

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

Revance Therapeutics, Inc.

Form 10-K

February 28, 2019

false--12-31FY20182018-12-3110-K0001479290YesfalseLarge Accelerated Filer1000000000Revance Therapeutics, Inc.falsefalseNoYesP6M629000000.0010.0010.00195000000950000009500000036516075369752033651607536975203P2Y5  
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us-gaap:ComputerEquipmentMember 2018-01-01 2018-12-31 0001479290  
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rvnc:ListLaboratoriesMember 2018-12-31 0001479290 us-gaap:ServiceAgreementsMember  
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rvnc:TwoThousandAndFourteenEquityIncentivePlanMember 2018-12-31 0001479290 srt:MaximumMember  
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**UNITED  
STATES  
SECURITIES  
AND  
EXCHANGE  
COMMISSION  
Washington,  
D.C. 20549**

**FORM 10-K**

( Mark One)

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**ANNUAL  
REPORT  
PURSUANT  
TO SECTION  
13 OR  
15(d) OF THE  
SECURITIES**

**EXCHANGE  
ACT OF 1934**

For the fiscal year  
ended December 31, 2018  
or

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

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

# Revance Therapeutics, Inc.

(Exact name of registrant as specified in its  
charter)

**Delaware**

State or other jurisdiction of  
incorporation or organization

**77-0551645**

(I.R.S. Employer  
Identification No.)

**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**

Common Stock, par value \$0.001 per  
share

**Name of Exchange on Which  
Registered**

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark 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

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

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  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 \$1.0 billion, based on the closing price of the registrant's common stock on the Nasdaq Global Market of \$27.45 per share for such date.

Number of shares outstanding of the registrant's common stock, par value \$0.001 per share, as of February 22, 2019 : 44,028,590

### **DOCUMENTS INCORPORATED BY REFERENCE**

Certain portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A, not later than April 30, 2019, in connection with the registrant's 2019 Annual Meeting of the Stockholders are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

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“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.

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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K, or Form 10-K, contains “forward-looking statements” within the meaning of Section 21E of the Securities Exchange Act of 1934, 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 DAXI, including but not limited to, for the treatment of glabellar (frown) lines, forehead lines, lateral canthal lines, cervical dystonia, plantar fasciitis, and adult upper limb spasticity in the United States (“U.S.”), Europe and other countries;
- our expectations regarding our future development of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates for other indications, including but not limited to, chronic migraine;
- our expectations regarding the development of future product candidates;
- the potential for commercialization by us of DAXI, if approved;
- our expectations regarding the potential market size, opportunity and growth potential for DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates, if approved for commercial use;
- our belief that DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates can expand overall demand for botulinum toxin;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners including distributors, to commercialize our product candidates, if approved;
- our ability to manufacture in our facility and to scale up our manufacturing capabilities and those of future third-party manufacturers if our product candidates are approved;
- estimates of our expenses, future revenue, capital requirements and our needs for additional financing;
- the timing or likelihood of regulatory filings and approvals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- the implementation of our business model, and strategic plans for our business, product candidates and technology;
- the initiation, timing, progress and results of future preclinical studies and clinical trials and our research and development programs;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our ability to establish collaborations or obtain additional funding;
- our financial performance, including future revenue targets; and
- developments and projections relating to our competitors and our industry.

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 impact may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Also, forward-looking statements represent our estimates and assumptions only as

of the date of this Form 10-K. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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**PART I**

**ITEM 1. BUSINESS**

**Overview**

Revance Therapeutics, Inc. (“we” or “the Company”) is a clinical-stage biotechnology company focused on the development, manufacturing and commercialization of novel neuromodulators 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 initial focus is on developing daxibotulinumtoxinA, our highly purified botulinum toxin Type A, for a broad spectrum of aesthetic and therapeutic indications, including facial wrinkles, muscle disorders, and chronic migraine.

Our lead drug candidate is DaxibotulinumtoxinA for Injection (“DAXI”). We used our unique proprietary peptide excipient technology to formulate DAXI. The noncovalent bond formed between the proprietary peptide excipient technology and the botulinum toxin may enable longer residence time of botulinum toxin Type A, which could explain DAXI’s long duration of effect. The process binds a highly purified botulinum toxin Type A with a unique proprietary stabilizing excipient peptide. We do not use human serum albumin (“HSA”) and other animal-sourced ingredients, which carry the risk of transmission of pathogens, to stabilize our product.

We are currently studying DAXI for the treatment of facial wrinkles, cervical dystonia, plantar fasciitis, adult upper limb spasticity and chronic migraine. We believe DAXI has the potential to expand into additional aesthetic and therapeutic indications in the future. We also are developing a topically applied neuromodulator for aesthetic and therapeutic indications, DaxibotulinumtoxinA Topical, and have a collaboration and license agreement with Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V. (“Mylan”), to develop and commercialize a biosimilar to BOTOX®.

**Pipeline Summary**

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### **Our Product Candidates**

#### **DaxibotulinumtoxinA for Injection (“DAXI”)**

We are developing an injectable formulation of botulinum toxin type A, which we refer to as DAXI, for indications where a long-lasting effect is desired. We believe, and our preclinical and clinical studies using DAXI indicate, that daxibotulinumtoxinA combined with our novel peptide may safely achieve enhanced clinical efficacy and duration without an increase in associated adverse events. We are currently focusing on developing DAXI for the treatment of both aesthetic and therapeutic indications.

#### ***Glabellar Lines***

The glabella is the area between the eyebrows and above the nose. Glabellar lines, often called “frown lines,” are vertical lines that develop between the eyebrows and may appear as a single vertical line or as two or more lines. When one frowns, the muscles of the glabella contract causing vertical creases to form between the eyebrows. Botulinum toxin is used to temporarily block the ability of nerves to trigger contraction of injected muscle, inhibiting movement of the muscles that cause the frown lines, giving the skin a smoother, more refreshed appearance. The most common cosmetic use of BOTOX® Cosmetic is for the treatment of glabellar lines. Consumers enjoy the benefits of currently available botulinum toxin 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 U.S. and, according to the American Society for Aesthetic Plastic Surgery (“ASAPS”), botulinum toxin treatment is the number one nonsurgical cosmetic procedure in the U.S. According to our 2018 Harris Poll survey results, 86 percent of the physicians surveyed want a neuromodulator that offers longer-lasting results than is available today and 88 percent of the patients consider long lasting duration very important or absolutely essential. Our primary qualitative market research among aesthetic physicians, patients, and office practice managers indicated that DAXI's longer lasting duration than what is available today is a differentiating and desirable attribute. A majority of those physicians interviewed reported that if DAXI confirmed 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 DAXI. 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 nearly twice per year for treatments and the longer duration would mean that they would enable patients to remain more satisfied between treatments.

#### ***Development of DAXI for Treatment of Glabellar Lines***

***Phase 1 and 2 Clinical Trials.*** DAXI has demonstrated long-lasting effect and appeared to provide safe administration of botulinum toxin in Phase 1 and 2 clinical trials, even with repeated doses. Long-lasting effect was first demonstrated in 2014 in the final cohort of a four-cohort Phase 1/2 dose escalation clinical trial conducted outside the U.S. for improvement of glabellar lines. In the trial, DAXI met its primary efficacy and safety endpoints. The open-label, dose escalating, Phase 1/2 trial enrolled 48 adults.

DAXI 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.

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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 DAXI 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 one-point improvement from baseline on the Investigator Global Assessment-Facial Wrinkle Severity ("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 DAXI, 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 DAXI achieved its primary efficacy measurement with high statistical significance. In addition, the 40 Unit dose of DAXI demonstrated a 23.6-week median duration, compared to BOTOX® Cosmetic with an 18.8-week median duration. Across all cohorts, DAXI appeared to be generally safe and well-tolerated.

*Phase 3 Clinical Trials.* The Phase 3 clinical program includes a) SAKURA 1 and SAKURA 2, two randomized, double-blind, placebo-controlled pivotal trials to evaluate the safety and efficacy of a single administration of DAXI for the treatment of moderate to severe glabellar lines in adults and b) SAKURA 3, a long-term, open-label safety trial designed to evaluate the long-term safety of DAXI for the treatment of moderate to severe glabellar lines in adults following both single and repeat treatment administration.

The SAKURA 1 and SAKURA 2 trials enrolled more than 600 subjects at 30 sites in the U.S. and Canada. In both trials, subjects were randomized in a 2:1 ratio to either the DAXI or placebo treatment groups, 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 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. 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 DAXI-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 DAXI-treated patients in SAKURA 1 and 91 percent of DAXI patients in SAKURA 2 said they were very satisfied or satisfied with their treatment experience.

There were several secondary endpoints used to evaluate duration of effect, including the proportion of patients achieving none or mild response on IGA-FWS compared to placebo, median duration for time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS, and median duration for time to return to baseline on both IGA-FWS and PFWS. The percentage of DAXI-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 DAXI-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 DAXI-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 DAXI-treated patients, and the results were 24.1 weeks for both SAKURA 1 and SAKURA 2, and 23.6 weeks for BELMONT.





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In December 2018, we announced top-line results for the SAKURA 3 open-label, long-term safety study. DAXI appeared to be generally well-tolerated, with no new tolerability or safety concerns reported. As was seen in the SAKURA 1 and SAKURA 2 pivotal trials, adverse events were mild, localized and transient. The rate of treatment-related adverse events decreased over successive treatments. The most common treatment-related adverse events per treatment of DAXI were headache (3.3 percent of treatments), injection site pain (2.7 percent), injection site erythema (2.5 percent), and injection site oedema (2.2 percent). There were no treatment-related serious adverse events. Eyelid ptosis was reported in 0.9 percent of treatments, decreased in frequency with successive treatments and was substantially lower than the rate observed in SAKURA 1 and SAKURA 2 (2.2 percent of treatments). The majority of ptosis events were characterized as mild in severity (85 percent) and transient. A high degree of efficacy was seen consistently across all three treatment cycles. Results were consistent with SAKURA 1 and SAKURA 2 based on the IGA-FWS and PFWS scales. As early as Week 1, over 90 percent of subjects across all three treatments had none or mild wrinkles on the IGA-FWS. At Week 4, the percentage of DAXI-treated patients who achieved a none or mild response on IGA-FWS was 95.8 percent, 96.6 percent, and 97.7 percent for first, second and third treatment for SAKURA 3, respectively, and 97.5 percent for SAKURA 2 and SAKURA 1. On the more stringent 2-point composite endpoint, which was the primary efficacy endpoint in SAKURA 1 and 2, efficacy improved with successive treatment cycles: 73.2 percent, 77.7 percent, and 79.6 percent for first, second and third treatment of SAKURA 3, respectively, and 73.6 percent and 74.0 percent for SAKURA 1 and 2, respectively.

As in the SAKURA 1 and SAKURA 2 pivotal trials, there were several secondary endpoints used to evaluate duration of effect, including median time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS, and median duration for time to return to baseline wrinkle severity on both IGA-FWS and PFWS. Duration was evaluated in the first two 36-week treatment cycles; the third treatment cycle was not evaluated for duration as the observation period ended at twelve weeks for the purpose of this study. Median time to return to baseline wrinkle severity on both IGA-FWS and PFWS is 28.0 weeks and 28.1 weeks for first and second treatment of SAKURA 3, respectively, 27.7 weeks for SAKURA 1, and 26.0 weeks for SAKURA 2. Median time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS is 24.0 weeks and 24.1 weeks for first and second treatment of SAKURA 3, respectively, 24.0 weeks for SAKURA 1, and 23.9 weeks for SAKURA 2. We held a pre-BLA meeting with U.S. Food and Drug Administration (“FDA”) in December 2018, to agree upon the content and format of the BLA, which we plan to submit in first half of 2019. We plan to file marketing applications in the European Union, Canada, and certain Latin American and Asian countries after filing in the U.S.

*European Union Agency Interactions.* We requested scientific guidance from the European Medicines Agency (“EMA”) on the development of DAXI 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 plan to provide data to support the various requests in the marketing application.

***Forehead Lines***

Forehead lines are produced by the action of the frontalis muscle, a large, thin, vertically-oriented muscle which lifts the eyebrows. The frontalis muscle serves as an antagonist to the glabellar musculature, a natural depressor that is responsible for frowning and associated eyebrow movement. As the eyebrow is considered the aesthetic center of the upper face, forehead lines can significantly impact the aesthetic appearance of the face, contribute to increased signs of aging and convey unwanted social signals. However, both men and women have identified internal factors, such as wanting to look good for their age or having a more youthful appearance as very important and have prioritized forehead lines as bothersome areas for potential treatment regardless of age or available income.

Minimally-invasive injectable treatments have become the most common procedure worldwide with an increase in frequency over the last decade since the first approval of botulinum neurotoxin Type A (BOTOX® Cosmetic [onabotulinumtoxinA] UPSI, Allergan, Inc. 2013). This is largely the result of years of experience of patients and injectors, and a favorable risk-benefit profile. BOTOX® Cosmetic was approved to treat forehead lines in 2017, and is currently the only toxin approved for that use, though other toxins are used off-label.

We initiated a Phase 2 study in forehead lines in January 2019.

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***Lateral Canthal Lines***

Lateral canthal lines (“LCL” or “crow’s feet”) are the spider-like fine lines around the outside corners of the eyes that become more obvious when someone smiles. These lines (also referred to as periorbital wrinkles, laugh lines or smile lines), fan out across the skin from the outer corner of each eye. Sometimes they extend down across the cheekbones to the lower cheeks. Repetitive motions, such as squinting and smiling, can lead to the increase of wrinkles and contribute to the severity and onset of crow’s feet. Age and exposure to sun also play significant roles in development of these lines, which can deepen over time. Current treatments include anti-wrinkle eye creams and moisturizers, topical tretinoin, botulinum toxin injections, dermal fillers and laser treatments. BOTOX® Cosmetic was approved to treat LCL in 2013, and is currently the only toxin approved for that use, though other toxins are used off-label.

We plan to initiate a Phase 2 study in LCL in the first quarter of 2019.

***Muscle Movement 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. 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 been 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. According to Global Industry Analytics, Inc. (“GIA”), the global opportunity for botulinum toxin for the treatment of muscle movement disorders, which includes cervical dystonia and upper limb spasticity, was estimated to be over \$1.0 billion in 2017. 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.

***DAXI for Treatment of Cervical Dystonia***

In 2015, we initiated a Phase 2 dose-escalating, open-label clinical study of DAXI to evaluate safety, preliminary efficacy, and duration of effect of DAXI 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 DAXI 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 DAXI, 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.

Key results of the cervical dystonia trial are as follows:

***Safety.*** In all three cohorts, DAXI 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 percent), of which all cases were mild in severity, injection site redness (8 percent), bruising (5 percent), injection site pain (5 percent), muscle

tightness (5 percent) and muscle weakness (5 percent). For reference, trials for botulinum type A products approved to treat cervical dystonia have reported adverse events for dysphagia ranging from 13 percent to 39 percent.

*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. DAXI showed a clinically significant mean reduction of 16.8 from baseline, or 38 percent, across all three cohorts at Week 4. This reduction continued to increase to 50 percent at Week 6 for all subjects, was 42 percent at Week 12 and was maintained at or above 30 percent 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 percent to 26 percent at Week 4 and 13 percent to 16 percent at Week 12.

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*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 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.

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

In June 2018, we announced the initiation of patient dosing in our ASPEN Phase 3 clinical program based on the Phase 2 safety and efficacy results and guidance from the FDA and EMA. The ASPEN Phase 3 clinical program consists of two trials to evaluate the safety and efficacy of DAXI for the treatment of cervical dystonia in adults including: a randomized, double-blind, placebo-controlled, parallel group trial, and an open-label, long-term safety trial. The program is expected to enroll approximately 300 patients in the pivotal trial and 350 patients in the open-label trial at multiple sites in the U.S., Canada, and Europe.

