reduces future capital and operating expenditures required in our primary manufacturing facility by outsourcing to an experienced partner.

We manufacture and perform testing for both bulk drug substance and finished dosage forms of drug product to support our RT002 injectable candidate. The additional components required for our product lines and the peptide for



RT002 injectable are manufactured by third parties under contract with us. See the section entitled “Outsourced Components” below for additional information.

10

---

## Table of Contents

### Drug Substance

Manufacture of the drug substance for 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 the RT002 injectable and topical development programs is currently performed at our fill-finish facility. The manufacturing process consists of bulk compounding, liquid fill and freeze-drying to support acceptable shelf-life duration. We plan to perform further scale-up of RT002 injectable drug product manufacturing to meet anticipated commercial demand and may utilize internal capacity, a third-party manufacturer such as Ajinomoto Althea, or a combination of both.

### Outsourced Components

We contract with third parties for the manufacture of our botulinum toxin and the additional components required for our products, which includes the manufacture of bulk peptide.

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. 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 2020 and may be terminated earlier by either party following advance notice or a material breach by either party.

American Peptide was acquired by Bachem.

Our agreement with Ajinomoto Althea includes manufacture and supply of drug product 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 drug product. Our agreement with Ajinomoto Althea will remain in effect for seven years 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 product quality and price, product technology, reputation, customer service and access to technical information. 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.



## Table of Contents

Upon marketing approval, the first expected uses of our products will be to treat glabellar lines, cervical dystonia and plantar fasciitis, followed by potential use to treat other aesthetic and therapeutic conditions. The technologies with which we expect to compete directly are injectable and topical neuromodulators.

### Injectable and Topical Neuromodulators

Our primary competitors for RT002 in the pharmaceutical market are expected to be 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, forehead lines, crow's feet, axillary hyperhidrosis, upper and lower limb spasticity, cervical dystonia, strabismus, blepharospasm, chronic migraine, incontinence, and overactive bladder. Allergan is a leading global pharmaceutical company with significant research, discovery, and delivery capabilities.

Dysport®, an injectable botulinum toxin for the treatment of cervical dystonia, glabellar lines and upper and lower limb spasticity, is marketed by Ipsen Ltd., or Ipsen, and Galderma, a Nestle company. Galderma has rights to market the product in the United States and Canada. Dysport® was approved by the FDA in 2009. Ipsen received marketing authorization for a cosmetic indication for Dysport® in Germany. Ipsen granted Galderma an exclusive 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. Galderma is Ipsen's sole distributor for Dysport® in Brazil, Argentina and Paraguay. The health authorities of 15 European Union countries have also approved Dysport® for glabellar lines under the trade name Azzalure®. Ipsen and Syntaxin are engaged in a research collaboration agreement to develop native and engineered formats of botulinum toxin.

Myobloc®, a neuromodulator currently marketed by US WorldMeds and approved by the FDA in 2000 for the treatment of cervical dystonia.

Xeomin®, an injectable botulinum toxin for the treatment of cervical dystonia, glabellar lines, blepharospasm, and upper limb spasticity, is marketed by Merz Pharma, or Merz. Xeomin is approved by the FDA for cervical dystonia and blepharospasm in adults, glabellar lines, and the treatment of upper limb spasticity. Xeomin® is also currently approved for glabellar lines in Korea, Argentina and Mexico, and 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, has approval for glabellar lines in Germany and the European Union.

We are aware of competing botulinum toxins currently being developed or commercialized in the U.S., Asia, South America and other markets. Some of these markets may or 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 some of these products may not meet 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 botulinum toxins for cosmetic and therapeutics indications and are conducting clinical trials for acne and facial aesthetic and hyperhidrosis.

### Aesthetic Medicine

Professional facial aesthetic medicine includes neuromodulators and dermal fillers, as well as polymer-based injectables. These and other products experience 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™. The FDA has 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. Allergan also has FDA approval for Juvéderm Volbella® XC, created specifically for lips for and longer-lasting results. Galderma has FDA approval for Restylane Refyne for the treatment of moderate to severe facial wrinkles and folds, and Restylane Defyne for the treatment of moderate to severe, deep facial wrinkles and folds. Additional competitors in the filler category include Radiesse®, a calcium hydroxylapatite from BioForm, acquired by

Merz, 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

## Table of Contents

dermal fillers. All new generation fillers now last at least 6 months. We believe a neuromodulator with a six month duration would allow physicians to coordinate treatments with 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 RT002 injectable for treatment of glabellar lines by the FDA, we plan to launch in North America with our own commercial organization. Specifically, we would access the North American market by hiring 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 RT002 injectable on these core specialties.

### Strategic Partnering

We plan to focus our efforts on developing and commercializing 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.

We also plan to leverage our proprietary peptide technology outside of our core focus in botulinum toxin by partnering with other companies.

### 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 using 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 or develop, 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, or any of our pending patent applications, may provide us with little or no competitive advantage, in which case we may abandon such patent, or patent applications, or license them to another entity. For more information, please see “Item 1A. Risk Factors — Risks Related to our Intellectual Property.”

On June 2, 2016, we entered into the Asset Purchase Agreement, or the Purchase Agreement, with Botulinum Toxin Research Associates, Inc., or BTRX. Under the Purchase Agreement, we acquired all rights, title and interest in a portfolio of botulinum toxin-related patents and patent applications from BTRX and were granted the right of first negotiation and of right of first refusal with respect to other botulinum toxin-related patents owned or controlled by BTRX.

As of February 6, 2018, we held approximately 298 issued patents and approximately 95 pending patent applications, including foreign counterparts of U.S. patents and applications. Thirty-one 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 December 10, 2019 for U. S. Patent No. 6,429,189.

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

## Table of Contents

Our registered and pending U.S. trademarks include REVANCE®, TransMTS®, MOTISTE®, "Remarkable Science Changes Everything®", MEYESMILE, Relastin®, "Remarkable Science. Enduring Performance®", and R Logo.

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, RT002 injectable and our topical product candidate, 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 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, potency, quality and purity, as well as compliance with applicable Quality System Regulations, or QSR, for devices;

• potential inspections 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.





## Table of Contents

### 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.

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. 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

## Table of Contents

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, potency, 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 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 during review. 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 submitted 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 supplement. 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 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.

## Table of Contents

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. 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

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.

### 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.

Table of Contents

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 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.

## Table of Contents

### 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. 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 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 \$80.4 million, \$50.4 million, and \$47.5 million during the years ended December 31, 2017, 2016, and 2015, respectively. We plan to increase our research and development expenses for the foreseeable future 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 cervical dystonia and plantar fasciitis.

### Employees

As of December 31, 2017, we had 134 employees. Of these employees, 102 employees were engaged in research and development and 32 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 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, proxy statements, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. You may obtain copies of these reports after the date of this Annual Report directly from us or from the SEC at the SEC's Public Reference Room at 100 F Street, N.E. Washington, D.C. 20549. In addition, the SEC maintains information for electronic filers (including Revance) at its website at [www.sec.gov](http://www.sec.gov). The public may obtain information regarding the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We make available on our website at [www.revance.com](http://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 \$1.07 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.



Table of Contents

20

---

Table of Contents

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 injectable product candidate RT002 injectable.

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

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

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

In 2015, we initiated a Phase 2 dose-escalating, open-label clinical study of RT002 injectable for the treatment of cervical dystonia. The Phase 2 study evaluated the safety, preliminary efficacy, and duration of effect of RT002 injectable in subjects with moderate to severe isolated cervical dystonia. The trial was designed to enroll 37 subjects following three sequential treatment cohorts for up to a total of 24 weeks after treatment for each cohort. The trial’s first cohort of 12 subjects received a single dose of up to 200 units of RT002 injectable, the second cohort of 12 subjects received between 200 and 300 units, and the third cohort of 13 subjects received from 300 to 450 units. In May 2017, we announced positive topline results from the Phase 2 trial. Past results may not be indicative of results from future trials. In November 2017, we completed our End-of-Phase 2 meeting with the FDA and received Scientific Advice from the EMA regarding RT002 for the treatment of cervical dystonia. Based on the Phase 2 safety and efficacy results and guidance from the FDA and EMA, we plan to proceed with a Phase 3 program for cervical dystonia in 2018. In November 2017, the FDA also granted orphan drug status to DaxibotulinumtoxinA for Injection for the treatment of cervical dystonia in adults.

In 2016, we also initiated a Phase 2 prospective, randomized, double-blinded, placebo-controlled trial of RT002 injectable in the therapeutic indication of plantar fasciitis. This study will evaluate the safety and efficacy of a single administration of RT002 injectable in reducing the signs and symptoms of plantar fasciitis. The study completed enrollment of 59 subjects in the United States in October 2017. The study's primary efficacy endpoint is the improvement in the American Orthopedic Foot and Ankle Score (AOFAS). In January 2018, we announced interim 8-week results from this study. The Company plans to complete the 16-week trial and then expects to conduct another Phase 2 trial with a modified design to demonstrate the ability of RT002 to treat plantar fasciitis in the second half of 2018.

Table of Contents

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

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

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of RT002 injectable, our topical product candidate, or any future product candidate to continue our business.

Table of Contents

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

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

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

Our business currently depends substantially on the successful development, regulatory approval and commercialization of our product candidates. Based on discussion with the FDA at a Pre-Phase 3 meeting in the second quarter of 2016 and the minutes received following the meeting, we submitted an IND in the United States and initiated subject dosing in Phase 3 clinical studies of RT002 injectable for the treatment of glabellar lines in 2016. In the first quarter of 2017, we completed patient enrollment in the two pivotal trials of our SAKURA Phase 3 program and in October 2017, we completed enrollment of SAKURA 3. In December 2017, we announced positive top-line results from the two pivotal trials. We plan to move forward with studies required for submission of a BLA. Such studies may increase the time, expense and uncertainty of our RT002 injectable development program, including, for example, because results of such studies may indicate to us a further need to refine the RT002 injectable product candidate.

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

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

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



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

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

Table of Contents

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

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

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

Since our inception, most of our resources have been dedicated to the research and preclinical and clinical development of our botulinum toxin product candidates, RT002 injectable and topical. In particular, our clinical programs for RT002 injectable and topical will require substantial additional funds to complete. We had an accumulated deficit through December 31, 2017 of \$542.2 million and a working capital surplus of \$264.3 million as of December 31, 2017, primarily as a result of our November 2015 and December 2017 follow-on public offerings, and at-the-market, or ATM, offerings in 2015 and 2017. Our recorded net losses were \$120.6 million, \$89.3 million and \$73.5 million, for the years ended December 31, 2017, 2016, and 2015, respectively. We have funded our operations primarily through the sale and issuance of convertible preferred stock, common stock, notes payable and convertible notes. As of December 31, 2017, we had capital resources consisting of cash and cash equivalents of \$282.9 million. We raised aggregate net proceeds of \$126.2 million and \$156.9 million in our follow-on public offerings in November 2015 and December 2017, respectively. In addition, we raised net proceeds of approximately \$10.0 million by selling an aggregate of 352,544 shares of our common stock under the 2015 ATM agreement, which was effectively terminated on March 7, 2016. On March 7, 2016, we entered into the 2016 ATM Agreement with Cowen, under which we may offer and sell shares of our common stock having aggregate gross proceeds of up to \$75 million through Cowen as our sales agent. In 2017, we sold 1,802,651 shares of our common stock under the 2016 ATM Agreement at a weighted average price of \$22.17 per share resulting in net proceeds of \$38.2 million, after underwriting discounts, commissions and other offering expenses. In December 2017, we sold 5,389,515 shares of common stock in a follow-on offering at a price of \$31.00 per share resulting in net proceeds of \$156.9 million, after underwriting discounts, commissions and other offering expenses. We believe that we will continue to expend substantial resources for the foreseeable future for the clinical development of RT002 injectable, topical, and development of any other indications and product candidates that we may choose to pursue. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, and manufacturing and supply as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of RT002 injectable and any future product candidates.

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

Our future capital requirements depend on many factors, including:

- the results of our clinical trials for RT002 injectable and preclinical trials of our topical product candidate or any future product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for RT002 injectable, or any future product candidates including topical;
- the number and characteristics of any additional product candidates we develop or acquire;

24

---

Table of Contents

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

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

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

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

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

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

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

affected.

25

---

## Table of Contents

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

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

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

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

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

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

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

Currently, we maintain insurance coverage totaling \$23.0 million against damage to our property, equipment and tenant improvements, \$2.0 million in general liability coverage, a \$9.0 million umbrella policy, and an additional \$45.0 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.

Table of Contents

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

We constructed a fill/finish line dedicated to the manufacture of topical and to support our regulatory license applications. We discontinued further clinical development of topical for the treatment of crow's feet and for the treatment of primary axillary hyperhidrosis in June 2016, following the results from our REALISE 1 Phase 3 clinical trial. During the year ended December 31, 2016 we recorded a loss on impairment of \$9.1 million related to certain components of the topical fill/finish line and other long-lived assets. During the year ended December 31, 2017, the Company assessed the topical fill/finish line and these other long-lived assets for impairment indicators and recorded a loss on impairment of \$2.9 million. As of December 31, 2017, the fill/finish line and these other long-lived assets had net book values of \$2.4 million and \$0.1 million, respectively. Under generally accepted accounting principles in the United States, long-lived assets, such as our fill/finish line, are required to be reviewed for impairment whenever adverse events or changes in circumstances indicate a possible impairment. If business conditions or other factors indicate that the carrying value of the asset may not be recoverable, we may be required to record additional non-cash impairment charges. Additionally, if the carrying value of our capital equipment exceeds current fair value as determined based on the discounted future cash flows of the related product, the capital equipment would be considered impaired and would be reduced to fair value by a non-cash charge to earnings, which could negatively affect our operating results. Events and conditions that could result in impairment in the value of our long-lived assets include adverse clinical trial results, changes in operating plans, unfavorable changes in competitive landscape, adverse changes in the regulatory environment, or other factors leading to reduction in expected long-term sales or profitability. We will evaluate the recoverability and fair value of our long-lived assets, including those related to other components of the fill/finish line, each reporting period to determine the extent to which further non-cash charges to earnings are appropriate. Additional impairment in the value of our long-lived assets may materially and negatively impact our operating results.

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

We are a clinical-stage biotechnology company. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We are not profitable and have incurred losses in each year since we commenced operations in 2002. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry. To date, we have not obtained any regulatory approvals for any of our product candidates or generated any revenue from product sales relating to RT002 injectable or our topical product candidate. We continue to incur significant research and development and other expenses related to our ongoing clinical trials and operations. We had an accumulated deficit through December 31, 2017 of \$542.2 million and a working capital surplus of \$264.3 million as of December 31, 2017, primarily as a result of our November 2015 follow-on public offerings, and sales under our 2015 ATM Agreement and 2016 ATM Agreement. Our recorded net losses were \$120.6 million, \$89.3 million and \$73.5 million, for the year ended December 31, 2017, 2016, and 2015, respectively. The net proceeds from the sale of the shares in our November 2015 and December 2017 follow-on public offerings and ATM offerings in 2015 and 2017, after deducting the underwriters' discount, commissions, and other offering expenses related to the respective offerings, were approximately \$126.2 million and \$156.9 million, \$10.0 million and \$38.2 million, respectively. Our capital requirements to implement our business strategy are substantial, including our capital requirements to develop and commercialize RT002 injectable. We believe that our currently available capital is sufficient to fund our operations through at least the next 12 months following the filing of this Form 10-K.

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



stock and our ability to raise capital and continue operations.

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

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

The degree and rate of market acceptance of RT002 injectable, topical, 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;

Table of Contents

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

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

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain.

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

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

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

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

manufacture sufficient quantities of product candidate for use in clinical trials.

Subject enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of

Table of Contents

the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

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

If we experience delays in the completion or termination of any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. We have no experience manufacturing our product candidates at full commercial scale. If our product candidates are approved, we will face certain risks associated with scaling up our manufacturing capabilities to support commercial production.