The program is expected to complete enrollment by early 2020, and we expect to release topline results in the second half of 2020.

### *DAXI for Treatment of Adult Upper Limb Spasticity*

We initiated a Phase 2 study (JUNIPER) in adult upper limb spasticity in December 2018. Our JUNIPER Phase 2 clinical trial of upper limb spasticity is a randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of DAXI at three dose levels versus placebo in reducing muscle tone of adult patients with upper limb spasticity due to stroke or traumatic brain injury over 36 weeks. The program is expected to enroll a total of approximately 128 patients, 18-70 years of age, at 25 sites in the U.S..

Patients will be randomized to one of three active treatment groups of DAXI or placebo. Post-treatment, patients will be followed for a maximum of 36 weeks. The co-primary efficacy endpoints of the trial will be the mean change from baseline in muscle tone using the Modified Ashworth Score (“MAS”) scale in the suprahypertonic muscle group (SMG - highest degree for muscle tone) of the elbow, wrist, or finger flexors at Week 6, and the mean score on the Physician Global Impression of Change (“PGIC”) scale at Week 6.

The JUNIPER study is expected to be fully enrolled by the second half of 2019, and we expect to release topline results in the second half of 2020.

### *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 20 million individuals in the U.S.. 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 U.S. 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 DAXI 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.

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*DAXI for Treatment of Plantar Fasciitis*

In 2016, we initiated a Phase 2 prospective, randomized, double-blinded, placebo-controlled trial of DAXI in the therapeutic indication of plantar fasciitis. This study evaluated the safety and efficacy of a single administration of DAXI in reducing the signs and symptoms of plantar fasciitis. The study completed enrollment of 59 subjects in the U.S. 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 percent reduction for patients treated with DAXI. In the intent-to-treat population, a mean reduction in the VAS score of 54.2 percent from baseline was achieved with DAXI, compared with a 42.6 percent 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 ( $p=0.39$ ), DAXI provided patients with considerable pain relief. Similar numeric trends were seen in the secondary and exploratory endpoints. DAXI 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 DAXI and placebo were injection site pain (10.0 percent and 10.3 percent) and muscle weakness (3.3 percent and 3.4 percent), both respectively, all of which were classified as mild in severity. We completed the 16-week trial which showed a 58 percent reduction of pain from baseline along with a strong placebo response, with the difference between the treatment groups not being statistically significant.

In September 2018, we completed a Type C meeting with FDA discussing the design of the Phase 2 dose-finding study. We initiated another Phase 2 trial in December 2018. The Phase 2 prospective, randomized, double-blind, multi-center, placebo-controlled study will evaluate the safety and efficacy of two doses of administration of our investigational drug candidate DAXI in reducing the signs and symptoms of plantar fasciitis. The study is expected to enroll approximately 150 adult patients with unilateral plantar fasciitis, from approximately 20 study centers in the U.S.. Patients will be randomized (1:1:1) to receive an injection of a low dose, high dose or placebo. The study's primary efficacy endpoint is the change from baseline in Numeric Pain Rating Scale ("NPRS") score at Week 8. Patients will be followed for up to 24 weeks post treatment to assess treatment response, tolerability and safety. We expect to complete enrollment in this Phase 2 trial during the second half of 2019 and release topline results in the second half of 2020.

*Chronic Migraine*

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

We are in the process of finalizing our Chronic Migraine Clinical Development strategy. We plan to study DAXI for the treatment of chronic migraine in 2019 or 2020.





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### **OnabotulinumtoxinA Biosimilar**

In February 2018, we entered into a collaboration and license agreement with Mylan (“Mylan Collaboration”) pursuant to which we will collaborate with Mylan exclusively, on a world-wide basis (excluding Japan) (the “ex-U.S. Mylan territories”), to develop, manufacture and commercialize a biosimilar to the branded biologic product (onabotulinumtoxinA) marketed as BOTOX®. As part of the Mylan Collaboration, Mylan agreed to pay a non-refundable upfront payment of \$25 million with additional 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 would pay us 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, we 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.

In February 2019, we and Mylan recently had a Biosimilar Initial Advisory Meeting with the FDA on a proposed biosimilar to BOTOX®. In this meeting, the FDA provided guidance on their expectations for a development program to establish biosimilarity to BOTOX®. Based on the agency’s feedback, we and Mylan believe that a 351(k) pathway for the development of a biosimilar to onabotulinumtoxinA is viable and provides the opportunity to develop and commercialize the first biosimilar product for all eleven currently approved indications of BOTOX® and BOTOX® Cosmetic.

### **DaxibotulinumtoxinA Topical**

DaxibotulinumtoxinA Topical presents several potential advantages, including painless topical administration, no bruising, ease of use and limited dependence on administration technique by physicians and medical staff. We believe these potential advantages may improve the experience of patients undergoing botulinum toxin procedures and could make DaxibotulinumtoxinA Topical suitable for multiple indications in the future. We are planning to conduct additional preclinical work for DaxibotulinumtoxinA Topical in therapeutic and aesthetic applications where botulinum toxin has shown efficacy and is particularly well suited for injection-free treatments.

### **Our Technology**

#### **Our Proprietary Peptide Excipient Technology**

Combining our proprietary peptide excipient technology with active drug macromolecules such as daxibotulinumtoxinA may help address currently unfulfilled needs in aesthetic medicine and therapeutic categories. Employing our proprietary peptide excipient technology may ensure overall formulation performance of the DAXI 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.

#### **DAXI Delivery of Botulinum Toxin**

DAXI utilizes our proprietary botulinum toxin-peptide complex in a saline-based formulation. In DAXI, 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 DAXI to neighboring muscles, DAXI is likely to be better tolerated at higher doses than BOTOX® Cosmetic. Additionally, at doses where the spread of BOTOX® Cosmetic and DAXI were compared, DAXI appeared to be more targeted with longer duration in our preclinical studies. Nonclinical and clinical data taken together suggest that DAXI 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 U.S. 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 U.S., 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.

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According to Millennium Research Group, Inc. ("MRG"), the global opportunity for botulinum toxin was estimated to be \$4.3 billion in 2018 compared to \$3.8 billion in 2017. The market is projected to reach approximately \$9.0 billion by 2027, registering a compounded annual growth rate of approximately 9 percent over the analysis period of 2017 to 2027. We estimate the market opportunity split between therapeutics and aesthetics is approximately 60 percent and 40 percent, respectively. We expect continued growth to be driven by new indications and product launches in new geographies. According to clinicaltrials.gov, as of December 31, 2018, there were more than 125 active clinical trials for a wide range of uses of botulinum toxin, with approximately 24 percent of these identified as being in Phase 3 clinical development. We are unaware of any clinical trials for potentially competitive long-lasting products that may realistically achieve commercialization before DAXI, but 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 U.S., 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 U.S. and the rest of the world. According to the 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. Non-surgical procedures account for approximately 68 percent of all procedures performed in 2017, according to the ASAPS 2017 annual statistics. Injectable botulinum toxin continued to be the most frequently performed non-surgical procedure in 2017, with 1.5 million procedures in the US, a 7.6 percent increase over 2016. Injectable treatments overall, botulinum toxins and dermal fillers, increased 5.1 percent in 2017, according to ASAPS. Injectable botulinum toxin treatments have been the number one nonsurgical procedure since 2000, according to ASAPS.

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

While currently approved botulinum toxin products may be better known for their aesthetic applications, according to MRG, the fastest-growing segment for botulinum toxin treatments globally is 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.

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 been proved 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.

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### **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, DAXI and DaxibotulinumtoxinA Topical, and participate in development and commercialization of biosimilar to BOTOX® with Mylan.

Key elements of our strategy are:

*Complete DAXI clinical development and file for marketing approval in frown lines in the U.S. followed by Europe.* We announced positive top-line results for DAXI in alleviating moderate-to-severe glabellar lines in two randomized, double-blind, placebo-controlled pivotal Phase 3 trials that evaluated the safety and efficacy of a single administration of DAXI 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 U.S. and Canada. We also completed our SAKURA Phase 3 open-label, long-term safety study program of DAXI for the treatment of glabellar lines in December of 2018, which enrolled a total of 2,691 patients at 66 sites in the U.S. and Canada. In the first half of 2019, we plan to submit a Biologics License Application (“BLA”) in the U.S. to gain marketing approval, followed by filings in other countries in 2020. In addition, we plan to initiate Phase 2 study for forehead lines and lateral canthal lines in conjunction with treatment of the frown lines in the first quarter of 2019.

*Advance DAXI 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 initiated our Phase 3 program for the treatment of cervical dystonia in June 2018, and the Phase 3 program is expected to enroll approximately 300 patients in the pivotal trial and 350 patients in the open-label trial at multiple sites in the U.S., Canada, and Europe. We are evaluating future development of DAXI in other indications. As part of this strategy, we initiated a Phase 2 study for upper limb spasticity and another Phase 2 study for plantar fasciitis in December 2018.

*Build our own sales and marketing capabilities to commercialize DAXI in North America.* We have expanded our pre-commercial activities in anticipation of approval of DAXI in glabellar lines. If DAXI 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 DAXI has the ability to expand the botulinum toxin opportunity by appealing to patients who seek a long-lasting effect. We also believe DaxibotulinumtoxinA Topical 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 excipient 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 DAXI outside of the U.S., 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 DAXI. As part of this strategy, in December 2018, we entered into a license agreement (the “Fosun License Agreement”) with Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd., a wholly-owned subsidiary of Shanghai Fosun Pharmaceutical (Group) Co., Ltd (“Fosun”), whereby we have granted Fosun the exclusive rights to develop and commercialize our proprietary DAXI in mainland China, Hong Kong and Macau (the

“Fosun Territory”) and certain sublicense rights. Additionally, our proprietary peptide excipient technology can be used for molecules other than botulinum toxin. We plan to partner or license the peptide excipient 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 us and for potential future partners. As part of this strategy, in February 2018, we entered into the Mylan Collaboration, pursuant to which we will collaborate with Mylan exclusively, on a world-wide basis (excluding Japan), to develop, manufacture and commercialize the biosimilar to BOTOX®.

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### **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 Tier 1 Select Agent under authority of the Centers for Disease Control and Prevention (“CDC”), and as such requires that we obtain a select agent registration and perform our operations in compliance with CDC regulations. We are in good standing under our select agent registration with the CDC. We have assembled a team of experienced individuals in the technical disciplines of chemistry, biology, biosafety, 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, we entered into a Technology Transfer, Validation and Commercial Fill/Finish Services Agreement (the “Althea Services Agreement”) with Ajinomoto Althea, Inc. (“Althea”), 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 DAXI. The Althea Services Agreement also mitigates supply chain risk by giving us a different manufacturing location for drug product manufacturing 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 DAXI candidate. The additional components required for our product lines and the peptide for DAXI are manufactured by third parties under contract with us. Refer to section entitled “Outsourced Components” below for additional information.

### **Drug Substance**

Manufacture of the drug substance for DAXI 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 dose forms to support the DAXI 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 DAXI drug product manufacturing to meet anticipated commercial demand and may utilize internal capacity, a third-party manufacturer such as 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. (“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 Company, Inc. (“American Peptide”), which was acquired by Bachem, 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.

Our agreement with 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 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.



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### **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.

Upon marketing approval, the first expected uses of our products will be to treat glabellar lines, cervical dystonia, plantar fasciitis, and adult upper limb spasticity, 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 Neuromodulators**

Our primary competitors for DAXI in the pharmaceutical market are expected to be companies offering injectable dose forms of botulinum toxin, including:

BOTOX® and BOTOX Cosmetic®, marketed by Allergan plc, 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 U.S. 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 U.S., 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® (rimabotulinumtoxinB) is 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.

Jeuveau™, an injectable botulinum toxin manufactured by Daewoong Pharmaceutical Co., Ltd. in South Korea, was approved in 2019 by the FDA in the U.S. for the treatment of glabellar lines only. It is marketed in the U.S. by Evolus, Inc. Jeuveau is also known as NABOTA® in South Korea along with other geographic areas and was designated Nuceiva™ in Canada.

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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 EMA 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 U.S. 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, 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 U.S., 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 long-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, other competitive products include products from Bloomage BioTechnology, LG Life Sciences, Medytox, Laboratories TEOXANE, Sinclair Pharma, and a large number of other hyaluronic acid, bioceramic, protein and other polymer-based dermal fillers. All new generation fillers now last at least six months. We believe a neuromodulator with a six-month duration of effect 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 DAXI 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 aesthetic physicians (dermatologists, plastic surgeons, facial plastic surgeons, oculo-plastic surgeons, and aesthetic practitioners) who perform the majority of the cosmetic procedures. Assuming approval to market in the U.S., we will focus our initial marketing of DAXI on these core specialties.

### **Strategic Partnering**

We plan to focus our efforts on developing and commercializing DAXI in North America and we intend to market on our own. Outside of North America, we will seek collaborations to maximize the commercial potential of our product candidates and delivery technology. As part of this strategy, in December 2018, we announced a collaboration with Fosun to develop and commercialize DAXI in China.

We also plan to leverage our botulinum toxin cell line and manufacturing assistance by partnering with other companies. In February 2018, we entered into a collaboration with Mylan pursuant to which Mylan and us will collaborate exclusively, on a world-wide basis (excluding Japan), to develop, manufacture and commercialize the biosimilar to BOTOX®.

## **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.

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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. Please refer to Item 1A. “Risk Factors—Risks Related to our Intellectual Property.” for more information.

In June 2016, we entered into an asset purchase agreement with Botulinum Toxin Research Associates, Inc. (“BTRX”) (the “BTRX Purchase Agreement”). Under the BTRX 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 January 16, 2019, we held approximately 419 issued patents and approximately 106 pending patent applications, including foreign counterparts of U.S. patents and applications. 37 of our patents are issued in the U.S., 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 U.S. as well as in Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, Korea, Mexico, and Singapore. The earliest that any of our U.S. patents will expire is December 10, 2019 for U.S. Patent No. 6429189, which is a patent acquired as part of the asset purchase from BTRX but does not disclose or claim our DAXI technology. The latest that any of our U.S. patents will expire is July 20, 2035. We will continue to pursue additional patent protection as well as take appropriate measures to obtain and maintain proprietary protection for our innovative technologies.

On May 2, 2018, Allergan plc filed an Opposition in the European Patent Office against our European Patent No. EP 2 661 276 titled “Topical composition comprising botulinum toxin and a dye.” While the opposed patent is not material to RT002 injectable, we will continue to take appropriate measures to defend the patent.

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 U.S.**

In the U.S., the FDA regulates drugs and biologic products under the Federal Food, Drug and Cosmetic Act (“FDCA”), its implementing regulations, and other laws, including, in the case of biologics, the Public Health Service Act (“PHSA”). Our product candidates, DAXI and DaxibotulinumtoxinA Topical, 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 U.S.

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 U.S. generally involves the following:

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completion of preclinical laboratory tests, animal studies and formulation studies performed in accordance with the FDA's current good laboratory practices ("GLPs");

submission to the FDA of an Investigational New Drug Application ("IND") which must become effective before human clinical trials in the U.S. may begin;

approval by an institutional review board ("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 ("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 ("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 ("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.

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### ***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.

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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 (“PDUFA”), the FDA has twelve months from submission in which to complete its initial review of a standard BLA and make a decision on the application, and eight months from submission for a priority BLA, and such deadline is referred to as the PDUFA date. The FDA does not always meet its PDUFA dates for either standard or priority BLAs. The review process and the PDUFA date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA date.

After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product’s identity, strength, 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 (“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.



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***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.

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 ("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, which initiates a process in which the innovator BLA holder and the biosimilar applicant identify patents that could be litigated and resolve patent disputes.

**Product Approval Process Outside the U.S.**

In addition to regulations in the U.S., 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.

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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 (“RMS”), and submitting to more than one member state at the same time. The RMS National Competent Authority conducts a detailed review and prepares an assessment report, to which concerned member states provide comment. The mutual recognition procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states post-initial approval. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

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

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

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and our practices may not in all cases meet all of the criteria for statutory exemptions or safe harbor protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to 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.

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

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

## **Environment, Health and Safety**

We are voluntarily assessing and publicly reporting our greenhouse gas emissions and water usage, and have begun to take action to reduce such emissions and usage. For example, we have established employee commuter programs, evaluated the energy efficiency of our buildings and installed low-flow water fixtures. Various laws and regulations have been implemented or are under consideration to mitigate the effects of climate change caused by greenhouse gas emissions. For example, the California Air Resources Board is in the process of drafting regulations to meet state emissions targets. Based on current information and subject to the finalization of the proposed regulations, we believe that our primary risk related to climate change is the risk of increased energy costs. However, because we are not an energy-intensive business, we do not anticipate being subject to a cap and trade system or any other mitigation measures that would likely be material to our capital expenditures, results of operations or competitive position.

We are also subject to other federal, state and local regulations regarding workplace safety and protection of the environment. We use hazardous materials, chemicals, 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. We plan to maintain or increase our research and development expenses for the foreseeable future to initiate and complete additional clinical trials and associated programs related to DAXI for aesthetic indications in areas such as forehead lines and lateral canthal lines, and therapeutic indications in areas such as cervical dystonia, plantar fasciitis, adult upper limb spasticity, and chronic



migraine.

**Customers**

For the year ended December 31 2018, revenue from Mylan represented 100 percent of our total revenue. For the years ended December 31, 2017 and 2016, all of our revenue was from Precision Dermatology, Inc. (“PDI”), which was subsequently acquired by Valeant Pharmaceuticals International, Inc.(“Valeant”).

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**Employees**

As of December 31, 2018, we had 170 employees. Of these employees, 111 employees were engaged in research and development and 59 employees were engaged in finance, marketing, human resources, facilities, information technology, general management, and administrative activities. We plan to continue to expand our research, development, and commercial activities next year. 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. 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.

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**ITEM 1A. RISK FACTORS**

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

**Risks Related to Our Business and Strategy**

**We are substantially dependent on the clinical and commercial success of our product candidate DAXI.**

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 DAXI.

We are in Phase 3 clinical development for DAXI in North America for the treatment of glabellar lines. From 2016 to 2018, we conducted and announced results relating to multiple pivotal and safety trials in our SAKURA Phase 3 program. The SAKURA 1 and SAKURA 2 trials were designed to evaluate the safety and efficacy of a single administration of DAXI for the treatment of moderate-to-severe glabellar lines in adults. In addition to the two pivotal trials, the Phase 3 program includes a long-term open-label safety trial (SAKURA 3), which is designed to evaluate the long-term safety and duration of DAXI for the treatment of moderate to severe glabellar lines in adults following both single and repeat treatment administration. SAKURA 3 was designed to support a safety database adequate for both domestic and international marketing applications. We plan to file marketing applications for DAXI for the treatment of glabellar lines first in the U.S. in the first half of 2019, followed by the European Union, Canada, and certain Latin American and Asian countries.

In 2015, we initiated a Phase 2 dose-escalating, open-label clinical study of DAXI for the treatment of cervical dystonia. The Phase 2 study evaluated the safety, preliminary efficacy, and duration of effect of DAXI in subjects with moderate to severe isolated cervical dystonia. Based on the Phase 2 safety and efficacy results and subsequent guidance from the FDA and EMA, in June 2018 we announced the initiation of patient dosing in our ASPEN Phase 3 clinical program. The ASPEN Phase 3 clinical program consists of two trials to evaluate the safety and efficacy of DAXI for the treatment of cervical dystonia in adults including: a randomized, double-blind, placebo-controlled, parallel group trial and an open-label, long-term safety trial.

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

In April 2018, we announced two new clinical programs for DAXI, including adult upper limb spasticity and chronic migraine. We initiated a Phase 2 study in adult upper limb spasticity in the fourth quarter of 2018 and we expect to have topline results in second half of 2020. In 2019, we plan to continue evaluating DAXI for the treatment of chronic

migraine.

Our near-term prospects, including our ability to finance our company and generate revenue, will depend heavily on the successful development, regulatory approval and commercialization of DAXI. Our longer-term prospects will depend on the successful development, regulatory approval and commercialization of DAXI, as well as DaxibotulinumtoxinA Topical, biosimilar 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:

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timely completion of, or need to conduct additional, clinical trials, including our clinical trials for DAXI, DaxibotulinumtoxinA Topical, biosimilar 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 DAXI, DaxibotulinumtoxinA Topical, biosimilar 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 DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;
- our success in educating physicians and patients about the benefits, administration and use of DAXI, DaxibotulinumtoxinA Topical, biosimilar 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 DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates or approved products;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative treatments;
- the effectiveness of our own or our current and any future potential strategic collaborators' marketing, sales and distribution strategy and operations;
- our ability to manufacture clinical trial supplies of DAXI, DaxibotulinumtoxinA Topical, biosimilar 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 DAXI, DaxibotulinumtoxinA Topical, biosimilar 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 DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;
- our ability to avoid third-party patent interference or intellectual property infringement claims;
- acceptance of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates, if approved, as safe and effective by patients and the medical community;
- the willingness of third-party payors to reimburse physicians or patients for DAXI and any future products we may commercialize for therapeutic indications;
- the willingness of patients to pay out of pocket for DAXI and any future products we may commercialize for aesthetic indications;
- the continued acceptable safety profile of DAXI, DaxibotulinumtoxinA Topical, biosimilar 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 DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidate to continue our business.

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

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

For example, we completed DaxibotulinumtoxinA 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 2016, we also initiated a Phase 2 trial of DAXI for the treatment of plantar fasciitis. In January 2018, we announced interim 8-week results from this study and subsequently completed the 16-week trial, which showed a strong placebo response, with the difference between the treatment groups not being statistically significant.

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 U.S. and initiated subject dosing in Phase 3 clinical studies of DAXI 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. In December 2018, we announced top-line results for the SAKURA 3 open-label, long-term safety study. We plan to move forward with studies required for submission of a BLA. In June 2018, we announced the initiation of patient dosing in our ASPEN Phase 3 clinical program for DAXI for the treatment of cervical dystonia. The program is expected to enroll approximately 300 patients in each of the two studies at multiple sites in the U.S., Canada, and Europe.

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

We currently have no drug or biologic products approved for sale, and we may never obtain regulatory approval to commercialize DAXI, DaxibotulinumtoxinA Topical or biosimilar. 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 U.S. and other countries, and such regulations differ from country to country. We are not permitted to market our product candidates in the U.S. until we receive approval of a BLA from the FDA. We are also not permitted to market our product candidates in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries.



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

- our inability to demonstrate to the satisfaction of the FDA or an applicable foreign regulatory body that DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates are safe and effective for the requested indication;
- our inability to demonstrate preclinical proof of concept of DaxibotulinumtoxinA Topical, biosimilar 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 DAXI, DaxibotulinumtoxinA Topical, biosimilar 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 DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;
- the FDA's or an applicable foreign regulatory agency's failure to approve our manufacturing processes or facilities, or the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA or an applicable foreign regulatory agency to significantly change in a manner rendering our clinical data insufficient for approval.

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

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

### **Even if we receive regulatory approval for our product candidates, we will be subject to ongoing FDA and foreign regulatory obligations and continued regulatory review.**

We and any third party contract development and manufacturers or suppliers are required to comply with applicable GMP regulations and other international regulatory requirements. The regulations require that our product candidates be manufactured and records maintained in a prescribed manner with respect to manufacturing, testing and quality control/quality assurance activities. Manufacturers and suppliers of materials must be named in a BLA submitted to the FDA for any product candidate for which we are seeking FDA approval. Additionally, third party manufacturers and suppliers and any manufacturing facility must undergo a pre-approval inspection before we can obtain marketing authorization for any of our product candidates. Even after a manufacturer has been qualified by the FDA, the manufacturer must continue to expend time, money and effort in the area of production and quality control to ensure full compliance with GMP. Manufacturers are subject to regular, periodic inspections by the FDA following initial approval. Further, to the extent that we contract with third parties for the manufacture of our products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection.



If, as a result of the FDA's inspections, it determines that the equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may not approve the product or may suspend the manufacturing operations. If the manufacturing operations of any of the suppliers for our product candidates are suspended, we may be unable to generate sufficient quantities of commercial or clinical supplies of product to meet market demand, which would harm our business. In addition, if delivery of material from our suppliers were interrupted for any reason, we might be unable to ship our approved product for commercial supply or to supply our products in development for clinical trials. Significant and costly delays can occur if the qualification of a new supplier is required.

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Failure to comply with regulatory requirements could prevent or delay marketing approval or require the expenditure of money or other resources to correct. Failure to comply with applicable requirements may also result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to renew marketing applications and criminal prosecution, any of which could be harmful to our ability to generate revenues and our stock price.

Any regulatory approvals that we receive for our product candidates are likely to contain requirements for post-marketing follow-up studies, which may be costly. Product approvals, once granted, may be modified based on data from subsequent studies or commercial use. As a result, limitations on labeling indications or marketing claims, or withdrawal from the market may be required if problems occur after approval and commercialization.

**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, DAXI, DaxibotulinumtoxinA Topical or biosimilar. In particular, our clinical programs for DAXI, DaxibotulinumtoxinA Topical or biosimilar will require substantial additional funds to complete. We had an accumulated deficit through December 31, 2018 of \$684.8 million and a working capital surplus of \$176.0 million as of December 31, 2018, primarily as a result of our November 2015 and December 2017 follow-on public offerings, and at-the-market (“ATM”) offerings in 2015 and 2017. Our recorded net losses were \$142.6 million, \$120.6 million and \$89.3 million, for the years ended December 31, 2018, 2017, and 2016, 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, 2018, we had capital resources consisting of cash and cash equivalents and short-term investments of \$175.8 million. We raised aggregate net proceeds of \$126.2 million and \$156.9 million in our follow-on public offerings in November 2015 and December 2017, respectively. In addition, we raised net proceeds of approximately \$10.0 million by selling an aggregate of 352,544 shares of our common stock under the 2015 ATM agreement, which was effectively terminated on March 7, 2016, and raised net proceeds of approximately \$38.2 million by selling an aggregate of 1,802,651 shares of our common stock under the 2016 ATM agreement. In March 2018, we terminated the 2016 ATM Agreement and entered into a Controlled Equity Offering sales agreement with Cantor Fitzgerald & Co., or Cantor Fitzgerald (the “2018 ATM Agreement”). Under the 2018 ATM Agreement, we may offer and sell common stock having aggregate proceeds of up to \$125.0 million from time to time through Cantor Fitzgerald as our sales agent. No sales of our common stock have taken place under the 2018 ATM Agreement as of December 31, 2018. We believe that we will continue to expend substantial resources for the foreseeable future for the clinical development of DAXI, DaxibotulinumtoxinA Topical or biosimilar 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 DAXI and any future product candidates.

We believe that our existing cash, cash equivalents, and short-term investments including the net proceeds from our 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.



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Our future capital requirements depend on many factors, including:

- the results of our clinical trials for DAXI and preclinical trials of DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for DAXI, or any future product candidates including DaxibotulinumtoxinA Topical or biosimilar;
- 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 DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;
- the cost of commercialization activities if DAXI or any future product candidates including DaxibotulinumtoxinA Topical or biosimilar are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates and any products we successfully commercialize and maintaining our related facilities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements including the Mylan collaboration, Fosun licensing, 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 DAXI, DaxibotulinumtoxinA Topical, biosimilar 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.

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

The commercial success of DAXI, and any future product candidates including DaxibotulinumtoxinA Topical or biosimilar, 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 DAXI and any future product candidates, if approved, will depend on a number of factors, including:

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

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

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

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

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

In aesthetic medicine, we plan to seek regulatory approval of DAXI for the treatment of glabellar lines. We anticipate that DAXI, 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 DAXI from biosimilar products and products based upon botulinum toxin. To compete successfully, we will have to demonstrate that the treatment of glabellar lines with DAXI 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 U.S.. 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.

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

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

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

We constructed a fill/finish line dedicated to the manufacture of DaxibotulinumtoxinA Topical and to support our regulatory license applications. We discontinued further clinical development of DaxibotulinumtoxinA 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 DaxibotulinumtoxinA Topical fill/finish line and other long-lived assets. The Company assessed the DaxibotulinumtoxinA Topical fill/finish line and these other long-lived assets for impairment indicators and recorded a loss on impairment of \$2.9 million for the year ended December 31, 2017. 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. There were no indicators of impairment for the year ended December 31, 2018. Under U.S. generally accepted accounting principles ("GAAP"), 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.





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**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 DAXI, DaxibotulinumtoxinA Topical or biosimilar. 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, 2018 of \$684.8 million and a working capital surplus of \$176.0 million as of December 31, 2018, primarily as a result of our November 2015 and December 2017 follow-on public offerings, and ATM offerings in 2015 and 2017. Our recorded net losses were \$142.6 million, \$120.6 million and \$89.3 million, for the year ended December 31, 2018, 2017, and 2016, respectively. We have funded our operations primarily through the sale and issuance of convertible preferred stock, common stock, notes payable and convertible notes. The net proceeds from the sale of the shares in our November 2015 and December 2017 follow-on public offerings and ATM offerings in 2015 and 2017, after deducting the underwriters' discount, commissions, and other offering expenses related to the respective offerings, were approximately \$126.2 million and \$156.9 million, \$10.0 million and \$38.2 million, respectively. Our capital requirements to implement our business strategy are substantial, including our capital requirements to develop and commercialize DAXI. 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 DAXI. 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 DAXI, DaxibotulinumtoxinA Topical, biosimilar, or any future product candidates obtain regulatory approval, they may never achieve market acceptance or commercial success.**

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

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

- the safety and efficacy of the product as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- the proper training and administration of our products by physicians and medical staff;
- the potential and perceived advantages of our products over alternative treatments;
- the cost of treatment in relation to alternative treatments and willingness to pay for our products, if approved, on the part of payors and patients;

- the willingness of patients to pay for DAXI, DaxibotulinumtoxinA Topical, 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 DAXI and any future products we may commercialize for therapeutic indications;
- the willingness of patients to pay out of pocket for DAXI and any future products we may commercialize for aesthetic indications;
- the relative convenience and ease of administration;
- the prevalence and severity of adverse events; and
- the effectiveness of our sales and marketing efforts.

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

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Furthermore, we rely on contract research organizations, or CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we have agreements governing the committed activities of our CROs, we have limited influence over their actual performance. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Furthermore, final results may differ from interim results. For example, any positive results generated to date in clinical trials for DAXI do not ensure that later clinical trials, including any DAXI 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 DaxibotulinumtoxinA Topical and we cannot be certain that we will not face other similar setbacks in the future for DAXI 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 IRB, approval at each site;
- recruit suitable subjects to participate in a trial;
- have subjects complete a trial or return for post-treatment follow-up;
- ensure clinical sites observe trial protocol or continue to participate in a trial;
- address any patient safety concerns that arise during the course of a trial;
- address any conflicts with new or existing laws or regulations;
- add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of product candidate for use in clinical trials.