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

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

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



Table of Contents

Reliance on third-party manufacturers entails additional risks, including the reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party, and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third-party manufacturers may not be able to comply with cGMP or Quality System Regulation, or QSR, or similar regulatory requirements outside the United States. Our failure or the failure of our third-party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of RT002 injectable, or any other product candidates or products that we may develop. Any failure or refusal to supply the components or services for RT002 injectable or any other product candidates or products that we may develop could delay, prevent or impair our clinical development or commercialization efforts.

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

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

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

We currently have limited marketing 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 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 RT002 injectable or any other future product candidates, if approved, in the United States, Europe and other jurisdictions we seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If RT002 injectable receives regulatory approval, we expect to market RT002 injectable as applicable, through our own sales force in North America, and in Europe and other countries through either our own sales force or a combination of our internal sales force and distributors or partners, which may be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified

individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize RT002 injectable or any future product candidates. If we are not successful in commercializing RT002 injectable or any future product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

Table of Contents

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, 2017, we had 134 employees. We will need to continue to expand our managerial, operational, and other resources to manage our operations and clinical trials, continue our development activities and commercialize RT002 injectable or any other product candidates, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

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

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

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

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

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

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



Table of Contents

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

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

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

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

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

FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA prohibitions on the sale or marketing of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry.

Table of Contents

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

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

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

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

- the success of any sales and marketing programs that we, or any third parties we engage, undertake, and as to which we have limited experience;

- the extent to which physicians recommend RT002 injectable to their patients;

- the extent to which RT002 injectable satisfies patient expectations;

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

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

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

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

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

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

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

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

We expect that private insurers will consider the efficacy, cost effectiveness and safety of RT002 injectable in determining whether to approve reimbursement for RT002 injectable and at what level. 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 RT002 injectable from private insurers on a timely or satisfactory basis. Our business could also be adversely affected if private insurers, including managed care organizations, the Medicare program or other reimbursing bodies or payors limit the indications for which RT002 injectable will be reimbursed to a smaller patient set than we believe they are effective in treating.

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

scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

33

---

Table of Contents

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

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

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

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

We have been, and in the future may be, subject to securities class action and 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. The Court granted final approval of the Settlement, as set forth in the Stipulation of Settlement, on July 28, 2017. While the litigation has ended, we may be subject to future securities class action and shareholder derivation actions, which may adversely impact our business, results of operations, financial position or cash flows and divert management's time and attention from the business.

## Table of Contents

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We believe that our future success is highly dependent upon the contributions of our senior management, particularly L. Daniel Browne, our President and Chief Executive Officer, Abhay Joshi, Ph.D., our Chief Operating Officer, Lauren P. Silvernail, our Chief Financial Officer and Chief Business Officer, and Todd Zavodnick, our Chief Commercial Officer and President, Aesthetics and Therapeutics, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, the completion of our planned clinical trials or the commercialization of RT002 injectable, topical, or any future products we develop.

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

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 previous research output.

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

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

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
-

a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable; and  
• intellectual property rights of third parties may potentially block our entry into certain markets or make such entry economically impracticable.

Table of Contents

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

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

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

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

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

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



damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

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

## Table of Contents

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

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

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

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

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

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

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

On December 22, 2017, new legislation that significantly revises the Internal Revenue Code of 1986, as amended, was signed into law. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%,

limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Table of Contents

Risks Related to Our Intellectual Property

If our efforts to protect our intellectual property related to RT002 injectable, or any future product candidates, including topical, 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 RT002 injectable, topical, and our development programs. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thereby eroding our competitive position in our market.

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

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

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

United States resulting from the Leahy-Smith America Invents Act signed into law on September 16, 2011. Among some of the other changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring

Table of Contents

to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and some of our competitors have substantially greater intellectual property portfolios and financial resources than we have.

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

If we infringe or are alleged to infringe intellectual property rights of third parties, our business could be harmed. Our research, development and commercialization activities may infringe or otherwise violate or be claimed to infringe or otherwise violate patents owned or controlled by other parties. Competitors in the field of cosmetics, pharmaceuticals and botulinum toxin have developed large portfolios of patents and patent applications in fields relating to our business. For example, there are patents held by third parties that relate to the treatment with botulinum toxin-based products for indications we are currently developing. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us. These third parties could bring claims against us that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product based on our current or future indications, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

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

Table of Contents

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

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

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

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

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

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

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

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

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





## Table of Contents

### 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 FFDCFA, the Public Health Service Act, or PHSA, and Controlled Substances Act, may subject us to operating restrictions and criminal prosecution, monetary penalties and other disciplinary actions, including, sanctions, warning letters, product seizures, recalls, fines, injunctions, suspension, revocation of approvals, or exclusion from future participation in the Medicare and Medicaid programs.

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

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

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug and biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. Neither we nor any collaboration partner are permitted to market RT002 injectable or any future product candidates in the United States until we receive approval of a BLA from the FDA. We have not submitted an application or obtained marketing approval for RT002 injectable anywhere in the world. After we submit a BLA for RT002 injectable, the FDA may refuse to file the application if it determines that the application is not sufficiently complete to permit substantive review. Even if filed by FDA, our BLA may receive a Complete Response Letter identifying deficiencies that must be addressed, rather than an approval. Obtaining regulatory approval of a BLA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

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

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

Regulatory approval of a BLA or BLA supplement is not guaranteed, and the approval process is expensive and may take several years. The FDA also has substantial discretion in the approval process. Despite the time and expense expended, failure can occur at any stage, and we could encounter problems that cause us to abandon or repeat clinical trials, or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials

that will be required for FDA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. The FDA can delay, limit or deny approval of a product candidate for many reasons, including the following:

41

---

Table of Contents

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

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

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

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

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;

- fines, warning letters or holds on clinical trials;

- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us or our strategic collaborators, or suspension or revocation of product license approvals;

- product seizure or detention, or refusal to permit the import or export of products;

- and

- injunctions or the imposition of civil or criminal penalties.

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

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

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing manufacturing, clinical trials, commercial sales and distribution of our future products. Whether or not we obtain FDA approval for a product candidate, we must obtain approval of the product by the comparable regulatory authorities of foreign countries before commencing clinical trials or marketing in those countries. The approval procedures vary

among countries and can involve additional clinical testing, or the time required to obtain approval may differ from that required to obtain FDA approval. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory

Table of Contents

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.

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

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

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

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

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

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents.

Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a

negative impact on our business, results of operations and reputation.

43

---

## Table of Contents

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

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

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

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

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

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

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

• expiration or termination of our potential relationships with customers and strategic partners; and  
• other factors described in this “Risk Factors” section.



## Table of Contents

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

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

As a smaller company, it may be difficult for us to attract or retain the interest of equity research analysts. A lack of research coverage may adversely affect the liquidity and market price of our common stock. We will not have any control of the equity research analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company, or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. On March 7, 2016, we entered into an ATM agreement, or the 2016 ATM Agreement, with Cowen, under which we may offer and sell shares of our common stock having aggregate gross proceeds of up to \$75.0 million through Cowen as our sales agent. In 2017, we sold 1,802,651 shares of our common stock under the 2016 ATM Agreement at a weighted average price of \$22.17 per share resulting in net proceeds of \$38.2 million, after underwriting discounts, commissions and other offering expenses. In December 2017, we sold 5,389,515 shares of the Company's common stock pursuant to the Company's effective shelf registration statement on

Form S-3ASR (Registration No. 333-221911), at a price to the public of \$31.00 per share, resulting in net proceeds to the Company of \$156.9 million, after underwriting discounts, commissions and other offering expenses.

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

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

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

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

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

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

45

---

Table of Contents

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

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

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

As of December 31, 2017, our directors, executive officers and each of our stockholders who own greater than 5% of our outstanding common stock and their affiliates, in the aggregate, beneficially owned approximately 62.4% of our common stock. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may have interests that differ from yours and may vote in a way with which you disagree and that may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might affect the market price of our common stock.

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

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

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

We will indemnify our directors and officers for serving us in those capacities, or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.

We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.

We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.

We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.

The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

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

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

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



Table of Contents

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

We are an “emerging growth company,” as defined in the JOBS Act and, for as long as we continue to be an “emerging growth company,” we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to “emerging growth companies,” including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will remain an “emerging growth company” until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenues of over \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

Table of Contents

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

48

---

Table of Contents

ITEM 2. PROPERTIES

Our headquarters is located in Newark, California, where we occupy approximately 90,000 square feet of office, laboratory and manufacturing space. The current term of our lease expires in January 2025. We have an option to extend the lease for two additional terms of seven years, which would extend our lease through January 2039. We believe that our current facilities are adequate for our needs and for the immediate future and that, should it be needed, additional space can be leased to accommodate any future growth.

49

---

Table of Contents

ITEM 3. LEGAL PROCEEDINGS

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business. From May 2015 until July 2017, the Company and certain of its directors and executive officers were subject to a securities class action complaint, pending in the Superior Court for the County of Santa Clara, captioned City of Warren Police and Fire Retirement System v. Revance Therapeutics Inc., et al., Case No. 15-CV-287794 (previously assigned Case No. CIV 533635 prior to transfer from San Mateo Superior Court). On October 31, 2016, the parties executed a stipulation of settlement (the "Stipulation"), pursuant to which, in exchange for a release of all claims by the plaintiff class, the Company agreed to settle the litigation for \$6.4 million in cash, of which \$5.9 million was covered by its insurance policies. The Stipulation maintained that the defendants, including the Company, deny all wrongdoing and liability related to the litigation. On July 28, 2017, the Court granted final approval of the Settlement, as set forth in the Stipulation, and entered a Judgment dismissing the action with prejudice, thereby ending the litigation. This litigation did not have a material adverse effect on our business, results of operations, financial position or cash flows.

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



Table of Contents

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

51

---

Table of Contents

## PART II

## ITEM 5 MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock has been trading on The Nasdaq Global Market under the symbol "RVNC" since our IPO on February 6, 2014. Prior to this date, there was no public market for our common stock. On February 23, 2018, the closing price of our common stock as reported on the Nasdaq Global Market was \$30.50 per share. The following table sets forth the high and low sales prices per share of our common stock on the Nasdaq Global Market for the quarterly periods indicated.

	High	Low
2017		
First Quarter	\$24.30	\$18.00
Second Quarter	\$28.30	\$18.42
Third Quarter	\$28.70	\$22.05
Fourth Quarter	\$37.20	\$24.50

2016		
First Quarter	\$34.55	\$15.63
Second Quarter	\$20.95	\$12.62
Third Quarter	\$17.94	\$12.54
Fourth Quarter	\$21.85	\$12.35

## Holders of Record

As of February 23, 2018, there were approximately 30 holders of record of our common stock.

## Dividend Policy

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will be dependent on a number of factors, including our earnings, capital requirements, overall financial conditions, business prospects, contractual restrictions and other factors our board of directors may deem relevant.

Table of Contents

## Stock Price Performance Graph

This performance graph shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our filings under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

This graph compares, for the period ended December 31, 2017, the cumulative total return on our common stock, the Nasdaq Biotechnology Index (NBI) and the Nasdaq Composite Index (CCMP). The graph assumes \$100 was invested on February 6, 2014, in our common stock, the NBI and CCMP, and assumes the reinvestment of any dividends. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

Company/Index	2/6/2014	3/31/2014	6/30/2014	9/30/2014	12/31/2014	3/31/2015	6/30/2015	9/30/2015	12/31/2015
Revance Therapeutics, Inc.	\$100.00	\$196.88	\$212.50	\$120.81	\$105.88	\$129.56	\$199.88	\$186.00	\$213.50
Nasdaq Biotechnology Index	\$100.00	\$99.80	\$108.67	\$115.72	\$128.67	\$145.74	\$156.71	\$128.61	\$143.81
Nasdaq Composite Index	\$100.00	\$103.67	\$109.18	\$111.62	\$117.98	\$122.45	\$124.94	\$116.08	\$126.20

Company/Index	3/31/2016	6/30/2016	9/30/2016	12/31/2016	3/31/2017	6/30/2017	9/30/2017	12/31/2017
Revance Therapeutics, Inc.	\$109.13	\$85.00	\$101.31	\$129.38	\$130.00	\$165.00	\$172.19	\$223.44
Nasdaq Biotechnology Index	\$110.90	\$109.66	\$123.36	\$113.11	\$125.37	\$132.73	\$143.00	\$137.58
Nasdaq Composite Index	\$123.13	\$122.84	\$135.15	\$137.39	\$151.30	\$157.60	\$167.16	\$178.11

## Recent Sales of Unregistered Securities

On December 26, 2017, Essex Capital Corporation net exercised warrants to purchase 7,482 shares into 490 shares of common stock at an exercise price of \$31.50.

Table of Contents

On July 12, 2017, Essex Capital Corporation net exercised warrants to purchase 20,000 shares into 9,388 shares of common stock at an exercise price of \$14.40.

The issuance of the security described in the above paragraphs were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipient of the security acquired it for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the security. The recipient of the security was an accredited or sophisticated person and had adequate access, through employment, business or other relationships, to information about us.

#### Issuer Purchases of Equity Securities

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

Period	Total Number of Shares Purchased (i)	Weighted-Average Price Paid per Share (ii)	Total Number of Share Purchased as Part of Publicly Announced Plan or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plan or Programs (in thousands)
October 1 through October 31, 2017	366	\$ 26.53	—	—
November 1 through November 30, 2017	1,175	25.02	—	—
December 1 through December 31, 2017	3,229	32.15	—	—
Total	4,770	\$ 29.94	—	\$ —

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

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

Table of Contents

## ITEM 6. SELECTED FINANCIAL DATA

The information set forth below for the five years ended December 31, 2017 is not necessarily indicative of results of future operations, and should be read in conjunction with Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, and the Consolidated Financial Statements and related notes thereto included in Item 8, Consolidated Financial Statements and Supplementary Data, of this Form 10-K to fully understand the factors that may affect the comparability of the information presented below.

## SELECTED CONSOLIDATED FINANCIAL DATA

(In thousands, except share and per share data)

	Year Ended December 31,				
	2017	2016	2015	2014	2013
Consolidated Statements of Operations Data:					
Revenue	\$262	\$300	\$300	\$383	\$617
Total operating expenses	\$120,686	\$88,515	\$72,617	\$52,433	\$38,842
Loss from operations	\$(120,424)	\$(88,215)	\$(72,317)	\$(52,050)	\$(38,225)
Interest expense	\$(457)	\$(1,082)	\$(1,190)	\$(10,672)	\$(15,164)
Net loss	\$(120,587)	\$(89,270)	\$(73,476)	\$(62,917)	\$(52,448)
Net income (loss) attributable to common stockholders:					
Basic <sup>(1)</sup>	\$(120,587)	\$(89,270)	\$(73,476)	\$(62,917)	\$258
Diluted <sup>(1)</sup>	\$(120,587)	\$(89,270)	\$(73,476)	\$(62,917)	\$1,083
Net income (loss) per share attributable to common stockholders:					
Basic <sup>(1)</sup>	\$(4.01)	\$(3.18)	\$(3.02)	\$(3.24)	\$1.17
Diluted <sup>(1)</sup>	\$(4.01)	\$(3.18)	\$(3.02)	\$(3.24)	\$1.05
Weighted-average number of shares used in computing net income (loss) per share attributable to common stockholders:					
Basic <sup>(1)</sup>	30,101,125	28,114,784	24,340,466	19,391,523	220,220
Diluted <sup>(1)</sup>	30,101,125	28,114,784	24,340,466	19,391,523	1,029,150

(1) For all periods presented these amounts reflect the one-for-fifteen reverse stock split effected on February 3, 2014.