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

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the data safety monitoring board, for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, failure of

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

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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 DAXI and expect to continue to do so to support further clinical trials and commercial scale production if DAXI is approved. This increases the risk that we will not have sufficient quantities of DAXI 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 DAXI for our clinical trials, and we expect to continue to rely on these or other manufacturers to support our commercial requirements if DAXI is approved. In particular, in March 2017, we entered into the Althea Services Agreement. We plan to utilize our internal and external Althea facility to support commercial production of DAXI, if approved. Some of our contracts with our manufacturers contain minimum order and pricing provisions and provide for early termination based on regulatory approval milestones.

Reliance on third-party manufacturers entails additional risks, including the reliance on the third party for regulatory compliance and quality assurance, the possible breach of the manufacturing agreement by the third party, and the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us. In addition, third-party manufacturers may not be able to comply with cGMP or Quality System Regulation, or QSR, or similar regulatory requirements outside the U.S.. 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 DAXI, or any other product candidates or products that we may develop. Any failure or refusal to supply the components or services for DAXI 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 DAXI 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.

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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 DAXI 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 DAXI 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 DAXI 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 DAXI or any future product candidates until they restore the affected facilities or we or they procure alternative facilities. Additionally, any damage to or destruction of our or our third party or suppliers' facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

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

We currently have limited marketing and sales capabilities and no field sales organization. To commercialize DAXI or any other future product candidates, if approved, in the U.S., 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 DAXI receives regulatory approval, we expect to market DAXI 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 DAXI or any future product candidates. If we are not successful in commercializing DAXI 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.

**As we evolve from a company primarily involved in research and development to a company potentially involved in commercialization, we will need to increase the size of our organization and we may experience difficulties in managing this growth.**

If we are successful in advancing DAXI through the development stage towards commercialization, we will need to expand our organization, including adding marketing, managerial, operational and sales capabilities, or contracting with third parties to provide these capabilities for us to manage our operations and clinical trials, continue our development activities and commercialize DAXI 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.

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As our operations expand, we expect that we will also need to manage additional relationships with various collaborative partners, suppliers and other third parties. Future growth will impose significant added responsibilities on our organization, in particular on management. Our future financial performance and our ability to commercialize DAXI and to compete effectively will depend, in part, on our ability to manage any future growth effectively. Due to our limited financial resources and our limited experience in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our development and strategic objectives, or disrupt our operations.

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

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

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

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

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

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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 any products we develop are not accepted by the market or if regulatory agencies limit our labeling indications, require labeling content that diminishes market uptake of our products or limits our marketing claims, we may be unable to generate significant revenues, if any.**

Even if we obtain regulatory approval for our product candidates and are able to commercialize them, our products may not gain market acceptance among physicians, patients, healthcare payors and the medical community.

The degree of market acceptance of any of our approved products will depend upon a number of factors, including:

- the indication for which the product is approved and its approved labeling;
- the presence of other competing approved treatments and therapies;
- the potential advantages of the product over existing and future treatment products;
- the relative convenience and ease of administration of the product;
- the strength of our sales, marketing and distribution support;
- the willingness of third-party payors to provide adequate reimbursement for our approved products, and the willingness of payments to pay for our approved products in the absence of third-party reimbursement; and
- the price and cost-effectiveness of the product.

The FDA or other regulatory agencies could limit the labeling indication for which our product candidates may be marketed or could otherwise limit marketing efforts for our products. If we are unable to achieve approval or successfully market any of our product candidates, or marketing efforts are restricted by regulatory limits, our ability to generate revenues could be significantly impaired.

**If DAXI 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 DAXI, 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.

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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 DAXI 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 or other aesthetic indications with DAXI 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 DAXI 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 DAXI to their patients;

- the extent to which DAXI satisfies patient expectations;

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

- the cost, safety and effectiveness of DAXI versus other treatments;

- consumer sentiment about the benefits and risks of aesthetic procedures generally and DAXI 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 DAXI 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 DAXI or any future product candidates, could hinder or prevent their commercial success.**

Our ability to commercialize DAXI 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 DAXI or any future product candidates for therapeutic indications, or we may be required to sell them at a discount.

We expect that third-party payors will consider the efficacy, cost effectiveness and safety of DAXI in determining whether to approve reimbursement for DAXI for therapeutic indications and at what level. Our business would be materially adversely affected if we do not receive coverage and adequate reimbursement of DAXI for therapeutic indications from private insurers on a timely or satisfactory basis. No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States; therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, coverage under certain government programs, such as Medicare and Medicaid, may not be available for certain of our product candidates. As a result, the coverage determination

process will likely be a time-consuming and costly process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our business could also be adversely affected if third-party payors limit the indications for which DAXI will be reimbursed to a smaller patient set than we believe they are effective in treating.

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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 DAXI, to other available therapies. If reimbursement for our product is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

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

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

- decreased demand for DAXI 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 DAXI 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 DAXI we intend to expand our insurance coverage to include the sale of DAXI as applicable; however, we may be unable to obtain this liability insurance on commercially reasonable terms.

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

We have been, and may in the future be, the target of securities class actions or stockholder derivative claims. On May 1, 2015, a securities class action complaint was filed on behalf of City of Warren Police and Fire Retirement System

against us and certain of our directors and executive officers at the time of our follow-on public offering, and the investment banking firms that acted as the underwriters in our follow-on public offering. The Court granted final approval of the Settlement, as set forth in the Stipulation of Settlement, on July 28, 2017. While the litigation has ended, we may be subject to future securities class action and shareholder derivation actions, which may adversely impact our business, results of operations, financial position or cash flows and divert management's time and attention from the business.



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**If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates, conduct our clinical trials and commercialize DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future products we develop.**

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

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

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

We could experience problems attracting and retaining qualified employees. For example, competition for qualified personnel in the biotechnology and pharmaceuticals field is intense and the turnover rate can be high due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their previous research output.

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

Although a substantial amount of our effort will focus on the continued clinical testing and potential approval of DAXI, a key element of our strategy is to discover, develop and commercialize a portfolio of botulinum toxin products for both aesthetic and therapeutic indications. We are seeking to do so through our internal research programs and may explore strategic collaborations for the development or acquisition of new products. While DAXI

is in the clinical development stage, DaxibotulinumtoxinA 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:

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

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

**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.

**We need to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act, and the failure to do so could have a material adverse effect on our business and stock price.**

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. We are required to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, or Section 404. Beginning with the 2018 Annual Report on Form 10-K, our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting. If we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our common stock could decline and we could be subject to actions or investigations by the SEC, or other regulatory authorities, which would require additional financial and management resources.

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**We may experience difficulties implementing and maintaining our new enterprise resource planning system.**

We purchased a new enterprise resource planning (“ERP”) system and are currently implementing the new system. ERP implementations are complex and time-consuming, and involve substantial expenditures on system software and implementation activities. The ERP system will be critical to our ability to provide important information to our management, obtain and deliver our products, provide services and customer support, send invoices and track payments, fulfill contractual obligations, accurately maintain books and records, provide accurate, timely and reliable reports on our financial and operating results or otherwise operate our business. ERP implementations also require transformation of business and financial processes in order to reap the benefits of the ERP system; any such transformation involves risks inherent in the conversion to a new computer system, including loss of information and potential disruption to our normal operations. The implementation and maintenance of the new ERP system has required, and will continue to require, the investment of significant financial and human resources and the implementation may be subject to delays and cost overruns. In addition, we may not be able to successfully complete the implementation of the new ERP system without experiencing difficulties. Any disruptions, delays or deficiencies in the design and implementation or the ongoing maintenance of the new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations, accurately maintain books and records, provide accurate, timely and reliable reports on our financial and operating results, or otherwise operate our business. Additionally, if we do not effectively implement the ERP system as planned or the system does not operate as intended, the effectiveness of our internal control over financial reporting could be adversely affected or our ability to assess it adequately could be delayed.

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

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

We may license or selectively pursue strategic collaborations for the development, validation and commercialization of DAXI, DaxibotulinumtoxinA Topical, biosimilar and any future product candidates. For instance, in February 2018, we and Mylan entered into the Mylan Collaboration, pursuant to which we and Mylan will collaborate exclusively, on a world-wide basis (excluding Japan), to develop, manufacture and commercialize our product candidates. In addition, in December 2018, we and Fosun entered into the Fosun License Agreement pursuant to which we have granted Fosun the exclusive rights to develop and commercialize DAXI in the Fosun Territory and certain sublicense rights. 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. Our collaboration with Mylan is for the development of a biosimilar product, which is subject to risks inherent with the relatively short history of biosimilar product approvals in the United States. The biosimilar product would be subject to similar commercial risks as our DAXI and Daxibotulinumtoxin A Topical product candidates. In February 2019, we and Mylan participated in a Biosimilar Initial Advisory Meeting ("BIAM") with the FDA to discuss the feasibility of a 351(k) biosimilar submission and the necessary development pathway for the biosimilar product candidate. While we believe that such a pathway is viable, the successful development and commercialization of a biosimilar product in any indications of BOTOX® or BOTOX Cosmetic® would be subject to FDA requirements that would need to be assessed by us and Mylan in determining the development of the biosimilar product candidate. Such requirements may also limit our ability to begin Phase 3 development of the biosimilar in 2020, as presently planned or at all. Even if successfully developed, the biosimilar product would be subject to similar commercial risks as our DAXI and Daxibotulinumtoxin A Topical product candidates.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Furthermore, the demand for aesthetic or therapeutic medical procedures may be particularly vulnerable to unfavorable economic conditions. We do not expect sales of DAXI 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 DAXI, DaxibotulinumtoxinA Topical, biosimilar 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.

In addition, changes in U.S. and foreign trade policies could trigger retaliatory actions by affected countries, resulting in "trade wars", which may reduce customer demand for goods exported out of the United States if the parties having to pay those tariffs increase their prices, or if trading partners limit their trade with the United States. If these consequences are realized, the price to the consumer of aesthetic or therapeutic medical procedures from products exported out of the United States may increase, resulting in a material reduction in the demand for our future product

candidates. Such a reduction may materially and adversely affect our potential sales and our business. In particular, under our Fosun License Agreement, we are responsible for manufacturing DAXI and supplying it to Fosun, which would then develop commercialize, market and sell it in mainland China, Hong Kong and Macau. If this arrangement is restricted in any way due to the US-China trade relation, the contingent payments we are entitled to receive under the agreement, which are based on product sales, among other things, may be adversely affected.

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.

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**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, legislation that significantly revised the Internal Revenue Code of 1986, as amended, was signed into law. The legislation, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35 percent to a flat rate of 21 percent, limitation of the tax deduction for interest expense to 30 percent of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80 percent 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 federal tax law changes 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.

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

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



or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. For example, in January 2019, we discovered that our e-mail server suffered unauthorized intrusions in which proprietary business information was accessed. Although we do not believe that we have experienced any material losses related to security breaches, including recent cybersecurity incidents, there can be no assurance that we will not suffer such losses in the future. Breaches and other inappropriate access can be difficult to detect and any delay in identifying them could increase their harm. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events. Any such breaches of security and inappropriate access could disrupt our operations, harm our reputation or otherwise have a material adverse effect on our business, financial condition and results of operations.

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The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical study data from completed or ongoing or planned clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems, corrupts our data or results in the unauthorized disclosure or release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, supervisory bodies, credit reporting agencies, the media or individuals pursuant to various federal, state and foreign data protection, privacy and security laws, regulations and guidelines, if applicable. For example, these may include the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009, and its implementing rules and regulations, U.S. state breach notification laws and the EU General Data Protection Regulation (EU) 2016/679, or GDPR. We would also be exposed to a risk of loss, enforcement measures, penalties, fines, indemnification claims or litigation and potential civil or criminal liability, which could materially adversely affect our business, results of operations and financial condition.

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

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

In the U.S., HIPAA imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In the event that we are subject to HIPAA or other U.S. privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. Many countries in these regions have established or are in the process of establishing privacy and data security legal frameworks with which we, our customers, or our vendors must comply. For example, the EU has adopted the GDPR, which went into effect in May 2018 and introduces strict requirements

for processing the personal information of EU subjects, including clinical trial data. The GDPR is likely to increase compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them. The processing of sensitive personal data, such as physical health condition, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for more robust regulatory enforcement and fines of up to €20 million or 4 percent of the annual global revenue of the noncompliant company, whichever is greater. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

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**Risks Related to Our Intellectual Property**

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

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

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of issued patents. The patent applications that we own or license may fail to result in issued patents in the U.S. 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. Our European Patent EP 2 661 276 for “Topical composition comprising botulinum toxin and a dye” was opposed in the European Patent Office by Allergan plc on May 2, 2018, and although this patent is not material to RT002 injectable, we will continue to take appropriate measures to defend the patent. 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 U.S. 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 U.S. 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 DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates is challenged, then it could threaten our ability to commercialize DAXI, DaxibotulinumtoxinA Topical, biosimilar 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 DAXI, 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 DaxibotulinumtoxinA Topical program.

Since patent applications in the U.S. 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 U.S. 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.

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

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

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

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

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

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

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation or post-grant proceedings declared or granted by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor,

could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

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**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 U.S.

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 U.S. can be less extensive than those in the U.S.. 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 U.S. 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 U.S., or from selling or importing products made using our inventions in and into the U.S. 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 U.S. 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.

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**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 U.S., 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 (“FFDCA”), the 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, we, and our direct and indirect suppliers, will 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 DAXI 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 U.S. and other countries, which regulations differ from country to country. Neither we nor any collaboration partner are permitted to market DAXI or any future product candidates in the U.S. until we receive approval of a BLA from the FDA. We have not submitted an application or obtained marketing approval for DAXI anywhere in the world. After we submit a BLA for DAXI, 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 U.S. 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.

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

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

If DAXI 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 DAXI 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, DAXI 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 DAXI 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 DAXI 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 DAXI 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 U.S. 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.

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**If we fail to obtain regulatory approvals in foreign jurisdictions for DAXI, or any future product candidates including DaxibotulinumtoxinA Topical or biosimilar, we will be unable to market our products outside of the U.S.**

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

**If approved, DAXI 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 DAXI. If we are successful in commercializing DAXI, or any other products including DaxibotulinumtoxinA Topical or biosimilar, 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 DAXI, if approved for the treatment of glabellar lines, will subject us to all of 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 and civil monetary penalties laws, including the civil 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.

HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

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The federal Physician Payments Sunshine Act, and its implementing regulations, require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members.

We may also be subject to analogous state laws and regulations, including: state anti-kickback and false claims laws, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources, state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities, and state and local laws that require the registration of our pharmaceutical sales representatives

State and federal authorities have aggressively targeted pharmaceutical manufacturers for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with physicians and other healthcare professionals, 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. Further, defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. 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. Even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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

**Legislative or regulatory healthcare reforms in the U.S. may make it more difficult and costly for us to obtain regulatory clearance or approval of DAXI, 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. In addition, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of, or affect the price that we may charge for, DAXI, or any future product candidates including DaxibotulinumtoxinA Topical or biosimilar. 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.

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**Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.**

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our 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 U.S. and foreign countries;
- results from or delays in clinical trials of our product candidates, including our ongoing SAKURA Phase 3 clinical program in glabellar lines our ongoing ASPEN Phase 3 clinical program in cervical dystonia and our Phase 2 program in plantar fasciitis all with DAXI;
- announcements of regulatory approval or disapproval of DAXI 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;
- the occurrence of trade wars or barriers, or the perception that trade wars or barriers will occur; and
- other factors described in this “Risk Factors” section.

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

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

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

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. We raised net proceeds of approximately \$10.0 million by selling an aggregate of 352,544 shares of our common stock under the 2015 ATM agreement, which was effectively terminated on March 7, 2016, and raised net proceeds of approximately \$38.2 million by selling an aggregate of 1,802,651 shares of our common stock under the 2016 ATM agreement. In March 2018, the Company terminated the 2016 ATM Agreement and entered into the 2018 ATM Agreement. Under the 2018 ATM Agreement, the Company may offer and sell common stock having aggregate proceeds of up to \$125.0 million from time to time through Cantor Fitzgerald as our sales agent. No sales of our common stock have taken place under the 2018 ATM Agreement as of December 31, 2018.

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

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

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

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

- only one of our three classes of directors will be elected each year;
- no cumulative voting in the election of directors;
-

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

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

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

stockholders cannot call a special meeting of stockholders;

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

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

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

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

Our amended and restated certificate of incorporation 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, 2018, our directors, executive officers and each of our stockholders who own greater than 5 percent of our outstanding common stock and their affiliates, in the aggregate, beneficially owned approximately 54.0 percent 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.

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**We recognize revenue in accordance with complex accounting standards and changes in the interpretation or application of generally accepted accounting principles may materially affect our financial statements.**

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued an accounting standard for revenue recognition, Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (“ASC 606”). Further, in April 2016, the FASB amended ASC 606 to provide additional guidance on revenue recognition as it pertains to licenses of intellectual property. We adopted ASC 606 and its related amendments on January 1, 2018.

The nature of our business requires the application of complex revenue recognition rules. Significant judgment is required in the interpretation and application of complex accounting guidance such as ASC 606. Our judgments and assumptions are based on the facts and circumstances of the underlying revenue transactions. The SEC, the American Institute of Certified Public Accountants (“AICPA”), the FASB and various other regulatory or accounting bodies may issue new positions, interpretive views or updated accounting standards on the treatment of complex accounting matters such as revenue recognition that may materially affect our financial statements.



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**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

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**ITEM 2. PROPERTIES**

Our headquarters is located in Newark, California, where we occupy approximately 109,000 square feet of office, laboratory and manufacturing space. The current term of our lease expires in January 2027. We have an option to extend the lease for two additional terms of seven years, which would extend our lease through January 2041. 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.

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**ITEM 3. LEGAL PROCEEDINGS**

From time to time, we may be involved in litigation relating to claims arising out of our operations. We are not currently involved in any known material legal proceedings. We may, however, be involved in material legal proceedings in the future. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position or cash flows.

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**ITEM 4. MINE SAFETY DISCLOSURES**

None.

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**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.

**Holders of Record**

As of February 22, 2019, there were approximately 25 holders of record of our common stock, one of which was Cede & Co., a nominee for Depository Trust Company (“DTC”). All of the shares of our common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC and are therefore considered to be held of record by Cede & Co. as one stockholder.

**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.

**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.

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This graph compares, for the period ended December 31, 2018, 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	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018
Revance Therapeutics, Inc.	\$100.00	\$105.88	\$213.50	\$129.38	\$223.44	\$125.81
Nasdaq Biotechnology Index	\$100.00	\$128.67	\$143.81	\$113.11	\$137.58	\$125.39
Nasdaq Composite Index	\$100.00	\$117.98	\$126.20	\$137.39	\$178.11	\$173.05

**Recent Sales of Unregistered Securities**

During the year ended December 31, 2018, there were no sales of unregistered securities.

**Issuer Purchases of Equity Securities**

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

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, 2018	7,732	\$ 23.94	—	—
November 1 through November 30, 2018	1,199	21.19	—	—
December 1 through December 31, 2018	4,841	19.91	—	—
Total	13,772	\$ 22.40	—	\$ —

(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, 2018 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,				
	2018	2017	2016	2015	2014
<b>Consolidated Statements of Operations Data:</b>					
Revenue	\$3,729	\$262	\$300	\$300	\$383
Total operating expenses	\$146,363	\$120,686	\$88,515	\$72,617	\$52,433
Loss from operations	\$(142,634)	\$(120,424)	\$(88,215)	\$(72,317)	\$(52,050)
Interest expense	\$(44)	\$(457)	\$(1,082)	\$(1,190)	\$(10,672)
Net loss	\$(142,568)	\$(120,587)	\$(89,270)	\$(73,476)	\$(62,917)
Basic and Diluted net loss attributable to common stockholders	\$(142,568)	\$(120,587)	\$(89,270)	\$(73,476)	\$(62,917)
Basic and Diluted net loss per share attributable to common stockholders	\$(3.94)	\$(4.01)	\$(3.18)	\$(3.02)	\$(3.24)
Basic and Diluted weighted-average number of shares used in computing net loss per share attributable to common stockholders	36,171,582	30,101,125	28,114,784	24,340,466	19,391,523

	As of December 31,				
	2018	2017	2016	2015	2014
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents	\$73,256	\$282,896	\$63,502	\$201,615	\$171,032
Short-term investments	\$102,556	\$—	\$122,026	\$52,439	\$—
Working capital surplus	\$175,952	\$264,309	\$173,048	\$241,926	\$162,495
Total Assets	\$226,348	\$295,699	\$204,360	\$275,822	\$192,469
Financing obligation, net of current portion	\$—	\$—	\$1,872	\$5,346	\$598
Accumulated deficit	\$(684,775)	\$(542,167)	\$(421,543)	\$(332,273)	\$(258,797)

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**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**

We are a clinical-stage biotechnology company focused on the development, manufacturing, and commercialization of novel neuromodulators 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 excipient technology, to address unmet needs in large and growing neuromodular markets. Our initial focus is on developing daxibotulinumtoxinA, our highly purified botulinum toxin Type A, for a broad spectrum of aesthetic and therapeutic indications, including facial wrinkles, muscle disorders, and chronic migraine.

Our lead drug candidate is DAXI. We used our unique proprietary peptide excipient technology to formulate DAXI. The noncovalent bond formed between the proprietary peptide excipient technology and the botulinum toxin may enable longer residence time of botulinum toxin Type A, which could explain DAXI's long duration of effect. The process binds a highly purified botulinum toxin Type A with a unique proprietary stabilizing excipient peptide. We do not use human serum albumin and other animal-sourced ingredients, which carry the risk of transmission of pathogens, to stabilize our product.

We are currently studying DAXI for the treatment of facial wrinkles, cervical dystonia, plantar fasciitis, adult upper limb spasticity and chronic migraine. We believe DAXI has the potential to expand into additional aesthetic and therapeutic indications in the future. We also are developing a topically applied neuromodulator for aesthetic and therapeutic indications, DaxibotulinumtoxinA Topical, and have a collaboration and license agreement with Mylan to develop and commercialize a biosimilar to BOTOX®.

**DAXI**

We are developing an injectable formulation of botulinum toxin type A, which we refer to as DAXI, for indications where a long-lasting effect is desired. We believe, and our preclinical and clinical studies using DAXI indicate, that daxibotulinumtoxinA combined with our novel peptide may safely achieve enhanced clinical efficacy and duration without an increase in associated adverse events. We are currently focusing on developing DAXI for the treatment of both aesthetic and therapeutic indications.

***Glabellar Lines***

The glabella is the area between the eyebrows and above the nose. Glabellar lines, often called "frown lines," are vertical lines that develop between the eyebrows and may appear as a single vertical line or as two or more lines. When one frowns, the muscles of the glabella contract causing vertical creases to form between the eyebrows. Botulinum toxin is used to temporarily block the ability of nerves to trigger contraction of injected muscle, inhibiting movement of the muscles that cause the frown lines, giving the skin a smoother, more refreshed appearance. In 2015, we reported results from BELMONT, a Phase 2 active comparator, placebo-controlled clinical trial for the treatment of glabellar lines against BOTOX® Cosmetic. The 24-week data showed that DAXI achieved its primary efficacy measurement for all doses of DAXI, and that such efficacy was highly statistically significant as compared to placebo. In addition, the 40 Unit dose of DAXI demonstrated a 23.6-week median duration versus BOTOX®



Cosmetic with an 18.8-week median duration. Across all cohorts, DAXI appeared to be generally safe and well-tolerated.

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The Phase 3 clinical program includes a) SAKURA 1 and SAKURA 2, two randomized, double-blind, placebo-controlled pivotal trials to evaluate the safety and efficacy of a single administration of DAXI for the treatment of moderate to severe glabellar lines in adults and b) SAKURA 3, a long-term, open-label safety trial designed to evaluate the long-term safety of DAXI for the treatment of moderate to severe glabellar lines in adults following both single and repeat treatment administration. In December 2017, we announced top-line results for the SAKURA 1 and SAKURA 2 pivotal trials. Both SAKURA 1 and SAKURA 2 met the primary composite endpoint by delivering highly statistically significant improvement against placebo in reducing the severity of glabellar lines. The percentage of DAXI-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 DAXI-treated patients in SAKURA 1 and 91 percent of DAXI patients in SAKURA 2 said they were very satisfied or satisfied with their treatment experience.

There were several secondary endpoints used to evaluate duration of effect, including the proportion of patients achieving none or mild response on IGA-FWS compared to placebo, median duration for time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS, and median duration for time to return to baseline on both IGA-FWS and PFWS. The percentage of DAXI-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 DAXI-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 DAXI-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 DAXI-treated patients, and the results were 24.1 weeks for both SAKURA 1 and SAKURA 2, and 23.6 weeks for BELMONT.

In December 2018, we announced top-line results for the SAKURA 3 open-label, long-term safety study. DAXI appeared to be generally well-tolerated, with no new tolerability or safety concerns reported. As was seen in the SAKURA 1 and SAKURA 2 pivotal trials, adverse events were mild, localized and transient. The rate of treatment-related adverse events decreased over successive treatments. The most common treatment-related adverse events per treatment of DAXI were headache (3.3 percent of treatments), injection site pain (2.7 percent), injection site erythema (2.5 percent), and injection site oedema (2.2 percent). There were no treatment-related serious adverse events. Eyelid ptosis was reported in 0.9 percent of treatments, decreased in frequency with successive treatments and was substantially lower than the rate observed in SAKURA 1 and SAKURA 2 (2.2 percent of treatments). The majority of ptosis events were characterized as mild in severity (85 percent) and transient. A high degree of efficacy was seen consistently across all three treatment cycles. Results were consistent with SAKURA 1 and SAKURA 2 based on the IGA-FWS and PFWS scales. As early as Week 1, over 90 percent of subjects across all three treatments had none or mild wrinkles on the IGA-FWS. At Week 4, the percentage of DAXI-treated patients who achieved a none or mild response on IGA-FWS was 95.8 percent, 96.6 percent, and 97.7 percent for first, second and third treatment for SAKURA 3, respectively, and 97.5 percent for SAKURA 2 and SAKURA 1. On the more stringent 2-point composite endpoint, which was the primary efficacy endpoint in SAKURA 1 and 2, efficacy improved with successive treatment cycles: 73.2 percent, 77.7 percent, and 79.6 percent for first, second and third treatment of SAKURA 3, respectively, and 73.6 percent and 74.0 percent for SAKURA 1 and 2, respectively.

As in the SAKURA 1 and SAKURA 2 pivotal trials, there were several secondary endpoints used to evaluate duration of effect, including median time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS, and median duration for time to return to baseline wrinkle severity on both IGA-FWS and PFWS. Duration was evaluated in the first two 36-week treatment cycles; the third treatment cycle was not evaluated for duration as the observation period ended at twelve weeks for the purpose of this study. Median time to return to baseline wrinkle severity on both IGA-FWS and PFWS is 28.0 weeks and 28.1 weeks for first and second treatment of SAKURA 3, respectively, 27.7 weeks for SAKURA 1, and 26.0 weeks for SAKURA 2. Median time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS is 24.0 weeks and 24.1 weeks for first and second treatment of SAKURA 3, respectively,

24.0 weeks for SAKURA 1, and 23.9 weeks for SAKURA 2. We held a pre-BLA meeting with U.S. Food and Drug Administration (“FDA”) in December 2018, to agree upon the content and format of the BLA, which we plan to submit in first half of 2019. We plan to file marketing applications in the European Union, Canada, and certain Latin American and Asian countries after filing in the U.S.

We held a pre-BLA meeting with the FDA in December 2018, to agree upon the content and format of the BLA, which we plan to submit in first half of 2019.

Table of Contents***Forehead Lines***

Forehead lines are produced by the action of the frontalis muscle, a large, thin, vertically-oriented muscle which lifts the eyebrows. The frontalis muscle serves as an antagonist to the glabellar musculature, a natural depressor that is responsible for frowning and associated eyebrow movement. As the eyebrow is considered the aesthetic center of the upper face, forehead lines can significantly impact the aesthetic appearance of the face, contribute to increased signs of aging and convey unwanted social signals. However, both men and women have identified internal factors, such as wanting to look good for their age or having a more youthful appearance as very important and have prioritized forehead lines as bothersome areas for potential treatment regardless of age or available income. We initiated a Phase 2 study in forehead lines in January 2019.

***Lateral Canthal Lines***

LCL, or "crow's feet," are the spider-like fine lines around the outside corners of the eyes that become more obvious when someone smiles. These lines (also referred to as periorbital wrinkles, laugh lines or smile lines), fan out across the skin from the outer corner of each eye. Sometimes they extend down across the cheekbones to the lower cheeks. Repetitive motions, such as squinting and smiling, can lead to the increase of wrinkles and contribute to the severity and onset of crow's feet. Age and exposure to sun also play significant roles in development of these lines, which can deepen over time. Current treatments include anti-wrinkle eye creams and moisturizers, topical tretinoin, botulinum toxin injections, dermal fillers and laser treatments. BOTOX® Cosmetic was approved to treat LCL in 2013, and is currently the only toxin approved for that use, though other toxins are used off-label. We plan to initiate a Phase 2 study in LCL in the first quarter of 2019.

***Cervical Dystonia***

We have been developing DAXI for the treatment of cervical dystonia, a muscle movement disorder. Muscle movement disorders 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 DAXI to evaluate the safety, preliminary efficacy, and duration of effect of DAXI in subjects with moderate to severe isolated cervical dystonia.

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 the three cohorts. The topline data also displayed a clinically significant impact on cervical dystonia signs and symptoms. At Week 4, DAXI 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 DAXI 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 percent), of which all cases were mild in severity, injection site redness (8 percent), injection site bruising (5 percent), injection site pain (5 percent), muscle tightness (5 percent) and muscle weakness (5 percent).

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

In June 2018, we announced the initiation of patient dosing in our ASPEN Phase 3 clinical program based on the Phase 2 safety and efficacy results and guidance from the FDA and EMA. The ASPEN Phase 3 clinical program consists of two trials to evaluate the safety and efficacy of DAXI for the treatment of cervical dystonia in adults including: a randomized, double-blind, placebo-controlled, parallel group trial, and an open-label, long-term safety trial. The program is expected to enroll approximately 300 patients in the pivotal trial and 350 patients in the open-label trial at multiple sites in the U.S., Canada, and Europe. The program is expected to complete enrollment by early 2020, and we expect to release topline results in the second half of 2020.

Table of Contents***Plantar Fasciitis***

In 2016, we initiated a Phase 2 prospective, randomized, double-blinded, placebo-controlled trial of DAXI in the therapeutic indication of plantar fasciitis. This study evaluated the safety and efficacy of a single administration of DAXI in reducing the signs and symptoms of plantar fasciitis. The study completed enrollment of 59 subjects in the U.S. in October 2017. The study's primary efficacy endpoint is the improvement in the 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 VAS for pain at Week 8, showed a robust impact on pain, with a greater than 50 percent reduction for patients treated with DAXI. In the intent-to-treat population, a mean reduction in the VAS score of 54.2 percent from baseline was achieved with DAXI, compared with a 42.6 percent 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 ( $p=0.39$ ), DAXI provided patients with considerable pain relief. Similar numeric trends were seen in the secondary and exploratory endpoints. DAXI 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 DAXI and placebo were injection site pain (10.0 percent and 10.3 percent) and muscle weakness (3.3 percent and 3.4 percent), both respectively, all of which were classified as mild in severity. We completed the 16-week trial which showed a 58 percent reduction of pain from baseline along with a strong placebo response, with the difference between the treatment groups not being statistically significant.