	As of December 31,				
	2017	2016	2015	2014	2013
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$282,896	\$63,502	\$201,615	\$171,032	\$3,914
Investments	\$—	\$122,026	\$52,439	\$—	\$—
Working capital surplus (deficit)	\$264,309	\$173,048	\$241,926	\$162,495	\$(42,747)
Total assets	\$295,699	\$204,360	\$275,822	\$192,469	\$22,645
Note payable, net of current portion	\$—	\$—	\$—	\$—	\$2,632
Financing obligation, net of current portion	\$—	\$1,872	\$5,346	\$598	\$—
Convertible preferred stock	\$—	\$—	\$—	\$—	\$123,982
Accumulated deficit	\$(542,167)	\$(421,543)	\$(332,273)	\$(258,797)	\$(195,880)

Table of Contents

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is intended to help the reader understand our results of operations and financial condition. MD&A is provided as a supplement to, and should be read in conjunction with, our audited Consolidated Financial Statements and the accompanying notes to the Consolidated Financial Statements and other disclosures included in this Annual Report on this Form 10-K (including the disclosures under "Item 1A. Risk Factors"). Our Consolidated Financial Statements have been prepared in accordance with U.S. generally accepted accounting principles and are presented in U.S. dollars.

Overview

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

DaxibotulinumtoxinA for Injection (RT002 or RT002 Injectable)

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

Glabellar Lines

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

We are in Phase 3 clinical development for RT002 injectable for the treatment of glabellar lines. During the fourth quarter of 2016, we initiated subject dosing in our SAKURA Phase 3 program. In December 2017, we announced top-line results for the SAKURA 1 and SAKURA 2 pivotal trials:

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

**Secondary Duration Endpoints.** There were several secondary endpoints used to evaluate duration of effect, including the proportion of patients achieving none or mild response on IGA-FWS compared to placebo, median duration for

time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS, and median duration for time to return to baseline on both IGA-

56

---

## Table of Contents

FWS and PFWS. The percentage of RT002-treated patients who achieved a none or mild response on IGA-FWS was 35.3 percent in SAKURA 1 and 29.4 percent at SAKURA 2 compared to placebo ( $p < 0.0001$ ) at Week 24. The median duration for time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS for RT002-treated patients was 24.0 weeks for SAKURA 1 and 23.9 weeks for SAKURA 2. The median duration for time to return to baseline wrinkle severity on both IGA-FWS and PFWS for RT002-treated patients was 27.7 weeks for SAKURA 1 and 26.0 weeks for SAKURA 2. For comparison, an additional exploratory duration endpoint was evaluated, which mirrors the duration measure used in the BELMONT Phase 2 study. This endpoint, was the median duration of greater or equal to 1 point improvement from baseline on IGA-FWS for RT002-treated patients, and the results were 24.1 weeks for both SAKURA 1 and SAKURA 2, and 23.6 weeks for BELMONT.

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

In October 2015, we reported results from BELMONT, a Phase 2 active comparator, placebo-controlled clinical trial for the treatment of glabellar lines against the market leader BOTOX® Cosmetic. The 24-week data, which we reported in October 2015, 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, 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.

### Cervical Dystonia

We have also been developing RT002 for the treatment of cervical dystonia, a muscle movement disorder. Muscle movement disorders, such as cervical dystonia, are neurological conditions that affect a person's ability to control muscle activity in one or more areas of the body. In 2015, we initiated a Phase 2 dose-escalating, open-label clinical study of RT002 injectable for the treatment of cervical dystonia. The Phase 2 study evaluated the safety, preliminary efficacy, and duration of effect of RT002 injectable in subjects with moderate to severe isolated cervical dystonia. The trial enrolled 37 subjects and followed three sequential treatment cohorts for up to a total of 24 weeks after treatment for each cohort. The trial's first cohort of 12 subjects received a single dose of up to 200 units of RT002 injectable, the second cohort of 12 subjects received between 200 and 300 units, and the third cohort of 13 subjects received from 300 to 450 units.

In May 2017, we announced positive 24 week topline results in all three cohorts from the Phase 2 trial. The topline data demonstrated a median duration of at least 24 weeks for each of all three cohorts. Duration of effect was defined as the number of weeks from treatment until the return of signs and symptoms that warrant retreatment, based on subjects reaching their target Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) score. The topline data also displayed clinically significant impact on cervical dystonia signs and symptoms. At Week 4, RT002 injectable showed a clinically significant mean reduction of 38% from baseline across all three cohorts. This reduction continued to increase to 50% at Week 6 for all subjects, was 42% at Week 12 and was maintained at or above 30% through Week 24. The topline data also showed that RT002 injectable appeared to be generally safe and well-tolerated through Week 24 in all three cohorts. There were no serious adverse events and no dose-dependent increase in adverse events. The treatment-related adverse events were generally transient and mild to moderate in severity, with one case of neck



pain reported as severe. The most common adverse events were dysphagia, or difficulty in swallowing (14%), of which all cases were mild in severity, injection site redness (8%), injection site bruising (5%), injection site pain (5%), muscle tightness (5%) and muscle weakness (5%).

In November 2017, we completed our End-of-Phase 2 meeting with the FDA and received Scientific Advice from the EMA regarding RT002 for the treatment of cervical dystonia. Based on the Phase 2 safety and efficacy results and guidance from the FDA and EMA, we plan to initiate our Phase 3 program for cervical dystonia in the second quarter of 2018. In November 2017, the FDA also granted orphan drug status to DaxibotulinumtoxinA for Injection for the treatment of cervical dystonia in adults.

Table of Contents

## Plantar Fasciitis

We are also developing RT002 for the treatment of plantar fasciitis. Plantar fasciitis is a painful affliction caused by inflammation of the ligament running along the bottom of the foot and is the most common cause of heel pain for patients who visit podiatrists and orthopedic foot and ankle surgeons. In 2016, we initiated a Phase 2 prospective, randomized, double-blinded, placebo-controlled trial of RT002 injectable in the therapeutic indication of plantar fasciitis. This study is evaluating the safety and efficacy of a single administration of RT002 injectable in reducing the signs and symptoms of plantar fasciitis. In April 2017, we expanded our plantar fasciitis Phase 2 program from a single-site study to a multi-center study with protocol updates. The primary efficacy endpoint is the reduction in the visual analog scale (VAS) for pain in the foot at eight weeks and subjects will be followed for 16 weeks following treatment. In October 2017, we completed patient enrollment. In January 2018, we announced the interim 8-week Phase 2a results for the plantar fasciitis trial. The trial's primary endpoint, the reduction in the patient-reported visual analog scale (VAS) for pain at Week 8, showed a robust impact on pain, with a greater than 50% reduction for patients treated with RT002. In the intent-to-treat population, a mean reduction in the VAS score of 54.2% from baseline was achieved with RT002, compared with a 42.6% reduction in the placebo group, which upon further subgroup analysis, was driven primarily by a strong placebo response in the control group at three of the five study sites. While the results are not statistically significant ( $p=0.39$ ), RT002 provided patients with considerable pain relief. Similar numeric trends were seen in the secondary and exploratory endpoints. RT002 appeared to be generally safe and well-tolerated through Week 8. The majority of adverse events in both treatment groups were mild in severity. There were no treatment-related serious adverse events. The most common treatment-related adverse events for RT002 and placebo were injection site pain (10.0 percent and 10.3 percent) and muscle weakness (3.3 percent and 3.4 percent), both respectively, all of which were classified as mild in severity. The Company plans to complete the 16-week trial and then expects to conduct another Phase 2 trial with a modified design to demonstrate the ability of RT002 to treat plantar fasciitis in the second half of 2018.

## DaxibotulinumtoxinA Topical

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

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

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

## Results of Operations

## Revenue

During the years ended December 31, 2017, 2016 and 2015, we recognized revenue from a royalty agreement and did not have any product revenue during those same years. The following table presents our revenue for the periods indicated and related changes from the prior period:

	2017	2016
Years Ended December 31		
	2016	2015

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

2017 2016 2015 % %  
(In thousands, except  
percentages)

Relastin Royalty 262 300 300 (13)% ~~%~~

Total revenue \$262 \$300 \$300 (13)% ~~%~~

Our total revenue for the year ended December 31, 2017 decreased, compared to the same period in 2016 and 2015, due to termination of the royalty revenue agreement related to the Relastin product (over the counter skin cream) in November 2017. The Company will no longer receive any future royalty revenue from Relastin.

58

---

Table of Contents

We recognized royalty revenue during the years ended December 31, 2017, 2016, and 2015 related to the Relastin asset purchase and royalty agreement. In August 2011, we entered into the Relastin asset purchase and royalty agreement to sell the business related to our Relastin product line, to Precision Dermatology, Inc., or PDI. The Relastin asset purchase and royalty agreement provided for a minimum royalty payment of \$0.3 million per year, to be paid quarterly for up to 15 years from the execution date. PDI was subsequently acquired by Valeant Pharmaceuticals International, Inc., or Valeant, in July 2014. On April 23, 2015, we received notice from Valeant terminating the asset purchase and royalty agreement effective as of July 23, 2015. The Company was entitled to the minimum royalty payment until Valeant returns the Relastin® intellectual property rights to the Company. In November 2017, Revance and Valeant entered into an Asset Transfer Agreement to finalize the termination of the asset purchase and royalty agreement and Valeant returned the Relastin® intellectual property rights to the Company. The Company does not have any current plans for future developments of Relastin® and its focus is primarily on the development of RT002 injectable.

Operating Expenses

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

Research and Development Expenses

We recognize research and development expenses as they are incurred. Since our inception, we have focused on our clinical development programs and the related research and development. We have been developing RT002 injectable and our topical product candidates since 2002 and we have typically shared our employees, consultants and infrastructure resources across both programs. Our research and development expenses consist primarily of:

- salaries and related expenses for personnel in research and development functions, including stock-based compensation;
- expenses related to the initiation and completion of clinical trials for RT002 injectable and our topical product candidate, including expenses related to production of clinical supplies;
- fees paid to clinical consultants, clinical trial sites, clinical research organizations (CROs) and other vendors, including all related fees for investigator grants, patient screening fees, laboratory work and statistical compilation and analysis;
- other consulting fees paid to third parties;
- expenses related to establishment and maintenance of our own manufacturing facilities;
- expenses related to the manufacture of drug substance and drug product supplies for ongoing and future preclinical and clinical trials;
- expenses to support our product development and establish manufacturing capabilities to support potential future commercialization of any products for which we may obtain regulatory approval;
- expenses related to license fees and milestone payments under in-licensing agreements;
- expenses related to compliance with drug development regulatory requirements in the United States, the European Union and other foreign jurisdictions; and
- depreciation and other allocated expenses.

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

Our research and development expenses fluctuate as projects transition from one development phase to the next. Depending on the stage of completion and level of effort related to each development phase undertaken, we may reflect

59

---

Table of Contents

variations in our research and development expense. We expense both internal and external research and development expenses as they are incurred. We typically share employees, consultants and infrastructure resources between the RT002 injectable and our topical programs. We believe that the strict allocation of costs by product candidate would not be meaningful. As such, we generally do not track these costs by product candidate.

Our research and development expenses are summarized as follows:

	Year Ended December 31,			2017	2016
	2017	2016	2015	vs. 2016	vs. 2015
Clinical and regulatory	43,915	15,060	14,921	192 %	1 %
Manufacturing and quality	21,545	19,956	18,534	8 %	8 %
Research	8,514	7,064	7,563	21 %	(7 )%
Stock-based compensation	5,902	5,557	6,511	6 %	(15 )%
Other research and development expenses	485	2,744	—	(82 )%	100 %
Total research and development expenses	80,361	50,381	47,529	60 %	6 %

**Clinical and regulatory costs**

Clinical expenses include personnel and occupancy costs, and external clinical trial costs for clinical sites, clinical research organizations, central laboratories, data management, contractors and regulatory activities associated with the development of RT002 injectable and our topical, including clinical trials of RT002 injectable for the improvement of glabellar lines, cervical dystonia and plantar fasciitis, and clinical trials of our topical product candidate for the treatment of crow's feet during 2015 and 2016. For the years ended December 31, 2017, 2016, and 2015, clinical and regulatory costs totaled \$43.9 million, or 55%, \$15.1 million, or 30%, \$14.9 million, or 31% of research and development expenses in 2017, 2016, and 2015, respectively.

Clinical and regulatory costs for the year ended December 31, 2017 increased by 192%, compared to the same period in 2016, primarily due to the ongoing clinical trials for RT002 for the treatment of glabellar lines, cervical dystonia, and plantar fasciitis. We expect our clinical and regulatory costs to continue to increase in the near term as we initiate and complete clinical trials and other associated programs related to RT002 for the treatment of glabellar lines, cervical dystonia, plantar fasciitis and other indications, and the Company's anticipated BLA submission upon the completion and success of the clinical trials for the RT002 glabellar lines indication.

**Manufacturing and quality efforts**

Manufacturing and quality efforts include personnel and occupancy expenses, external contract manufacturing costs and pre-approval manufacturing of drug product used in research and our development of RT002 injectable and our topical product candidate. Manufacturing and quality efforts also include raw materials, lab supplies, and storage and shipment of our product candidates to support quality control and assurance activities. These costs do not include clinical costs associated with the development of RT002 injectable and our topical. For the years ended December 31, 2017, 2016, and 2015, costs associated with our manufacturing and quality efforts for both RT002 injectable and topical development totaled \$21.5 million, or 27%, \$20.0 million, or 40%, and \$18.5 million, or 39% of research and development expenses in 2017, 2016, and 2015, respectively.

Manufacturing and quality efforts for the year ended December 31, 2017 increased by 8%, compared to the same period in 2016, primarily due to increased costs related to hiring additional personnel as well as an increase in outside services and consulting for compliance requirements. Manufacturing and quality efforts for the year ended December 31, 2016 increased by 8%, compared to the same period in 2015, primarily due to increased costs related to consulting and outside services offset by a decrease in personnel costs. We expect our manufacturing and quality efforts to continue to increase as the Company approaches commercialization.

**Research costs**

Research costs include expenses for personnel and occupancy, contract research organizations, consultants, raw materials, and lab supplies used to conduct preclinical research and development of RT002 injectable and our topical product candidate. For the years end December 31, 2017, 2016, and 2015, costs associated with our preclinical development totaled, \$8.5 million,

60

---

Table of Contents

or 11%, \$7.1 million, or 14%, \$7.6 million, or 16% of research and development expenses in 2017, 2016, and 2015, respectively.

Research expenses for the year ended December 31, 2017 increased by 21%, compared to the same period in 2016, primarily due to increased costs related to personnel and consulting on research projects. Research expenses for the year ended December 31, 2016 decreased by 7%, compared to the same period in 2015, primarily due decreased costs related to preclinical personnel involved with our topical Phase 2 study for the treatment of hyperhidrosis. We expect our preclinical costs to continue to increase as the Company expands into other indications.

#### Stock-based compensation

Stock-based compensation for research and development for the year ended December 31, 2017 increased by \$0.3 million, compared to the same period in 2016, primarily due to an increase in employee headcount and an increase in stock price. Stock-based compensation for research and development for the year ended December 31, 2016 decreased by \$1.0 million, compared to the same period in 2015, primarily due to equity award modifications and offset by an increase in employee headcount.

#### Other research and development expenses

Other research and development expenses for the years ended December 31, 2017 and 2016 includes license fees for BioSentinel, Inc.'s technology and expertise for research and development and manufacturing purposes and, in 2016, a milestone of \$2.0 million to Botulinum Toxin Research Associates, Inc. ("BTRX") to acquired a portfolio of patents. For the years ended December 31, 2017 and 2016, other research and development expenses represented \$0.5 million, or 1%, and \$2.7 million, or 5%, of research and development expenses in 2017 and 2016, respectively. There were no expenses classified as other research and development expenses for the year ended December 31, 2015.