In September 2018, we completed a Type C meeting with FDA discussing the design of the Phase 2 dose-finding study. We initiated another Phase 2 trial in December 2018. The Phase 2 prospective, randomized, double-blind, multi-center, placebo-controlled study will evaluate the safety and efficacy of two doses of administration of our investigational drug candidate DAXI in reducing the signs and symptoms of plantar fasciitis. The study is expected to enroll approximately 150 adult patients with unilateral plantar fasciitis, from approximately 20 study centers in the U.S.. Patients will be randomized (1:1:1) to receive an injection of a low dose, high dose or placebo. The study's primary efficacy endpoint is the change from baseline in NPRS score at Week 8. Patients will be followed for up to 24 weeks post treatment to assess treatment response, tolerability and safety. We expect to complete enrollment in this Phase 2 trial during the second half of 2019 and release topline results in the second half of 2020.

***Adult Upper Limb Spasticity***

Adult upper limb spasticity is a chronic movement disorder (an inability to produce and control bodily movements), that presents as increased tone or stiffness of the muscles. Spasticity results from neurological insults (e.g., stroke, multiple sclerosis, spinal cord injury and traumatic brain injury) to the brain that control voluntary movement of the body, arms and legs. According to GIA, the global opportunity for botulinum toxin for the treatment of muscle movement disorders, which includes cervical dystonia and upper limb spasticity, was estimated to be over \$1.0 billion in 2017. We initiated a Phase 2b study (JUNIPER) in adult upper limb spasticity in December 2018, and we expect to release topline results in the second half of 2020.

***Chronic Migraine***

Migraine headache is a central nervous system disorder characterized as moderate to severe headache and often includes other symptoms such as nausea and vomiting. Migraine headache affects more than 38 million people in the U.S., of which more than 3 million of whom suffer from chronic migraine headache. Chronic migraine headache is both undertreated and underdiagnosed, and is defined as more than fifteen headache days per month over a three-month period of which more than eight are migrainous, in the absence of medication overuse. According to GIA, the global opportunity for botulinum toxin for the treatment of chronic migraine was estimated to be approximately \$600 million in 2017. We are in the process of finalizing our Chronic Migraine Clinical Development strategy. We plan to study DAXI for the treatment of chronic migraine in 2019 or 2020.

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**OnabotulinumtoxinA Biosimilar**

In February 2018, we entered into a collaboration and license agreement with Mylan, pursuant to which we will collaborate with Mylan exclusively, on a world-wide basis (excluding Japan), to develop, manufacture and commercialize a biosimilar to BOTOX®. As part of the agreement Mylan agreed to pay a non-refundable upfront payment of \$25 million with additional 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 would pay us 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, we 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. In February 2019, we and Mylan recently had a Biosimilar Initial Advisory Meeting with the FDA on a proposed biosimilar to BOTOX®. In this meeting, the FDA provided guidance on their expectations for a development program to establish biosimilarity to BOTOX®. Based on the agency's feedback, we and Mylan believe that a 351(k) pathway for the development of a biosimilar to onabotulinumtoxinA is viable and provides the opportunity to develop and commercialize the first biosimilar product for all eleven currently approved indications of BOTOX® and BOTOX® Cosmetic.

**DaxibotulinumtoxinA Topical**

DaxibotulinumtoxinA Topical presents several potential advantages, including painless topical administration, no bruising, ease of use and limited dependence on administration technique by physicians and medical staff. We believe these potential advantages may improve the experience of patients undergoing botulinum toxin procedures and could make DaxibotulinumtoxinA Topical suitable for multiple indications in the future. We are planning to conduct additional preclinical work for DaxibotulinumtoxinA Topical in therapeutic and aesthetic applications where botulinum toxin has shown efficacy and is particularly well suited for injection-free treatments.

**Fosun License Agreement**

In December 2018, we and Fosun entered into the Fosun License Agreement, whereby we have granted Fosun the exclusive rights to develop and commercialize our proprietary DAXI in the Fosun Territory and certain sublicense rights. Additionally, our proprietary peptide excipient technology can be used for molecules other than botulinum toxin. We plan to partner or license the peptide excipient technology opportunistically to monetize our technology platform.

Under the Fosun License Agreement, we are eligible to receive a non-refundable upfront payment of \$30.0 million within 30 business days of the date of the Fosun License Agreement, which was received in January 2019 net of foreign withholding tax of \$3.0 million. We are also eligible to receive (i) additional contingent payments of up to \$230.5 million upon the achievement of specified milestones based on (a) the submission and approval of BLAs for certain aesthetic and therapeutic indications and (b) first time calendar year net sales, and (ii) tiered royalty payments in low double digit to high teen percentages on annual net sales. The royalty percentages are subject to reduction in the event that (i) we do not have any valid and unexpired patent claims that cover the product in the Fosun Territory, (ii) biosimilars of the product are sold in the Fosun Territory or (iii) Fosun needs to pay compensation to third parties to either avoid patent infringement or market the product in the Fosun Territory.

Table of Contents**Results of Operations****Revenue**

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

	Years Ended December 31,			2018 vs.	2017 vs.
	2018	2017	2016	2017	2016
				%	%
<b>(In thousands, except percentages)</b>					
Milestone	\$3,729	\$—	\$—	—	% — %
Relastin Royalty	—	262	300	(100)	% (13)%
Total revenue	\$3,729	\$262	\$300	1,323	% (13)%

Our total revenue for the year ended December 31, 2018 increased compared to the same period in 2017 and 2016, primarily due to revenue recognized from the collaboration and license agreement with Mylan.

In February 2018, we entered into the Mylan Collaboration, pursuant to which we will collaborate with Mylan exclusively, on a world-wide basis (excluding Japan) to develop, manufacture, and commercialize a biosimilar to BOTOX®. As part of the Mylan Collaboration, Mylan paid us a non-refundable upfront payment of \$25 million with additional contingent payments of up to \$100 million, in the aggregate, upon the achievement of specified clinical and regulatory (i.e., biosimilar biological pathway) milestones and of specified, tiered sales milestones of up to \$225 million. We recognized revenue based on the estimated cost of services incurred over the estimated cost of services to be provided for the development period.

We recognized royalty revenue during the years ended December 31, 2017 and 2016 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 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 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. We were entitled to the minimum royalty payment until Valeant returned the Relastin® intellectual property rights to us. In November 2017, we 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 us. We do not have any current plans for future developments of Relastin® and our primary focus is on the development of DAXI.

**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 DAXI for the treatment of glabellar lines and indications in muscle movement and other disorders, such as cervical dystonia, plantar fasciitis, upper limb spasticity, chronic migraine, and our biosimilar product candidate.

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**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 DAXI, DaxibotulinumtoxinA Topical, and our biosimilar product candidate 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 DAXI and DaxibotulinumtoxinA Topical, including expenses related to production of clinical supplies;
- fees paid to clinical consultants, 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 and other pre-commercial supplies;
- 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 U.S., 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 maintain or increase as we continue our clinical development of DAXI for the treatment of facial wrinkles and other neuroscience indications, such as cervical dystonia, plantar fasciitis, adult upper limb spasticity, and chronic migraine, any future new indications, and our biosimilar product candidate or if the FDA requires us to conduct additional clinical trials for approval.

Our research and development expenses fluctuate as projects transition from one development phase to the next. Depending on the stage of completion and level of effort related to each development phase undertaken, we may reflect variations in our research and development expense. We expense both internal and external research and development expenses as they are incurred. We typically share employees, consultants and infrastructure resources among the programs related to DAXI, our biosimilar product candidate, and DaxibotulinumtoxinA Topical. 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,			2018	2017 vs.
	2018	2017	2016	vs.	2016
				2017	2016
				%	%
	<b>(In thousands, except percentages)</b>				
Clinical and regulatory	\$47,777	\$43,915	\$15,060	9 %	192 %
Manufacturing and quality efforts	25,857	21,545	19,956	20%	8 %



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Stock-based compensation	7,480	5,902	5,557	27%	6	%
Other research and development expenses	11,386	8,999	9,808	27%	(8)	%
Total research and development expenses	\$92,500	\$80,361	\$50,381	15%	60	%

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Clinical expenses include personnel costs, and external clinical trial costs for clinical sites, clinical research organizations, central laboratories, data management, contractors and regulatory activities associated with the development of DAXI and DaxibotulinumtoxinA Topical, including clinical trials of DAXI for the improvement of glabellar lines, cervical dystonia and plantar fasciitis. For the years ended December 31, 2018, 2017, and 2016, clinical and regulatory costs totaled \$47.8 million, or 52%, \$43.9 million, or 55%, and \$15.1 million, or 30% of the total research and development expenses in 2018, 2017, and 2016, respectively.

Clinical and regulatory costs for the year ended December 31, 2018 increased by 9%, compared to the same period in 2017, primarily due to increased costs related to hiring additional personnel and outside services to address compliance requirements and infrastructure build-out as well as studies related to cervical dystonia, adult upper limb spasticity, plantar fasciitis, forehead lines and lateral canthal lines, offset by a decrease in clinical trial costs related to glabellar lines as the SAKURA trials wind down. 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 DAXI for the treatment of glabellar lines, cervical dystonia, and plantar fasciitis.

We expect to maintain or increase our clinical and regulatory costs in the near term as we initiate and complete clinical trials and other associated programs related to DAXI for the treatment of glabellar lines, forehead lines, lateral canthal lines, cervical dystonia, plantar fasciitis, adult upper limb spasticity, chronic migraine, and other indications, and our anticipated BLA submission upon the completion and success of the clinical trials for the DAXI 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 DAXI. Manufacturing and quality efforts also include raw materials, lab supplies, and storage and shipment of our product to support quality control and assurance activities. These costs do not include clinical costs associated with the development of DAXI. For the years ended December 31, 2018, 2017, and 2016, costs associated with our manufacturing and quality efforts for both DAXI and DaxibotulinumtoxinA Topical development totaled \$25.9 million, or 28%, \$21.5 million, or 27%, and \$20.0 million, or 40% of the total research and development expenses in 2018, 2017, and 2016, respectively. Manufacturing and quality efforts for the year ended December 31, 2018 increased by 20%, compared to the same period in 2017, primarily due to increased costs related to hiring additional personnel and outside services to address compliance requirements and infrastructure build-out. 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. We expect our manufacturing and quality efforts to continue to increase as we approach commercialization.

*Stock-based compensation*

Stock-based compensation for research and development increased by \$1.6 million for the year ended December 31, 2018 compared to the same period in 2017, and increased by \$0.3 million for the year ended December 31, 2017 compared to the same period in 2016, primarily due to increased employee headcount and an average increase in fair value of stock option granted during those periods.

*Other research and development expenses*

Other research and development expenses include expenses for personnel, contract research organizations, consultants, raw materials, and lab supplies used to conduct preclinical research and development of DAXI, our DaxibotulinumtoxinA Topical, and biosimilar product candidates. Other research and development expenses represented \$11.4 million, or 12%, \$9.0 million, or 11%, and \$9.8 million, or 19% for the years end on December 31, 2018, 2017, and 2016, respectively.

Other research and development expenses for the year ended December 31, 2018 increased by 27%, compared to the same period in 2017, primarily due to increased consulting costs on preclinical research and development of DAXI, our DaxibotulinumtoxinA Topical, and biosimilar product candidates. Other research and development expenses for the year ended December 31, 2017 decreased by 8%, compared to the same period in 2016, primarily due to a

milestone payment of \$2.0 million to BTRX to acquire a portfolio of patents.

Table of Contents**General and Administrative Expenses**

General and administrative expenses consist primarily the following:

personnel and service costs in our finance, information technology, investor relations, legal, human resources, and other administrative functions;  
 professional fees for accounting and legal services, including legal services associated with obtaining and maintaining patents and litigation; and  
 pre-commercial activities including market research, public relations, promotion and advertising.  
 We expect that our general and administrative expenses will maintain or increase with the continued development of, and if approved, the commercialization of DAXI. The following table presents our general and administration expenses for the periods indicated and related changes from the prior period.

	Year Ended December 31,			2018	2017
	2018	2017	2016	vs. 2017	vs. 2016
				%	%
<i>(In thousands, except percentages)</i>					
General and administrative expenses before stock-based compensation	\$45,070	\$30,070	\$22,679	50%	33%
Stock-based compensation	8,793	7,328	6,396	20%	15%
Total general and administrative expenses	\$53,863	\$37,398	\$29,075	44%	29%

**General and administrative expenses before stock-based compensation**

General and administrative expenses for the year ended December 31, 2018 increased by 50%, compared to the same period in 2017. General and administrative expenses for the year ended December 31, 2017 increased by 33%, compared to the same period in 2016. For both periods presented, the increases are primarily due to i) increased personnel in information technology, accounting, legal, and other administrative functions; ii) cost related to pre-commercial initiatives to support our future product launch following our anticipated BLA submission upon the completion and success of the clinical trials for the DAXI glabellar lines indication, iii) costs related to accounting and legal services, and iv) other costs related to infrastructure build-out.

**Stock-based compensation**

Stock-based compensation for general and administrative expenses increased for the periods presented primarily due to an increase in employee headcount and an average increase in the fair value of stock option granted during those periods.

**Loss on Impairment**

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

Year Ended December 31,	2018 vs.		2017 vs.	
	2017	2016	2017	2016
	%	%	%	%
<i>(In thousands, except percentages)</i>				

Loss on impairment \$-\$2,927 \$9,059 (100)% (68)%

We constructed a large capacity fill/finish line dedicated to the manufacturing of DaxibotulinumtoxinA Topical and to support our regulatory license applications. In June 2016, we discontinued clinical development of DaxibotulinumtoxinA Topical for the treatment of crow's feet and axillary hyperhidrosis. As a result, we recorded a loss on impairment of \$9.1 million and \$2.9 million, respectively, related to our DaxibotulinumtoxinA Topical fill/finish line and certain other assets, during the years ended December 31, 2017, and 2016. No impairment loss was recorded during the year ended December 31, 2018.



Table of Contents**Net Non-Operating Income and Expense*****Interest Income***

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

***Interest Expense***

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

***Change in Fair Value of Derivative liability associated with the Medicis settlement***

The product approval payment associated with the Medicis settlement is classified as a liability on our Consolidated Balance Sheet. This liability is remeasured to fair value at each balance sheet date with the corresponding gain or loss from the adjustment recorded in the Consolidated Statements of Operations and Comprehensive Loss. We will continue to record adjustments to the fair value of the Medicis settlement derivative liability until the product approval payment has been paid. The decrease recorded during the year ended December 31, 2018 reflects an increase to the valuation of the derivative liability based on assumptions related to the development of DAXI for glabellar lines.

***Other Expense, net***

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

The following table presents our net non-operating income and expense for the periods indicated and related changes from the prior period:

	Years Ended December 31,			2018 vs.	2017 vs.
	2018	2017	2016	2017	2016
				%	%
	<b>(In thousands, except percentages)</b>				
Interest income	\$4,023	\$1,410	\$1,170	185	21
Interest expense	(44)	(457)	(1,082)	(90)	(58)
Changes in fair value of derivative liability associated with the Medicis settlement	(140)	(591)	(608)	(76)	(3)
Other expense, net	(773)	(525)	(535)	47	(2)
Total net non-operating income (expenses)	\$3,066	\$(163)	\$(1,055)	N/M*	N/M*

\*NM - not meaningful

Our total net non-operating income for the year ended December 31, 2018 increased by \$3.2 million, compared to the same period in 2017, primarily due to an increase in interest income from our short-term investments. Our total net non-operating expense for the year ended December 31, 2017 decreased by \$0.9 million, compared to the same period in 2016, primarily due to lower interest expense resulting from the declining principal balance on the Essex Capital Lease offset by an increase in the interest income from a stronger investment portfolio.



Table of Contents**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.

Tax provision for the year ended December 31, 2018 is \$3.0 million. The tax provision is related to foreign withholding taxes. There was no provision or benefit from income taxes during the years ended December 31, 2017 and 2016.

In December 2017, the U.S. government enacted the Tax Cuts and Jobs Act (the “Tax Reform Act”). The Tax Reform Act includes but is not limited to, reducing the U.S. federal corporate tax rate from 35 percent to 21 percent, allowing for federal net operating losses (“NOL”) to be carried over indefinitely for NOL generated after December 31, 2017, and creating a new limitation on deductible interest expense.

In March 2018, the SEC staff issued 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*. We completed our assessment of the accounting impact resulting from the Tax Reform Act in December 2018. The impact of the Tax Reform Act includes:

- a decrease in deferred tax assets resulting from the change in tax rate in the amount of \$62.9 million;
  - an increase of net operating loss of \$43.5 million as a result of the reversal of the intra-entity transfer of certain intellectual properties, refer below for further information related to this transaction;
  - a decrease in net operating loss of \$3.8 million related to a research and development credit adjustment.
- The aggregated impact resulting from the Tax Reform Act to deferred taxes is \$68.1 million, which continues to be fully offset by a valuation allowance.

We follow 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 that the liabilities have been netted against deferred attribute carryovers. It is our policy to include penalties and interest related to income tax matters in income tax expense.

**Liquidity and Capital Resources**

	Year Ended December 31,		Increase (Decrease)
	2018	2017	
Cash, cash equivalents, and short-term investments	\$ 175,812	\$ 282,896	\$(107,084)
Financing obligations	—	1,872	(1,872)
Working Capital	175,952	264,309	(88,357)
Stockholders' Equity	145,622	268,845	(123,223)

**Sources and Uses of Cash**

We hold our cash, cash equivalents, and short-term investments in a variety of non-interest bearing bank accounts and interest-bearing instruments subject to investment guidelines allowing for holdings in U.S. government and agency securities and money market accounts. Our investment portfolio is structured to provide for investment maturities and access to cash to fund our anticipated working capital needs.

Our cash, cash equivalents and short-term investments totaled \$175.8 million at December 31, 2018 compared to \$282.9 million at December 31, 2017, representing a decrease of \$107.1 million, which was primarily due to cash used in operations, purchase of property and equipment of \$7.0 million, and purchases of short-term investments of



\$314.9 million. These decreases were primarily offset by the proceeds from maturities of short-term investments of \$146.0 million and the proceeds from sales of short-term investments of \$67.4 million.

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Through December 31, 2018, we have funded substantially all of our operations through the sale and issuance of our common stock, preferred stock, venture debt, and convertible debt. Due to our substantial research and development expenditures, we have generated significant operating losses since our inception. Our expenditures are primarily related to research and development activities. We expect to continue to incur net operating losses for at least the next several years as we advance DAXI 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, 2018, we had available cash and cash equivalents and short-term investments of \$175.8 million.

We derived the following summary of our Consolidated Statement of 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,		
	2018	2017	2016
Net cash provided by (used in):			
Operating activities	\$(104,246)	\$(95,342)	\$(59,827)
Investing activities	(107,026 )	118,792	(75,499 )
Financing activities	1,782	195,944	(2,642 )

***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, 2018 of \$104.2 million was primarily due to clinical spend of approximately \$38.5 million to advance our clinical programs toward commercialization; investing in our personnel and talent retention, which represents approximately \$31.0 million; and professional services and consulting of approximately \$32.0 million, offset by the \$25.0 million upfront payment received from the Mylan Collaboration. The remaining balance of operating activities related primarily to rent, utilities, and other supplies.

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 our clinical programs toward commercialization; investing in our personnel and talent retention, which represents approximately \$25 million; and professional services and consulting of approximately \$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 DAXI program and DaxibotulinumtoxinA Topical, 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 approximately \$10 million. The remaining balance of operating activities related primarily to rent, utilities, and other supplies.

***Cash Flows from Investing Activities***

Net cash provided by or used in investing activities for the years ended December 31, 2018, 2017 and 2016 was primarily due to purchases of property and equipment, proceeds from sale of assets, and fluctuations in the timing of purchases and maturities of short-term investments.

***Cash Flows from Financing Activities***

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

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***Follow-On Public Offerings***

In December 2017, we completed a follow-on public offering, or the 2017 follow-on offering, pursuant to which we 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.

In January 2019, we completed a follow-on public offering, or the 2019 follow-on offering, pursuant to which we issued 6,764,705 shares of common stock at \$17.00 per share, including the exercise of the underwriters' over-allotment option to purchase 882,352 additional shares of common stock, for net proceeds of \$107.6 million, after underwriting discounts, commissions and other offering expenses.

***ATM Offering***

In March 2016, we entered into an At-the-market Issuance Sales Agreement with Cowen and Company, LLC (“Cowen”) (the “2016 ATM agreement”). Under the 2016 ATM agreement, we 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, we 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.

In March 2018, we terminated the 2016 ATM Agreement and entered into the 2018 ATM Agreement. Under 2018 ATM Agreement, we may offer and sell common stock having aggregate proceeds of up to \$125.0 million from time to time through Cantor Fitzgerald as our sales agent. No sales of our common stock have taken place under the 2018 ATM Agreement as of December 31, 2018.

**Common Stock and Common Stock Equivalents**

As of February 22, 2019, the number of shares outstanding of our common stock is 44,028,590, which includes restricted stock awards. We had outstanding common stock options of 4,363,688, outstanding common stock warrants of 34,113, unvested restricted stock awards of 843,853, and shares expected to be purchased on June 30, 2019 under the 2014 ESPP of 10,405 as of February 22, 2019.

**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 DAXI for the treatment of glabellar lines, cervical dystonia, plantar fasciitis, upper limb spasticity, migraine headache, and other indications, seek regulatory approval, prepare for and, if approved, proceed to commercialization. We believe that our existing capital resources will be sufficient to fund our operations for at least the next 12 months following the filing of this Form 10-K. However, we anticipate that we will need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may seek to sell additional equity or issue debt, convertible debt or other securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of debt or convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring

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

If adequate funds are not available to us on a timely basis, or at all, we may be required to terminate or delay clinical trials or other development activities for DAXI, our biosimilar product candidate and DaxibotulinumtoxinA Topical, 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:

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the results of our clinical trials for DAXI and preclinical trials of DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;

the timing of, and the costs involved in, obtaining regulatory approvals for DAXI, or any future product candidates including DaxibotulinumtoxinA Topical or biosimilar;

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 DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;

the cost of commercialization activities if DAXI or any future product candidates including DaxibotulinumtoxinA Topical or biosimilar are approved for sale, including marketing, sales and distribution costs;

the cost of manufacturing DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates and any products we successfully commercialize and maintaining our related facilities;

our ability to establish and maintain strategic collaborations, licensing or other arrangements including the Mylan collaboration, Fosun licensing, 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 Part I, Item 1A. "Risk Factors" in this Form 10-K for additional risks associated with our substantial capital requirements.

Since inception, we have devoted substantially all of our efforts to identifying and developing product candidates for the aesthetic and therapeutic pharmaceutical markets, recruiting personnel, raising capital, conducting preclinical and clinical development of, and manufacturing development for DAXI and DaxibotulinumtoxinA Topical. We have incurred losses and negative cash flows from operations. We have not yet commenced commercial operations, have not generated product revenue to date, and will continue to incur significant research and development and other expenses related to our ongoing operations. We have recorded net losses of \$142.6 million, \$120.6 million, and \$89.3 million for the years ended December 31, 2018, 2017, and 2016, respectively. As of December 31, 2018, we had a working capital surplus of \$176.0 million and an accumulated deficit of \$684.8 million. We have funded our operations primarily through the sale and issuance of common stock, convertible preferred stock, notes payable, and convertible notes. As of December 31, 2018, we had capital resources consisting of cash, cash equivalents, and short-term investments of \$175.8 million. In January 2019, we completed the 2019 follow-on offering for net proceeds of \$107.6 million after underwriting discounts, commissions and other offering expenses. In January 2019, we received \$27.0 million for an upfront payment net of foreign withholding tax from Fosun. We believe that our existing cash and cash equivalents will allow us to fund our operating plan through at least the next 12 months following the issuance of this Form 10-K, and may identify additional capital resources to fund our operations.

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**Critical Accounting Policies and Estimates**

Our Consolidated Financial Statements are prepared in accordance with GAAP. 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 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.

**Revenue**

Effective January 1, 2018, we adopted Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606), using the full retrospective transition method. We evaluated our prior contractual revenue arrangement with PDI, which was acquired by Valeant in 2014. After Valeant notified us that it intended to terminate the asset purchase and royalty agreement in 2015, we continued to receive royalties of \$75,000 each quarter until November 2017 when Valeant and us 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 us. Based on its evaluation, we determined that the new guidance had no impact to the revenue recognized prior to January 1, 2018 and, accordingly, had no impact on the accumulated deficit as of January 1, 2018.

We elected to use certain practical expedients permitted related to adoption (Part IV, Item 15. “Exhibits and Financial Statement Schedules—Notes to Consolidated Financial Statements—Note 3—Revenue” in this Form 10-K.) and the adoption of ASC 606 had no impact on our financial position, results of operations or liquidity. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services.

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

**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 (“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, 2018, there have not been any material adjustments to our estimated accrued clinical expenses.



Table of Contents**Stock-Based Compensation**

We recognize compensation costs related to stock options granted to employees, non-employee consultants, 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, 2018, 2017, and 2016 were calculated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	Year Ended December 31,		
	2018	2017	2016
Expected term (in years)	6.0	6.0	6.0
Expected volatility	60.2%	67.7%	61.9%
Risk-free interest rate	2.7 %	2.1 %	1.4 %
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 us, whereas prior to 2017, the expected volatility was based solely on the historical volatility of a group of similar entities. In evaluating similarity, we 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.

As of July 1, 2018, we adopted ASU 2018-07 and began accounting for share-based payment transactions for acquiring goods and services from non-employees (excluding non-employee directors) using a retroactive approach. Under ASU 2018-07, equity-classified non-employee share-based payment awards are measured at the fair value on the grant date, and expense is recognized in the same period and in the same manner as if we had paid cash for the goods or services received. With the adoption of ASU 2018-07, we recorded a cumulative charge of less than \$0.1 million to the Accumulated Deficit balance as of January 1, 2018.

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.

Table of Contents***Derivative Liabilities***

We bifurcated and separately accounted for derivative instruments related to payment provisions underlying the Medicis settlement. This derivative is accounted for as a liability, which will be remeasured to fair value as of each balance sheet date, with changes in fair value recognized in the Consolidated Statements of Operations and Comprehensive Loss. We will continue to record adjustments to the fair value of the derivative liability associated with the Medicis settlement until the remaining settlement payment has been paid.

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, 2017, the fair value of the product approval payment derivative of \$2.6 million was determined by updating the timing and probability estimate of the related approval and applying a discount factor assuming a term of 2.5 years, a risk-free rate of 2.0% and a credit risk adjustment of 6.5%. As of December 31, 2018, we determined the fair value of its liability for the product approval payment was \$2.7 million, which was measured by assuming a term of 1.5 years, a risk-free rate of 2.6% and a credit risk adjustment of 8.0%. Our assumption for the expected term is based on an expected BLA approval in 2020. We did not make any payments under the product approval payment during the years ended December 31, 2018 and 2017. As a result of the fair value remeasurements during the years ended December 31, 2018, 2017, and 2016, we recognized aggregate losses of \$0.1 million, \$0.6 million, and \$0.6 million, respectively.

***Impairment of Long-Lived Assets***

We evaluate long-lived assets, such as property and equipment subject to depreciation, for impairment whenever events or changes in circumstances indicate that the carrying value of long-lived assets may not be recoverable. Events and changes in circumstances considered important that could result in an impairment review of long-lived assets include (i) a significant decrease in the market price of a long-lived asset; (ii) a significant adverse change in the extent or manner in which a long-lived asset is being used or in its physical condition; (iii) 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; (iv) an accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction of a long-lived asset; (v) a 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 (vi) a current expectation that, more likely than not (more than 50 percent), a long-lived asset will be sold or otherwise disposed of significantly before the end of its previously estimated useful life. The impairment evaluation of long-lived assets includes an analysis of estimated future undiscounted net cash flows expected to be generated by the long-lived assets over their remaining estimated useful lives. If the estimate of future undiscounted net cash flows is insufficient to recover the carrying value of the long-lived assets over the remaining estimated useful lives, we record an impairment loss in the amount by which the carrying value of the long-lived assets exceeds the fair value. Fair value is generally measured based on discounted cash flow analysis.

We constructed a fill/finish line for the future commercial manufacturing of our DaxibotulinumtoxinA Topical 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 our DaxibotulinumtoxinA 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 DaxibotulinumtoxinA 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 DaxibotulinumtoxinA Topical fill/finish line would be repurposed for commercial-scale manufacturing of DAXI. 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, 2017, we recorded a loss on impairment of \$2.9 million.

During the year ended December 31, 2018, we sold certain component relating to the fill/finish line manufacturing equipment and recognized a gain of \$1.5 million, which is included in Research and Development expenses in the Consolidated Statements of Operations and Comprehensive Loss. There was no impairment of long-lived assets during the year ended December 31, 2018.

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***Income Taxes***

We account for income taxes under the asset and liability method. 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 the 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 NOL or credit carryforwards are utilized. Accordingly, realization of our deferred tax assets is dependent on future taxable income against which these deductions, losses and credits 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, we establish a valuation allowance. Based on the available evidence, we are unable, at this time, to support the determination that it is more likely than not that its deferred tax assets will be utilized in the future. Accordingly, we recorded a full valuation allowance as of December 31, 2018 and 2017. We intend to maintain valuation allowances until sufficient evidence exists to support its reversal.

As of December 31, 2018, we had NOL carryforwards available to reduce future taxable income, if any, for federal, California, and other states income tax purposes of \$638.6 million, \$179.1 million, and \$703.9 million, respectively. The California NOL carryforwards began to expire in 2010. The federal NOL carryforwards will begin expiring in 2020, and the other states NOL carryforwards will begin expiring in 2030 if they are not utilized. As a result of the Tax Reform Act, the federal NOL generated after December 31, 2017 will carryover indefinitely with statutory limitations to the annual utilization.

As of December 31, 2018, we had research and development credit carryforwards of \$7.3 million and \$6.7 million available to reduce future taxable income, if any, for federal and California income tax purposes, respectively. The federal research and development credit carryforwards will begin expiring in 2023 if they are not utilized, and the California research and development credit carryforwards have no expiration date.

In general, if we experience 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 Internal Revenue Code Section 382 (California and other states have similar laws). The annual limitation generally is determined by multiplying the value of our 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. We determined that an ownership change occurred on April 7, 2004 but that all carryforwards can be utilized prior to the expiration. We also determined that an ownership change occurred in February 2014, and as a result, we reduced the deferred tax assets and the corresponding valuation allowance to account for this limitation. Since the research and development credits for California carry over indefinitely, there was no change to the California research and development credits. We reviewed our Internal Revenue Code Section 382 limitation through December 31, 2018 and have not identified any ownership changes resulting in a limitation.