#### General and Administrative Expenses

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

	2017		2016		2016		2015	
	Year Ended December 31,		vs.		2016		2015	
	2017	2016	2015	%	%	%	%	
	(In thousands, except percentages)							
Finance and administration	23,084	19,790	17,396	17 %	14 %			
Commercial	6,986	2,889	1,815	142 %	59 %			
Stock-based compensation	7,328	6,396	5,877	15 %	9 %			
Total general and administrative expenses	37,398	29,075	25,088	29 %	16 %			

#### Finance and administration

Finance and administration expenses consist primarily of personnel and consulting costs, for employees in our finance, information technology, investor relations, legal, human resources and other administrative functions. Other significant expenses include professional fees for accounting and legal services, including legal services associated with obtaining and maintaining patents and litigation. Finance and administration expenses for the year ended December 31, 2017 increased by 17%, compared to the same period in 2016, primarily due to increased costs related to personnel and consulting costs to support the Company's infrastructure.

Finance and administration expenses for the year ended December 31, 2016 increased by 14%, compared to the same period in 2015, primarily due to increased costs related to personnel and legal fees related to the legal matter described in Note 10, offset by a decrease in professional fees.

#### Commercial



Commercial expenses consist primarily of market research, public relations, promotion and advertising costs. Commercial expenses increased by 142% compared to the same period in 2016, due to increased costs related to personnel, consulting costs,

61

---

Table of Contents

and pre-commercial initiatives to support our future product launch following the Company's anticipated BLA submission upon the completion and success of the clinical trials for the RT002 glabellar lines indication.

Commercial expenses increased by 59% compared to the same period in 2015, due to increased costs related to personnel, consulting costs, and marketing initiatives to prepare for launch of RT002 upon its approval.

## Stock-based compensation

Stock-based compensation for selling, general and administrative expenses increased for the periods presented primarily due to an increase in employee headcount and an increase in stock price.

## Loss on Impairment

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

	2017		2016	
	Year Ended December 31,		vs.	
	2017	2016	2016	2015
			%	%
Loss on impairment	\$2,927	\$9,059	\$(68)%	%

(In thousands, except percentages)

We constructed a large capacity fill/finish line dedicated to the manufacture of our topical product candidate and to support our regulatory license applications. We discontinued clinical development of our topical product candidate for the treatment of crow's feet and axillary hyperhidrosis in June 2016, following results from our REALISE 1 Phase 3 clinical trial to treat crow's feet.

Under generally accepted accounting principles in the United States, long-lived assets, such as our topical fill/finish line, are required to be reviewed for impairment whenever adverse events or changes in circumstances indicate a possible impairment. If business conditions or other factors indicate that the carrying value of the asset may not be recoverable, we may be required to record additional non-cash impairment charges. Additionally, if the carrying value of our capital equipment exceeds current fair value as determined based on the discounted future cash flows of the related product, the capital equipment would be considered impaired and would be reduced to fair value by a non-cash charge to earnings, which could negatively affect our operating results. During the years ended December 31, 2017 and 2016, we recorded a loss on impairment of \$2.9 million and \$9.1 million, respectively, related to our topical fill/finish line and certain other assets. We did not identify any indicators of impairment during the year ended December 31, 2015.

## Net Non-Operating Expense

## Interest Income

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

## Interest Expense

Interest expense primarily consists of the interest charges associated with our notes payable, financing obligations, and capitalized interest. Notes payable under our term loan agreement with Hercules, which matured and was fully paid off in March 2015, bore interest at a rate which is the greater of (i) 9.85% per annum or (ii) 9.85% per annum plus the difference of the prime rate less 3.25%. Interest expense, includes cash and non-cash components with the non-cash components consisting of (i) interest recognized from the amortization of debt issuance costs, which were capitalized on the Consolidated Balance Sheets, that are generally derived from cash payments related to the issuance of notes payable, (ii) interest recognized from the amortization of debt discounts, which were capitalized on the Consolidated Balance Sheets, derived from the issuance of warrants and derivatives issued in conjunction with notes payable, (iii)

interest capitalized for assets constructed for use in operations, and (iv) effective interest recognized on the financing obligation. The capitalized amounts related to the debt issuance costs and debt discounts are generally amortized to interest expense over the term of the related debt instruments.

Table of Contents

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

In October 2012, we entered into a settlement and termination agreement with Medicis. The terms of the settlement provided for the reacquisition of the rights related to all territories of RT002 injectable and RT001 topical from Medicis and for consideration payable by us to Medicis of up to \$25.0 million, comprised of (i) an upfront payment of \$7.0 million, which was paid in 2012, (ii) a proceeds sharing arrangement payment of \$14.0 million of which \$6.9 million was paid in 2013 and the remaining \$7.1 million was paid in 2014, and (iii) \$4.0 million to be paid upon the achievement of regulatory approval of RT002 injectable or RT001 topical.

We determined that the settlement provisions related to (ii) and (iii) above were derivative instruments that required fair value accounting at the time of settlement and fair value remeasurements on a periodic basis going forward. Accordingly, we recorded derivative liabilities on the balance sheet based on their respective fair values on the settlement date.

Our outstanding derivative liability associated with the Medicis settlement is classified as a liability on our Consolidated Balance Sheet. The remaining liability will be remeasured to fair value at each balance sheet date with the corresponding gain or loss from the adjustment recorded in the Consolidated Statement of Operations and Comprehensive Loss. We will continue to record adjustments to the fair value of the Medicis settlement derivative liability until the Product Approval Payment has been paid.

Other Expense, net

Other expense, net is comprised of miscellaneous tax and other expense items.

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

	Years Ended December 31,			2017	2016
	2017	2016	2015	vs. 2016	vs. 2015
				%	%
	(In thousands, except percentages)				
Interest income	\$1,410	\$1,170	\$231	21 %	406 %
Interest expense	(457 )	(1,082 )	(1,190 )	(58)%	(9 )%
Change in fair value of derivative liabilities associated with the Medicis settlement	(591 )	(608 )	127	(3 )%	(579)%
Other expense, net	(525 )	(535 )	(327 )	(2 )%	64 %
Total net non-operating expenses	\$(163 )	\$(1,055 )	\$(1,159 )	(85)%	(9 )%

Our total net non-operating expense for the year ended December 31, 2017 decreased by 85%, compared to the same period in 2016, primarily due to lower interest expense resulting from the declining principal balance on the Essex Capital Facility, which is described below, offset by an increase in the interest income from a stronger investment portfolio.

Our total net non-operating expense for the year ended December 31, 2016 decreased by 9%, compared to the same period in 2015, primarily due to a decrease in interest expense which is described below, offset by an increase in the fair value of the Medicis derivative liabilities and other taxes and fees.

Interest expense for the year ended December 31, 2017 decreased by 58%, compared to the same period in 2016, primarily due to the lower interest resulting from the declining principal balance on the Essex Capital Facility offset by an increase in capitalized interest associated with construction in progress.

Interest expense for the year ended December 31, 2016 decreased by 9%, compared to the same period in 2015, primarily due to the lower interest resulting from the declining principal balance on the Essex Capital Facility.

Income Taxes

Since inception, we have incurred net losses and have not recorded any U.S. federal or state income tax and the tax benefits of our operating losses have been fully offset by valuation allowances.

There was no provision or benefit from income taxes during the years ended December 31, 2017, 2016 and 2015.

Table of Contents

On December 22, 2017, the U.S. government enacted a comprehensive tax reform legislation, commonly referred to as the Tax Cuts and Jobs Act (the “Tax Reform Act”). The Tax Reform Act makes broad and complex changes to the US tax code including but not limited to, (1) reducing the U.S. federal corporate tax rate from 35% to 21%; (2) requiring companies to pay a one-time transition tax on certain repatriated earnings of foreign subsidiaries, which has no impact to the Company; (3) generally eliminating US federal income taxes on dividends from foreign subsidiaries; (4) requiring a current inclusion in US federal income of certain earnings of controlled foreign corporations; (5) creating a new limitation on deductible interest expense; and (6) changing rules related to the uses and limitations of net operating loss carryforwards created in tax years beginning after December 31, 2017.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (“SAB 118”) which provides guidance on accounting for the tax effects of the Tax Reform Act. SAB 118 provides a measurement period that should not extend beyond one year from the Tax Reform Act enactment date for companies to complete the accounting under ASC 740, Income Taxes. In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the Tax Reform Act for which the accounting under ASC 740 is complete. To the extent that a company’s accounting for certain income tax effects of the Tax Reform Act is incomplete but it is able to determine a reasonable estimate, it must record a provisional estimate in the financial statements. If a company cannot determine a provisional estimate, it should continue to apply ASC 740 on the basis of the provisions of the tax laws that were in effect immediately before the enactment of the Tax Reform Act.

Effect of Tax Reform Act and SAB 118 - The Tax Reform Act reduces the corporate tax rate to 21 percent, effective January 1, 2018. In addition, the Company’s accounting for the tax effects of enactment of the Tax Reform Act is incomplete; however, in certain cases, as described below, we have made a reasonable estimate of the effects on our existing deferred tax balances and valuation allowance. In certain aspects, we have not been able to make a reasonable estimate and continue to account for those items based on our existing accounting under ASC 740, Income Taxes, and the provisions of the tax laws that were in effect immediately prior to enactment. The Company has determined that the \$62.9 million recorded in connection with the re-measurement of certain deferred tax assets and liabilities, and corresponding valuation allowance was a provisional amount and a reasonable estimate at December 31, 2017. We have not completed our accounting with regard to the tax effects associated with an intra-entity transfer of certain intellectual property rights with the enactment of Tax Reform Act. Our accounting for the intra-entity transfer reflects the utilization of net operating losses on the basis of the laws in effect before the Tax Reform Act. The Company is evaluating the impact under Tax Reform Act on the Company’s global business structure. In all aspects, the Company will continue to make and refine calculations as additional analysis is completed. The Company expects to complete the accounting assessment during the one year measurement period provided by SAB 118.

The Company follows the provisions of the FASB’s guidance for accounting for uncertain tax positions. The guidance indicates a comprehensive model for the recognition, measurement, presentation and disclosure in financial statements of any uncertain tax positions that have been taken or expected to be taken on a tax return. No liability related to uncertain tax positions is recorded in the financial statements due to the fact the liabilities have been netted against deferred attribute carryovers. It is the Company’s policy to include penalties and interest related to income tax matters in income tax expense.

**Liquidity and Capital Resources**

Our financial condition is summarized as follows:

	Year Ended December 31,		Increase (Decrease)
	2017	2016	2017
Cash, cash equivalents, and investments	\$ 282,896	\$ 185,528	\$ 97,368
Financing obligations	1,872	5,347	(3,475 )
Working Capital	264,309	173,048	91,261
Stockholders' Equity	268,845	177,071	91,774

**Sources and Uses of Cash**

Our cash, cash equivalents and investments totaled \$282.9 million at December 31, 2017 compared to \$185.5 million at December 31, 2016, representing an increase of \$97.4 million. We hold our cash, cash equivalents, and investments

in a variety of non-interest bearing bank accounts and interest-bearing instruments subject to investment guidelines allowing for

64

---

Table of Contents

holdings in U.S. government and agency securities and money market accounts. Our investment portfolio is structured to provide for investment maturities and access to cash to fund our anticipated working capital needs.

The increase in cash, cash equivalents and investments of \$97.4 million was primarily due to the receipt of \$200.0 million of net cash proceeds from the follow-on public and at-the-market offerings, stock option exercises, employee stock plan purchases, and royalty revenue. These increases were primarily offset by cash used in operations, purchases of property and equipment of \$2.5 million, and equipment lease payments on our financing obligations of \$3.6 million.

Through December 31, 2017, we have funded substantially all of our operations through the sale and issuance of our common stock, preferred stock, venture debt, and convertible debt. Due to our substantial research and development expenditures, we have generated significant operating losses since our inception. Our expenditures are primarily related to research and development activities. We expect to continue to incur net operating losses for at least the next several years as we advance RT002 injectable through clinical development, seek regulatory approval, prepare for and, if approved, proceed to commercialization. As a result, we will need additional capital to fund our operations which we may obtain from additional financings, public offerings, or other sources. As of December 31, 2017, we had available cash and cash equivalents of \$282.9 million.

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

	Year Ended December 31,		
	2017	2016	2015
Net cash provided by (used in):			
Operating activities	\$(95,342)	\$(59,827)	\$(55,669)
Investing activities	118,792	(75,499 )	(56,415 )
Financing activities	195,944	(2,642 )	142,592

#### Cash Flows from Operating Activities

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

Net cash used in operating activities for the year ended December 31, 2017 of \$95.3 million was primarily due to clinical spend of more than \$30 million to advance the Company's clinical programs toward commercialization; investing in our personnel and talent retention, which represents approximately \$25 million; and professional services and consulting of more than \$15 million. The remaining balance of operating activities related primarily to rent, utilities, and other supplies.

Net cash used in operating activities of \$59.8 million in the year ended December 31, 2016 was largely due to ongoing clinical trial activities for our RT002 injectable program and our topical product candidate, including more than \$10 million for payments to clinical trial vendors; investing in our personnel, including those that support the clinical programs, and talent retention, which represents more than \$20 million; and professional services and consulting of more than \$10 million. The remaining balance of operating activities related primarily to rent, utilities, and other supplies.

Net cash used in operating activities was \$55.7 million in the year ended December 31, 2015 was primarily due to increased costs associated with being a public company, including fees for professional services, consultants, and ongoing clinical trial activities for our topical product candidate and our RT002 injectable program, which included more than \$20 million for payments to clinical trial vendors, consultants, and other professional service providers. In 2015, we also invested in building our workforce to support our clinical development programs and the operations of a public company, which represented more than \$15 million of our operating activities. The remaining balance of



operating activities related primarily to rent, utilities, and other supplies.

65

---

## Table of Contents

### Cash Flows from Investing Activities

Net cash provided by or used in investing activities for the years ended December 31, 2017, 2016 and 2015 was primarily due to purchases of property and equipment, costs related to purchasing the BTRX patent portfolio in 2016, and fluctuations in the timing of maturities and sales of investments. As of December 31, 2017, all of our investments had matured. We intend to reinvest a substantial portion of our cash and cash equivalents in short-term investments in 2018.

### Cash Flows from Financing Activities

Increases in our cash flows from financing activities are primarily driven by proceeds from the issuance of our common stock in connection with follow-on offerings (as described below), ATM offerings (as described below), stock option exercises and employee stock plan purchases. In 2015, the Company also received proceeds of \$9.8 million for the sale/leaseback of equipment from Essex Capital. Decreases in our cash flows from financing activities are primarily due to principal payments on the aforementioned equipment lease with Essex Capital, principal payments on notes payable in 2015, and payments to settle employee tax obligations resulting from net settlement of restricted stock awards.

### Follow-On Public Offerings

In November 2015, the Company completed a follow-on public offering, or the 2015 follow-on offering, pursuant to which the Company issued 3,737,500 shares of common stock at \$36.00 per share, including the exercise of the underwriters' over-allotment option to purchase 487,500 additional shares of common stock, for net proceeds of \$126.2 million, after underwriting discounts, commissions and other offering expenses.

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

### At-The-Market Offering

In March 2015, the Company entered into an At-The-Market Issuance Sales Agreement, or the 2015 ATM agreement, with Cowen and Company, LLC, or Cowen, under which the Company could offer and sell common stock having aggregate proceeds of up to \$50.0 million from time to time through Cowen as our sales agent. During the year ended December 31, 2015, the Company sold 352,544 shares of common stock under the ATM agreement at a weighted average price of \$30.76 per share resulting in gross proceeds of \$10.8 million, and net proceeds of \$10.0 million, after underwriting discounts, commissions, and other offering expenses.

In March 2016, the Company entered into an At-The-Market Issuance Sales Agreement, or the 2016 ATM agreement, with Cowen and Company, LLC, or Cowen, under which the Company may offer and sell common stock having aggregate proceeds of up to \$75.0 million from time to time through Cowen as our sales agent. During the year ended December 31, 2017, the Company sold 1,802,651 shares of common stock under the 2016 ATM Agreement at a weighted average price of \$22.17 per share resulting in gross proceeds of \$40.0 million, and net proceeds of \$38.2 million, after underwriting discounts, commissions, and offering expenses. As of February 28, 2018, approximately \$35.0 million remains available to us under the 2016 ATM agreement.

### Operating and Capital Expenditure Requirements

We have not achieved profitability on a quarterly or annual basis since our inception and we expect to continue to incur net losses for the foreseeable future. We expect to make additional capital outlays to increase operating expenditures over the next several years to support the completion of the clinical trials and other associated programs relating to RT002 injectable for the treatment of glabellar lines, cervical dystonia, plantar fasciitis and other indications, seek regulatory approval, prepare for and, if approved, proceed to commercialization. We believe that our existing capital resources, the net proceeds from our follow-on public and ATM offerings will be sufficient to fund our operations for at least the next 12 months. However, we anticipate that we will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may seek to sell additional equity or issue debt, convertible debt or other securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of debt or convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. There can be no

assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or

66

---

Table of Contents

declaring dividends. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations, and financial condition.

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

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

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

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

We have based our estimates of future capital requirements on a number of assumptions that may prove to be wrong, and changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our ongoing clinical trials of RT002 injectable may encounter technical or other difficulties that could increase our development costs more than we currently expect or the FDA or EMA may require us to conduct additional clinical trials prior to approving RT002 injectable or future products we may develop. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials beyond 2018.

**Critical Accounting Policies and Estimates**

Our Consolidated Financial Statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of these Consolidated Financial Statements requires our management to make

estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the Consolidated Financial Statements, and the reported amounts of revenue and expenses during the applicable periods. We base our estimates, assumptions and judgments on historical experience and on various other factors that

Table of Contents

we believe to be reasonable under the circumstances. Different assumptions and judgments would change the estimates used in the preparation of our Consolidated Financial Statements, which, in turn, could change the results from those reported. We evaluate our estimates, assumptions and judgments on an ongoing basis.

The critical accounting estimates, assumptions and judgments that we believe have the most significant impact on our Consolidated Financial Statements are described below.

**Clinical Trial Accruals**

Clinical trial costs are charged to research and development expense as incurred. We accrue for expenses resulting from contracts with clinical research organizations, or CROs, investigators and consultants, and under certain other agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided. Our objective is to reflect the appropriate trial expense in the Consolidated Financial Statements by matching the appropriate expenses with the period in which services and efforts are expended. In the event advance payments are made to a CRO, the payments will be recorded as a prepaid asset, which will be amortized as services are rendered.

The CRO contracts generally include pass-through fees including, but not limited to, regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. We estimate our clinical accruals based on reports from and discussion with clinical personnel and outside services providers as to the progress or state of completion of trials, or the services completed. We estimate accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. Our clinical trial accrual is dependent, in part, upon the receipt of timely and accurate reporting from the CROs and other third-party vendors. As of December 31, 2017, there have not been any material adjustments to our estimated accrued clinical expenses.

**Stock-Based Compensation**

We recognize compensation costs related to stock options granted to employees and non-employee directors based on the estimated fair value of the awards on the date of grant, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is recognized over the requisite service period, which is generally the vesting period of the respective awards. Stock-based compensation expenses are classified in the Consolidated Statements of Operations and Comprehensive Loss based on the functional area to which the related recipients belong.

The estimated grant date fair values of the option awards granted to employees and non-employee directors during the years ended December 31, 2017, 2016, and 2015 were calculated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,		
	2017	2016	2015
Expected term (in years)	6.0	6.0	6.0
Expected volatility	67.7 %	61.9 %	62.2 %
Risk-free interest rate	2.1 %	1.4 %	1.6 %
Dividend rate	0.0 %	0.0 %	0.0 %

The Black-Scholes option-pricing model requires the use of highly subjective and complex assumptions that determine the fair value of options. These assumptions are as follows:

Expected term — The expected term represents the period that our options are expected to be outstanding and is calculated using the simplified method. We qualify for the simplified method as our stock options have the following characteristics: (i) granted at-the-money; (ii) exercisability is conditioned upon service through the vesting date; (iii) termination of service prior to vesting results in forfeiture; (iv) limited exercise period following termination of service; and (v) options are non-transferable and non-hedgeable, or “plain vanilla” options, and we have limited history of exercise data.

•

Expected volatility — Beginning on January 1, 2017, the expected volatility is based on the historical volatility of a group of similar entities combined with the historical volatility of the Company, whereas prior to 2017, the

## Table of Contents

expected volatility was based solely on the historical volatility of a group of similar entities. In evaluating similarity, the Company considered factors such as industry, stage of life cycle, capital structure, and size.

**Risk-free interest rate** — The risk-free interest rate is based on the U.S. Treasury constant maturity rates with terms similar to the option's expected term.

**Dividend rate** — The expected dividend was assumed to be zero as we have never paid dividends and have no current plans to do so.

As of January 1, 2017, we began accounting for forfeitures as they occur, which was an acceptable change in accordance with ASU 2016-09. In connection with changing the forfeiture rate methodology, we recorded a cumulative charge of less than \$0.1 million to the Accumulated Deficit balance as of January 1, 2017.

We will continue to use judgment in evaluating the expected term and expected volatility related to our stock-based compensation calculations on a prospective basis. As we continue to accumulate additional data related to our common stock, we may make refinements to the estimates of our expected terms and expected volatility that could materially impact our future stock-based compensation.

### Derivative Liabilities Associated with the Medicis Settlement

In October 2012, we entered into a settlement and termination agreement with Medicis. The terms of the settlement provided for the reacquisition of the rights related to all territories of RT002 injectable and RT001 topical from Medicis and for consideration payable by us to Medicis of up to \$25.0 million, comprised of (i) an upfront payment of \$7.0 million, which was paid in 2012, (ii) a Proceeds Sharing Arrangement Payment of \$14.0 million of which \$6.9 million was paid in 2013 and the remaining \$7.1 million was paid in 2014, and (iii) \$4.0 million to be paid upon the achievement of regulatory approval of RT002 injectable or RT001 topical, or Product Approval Payment.

We determined that the settlement provisions related to (ii) and (iii) above were derivative instruments that should be measured at fair value at the time of settlement and remeasured to fair value at each reporting period going forward. Accordingly, we recorded derivative liabilities on the balance sheet based on their respective fair values on the settlement date. These derivative liabilities will be reduced as the related payments are made under the settlement agreement. The remaining liabilities will be subsequently remeasured to fair value as of each balance sheet date with the related remeasurement adjustments recognized in the Consolidated Statements of Operations and Comprehensive Loss.

The fair value of the Product Approval Payment derivative was determined by estimating the timing and probability of the related approval and multiplying the payment amount by this probability percentage then applying a discount factor. As of December 31, 2016, we determined the fair value of the liability for the Product Approval Payment was \$2.0 million, which was measured by assuming a term of 3.25 years, a risk-free rate of 1.5% and a credit risk adjustment of 9.0%. As of December 31, 2017, we determined the fair value of the liability for the Product Approval Payment was \$2.6 million, which was measured by assuming a term of 2.5 years, a risk-free rate of 2.0% and a credit risk adjustment of 6.5%. Our assumption for the expected term as of December 31, 2017 is based on an expected Biologics License Application, or BLA, approval for RT002 in the first half of 2020. The primary drivers of any fair value movements for the Product Approval Payment derivative are the estimated probability of the related approval and the credit risk adjustment. If the probability estimate increases (decreases) and the credit risk adjustment decreases (increases), the fair value of the derivative will increase (decrease).

We will record adjustments to the fair value of the derivative liabilities associated with the Medicis settlement until the Product Approval Payment has been paid. At that time, the Product Approval Payment derivative will be adjusted to fair value one last time immediately prior to settlement.



## Table of Contents

### Impairment of Long-Lived Assets

We assess the impairment of long-lived assets, such as property and equipment subject to depreciation and amortization, when events or changes in circumstances indicate that their carrying amount may not be recoverable. Among the factors and circumstances we considered in determining recoverability are: (i) a significant adverse change in the extent to which, or manner in which, a long-lived asset is being used or in its physical condition; (ii) a significant adverse change in legal factors or in the business climate that could affect the value of a long-lived asset, including an adverse action or assessment by a regulator; (iii) an accumulation of costs significantly in excess of the amount originally expected for the acquisition; (iv) current-period operating or cash flow loss combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with the use of a long-lived asset; and (v) current expectation that, more likely than not, a long-lived asset will be sold or otherwise disposed of significantly before the end of its previously estimated useful life. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset exceeds the fair value of the asset.

We constructed a fill/finish line for the future commercial manufacturing of its topical product candidate and to support its clinical trials and regulatory license applications. In 2016, following the results of the REALISE 1 Phase 3 clinical trial for crow's feet, we discontinued its topical clinical development programs for the treatment of crow's feet and for the treatment of primary axillary hyperhidrosis. We performed an impairment analysis of the topical fill/finish line and other fixed assets to determine fair value based on highest and best use. We concluded that only certain equipment comprising the topical fill/finish line would be repurposed for commercial-scale manufacturing of RT002 injectable. As a result, we determined fair value based on its highest and best use and that for certain components of the fill/finish line and other fixed assets, the carrying value of the assets was not entirely recoverable and the fair value, which was calculated using the market or cost approach depending on the specific asset, was lower than the carrying value. Accordingly, during the year ended December 31, 2016, we recorded a loss on impairment of \$9.1 million. As of December 31, 2016, the fill/finish line and other fixed assets had net book values of \$5.1 million and \$0.2 million, respectively.

During the three months ended December 31, 2017, we identified an additional indicator of impairment, an adverse change in the market value resulting from further negotiations with a potential buyer during the quarter, for the topical fill/finish line and other fixed assets. We continue to believe that certain equipment comprising the topical fill/finish line with a net book value of \$2.4 million will be repurposed for commercial-scale manufacturing of RT002 injectable. As a result, we determined fair value based on its highest and best use and that for certain components of the fill/finish line and other fixed assets, the carrying value of the assets was not entirely recoverable and the fair value, which was calculated using the market or cost approach depending on the specific asset, was lower than the carrying value. Accordingly, we recorded a loss on impairment of \$2.9 million, during the year ended December 31, 2017. Nonetheless, it is reasonably possible that our estimate of the recoverability of the equipment's carrying value could change, and may result in the need to write down the assets to fair value. As of December 31, 2017, the fill/finish line and other fixed assets had net book values of \$2.4 million and \$0.1 million, respectively.

### Income Taxes

We are subject to income taxes in the United States, and we use estimates in determining our provision for income taxes. We use the asset and liability method of accounting for income taxes. Under this method, we calculate deferred tax asset or liability account balances at the balance sheet date using current tax laws and rates in effect for the year in which the differences are expected to affect our taxable income.

We estimate actual current tax exposure together with assessing temporary differences resulting from differences in accounting for reporting purposes and tax purposes for certain items, such as accruals and allowances not currently deductible for tax purposes. These temporary differences result in deferred tax assets and liabilities, which are included in our Consolidated Balance Sheets. In general, deferred tax assets represent future tax benefits to be

received when certain expenses previously recognized in our Consolidated Statements of Operations and Comprehensive Loss become deductible expenses under applicable income tax laws or when net operating loss or credit carryforwards are utilized. Accordingly, realization of our deferred tax assets is dependent on future taxable income against which these deductions, losses and credit carryforwards can be utilized.

We must assess the likelihood that our deferred tax assets will be recovered from future taxable income, and to the extent we believe that recovery is not likely, establish a valuation allowance.

Table of Contents

As of December 31, 2017, we had net operating loss carryforwards available to reduce future taxable income, if any, for federal, California, and New Jersey income tax purposes of \$453.1 million, \$160.2 million, and \$378.7 million, respectively. If not utilized, the federal net operating loss carryforward begin expiring in 2020, the California net operating loss carryforwards began expiring in 2010, and the New Jersey state net operating loss carryforwards begin expiring in 2030.

As of December 31, 2017, we also had research and development credit carryforwards of \$4.3 million and \$6.1 million available to reduce future taxable income, if any, for federal and California state income tax purposes, respectively. If not utilized, the federal credit carryforwards will begin expiring in 2023 and the California credit carryforwards have no expiration date.

In general, if the Company experiences a greater than 50 percentage point aggregate change in ownership over a 3-year period (a Section 382 ownership change), utilization of its pre-change NOL carryforwards are subject to an annual limitation under Section 382 of the Internal Revenue Code (California and New Jersey have similar laws). The annual limitation generally is determined by multiplying the value of the Company's stock at the time of such ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization. The Company determined that an ownership change occurred on April 7, 2004 but that all carryforwards can be utilized prior to the expiration. The Company also determined that an ownership change occurred in February 2014. As a result of the 2014 change, the Company reduced the deferred tax assets and the corresponding valuation allowance to account for this limitation. Since the R&D credits for California carry over indefinitely, there was no change to the California R&D credits. The Company has reviewed its IRC §382 limitation through December 31, 2017 and have not identified any ownership changes resulting in a limitation.

**JOBS Act**

We are an "emerging growth company," as defined in the JOBS Act and, for as long as we continue to be an "emerging growth company," we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We will remain an "emerging growth company" until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO on February 6, 2014, (b) in which we have total annual gross revenues of over \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

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

**Contractual Obligations**

Our contractual commitments will have an impact on our future liquidity. The following table, which summarizes our contractual obligations as of December 31, 2017, represents material expected or contractually committed future obligations, with terms in excess of one year. We believe that we will be able to fund these obligations through cash generated funding activities and from our existing cash balances.

Contractual Obligations:	Payments Due by Period				
	Total	Year 1	Years 2 to 3	Years 4 to 5	More than

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

					5 Years
	(In thousands)				
Operating lease obligations <sup>(1)</sup>	\$38,121	\$5,628	\$ 11,808	\$ 10,815	\$ 9,870
Financing obligations reflected on our balance sheet under GAAP <sup>(2)</sup>	1,932	1,932	—	—	—
Total	\$40,053	\$7,560	\$ 11,808	\$ 10,815	\$ 9,870

71

---

Table of Contents

(1) Operating lease agreements represent our obligations to make payments under non-cancelable lease agreements for our facilities and leased equipment.

(2) Financing obligations reflected on our balance sheet under GAAP represents our obligation to make lease payments and the purchase price of the leased equipment under the Loan and Lease Agreement with Essex Capital.

This table does not include any milestone or royalty payments, which may become payable to third parties under agreements, as the timing and likelihood of such payments are not known.

• We are obligated to pay milestone and royalties to List Laboratories on future sales of botulinum toxin products.

• We also have one remaining future milestone payment of \$4.0 million due and payable to Valeant Pharmaceuticals International, Inc. upon the achievement of regulatory approval for RT002 injectable or RT001 topical.

• In 2016, we entered into an asset purchase agreement with Botulinum Toxin Research Associates, Inc., or BTRX (the "BTRX Purchase Agreement") in which we agreed to pay up to an additional \$16.0 million in aggregate upon the satisfaction of specified milestones relating to our sales revenue, intellectual property, and clinical and regulatory events. In exchange, the Company acquired all rights, title and interest in a portfolio of botulinum toxin-related patents and patent applications from BTRX and was granted the right of first negotiation and first refusal with respect to other botulinum toxin-related patents owned or controlled by BTRX.

• On April 11, 2016, we entered into an agreement with BioSentinel, Inc. to in-license their technology and expertise for research and development and manufacturing purposes. In addition to minimum quarterly use fees, we are obligated to make a one-time future milestone payment of \$0.3 million payable to BioSentinel, Inc. upon the achievement of regulatory approval.

• On March 14, 2017, the Company entered into a Technology Transfer, Validation and Commercial Fill/Finish Services Agreement (the "Services Agreement") and Statement of Work ("SoW") with Ajinomoto Althea, Inc., a contract development and manufacturing organization ("Althea"). Under the Services Agreement, Althea has agreed, among other things, to provide the Company with a future source of commercial fill/finish services for the Company's neuromodulator products. The Services Agreement has an initial term that will expire in seven years, unless terminated sooner by either party. In accordance with the Services Agreement, the Company will have minimum purchase obligations based on its production forecasts. As of December 31, 2017, the Company made non-refundable advanced payments of \$1.2 million in accordance with the terms of the arrangement. The remaining services are cancellable at any time, with the Company required to pay costs incurred through the cancellation date.

This table does not include a liability for unrecognized tax benefits related to various federal and state income tax matters of \$2.6 million at December 31, 2017. The timing of the settlement of these amounts was not reasonably estimable at December 31, 2017. We do not expect payment of amounts related to the unrecognized tax benefits within the next twelve months.

Off-Balance Sheet Arrangements

As of December 31, 2017, we did not have any off-balance sheet arrangements or any relationships with any entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

Recent Accounting Pronouncements

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

72

---

Table of Contents

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

**Interest Rate Sensitivity**

Our exposure to market risk for changes in interest rates relates primarily to our cash, cash equivalents, and investments. We had cash, cash equivalents, and investments of \$282.9 million and \$185.5 million as of December 31, 2017 and 2016, respectively. As of December 31, 2017, our cash and cash equivalents were held in deposit and money market fund accounts. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates in the United States. A hypothetical 10% movement in interest rates would not be expected to have a material impact on our Consolidated Financial Statements. We mitigate market risk for changes in interest rates by holding our investments in money market fund accounts.

**Foreign Exchange**

Our operations are primarily conducted in the United States using the U.S. Dollar. However, we conduct limited operations in foreign countries, primarily for clinical and regulatory services, whereby settlement of our obligations are denominated in the local currency. Transactional exposure arises when transactions occur in currencies other than the U.S. Dollar. Transactions denominated in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction with the resulting liabilities being translated into the U.S. Dollar at exchange rates prevailing at the balance sheet date. The resulting gains and losses, which were insignificant for the years ended December 31, 2017, 2016 and 2015, are included in other expense in the Consolidated Statements of Operations and Comprehensive Loss. We do not use currency forward exchange contracts to offset the related effect on the underlying transactions denominated in a foreign currency.

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this item are set forth beginning on page F-3 of this Annual Report on this Form 10-K and are incorporated herein by reference.

74

---



Table of Contents

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND  
FINANCIAL DISCLOSURE

None.

75

---

Table of Contents

ITEM 9A. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of December 31, 2017, the end of the period covered by this report.

(b) Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles, or GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets, (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2017 based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Based on our evaluation under the criteria set forth in Internal Control - Integrated Framework (2013) issued by the COSO, our management concluded our internal control over financial reporting was effective as of December 31, 2017.

(c) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

ITEM 9B. OTHER INFORMATION

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

Under the Agreement, Revance will be primarily responsible for (a) non-clinical development activities, (b) clinical development activities in North America, and (c) manufacturing and supply of clinical drug substance and drug product; and Mylan will be primarily responsible for (a) clinical development activities outside of North America (excluding Japan) (the “ex-U.S. Mylan territories”), (b) regulatory activities, and (c) commercialization for any approved product. Revance will be solely responsible for an initial portion of non-clinical development costs. The remaining portion of any non-clinical development costs and clinical development costs for obtaining approval in the U.S. and Europe will be shared equally between the parties, and Mylan will be responsible for all other clinical development costs and commercialization expenses. Revance and Mylan will form a joint steering committee, consisting of an equal number of members from Revance and Mylan, to oversee and manage the development, manufacture and commercialization of the biosimilar. The parties will also enter into a separate agreement, within six months, covering supply of drug substance and drug product. In addition, Mylan may elect to have the drug product manufactured by another party, including a third-party contract manufacturing organization or a Mylan affiliate.

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

Mylan has agreed to pay Revance a non-refundable upfront payment of \$25 million with contingent payments of up to \$100 million, in the aggregate, upon the achievement of specified clinical and regulatory (i.e. biosimilar biological pathway) milestones and of specified, tiered sales milestones of up to \$225 million. In addition, Mylan will pay Revance royalties on sales of the biosimilar in the Mylan territories. With respect to royalties on sales of the biosimilar in the Mylan territories, Mylan would pay Revance low to mid double digit royalties on any sales of the biosimilar in the U.S., mid double digit royalties on any sales in Europe, and high single digit royalties on any sales in other ex-U.S. Mylan territories. However, Revance has agreed to waive royalties for U.S. sales, up to a limit of \$50 million in annual sales, during the first approximately four years after commercialization to defray launch costs.

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

The Agreement contains various representations and warranties, covenants and other provisions that are customary for a transaction of this nature. The representations, warranties and covenants contained in the Agreement were made only for purposes of the Agreement and as of specific dates, were solely for the benefit of the parties to the Agreement, and may be subject to limitations agreed upon by the parties. The representations and warranties may have been made for the purposes of allocating contractual risk between the parties to the Agreement instead of establishing these matters as facts.

The foregoing is a summary of the terms of the Agreement and is qualified in its entirety by reference to the Agreement, a copy of which will be filed as an exhibit to a future amendment of this Current Report on Form 8-K or as exhibits to the Company’s Quarterly Report on Form 10-Q for the quarter ending March 31, 2018.

BOTOX® is a registered trademark of Allergan plc.

77

---

Table of Contents

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Board of Directors

Our board of directors currently consists of eight members. In accordance with our amended and restated certificate of incorporation, our board of directors is divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. The term of Class I directors will expire at the annual meeting of stockholders to be held in 2018; the term of the Class II director will expire at the annual meeting of stockholders to be held in 2019; and the term of Class III directors will expire at the annual meeting of stockholders to be held in 2020.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that the authorized number of directors may be changed only by resolution approved by a majority of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

The following is a brief biography of each member of our board of directors, as of December 31, 2017, with each biography including information regarding the experiences, qualifications, attributes or skills that caused our board of directors to determine that each member of our board of directors should serve as a director as of the date of this Form 10-K.

Class I Directors

Angus C. Russell, age 62, has served as a director and Chairman of the Board of our company since March 2014. Mr. Russell was Chief Executive Officer of Shire plc, or Shire, a biopharmaceutical company, from June 2008 until April 2013, and a member of its board of directors from 1999 until 2013. From December 1999 to June 2008, Mr. Russell served as Chief Financial Officer of Shire. Prior to joining Shire, Mr. Russell served at AstraZeneca plc, a pharmaceutical and biologics company, most recently as VP of Corporate Finance. Mr. Russell is a former Non-Executive Director of the City of London Investment Trust plc. Mr. Russell is a Chartered Accountant and is a Fellow of the Association of Corporate Treasurers. Mr. Russell has served on the board of directors at Mallinckrodt plc, a pharmaceuticals company, since August 2014, BioTime, Inc., a biotechnology company, since December 2014 and TherapeuticsMD, Inc., a pharmaceutical company, since March 2015. Our board of directors believes that Mr. Russell's financial expertise, experience at multiple public pharmaceutical companies and his expertise in the development and commercialization of specialty pharmaceutical products make him qualified to serve on our board of directors.

Phyllis Gardner, M.D., age 67, has served as a director of our Company since December 2006. Dr. Gardner has spent over 35 years in academia, medicine and industry. She served at Essex Woodlands, a growth equity firm that focuses on the healthcare industry, from June 1999 to 2014, in various capacities including as an adjunct Partner. Dr. Gardner has served on the board of directors of several public and private companies, including Corium International, Inc. since November 2007. She began her academic medical career at Stanford University, where she has held several positions including Senior Associate Dean for Education and Student Affairs and remains today as Professor of Medicine. From 1994 to 1998, she took a leave of absence from Stanford University to serve as Principal Scientist, Vice President of Research and Head of ALZA Technology Institute, a major drug delivery company. Dr. Gardner holds a B.S. from the University of Illinois and an M.D. from Harvard University. Our board of directors believes that Dr. Gardner's medical, healthcare and private equity experience, operating experience and significant experience serving as a director of our company and other healthcare companies make her qualified to serve on our board of directors.

Julian S. Gangolli, age 60, has served as a director since July 2016. He is President, North America of GW Pharmaceuticals Inc. and President of Greenwich Biosciences, Inc., the U.S. subsidiary of GW Pharmaceuticals, spearheading the buildout of the company's U.S. commercial infrastructure in advance of the potential launch of its

lead therapeutic candidate, Epidiolex® (cannabidiol or CBD), which is in late-stage development for a number of child-onset epilepsy syndromes. Prior to joining GW Pharma, Mr. Gangolli served as President of the North American Pharmaceutical division of Allergan Inc. for 11 years. Prior to that, he served as Senior Vice President, U.S. Eye Care at Allergan. Prior to Allergan, Mr. Gangolli served in sales and marketing positions at VIVUS, Inc., Syntex Pharmaceuticals, Inc., and Ortho-Cilag Pharmaceuticals Ltd in the United Kingdom. Our board of directors believes that Mr. Gangolli's operating experience in the

Table of Contents

biopharmaceutical industry, experience at multiple public pharmaceutical companies and his expertise in the development and commercialization of specialty pharmaceutical products make him qualified to serve on our board of directors.

**Class II Director**

Mark J. Foley, age 52, has served as a director of our company since September 2017. Mr. Foley has more than 25 years of operational and investment experience in the healthcare arena. He is currently Managing Director of RWI Ventures, a venture capital firm focused on life sciences, networking, semiconductor and software investments. Previously, Mr. Foley was Chairman, President and CEO of ZELTIQ Aesthetics (ZLTQ), serving from 2012 through the company's acquisition in 2017 by Allergan (AGN). Prior to ZELTIQ, Mr. Foley held a variety of senior operating roles in large public companies and venture-backed startups, including U.S. Surgical Corporation, Guidant Corporation, Devices for Vascular Intervention (acquired by Eli Lilly), Perclose (acquired by Abbott) and Ventrica (acquired by Medtronic) where he was the founder and CEO. He is a board member at Glaukos (GKOS) and also serves as Chairman of ULab, HintMD and Arrinex. Mr. Foley received a Bachelor of Arts degree from the University of Notre Dame. Our board of directors believes that Mr. Foley's financial expertise, experience at multiple public pharmaceutical companies and his expertise with the development and commercialization in medical device and biotechnology industries make him qualified to serve on our board of directors.

**Class III Directors**

L. Daniel Browne, age 56, is one of our co-founders and has served as our President and Chief Executive Officer and a member of our board of directors since we commenced operations in 2002. Mr. Browne served as President and Chief Executive Officer of Neomend, Inc., a medical technology and biomaterials company, from 2001 to 2003. From 1997 through 2000, Mr. Browne served as President of Prograft Medical Inc., a medical technology company. Previously, Mr. Browne served for more than 16 years in leadership positions in product development, sales and marketing and business development in the Gore Medical Products Division of W.L. Gore & Associates, Inc., a global technology company, lastly as Business Leader in the Medical Products Division. Mr. Browne holds a B.S. from the University of Hawaii in Cell and Molecular Biology and an M.B.A. from Pepperdine University. Our board of directors believes that Mr. Browne is qualified to serve on our board of directors based on such experience and leadership roles, and his management perspective of the company, including our strategic opportunities and challenges and his track record of new product development, sales and marketing and value creation, each of which relates to our commercial opportunities.

Robert Byrnes, age 73, has served as a director of our company since August 2004. Mr. Byrnes has spent over forty years in the medical device and biotechnology industries. From October 1997 until October 2002, and from January 2005 to the present, Mr. Byrnes has served as the President and Chief Executive Officer of Roan Advisors, Inc., an advisory service for healthcare organizations. From November 2002 to January 2005, he served as the President and Chief Executive Officer of Thermage, Inc., a medical device company focused on non-invasive tissue tightening. Mr. Byrnes has also served as Chairman and Chief Executive Officer of Tokos Medical Corporation, a healthcare services company, President of Caremark, Inc., a home healthcare service company, and Vice President of Marketing and Business Development for Genentech, Inc., a biotechnology company. He currently serves on the board of directors of Allego Ophthalmics, LLC. Mr. Byrnes holds a B.S. in Pharmacy from Ferris State University and an M.B.A degree in Marketing and Finance from Loyola University, Chicago. Our board of directors believes that Mr. Byrnes's operating experience in the medical device and biotechnology industries, combined with his prior board positions, make him qualified to serve on our board of directors.

Philip J. Vickers, Ph.D., age 58, has served as a director of our company since February 2015. Dr. Vickers has over 25 years in the pharmaceutical industry experience. Since November 2017, he has been serving as the Chief Executive Officer and a member of the board of directors of Northern Biologics Inc. From 2011 until June 2017, Dr. Vickers served as Global Head of Research and Development and a member of the Executive Committee of Shire Plc, or Shire, a biotechnology company focused on the development of therapies for the treatment of rare and specialty conditions. Under Dr. Vickers' leadership Shire's pipeline had approximately 40 programs in clinical development in the areas of Genetic Disease, GI disease, Hematology, Immunology, Neuroscience, Ophthalmology and Oncology. Prior to Shire, Dr. Vickers held positions of increasing responsibility in Research and Development at Merck, Pfizer,

Boehringer-Ingelheim and Resolvix Pharmaceuticals. Dr. Vickers obtained his PhD in Biochemistry from the University of Toronto, which was followed by postdoctoral research in mechanisms of multidrug resistance in breast cancer at the National Cancer Institute in Bethesda, Maryland. Our board of directors believes that Dr. Vickers' experience at multiple pharmaceutical companies and his expertise in the development and commercialization of pharmaceutical products make him qualified to serve on our board of directors.



Table of Contents

## Executive Officers

The following table sets forth information concerning our executive officers as of December 31, 2017:

Name	Age	Position(s)
Executive Officers		
L. Daniel Browne	56	President, Chief Executive Officer and Director
Abhay Joshi, Ph.D.	55	Chief Operating Officer
Todd E. Zavodnick	46	Chief Commercial Officer and President, Aesthetics & Therapeutics
Lauren P. Silvernail	59	Chief Financial Officer and Chief Business Officer
L. Daniel Browne. Mr. Browne's biography is included above under the section titled "Board of Directors — Class III Directors."		

Abhay Joshi, Ph.D. has served our Chief Operating Officer since December 2015. Dr. Joshi brings over twenty-five years of global experience as a pharmaceutical and biotechnology executive. From March of 2007 to December 2015, Dr. Joshi served as the President and Chief Executive Officer of Alvine Pharmaceuticals, Inc., a pharmaceutical company developing therapeutic products for the treatment of autoimmune and inflammatory diseases, where he was responsible for overseeing all aspects of the company's business. Prior to Alvine Pharmaceuticals, he served as an Executive Vice President, Chief Technical Officer and member of the Executive Committee at CoTherix, Inc., which was acquired by Actelion Ltd in 2007. Prior to CoTherix, Dr. Joshi was the Vice President of Global Technical Operations, Specialty Pharmaceuticals at Allergan, Inc., where he was responsible for the company's global biologics manufacturing operations for BOTOX® and its Latin America and Asia Pacific pharmaceutical operations, and held a series of senior management positions. Dr. Joshi currently serves on the board of directors of Genyous Biomed International and Sira Pharmaceuticals, Inc. Dr. Joshi received his B.Tech in Chemical Engineering from the Indian Institute of Technology, New Delhi, an M.S.E. and a Ph.D. in Chemical Engineering from the University of Michigan, Ann Arbor, and an MBA from the University of California, Irvine.

Todd E. Zavodnick has served as our Chief Commercial Officer and President, Aesthetics & Therapeutics since September 2017. Mr. Zavodnick joined Revance from ZELTIQ Aesthetics, Inc., developer and marketer of the #1 non-invasive fat-reduction procedure known as CoolSculpting, where he was President of International prior to the company's acquisition by Allergan plc on April 28, 2017. Previously, he served in leadership roles at Galderma Laboratories, most recently as President and General Manager, North America. Prior to this, Mr. Zavodnick managed a successful 14-year career at Alcon Laboratories in a series of ascending sales and marketing positions both domestically and internationally, ultimately serving as President of Alcon China and Mongolia. He serves on the board of directors for NovaBay Pharmaceuticals (NYSE: NBY), Inc., Allurion Technologies, and the Children's Skin Disease Foundation. Mr. Zavodnick holds a M.B.A. from The University of Texas at Dallas and a B.S. in Pharmacy from Rutgers University.

Lauren P. Silvernail has served as our Chief Financial Officer and Chief Business Officer since December 2015 and Chief Financial Officer and Executive Vice President, Corporate Development from March 2013 to December 2015. From 2003 to 2012, Mrs. Silvernail was Chief Financial Officer and Vice President of Corporate Development at ISTA Pharmaceuticals, Inc., a pharmaceutical research and development company. During her tenure at ISTA, revenues grew to more than \$160 million and headcount increased to more than 340 employees by the time ISTA was purchased by Bausch & Lomb in June 2012. From 1995 to 2003, Mrs. Silvernail served in various operating and corporate development positions with Allergan, Inc., a pharmaceutical company, including Vice President, Business Development. Prior to joining Allergan, Inc., Mrs. Silvernail worked at Glenwood Ventures, an investment firm, as a General Partner. She currently serves on the board of directors and the audit committee of Nicox S.A. Mrs. Silvernail holds a B.A. in Biophysics from the University of California, Berkeley and an M.B.A. from the Anderson Graduate School of Management at the University of California, Los Angeles.

## Governance and Board Composition

**Board Committees.** Our board of directors has an audit committee, a compensation committee, a nominating and corporate governance committee and a science and technology committee. Our board of directors may establish other committees to facilitate the management of our business. Members serve on these committees until their resignation or

until otherwise determined by our board of directors.

Audit Committee. Our audit committee currently consists of Mr. Foley, Mr. Byrnes, and Mr. Gangolli. Our board of directors has determined that all current members of our audit committee satisfy the independence requirements under the

80

---

## Table of Contents

Nasdaq listing rules and Rule 10A-3(b)(1) of the Exchange Act. Each member of the audit committee meets the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq. The chair of our audit committee is Mark J. Foley. Our board of directors has determined that each of Messrs. Byrnes and Foley is an “audit committee financial expert” within the meaning of the SEC regulations. Our board of directors has determined that the composition of our audit committee meets the criteria for independence under, and the functioning of our audit committee complies with, the applicable requirements of the Sarbanes-Oxley Act, applicable requirements of the Nasdaq listing rules and SEC rules and regulations. We intend to continue to evaluate the requirements applicable to us and comply with future requirements to the extent that they become applicable to our audit committee. The principal duties and responsibilities of our audit committee include:

appointing and retaining an independent registered public accounting firm to serve as independent auditor to audit our Consolidated Financial Statements, overseeing the independent auditor’s work and determining the independent auditor’s compensation;

approving in advance all audit services and non-audit services to be provided to us by our independent auditor;

establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls, auditing or compliance matters, as well as for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;

reviewing and discussing with management and our independent auditor the results of the annual audit and the independent auditor’s review of our quarterly Consolidated Financial Statements; and

conferring with management and our independent auditor about the scope, adequacy and effectiveness of our internal accounting controls, the objectivity of our financial reporting and our accounting policies and practices.

**Director Nominations.** The nominating and corporate governance committee of the board of directors, to date, has not adopted a formal policy with regard to the consideration of director candidates recommended by stockholders and will consider director candidates recommended by stockholders on a case-by-case basis, as appropriate. Stockholders wishing to recommend individuals for consideration by the nominating and corporate governance committee may do so by delivering a written recommendation to our Secretary at 7555 Gateway Boulevard, Newark, California 94560 and providing the candidate’s name, biographical data and qualifications and a document indicating the candidate’s willingness to serve if elected. The nominating and corporate governance committee does not intend to alter the manner in which it evaluates candidates based on whether the candidate was recommended by a stockholder or not. To date, the nominating and corporate governance committee has not received any such nominations nor has it rejected a director nominee from a stockholder or stockholders holding more than 5% of our voting stock.

**Code of Business Conduct.** Our board of directors adopted a Code of Business Conduct and Ethics that applies to all of our employees, officers, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions and agents and representatives, including directors and consultants. The full text of our Code of Business Conduct and Ethics is posted on our website at [www.revance.com](http://www.revance.com). We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics, or waivers of such provisions applicable to any principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and our directors, on our website identified above.

### Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities of our company. Officers, directors and greater than ten percent stockholders are required by SEC regulation

to furnish us with copies of all Section 16(a) forms they file.

To the best of our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required, during the fiscal year ended December 31, 2017, all of our officers, directors and greater than ten percent beneficial owners complied with all Section 16(a) filing requirements applicable to them.

Table of Contents

## ITEM 11. EXECUTIVE COMPENSATION

Our named executive officers, or NEOs, consisting of our principal executive officer and the next two most highly compensated executive officers during 2017, are:

• Daniel Browne, President and Chief Executive Officer;

• Todd E. Zavodnick, Chief Commercial Officer and President, Aesthetics & Therapeutics

• Abhay Joshi, Ph.D., Chief Operating Officer.

## Summary Compensation Table

The following table sets forth all of the compensation awarded to, earned by or paid to our NEOs during 2017 and 2016.

Name and Principal Position	Year	Salary(\$)	Bonus(\$)	Stock Awards	Option Awards(\$) <sup>(2)</sup>	Nonequity Incentive Plan Compensation <sup>(1)</sup>	All Other Compensation(\$)	Total(\$)
L. Daniel Browne President and Chief Executive Officer	2017	\$525,300	\$—	\$508,260	\$1,905,694	\$466,038	\$—	\$3,405,292
	2016	\$510,000	\$—	\$428,000	\$1,689,835	\$273,488	\$—	\$2,901,323
Todd E. Zavodnick Chief Commercial Officer and President, Aesthetics & Therapeutics	2017	\$116,667 <sup>(3)</sup>	\$—	\$2,318,000	\$520,282	\$103,846	\$22,244	<sup>(4)</sup> \$3,081,039
	2016	\$—	\$—	\$—	\$—	\$—	\$—	\$—
Abhay Joshi, Ph.D. Chief Operating Officer	2017	\$453,200	\$—	\$258,070	\$971,289	\$344,728	\$—	\$2,027,287
	2016	\$440,000	\$200,000	\$606,600	\$—	\$160,875	\$—	\$1,407,475

Amounts shown in this column represent cash bonus awards granted to our NEOs under our annual incentive plan.

(1) Such bonuses are tied to achievement against clinical and financial goals that are set in the first quarter of the applicable fiscal year, with payouts determined after the close of the year and primarily based on our level of achievement against those goals.

The dollar amounts in this column represent the aggregate grant date fair value of all option awards granted during the indicated year. These amounts have been calculated in accordance with FASB ASC Topic 718, or ASC 718, using the Black-Scholes option-pricing model. For a discussion of valuation assumptions, see Note 11 to our financial statements and the discussion under “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates — Stock-Based Compensation” included elsewhere in this Form 10-K. These amounts do not necessarily correspond to the actual value that may be recognized from the option awards by the NEOs.

(2) Mr. Zavodnick's annual base salary for 2017 was \$400,000. The amount shown reflects the salary earned from his date of hire on September 18, 2017 through December 31, 2017.

(3) Represents taxable fringe benefits for housing and travel.

Table of Contents

## Outstanding Equity Awards at December 31, 2017

The following table provides information regarding outstanding equity awards held by each of our NEOs as of December 31, 2017.

	Option Awards				Stock Awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares that Have Not Vested	Market Value of Shares That Have Not Vested
L. Daniel Browne	20,000	—	\$ 2.55	4/29/2018	—	—
	10,990	—	\$ 2.55	7/20/2020	—	—
	298,750	—	\$ 8.70	5/26/2023	—	—
	99,583	—	\$ 9.15	12/16/2023	—	—
	264,987(1)	30,813	\$ 32.22	5/18/2024	—	—
	179,739(2)	66,761	\$ 16.23	1/27/2025	—	—
	80,208 (7)	94,792	\$ 17.12	2/8/2026	—	—
	35,520 (9)	119,480	\$ 19.70	1/25/2027	—	—
	—	—	\$ —	—	14,500(3)	\$518,375
	—	—	\$ —	—	16,667(8)	\$595,845
	—	—	\$ —	—	25,800(10)	\$922,350
Todd E. Zavodnick	—	(11)35,000	\$ 24.40	9/17/2027	—	—
	—	—	\$ —	—	95,000(12)	\$3,396,250
Abhay Joshi, Ph.D.	666	—	\$ 4.20	4/28/2019	—	—
	666	—	\$ 2.55	4/29/2018	—	—
	103,124(4)	103,126	\$ 36.32	12/13/2025	—	—
	18,104 (9)	60,896	\$ 19.70	1/25/2027	—	—
	—	—	\$ —	—	17,187(5)	\$614,435
	—	—	\$ —	—	36,000(6)	\$1,287,000
	—	—	\$ —	—	13,100(10)	\$468,325

This option was granted on May 19, 2014. The shares subject to the stock option vest over a four year period, with (1) one-forty-eighth of the shares vesting each month, subject to providing continued service to us through each vesting date.

This restricted stock award was granted on January 28, 2015. The shares subject to the stock option vest over a four (2) year period, with one-forty-eighth of the shares vesting each month, subject to providing continued service to us through each vesting date.

This restricted stock award was granted on January 28, 2015. The shares subject to the stock award vest over a (3) three year period, with one-third of the shares vesting each year, subject to providing continued service to us through each vesting date.

This option was granted on December 14, 2015. The shares subject to the stock option vest over a four year period, (4) with 25% vesting on December 14, 2016 and the balance vesting each month over the remaining three-year period, subject to providing continued service to us through each vesting date.

This restricted stock award was granted on December 14, 2015. The shares subject to the stock award vest over a (5) four year period, with one-fourth of the shares vesting each year, subject to providing continued service to us through each vesting date.

(6)

This restricted stock award was granted on December 15, 2016. The shares subject to the stock award vest over a three year period, with one-third of the shares vesting each year, subject to providing continued service to us through each vesting date.

This option was granted on February 9, 2016. The shares subject to the stock option vest over a four year period, (7) with one-forty-eighth of the shares vesting each month, subject to providing continued service to us through each vesting date.

## Table of Contents

This restricted stock award was granted on February 9, 2016. The shares subject to the stock award vest over a (8)three year period, with one-third of the shares vesting each year, subject to providing continued service to us through each vesting date.

This option was granted on January 26, 2017. The shares subject to the stock option vest over a four year period, (9)with one-forty-eighth of the shares vesting each month, subject to providing continued service to us through each vesting date.

This restricted stock award was granted on January 26, 2017. The shares subject to the stock award vest over a (10)three year period, with one-third of the shares vesting each year, subject to providing continued service to us through each vesting date.

This option was granted on September 18, 2017. The shares subject to the stock option vest over a four year (11)period, with 25% vesting on September 18, 2018, and the balance vesting each month over the remaining three-year period, subject to providing continued service to us through each vesting date.

This restricted stock award was granted on September 18, 2017. The shares subject to the stock award vest over a (12)four year period, with one-fourth of the shares vesting each year beginning on October 15, 2018, subject to providing continued service to us through each vesting date.

### Executive Employment Arrangements

We have entered into employment agreements with each of our named executive officers; these agreements have no specific term of employment and provide for at-will employment. Each employment agreement provides the NEO with an annual base salary and target bonus opportunity, eligibility for employee benefits offered to our other employees, as well as eligibility under our Executive Severance Plan, described below. The target annual bonus opportunity (expressed as a percentage of base salary) for Mr. Browne was 66% for 2017 and 2018; for Mr. Zavodnick was 75% for 2017 and 2018; and for Dr. Joshi was 45% for 2017 and 2018.

### Severance and Change of Control Benefits

Each of our NEOs is eligible for our Executive Severance Plan, which provides severance benefits in the event of certain qualifying terminations of employment, subject to the executive's execution of a waiver and release of claims in favor of the company.

Under the Severance Plan, upon an involuntary termination of a participant other than for cause, and where such termination is not within 12 months following a change of control, the benefits provided under the Severance Plan consist of: (i) salary continuation payments for 15 months in the case of our chief executive officer, and for nine months in the case of the other NEOs; and (ii) payment by us of COBRA premiums for the participant and his eligible dependents for a period of up to 15 months in the case of our chief executive officer, and up to nine months in the case of the other NEOs.

For a period of 12 months following a change in control, if we involuntarily terminate a participant for any reason other than cause, or the participant resigns for "good reason" (each as defined in the Severance Plan), then the benefits provided by the Severance Plan will consist of: (i) a lump sum payment equal to the sum of the participant's monthly base salary and monthly annual target bonus, multiplied by 21 in the case of our chief executive officer, and by 12 in the case of the other NEOs; (ii) payment of COBRA premiums for the named executive officer and his eligible dependents for a period of up to 21 months in the case of our chief executive officer, and up to 12 months in the case of the other NEOs; and (iii) accelerated vesting of all unvested stock options then held by the NEO.

Under the Severance Plan, a "change of control" is defined the same way it is under our 2014 Equity Incentive Plan. If any of the benefits provided under the Severance Plan would constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended, or the Code, such that the payments would become subject to the excise tax imposed by Section 4999 of the Code, then the payments will either be paid in full to the participant, or reduced so that a smaller amount or no portion of such benefits will be subject to the excise tax, whichever provides the greater after-tax benefit to the participant.





Table of Contents

## Employee Benefit Plans

## 401(k) Plan

We sponsor a 401(k) retirement plan in which our named executive officers participate on the same basis as our other U.S. employees. During the year ended December 31, 2017, the Company made contributions to the plan of approximately \$0.2 million.

## Pension Benefits

We do not maintain a defined benefit pension plan for any of our employees.

## Nonqualified Deferred Compensation

We do not maintain a plan providing nonqualified deferred compensation for any of our employees.

## 2017 Director Compensation Table

The compensation provided to our non-employee directors in 2017 is enumerated in the table below. Mr. Browne, who is also one of our employees, did not and will not receive any compensation for his services as a director.

The following table sets forth a summary of the compensation received during the year ended December 31, 2017:

Name	Fees Earned (\$) and	Stock Options Awards (\$)*	Total (\$)
Robert Byrnes	67,777	135,513 (1)	203,290
Ronald W. Eastman <sup>(2)</sup>	30,011	135,513	165,524
Mark J. Foley <sup>(3)</sup>	19,079	318,733 (4)	337,812
Julian S. Gangolli	47,000	135,513 (5)	182,513
Phyllis Gardner, M.D.	49,500	135,513 (6)	185,013
Mark A. Prygocki <sup>(7)</sup>	21,577	—	21,577
Angus C. Russell	83,581	135,513 (8)	219,094
Philip Vickers	51,750	135,513 (9)	187,263

The dollar amounts in this column represent the grant date fair value of the stock option award. These amounts have been calculated in accordance with ASC 718 using the Black-Scholes option-pricing model. For a discussion of valuation assumptions, see Note 11 to our financial statements and the discussion under “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates — Stock-Based Compensation” included elsewhere in this Form 10-K. These amounts do not necessarily correspond to the actual value that may be recognized from the option and awards by the applicable directors.

(1) As of December 31, 2017, Mr. Byrnes had options to purchase 53,333 shares of our common stock and restricted stock awards of 3,000 shares.

(2) Mr. Eastman resigned from our Board effective September 5, 2017.

(3) Mr. Foley joined our Board effective September 5, 2017.

(4) As of December 31, 2017, Mr. Foley had options to purchase 12,000 shares of our common stock and restricted stock awards of 6,000 shares.

(5) As of December 31, 2017, Mr. Gangolli had options to purchase 24,000 shares of our common stock and restricted stock awards of 3,000 shares.

(6) As of December 31, 2017, Dr. Gardner had options to purchase 35,333 shares of our common stock and restricted stock awards of 3,000 shares.

(7) Mr. Prygocki resigned from our Board effective May 11, 2017.

(8) As of December 31, 2017, Mr. Russell had options to purchase 40,000 shares of our common stock and restricted stock awards of 3,000 shares.

(9) As of December 31, 2017, Dr. Vickers had options to purchase 40,000 shares of our common stock and restricted stock awards of 3,000 shares.



Table of Contents

## Non-employee Director Compensation

In December 2013, our board of directors approved a non-employee director compensation policy that became effective upon the completion of our IPO, which was subsequently amended effective as of July 30, 2015, January 1, 2016 and February 16, 2017.

Under this policy, we pay each of our non-employee directors a cash retainer for service on the board of directors and for service on each committee on which the director is a member. The chairman of each committee receives a higher retainer for such service. These retainers are payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on our board of directors. The retainers paid to non-employee directors for service on the board of directors and for service on each committee of the board of directors on which the director is a member are as follows:

	Member Annual Service Retainer	Chairman Additional Annual Service Retainer
Board of Directors	\$ 39,500	\$ 34,500
Audit Committee	7,500	12,500
Compensation Committee	5,000	7,250
Nominating and Corporate Governance Committee	4,500	3,500
Science & Technology Committee	5,000	7,250

In addition, on the date of each annual meeting of stockholders held, each non-employee director that continues to serve as a non-employee member on our board of directors will receive an option to purchase 6,000 shares of our common stock and 3,000 shares of restricted stock. The exercise price of these options will equal the fair market value of our common stock on the date of grant, and these options will vest on the one-year anniversary of the grant date, subject to the director's continued service as a director. This policy is intended to provide a total compensation package that enables us to attract and retain qualified and experienced individuals to serve as directors and to align our directors' interests with those of our stockholders.

Directors have been and will continue to be reimbursed for expenses directly related to their activities as directors, including attendance at board and committee meetings. Directors are also entitled to the protection provided by their indemnification agreements and the indemnification provisions in our certificate of incorporation and bylaws.

## Compensation Committee Interlocks and Insider Participation

During the fiscal year ended December 31, 2017, Mr. Byrnes and Dr. Gardner served on the compensation committee, with Mr. Byrnes serving as its chair. Neither Mr. Byrnes nor Dr. Gardner are currently nor have been at any time one of our employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

Table of Contents

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

## Equity Compensation Plan Information

The following table provides certain information with respect to our equity compensation plans in effect as of December 31, 2017.

Plan Category	Number of securities	Weighted-average exercise price of outstanding options, warrants and rights (b) <sup>(3)</sup>	Number of securities
	to be issued upon exercise of outstanding options, warrants and rights (a)		remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders: <sup>(1)</sup>	2,837,150	\$ 19.29	1,819,883 <sup>(4)</sup>
Equity compensation plans not approved by security holders: <sup>(2)</sup>	373,250	28.96	292,096
Total	3,210,400	\$ 20.41	2,111,979

(1) Includes securities issuable under the 2002 Equity Incentive Plan, the 2012 Equity Incentive Plan, the 2014 Equity Incentive Plan, or the 2014 plan, and the 2014 Employee Stock Purchase Plan, or the 2014 ESPP.

(2) Includes securities issuable under the 2014 Inducement Plan adopted exclusively for grants of awards to individuals that were not previously our employees or directors, as an inducement material to the individual's entry into employment with us within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules.

(3) The weighted average exercise price excludes restricted stock awards, which have no exercise price.

(4) Includes (i) 903,049 shares of common stock available for issuance under our 2014 plan and (ii) 916,834 shares of common stock available for issuance under our 2014 ESPP. The number of shares of our common stock reserved for issuance under the 2014 plan automatically increases on January 1st of each year, starting on January 1, 2015 and continuing through January 1, 2024, by 4% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, or such lesser number of shares of common stock as determined by our Board of Directors. The maximum number of shares that may be issued pursuant to the exercise of incentive

(4) stock options under the 2014 plan is 2,000,000 shares. The number of shares of our common stock reserved under the 2014 ESPP for issuance automatically increases on January 1st each year, starting January 1, 2015 and continuing through January 1, 2024, in an amount equal to the lower of (i) 1% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, and (ii) 300,000 shares of common stock, or such lesser number of shares of common stock as determined by our Board of Directors. If a purchase right granted under our 2014 ESPP terminates without having been exercised, the shares of our common stock not purchased under such purchase right will be available for issuance under our 2014 ESPP.

## Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding the ownership of our common stock as of January 15, 2018 by: (i) each director; (ii) each named executive officer; (iii) all of our executive officers and directors as a group; and (iv) all those known by us to be beneficial owners of more than five percent of our common stock. We are aware that one or more institutional investors purchased a number of shares of our common stock in amounts representing in excess of five percent of our common stock as of January 15, 2018, and as a result, one or more of such institutional investors may continue to beneficially own in excess of five percent of our common stock as of January 15, 2018. However, as of the date of this Form 10-K, other than as disclosed below, we are not aware of any filings made with the SEC with respect to the beneficial ownership of our common stock by such institutional investors and we were

otherwise unable to verify the beneficial ownership of our common stock by any such institutional investor as of the date of this Form 10-K.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power. Shares of common stock issuable under options or warrants that are exercisable within 60 days after January 15, 2018, are deemed beneficially owned and such shares are used in computing the percentage ownership of the person holding the options or warrants but are not deemed outstanding for the purpose of

Table of Contents

computing the percentage ownership of any other person. The percentage of beneficial ownership is based on 36,502,409 shares of our common stock outstanding as of January 15, 2018.

The information contained in the following table is not necessarily indicative of beneficial ownership for any other purpose and the inclusion of any shares in the table does not constitute an admission of beneficial ownership of those shares.

Unless otherwise indicated below, to our knowledge, all persons named in the table have sole voting and dispositive power with respect to their shares of common stock, except to the extent authority is shared by spouses under community property laws. Unless otherwise indicated below, the address of each beneficial owner listed in the table below is c/o Revance Therapeutics, Inc., 7555 Gateway Blvd., Newark, CA 94560.

Name of Beneficial Owner	Beneficial Ownership Number of Shares	Percentage of Total
Named Executive Officers and Directors:		
L. Daniel Browne <sup>(1)</sup>	1,163,491	3.10 %
Abhay Joshi <sup>(2)</sup>	212,098	*
Todd E. Zavodnick <sup>(16)</sup>	95,000	*
Robert Byrnes <sup>(3)</sup>	63,998	*
Mark J. Foley <sup>(17)</sup>	26,000	*
Phyllis Gardner, M.D. <sup>(4)</sup>	32,333	*
Angus C. Russell <sup>(5)</sup>	37,000	*
Philip J. Vickers, Ph.D. <sup>(6)</sup>	37,000	*
Julian S. Gangolli <sup>(7)</sup>	21,000	*
Directors and officers as a group (total of 10 persons) <sup>(8)</sup>	1,920,395	5.05 %
Greater than 5% Stockholders:		
Entities affiliated with Essex VIII <sup>(9)</sup>	3,842,047	10.53 %
Entities affiliated with NovaQuest <sup>(10)</sup>	3,096,650	8.48 %
Entities affiliated with Franklin Resources, Inc. <sup>(11)</sup>	3,394,202	9.30 %
Entities affiliated with JPMorgan Chase & Co. <sup>(12)</sup>	3,561,679	9.76 %
Entities affiliated with The Bank of New York Mellon Corporation <sup>(13)</sup>	2,144,669	5.88 %
Entities affiliated with BlackRock, Inc. <sup>(14)</sup>	2,168,211	5.94 %
Entities affiliated with Wellington Management Group LLP <sup>(15)</sup>	3,573,150	9.79 %

\* Represents beneficial ownership of less than 1% of the outstanding common stock

(1) Consists of 133,315 shares of common stock and 1,029,767 shares of common stock underlying options that are vested and exercisable within 60 days of January 15, 2018 and 409 shares of common stock held by the Dan and Brenda Browne Living Trust. Mr. Browne is a Trustee of the Dan and Brenda Browne Living Trust.

(2) Consists of 73,356 shares of common stock and 138,742 shares of common stock underlying options that are vested and exercisable within 60 days of January 15, 2018

(3) Consists of 3,000 shares of common stock and 47,333 shares of common stock underlying options that are vested and exercisable within 60 days of January 15, 2018, and 13,665 shares of common stock held by the Byrnes Family Trust. Mr. Byrnes is a Trustee of the Byrnes Family Trust.

(4) Consists of 3,000 shares of common stock and 29,333 shares of common stock underlying options that are vested and exercisable within 60 days of January 15, 2018.

(5) Consists of 3,000 shares of common stock and 34,000 shares of common stock underlying options that are vested and exercisable within 60 days of January 15, 2018.

(6)

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

Consists of 3,000 shares of common stock and 34,000 shares of common stock underlying options that are vested and exercisable within 60 days of January 15, 2018.

(7) Consists of 3,000 shares of common stock and 18,000 shares of common stock underlying options that are vested and exercisable within 60 days of January 15, 2018.

Includes shares beneficially owned by all current executive officers and directors of the company. Consists of (8) 423,700 shares of common stock and 1,496,695 shares of common stock underlying options that are vested and exercisable within 60 days of January 15, 2018.



Table of Contents

Consists of 3,067,607 shares of common stock held by Essex Woodlands Health Ventures Fund VIII, L.P. (“Essex Fund VIII”), 457,085 shares of common stock held by Essex Woodlands Health Ventures Fund V, L.P. (“Essex Fund V”), 221,197 shares of common stock held by Essex Woodlands Health Ventures Fund VIII-A, L.P. (“Essex Fund VIII-A”) and 96,158 shares of common stock held by Essex Woodlands Health Ventures Fund VIII-B, L.P. (“Essex Fund VIII-B”). Essex Woodlands Health Ventures VIII, LLC, the general partner of Essex Fund VIII, Essex Fund V, Essex Fund VIII-A and Essex Fund VIII-B, may be deemed to have sole power to vote and sole power to dispose of shares directly owned by Essex Fund VIII, Essex Fund V, Essex Fund VIII-A and Essex Fund VIII-B. The address for Essex Fund VIII is 21 Waterway Avenue, Suite 225, The Woodlands, Texas 77380.

(9) The indicated ownership is based on Schedule 13G/A filed with the SEC by the reporting persons on February 9, 2016, reporting beneficial ownership as of December 31, 2016. According to the Schedule 13G/A, the reporting persons beneficially own 3,096,650 shares of common stock held by NovaQuest Pharma Opportunities Fund III, L.P. (“NovaQuest”), NQ HCIF General Partner, L.P., and NQ HCIF GP, Ltd.. The address for each of the foregoing persons and entities is 4208 Six Forks Road, Suite 920, Raleigh, North Carolina 27609.

(10) The indicated ownership is based on a Schedule 13G/A filed with the SEC by the reporting persons on February 7, 2018, reporting beneficial ownership as of December 31, 2017. According to the Schedule 13G/A, the reporting persons beneficially own a total of shares of 3,370,402 common Stock held by Franklin Advisors, Inc. and 23,800 shares of Common Stock held by Fiduciary Trust Company International. The address for each of the foregoing persons and entities is One Franklin Parkway, San Mateo, CA 94403.

(11) The indicated ownership is based on a Schedule 13G/A filed with the SEC by the reporting persons on January 25, 2018, reporting beneficial ownership as of December 29, 2017. According to the Schedule 13G/A, the reporting persons beneficially own a total of 3,561,679 shares of Common Stock held by JPMorgan Chase & Co. and its wholly owned subsidiaries JPMorgan Chase Bank, National Association, J.P. Morgan Investment Management Inc., and JPMorgan Asset Management (UK) Limited. The address for each of the foregoing persons and entities is 270 Park Ave. New York, NY 10017.

(12) The indicated ownership is based on a Schedule 13G/A filed with the SEC by the reporting persons on February 7, 2018, reporting beneficial ownership as of December 31, 2017. According to the Schedule 13G/A, the reporting persons beneficially own a total of 2,144,669 shares of Common Stock held by The Bank of New York Mellon Corporation and its following affiliates: The Bank of New York Mellon, The Boston Company Asset Management LLC, The Dreyfus Corporation (parent holding company of MBSC Securities Corporation), Mellon Capital Management Corporation, MAM (MA) Holding Trust (parent holding company of Standish Mellon Asset Management Company LLC; The Boston Company Asset Management LLC) and MBC Investments Corporation (parent holding company of Mellon Capital Management Corporation; BNY Mellon Investment Management (Jersey) Ltd.). The address for each of the foregoing persons and entities is 225 Liberty Street, New York, NY 10286.

(13) The indicated ownership is based on a Schedule 13G filed with the SEC by the reporting persons on January 23, 2018, reporting beneficial ownership as of December 31, 2017. According to the Schedule 13G, the reporting persons beneficially own a total of 2,168,211 shares of Common Stock held by BlackRock Inc. and its subsidiaries BlackRock Advisors, LLC, BlackRock Asset Management Canada Limited, BlackRock Asset Management Ireland Limited, BlackRock Asset Management Schweiz AG, BlackRock Fund Advisors, BlackRock Institutional Trust Company, N.A. and BlackRock Investment Management, LLC. The address for each of the foregoing persons and entities is 55 East 52nd Street, New York, NY 10055.

(14) The indicated ownership is based on a Schedule 13G filed with the SEC by the reporting persons on February 8, 2018, reporting beneficial ownership as of December 29, 2017. According to the Schedule 13G, the reporting persons beneficially own a total of 3,573,150 shares of Common Stock held by Wellington Management Group LLP and its following affiliates: Wellington Management Group LLP, Wellington Group Holdings LLP, Wellington Investment Advisors Holdings LLP, and Wellington Management Company LLP. The address for each of the foregoing persons and entities is 280 Congress Street, Boston, MA 02210.

(15) Consists of 95,000 shares of common stock.

- (17) Consists of 6,000 shares of common stock, and 20,000 shares of common stock held by the Mark J Foley Living Trust. Mr. Foley is a Trustee of the Mark J Foley Living Trust.

Table of Contents

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The following is a summary of transactions since January 1, 2017 in which (i) we have been a participant, (ii) the amount involved exceeded or will exceed \$120,000, and (iii) any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of their immediate family or person sharing their household, had or will have a direct or indirect material interest, other than indemnification agreements, which are described below, and compensation arrangements, which are described under “Item 11. Executive Compensation.”

Of the Company's total cash, cash equivalents, and short-term investments of \$282.9 million as of December 31, 2017, the Company held cash equivalents and short-term investments with a total fair value of \$150.7 million in an investment account with a related party, J.P. Morgan Securities LLC. As of December 31, 2017, JPMorgan Chase & Co. and its wholly owned subsidiaries JPMorgan Chase Bank, National Association (NA), J.P. Morgan Investment Management Inc., and JPMorgan Asset Management (UK) Limited held 3,561,679 shares of the Company's common stock, which represents approximately 9.75% of the Company's outstanding common stock. J.P. Morgan Securities LLC, who acts as a custodian and trustee for certain Company investments, is an affiliate of JPMorgan Chase Bank, NA.

**Indemnification Agreements.** We have entered, or will enter, into an indemnification agreement with each of our directors and executive officers. The indemnification agreements and our certificate of incorporation and bylaws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law. For a description of these indemnification agreements, see the section entitled “Executive Compensation — Limitations on Liability and Indemnification Matters.”

**Policies and Procedures for Related Party Transactions.** All transactions between us and our officers, directors, principal stockholders and their affiliates are subject to approval by the audit committee, or a similar committee consisting of entirely independent directors, according to the terms of our written Related-Person Transactions Policy and Code of Business Conduct and Ethics.

**Director Independence**

Our board of directors undertook a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise his ability to exercise independent judgment in carrying out his responsibilities. As a result of this review, our board of directors determined that all of our directors except for Mr. Browne, our President and Chief Executive Officer, representing seven of our eight directors, are “independent directors” as defined under Nasdaq listing rules and the independence requirements of Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

Table of Contents

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to the Independent Registered Public Accounting Firm

The following table presents fees for professional audit services and other services rendered to our company by PricewaterhouseCoopers, or PwC, for the fiscal years ended December 31, 2017 and 2016.

	2017	2016
Audit Fees <sup>(1)</sup>	\$752,645	