Our ability to use our remaining NOL carryforwards may be further limited if we experience a Section 382 ownership change as a result of future changes in its stock ownership.

Table of Contents**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, 2018, 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	Payment due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
	( In thousands)				
Operating lease obligations	\$48,995	\$6,339	\$13,677	\$11,021	\$17,958
Total	\$48,995	\$6,339	\$13,677	\$11,021	\$17,958

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 upon the achievement of regulatory approval for DAXI or DaxibotulinumtoxinA Topical.

In June 2016, we entered into 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, we acquired all rights, title and interest in a portfolio of botulinum toxin-related patents and patent applications from BTRX and was granted the right of first negotiation and first refusal with respect to other botulinum toxin-related patents owned or controlled by BTRX.

In April 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.

In March 2017, we entered into the Althea Services Agreement, under which Althea has agreed to provide us with a future source of commercial fill/finish services for our neuromodulator products. The Althea Services Agreement has an initial term that will expire in 2024, unless terminated sooner by either party. In accordance with the Althea Services Agreement, we will have minimum purchase obligations based on its production forecasts. As of December 31, 2018, we made non-refundable advanced payments of \$1.9 million in accordance with the terms of the Althea Services Agreement. The remaining services are cancellable at any time, with the costs we are required to pay that 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 \$4.2 million at December 31, 2018. The timing of the settlement of these amounts was not reasonably estimable at December 31, 2018. 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, 2018, we did not have any off-balance sheet arrangements or any relationships with any entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes.

**Recent Accounting Pronouncements**

Refer to Part IV, Item 15. "Exhibits and Financial Statement Schedules—Notes to Consolidated Financial Statements—Note 2—Summary of Significant Accounting Policies" in this Form 10-K.



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**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 short-term investments. We had cash, cash equivalents, and short-term investments of \$175.8 million and \$282.9 million as of December 31, 2018 and 2017, respectively. As of December 31, 2018, our cash, cash equivalents, and short-term investments were held in deposit, money market funds, U.S. treasury securities and U.S. government agency obligations. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates in the U.S. 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 short-term investments in U.S. treasury and government agency obligations to maturity.

**Foreign Exchange**

Our operations are primarily conducted in the U.S. 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, 2018, 2017 and 2016, 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.



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**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.

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

None.

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**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, our principal financial officer and our principal accounting officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer, our principal financial officer, and our principal accounting officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer, our principal financial officer, and our principal accounting officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of December 31, 2018, 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 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 principal executive officer, principal financial officer, and principal accounting officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018 based on the criteria established in *Internal Control - Integrated Framework (2013)* 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, 2018.

The effectiveness of the Company's internal control over financial reporting as of December 31, 2018 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report on page F-2 in Part IV, Item 15 of this Form 10-K and is incorporated herein by reference.

(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, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**ITEM 9B. OTHER INFORMATION**

None.

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**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this Item will be included in the Company's proxy statement for the 2019 Annual Meeting of the Stockholders ("2019 Proxy Statement"), under the sections labeled "Proposal 1 - Election of Directors", "Section 16(a) Beneficial Ownership Reporting Compliance", "Information Regarding the Board of Directors and Corporate Governance" and "Executive Officers of the Company" and is incorporated by reference. The 2019 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates.

*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.

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**ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item will be included in the sections labeled “Executive Compensation”, “Information Regarding the Board of Directors and Corporate Governance - Non-Employee Director Compensation”, “Information Regarding the Board of Directors and Corporate Governance - Compensation Committee Interlocks and Insider Participation” and “Information Regarding the Board of Directors and Corporate Governance - Compensation Committee Report” appearing in our 2019 Proxy Statement, and is incorporated herein.

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

The information required by this Item will be included in the sections labeled “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” appearing in our 2019 Proxy Statement, and is incorporated by reference.

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

The information required by this Item will be included in the sections labeled "Transactions with Related Persons" and "Information Regarding the Board of Directors and Corporate Governance" appearing in our 2019 Proxy Statement, and is incorporated by reference.



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**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this Item will be included in the section labeled “Proposal 2 - Ratification of Selection of Independent Registered Public Accounting Firm” appearing in our 2019 Proxy Statement, and is incorporated by reference.

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Table of Contents**PART IV****ITEM 15. EXHIBITS AND FINANCIALS STATEMENT SCHEDULES**

(a) The following documents are filed as part of this Annual Report on this Form 10-K:

(1) Financial Statements. The financial statements required by this item are set forth beginning at F-1 of this Annual Report on this Form 10-K and are incorporated herein by reference.

(2) Financial Statement Schedules. None. Financial statement schedules have been omitted because they are not applicable.

(3) Exhibits: See Item 15(b) below.

(b) Exhibits. The following exhibits are included herein or incorporated herein by reference:

**EXHIBIT INDEX**

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	<u>Amended and Restated Certificate of Incorporation</u>	8-K	001-36297	3.1	February 11, 2014	
3.2	<u>Amended and Restated Bylaws</u>	S-1	333-193154	3.4	December 31, 2013	
4.2	<u>Form of Common Stock Certificate</u>	S-1/A	333-193154	4.4	February 3, 2014	
10.1*	<u>Revance Therapeutics, Inc. 2002 Equity Incentive Plan</u>	S-1	333-193154	10.1	December 31, 2013	
10.2*	<u>Form of Stock Option Agreement and Option Grant Notice for Revance Therapeutics, Inc. 2002 Equity Incentive Plan</u>	S-1	333-193154	10.2	December 31, 2013	
10.3*	<u>Revance Therapeutics, Inc. Amended and Restated 2012 Equity Incentive Plan</u>	S-1	333-193154	10.3	December 31, 2013	
10.4*	<u>Form of Stock Option Agreement and Option Grant Notice for Revance Therapeutics, Inc. Amended and Restated 2012 Equity Incentive Plan</u>	S-1	333-193154	10.4	December 31, 2013	
10.5*	<u>Revance Therapeutics, Inc. 2014 Equity Incentive Plan</u>	S-1/A	333-193154	10.5	January 27, 2014	
10.6*	<u>Form of Restricted Stock Unit Award Agreement and Grant Notice for Revance Therapeutics, Inc. 2014 Equity Incentive Plan</u>	10-K	001-36297	10.6	March 4, 2016	
10.7*	<u>Form of Stock Option Agreement and Grant Notice for Revance Therapeutics, Inc. 2014 Equity Incentive Plan</u>	10-Q	001-36297	10.3	November 10, 2015	
10.8*	<u>Form of Restricted Stock Bonus Agreement and Grant Notice for Revance Therapeutics, Inc. 2014 Equity Incentive Plan</u>	10-K	001-36297	10.8	March 4, 2016	
10.9*	<u>Revance Therapeutics, Inc. 2014 Employee Stock Purchase Plan</u>	S-1/A	333-193154	10.7	January 27, 2014	
10.10*	<u>Form of Indemnity Agreement by and between Revance Therapeutics, Inc. and each of its officers and directors</u>	S-1/A	333-193154	10.8	January 27, 2014	
10.11	<u>Lease Agreement dated March 31, 2008 by and between Revance Therapeutics, Inc. and BMR-Gateway Boulevard LLC</u>	S-1	333-193154	10.9	December 31, 2013	

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Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	File No.	Exhibit Filing Date	
10.12	<u>First Amendment to Office Lease dated April 7, 2008 by and between Revance Therapeutics, Inc. and BMR-Gateway Boulevard LLC</u>	S-1	333-193154	10.10	December 31, 2013
10.13	<u>Second Amendment to Office Lease and Lease dated May 17, 2010 by and between Revance Therapeutics, Inc. and BMR-Gateway Boulevard LLC</u>	S-1	333-193154	10.11	December 31, 2013
10.14	<u>Third Amendment to Lease, dated February 26, 2014 by and between Revance Therapeutics, Inc. and BMR-Gateway Boulevard LLC</u>	8-K	001-36297	10.35	March 4, 2014
10.15	<u>Fourth Amendment to Lease, dated May 10, 2018, by and between Revance Therapeutics, Inc. and BMR-Pacific Research Center LP.</u>	8-K	001-36297	10.1	May 11, 2018
10.16+	<u>License and Service Agreement dated February 8, 2007 between Revance Therapeutics, Inc. and List Biological Laboratories, Inc.</u>	S-1	333-193154	10.15	December 31, 2013
10.17+	<u>First Addendum to the License and Service Agreement dated April 21, 2009 between Revance Therapeutics, Inc. and List Biological Laboratories, Inc.</u>	S-1	333-193154	10.16	December 31, 2013
10.18+	<u>Development and Supply Agreement dated December 11, 2009 between Revance Therapeutics, Inc. and Hospira Worldwide, Inc.</u>	S-1	333-193154	10.18	December 31, 2013
10.19+	<u>First Amendment to Development and Supply Agreement dated May 29, 2013 between Revance Therapeutics, Inc. and Hospira Worldwide, Inc.</u>	S-1	333-193154	10.20	December 31, 2013
10.20+	<u>Second Amendment to Development and Supply Agreement dated August 31, 2015 between Revance Therapeutics, Inc. and Hospira Worldwide, Inc.</u>	10-Q	001-36297	10.1	November 10, 2015
10.21+	<u>Manufacture and Development Agreement dated May 20, 2013 between Revance Therapeutics, Inc. and American Peptide Company, Inc.</u>	S-1	333-193154	10.19	December 31, 2013
10.22	<u>First Amendment to Manufacture and Development Agreement dated April 13, 2018 between Revance Therapeutics, Inc. and Bachem Americas, Inc.</u>	10-Q	001-36297	10.3	August 3, 2018
10.23	<u>Loan and Lease Agreement dated as of December 20, 2013 by and between Revance Therapeutics, Inc. and Essex Capital Corporation</u>	S-1	333-193154	10.21	December 31, 2013
10.24	<u>First Amendment to Loan and Lease Agreement, dated December 17, 2014, by and between Revance Therapeutics, Inc. and Essex Capital Corporation</u>	8-K	001-36297	10.1	December 22, 2014
10.25	<u>Second Amendment to Loan and Lease Agreement, dated February 26, 2015, by and between Revance Therapeutics, Inc. and Essex Capital Corporation</u>	10-K	001-36297	10.25	March 4, 2015

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Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith	
		Form	File No.	Exhibit Filing Date		
10.26*	<u>Revance Therapeutics, Inc. Third Amended and Restated Executive Severance Benefit Plan</u>	10-K	001-36297	10.24	March 2, 2018	
10.27*	<u>Revance Therapeutics, Inc. Amended and Restated Non-Employee Director Compensation Policy</u>	—	—	—	—	X
10.28*	<u>Revance Therapeutics, Inc. 2019 Management Bonus Plan</u>	—	—	—	—	X
10.29*	<u>Revance Therapeutics, Inc. Amended and Restated 2014 Inducement Plan</u>	8-K	001-36297	99.1	December 14, 2015	
10.30*	<u>Form of Stock Option Agreement and Grant Notice under Amended and Restated Revance Therapeutics, Inc. 2014 Inducement Plan</u>	10-Q	001-36297	10.5	November 10, 2015	
10.31*	<u>Form of Restricted Stock Agreement and Grant Notice under Amended and Restated Revance Therapeutics, Inc. 2014 Inducement Plan</u>	10-K	001-36297	10.31	March 4, 2016	
10.32*	<u>Executive Employment Agreement dated December 30, 2013 by and between Revance Therapeutics, Inc. and L. Daniel Browne</u>	S-1/A	333-193154	10.25	January 27, 2014	
10.33*	<u>Executive Employment Agreement dated December 31, 2013 by and between Revance Therapeutics, Inc. and Lauren Silvernail</u>	S-1/A	333-193154	10.27	January 27, 2014	
10.34*	<u>Executive Employment Agreement dated December 14, 2015 by and between Revance Therapeutics, Inc. and Abhay Joshi.</u>	10-K	001-36297	10.34	March 4, 2016	
10.35*	<u>Executive Employment Agreement dated September 18, 2017 by and between Revance Therapeutics, Inc. and Todd Zavodnick.</u>	10-Q	001-36297	10.1	November 3, 2017	
10.36*	<u>Executive Employment Agreement dated May 1, 2018 by and between Company and Caryn G. McDowell</u>	10-Q	001-36297	10.1	August 3, 2018	
10.37*	<u>Executive Employment Agreement dated November 5, 2018 by and between Revance Therapeutics, Inc. and Tobin Schilke</u>	—	—	—	—	X
10.38*	<u>Employment Agreement dated November 7, 2018 by and between Revance Therapeutics, Inc. and Cyril Allouche</u>	—	—	—	—	X
10.39	<u>Technology Transfer, Validation and Commercial Fill/Finish Services Agreement dated March 14, 2017 between Revance Therapeutics, Inc. and Ajinomoto Althea, Inc.</u>	10-Q	001-36297	10.4	May 9, 2017	
10.40	<u>Controlled Equity Offering<sup>SM</sup> Sales Agreement, dated March 13, 2018, by and between Revance Therapeutics, Inc. and Cantor Fitzgerald &amp; Co.</u>	8-K	001-36297	99.1	March 13, 2018	
10.41+	<u>Collaboration and License Agreement, dated February 28, 2018, by and between Revance Therapeutics, Inc. and Mylan Ireland Ltd</u>	10-Q	001-36297	10.1	May 9, 2018	

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Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.42++	<u>License Agreement, dated December 4, 2018, by and between Revance Therapeutics, Inc. and Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd.</u>	—	—	—	—	X
21.1	<u>List of Subsidiaries of the Registrant</u>	—	—	—	—	X
23.1	<u>Consent of Independent Registered Public Accounting Firm</u>	—	—	—	—	X
24.1	<u>Power of Attorney (contained in the signature page to this Annual Report on Form 10-K)</u>	—	—	—	—	X
31.1	<u>Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) promulgated under the Exchange Act</u>	—	—	—	—	X
31.2	<u>Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) promulgated under the Exchange Act</u>	—	—	—	—	X
32.1†	<u>Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>	—	—	—	—	X
32.2†	<u>Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>	—	—	—	—	X
101.INS	XBRL Instance Document	—	—	—	—	X
101.SCH	XBRL Taxonomy Extension Schema Document	—	—	—	—	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	—	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	—	X
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document	—	—	—	—	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	—	X

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

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

++ Confidential treatment has been requested for certain portions of this exhibit.

The certifications attached as Exhibit 32.1 and 32.2 that accompany this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Revance Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-K, irrespective of any general incorporation language contained in such filing.

**ITEM 16. FORM 10-K SUMMARY**

None.

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**REVANCE THERAPEUTICS, INC.**

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of Revance Therapeutics, Inc.

***Opinions on the Financial Statements and Internal Control over Financial Reporting***

We have audited the accompanying consolidated balance sheets of Revance Therapeutics, Inc. and its subsidiaries (the “Company”) as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, of stockholders’ equity and of cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the “consolidated financial statements”). We also have audited the Company’s internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

***Basis for Opinions***

The Company’s management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management’s Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company’s consolidated financial statements and on the Company’s internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

***Definition and Limitations of Internal Control over Financial Reporting***

A company's 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 generally accepted accounting principles. A company's 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 the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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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.

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP  
San Jose, California  
February 28, 2019

We have served as the Company's auditor since 2005.

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Table of Contents**REVANCE THERAPEUTICS, INC.****Consolidated Balance Sheets****(In thousands, except share and per share amounts)**

	<b>As of December 31,</b>	
	<b>2018</b>	<b>2017</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$73,256	\$282,896
Short-term investments	102,556	—
Accounts and other receivables	27,000	48
Prepaid expenses and other current assets	5,110	2,267
Total current assets	207,922	285,211
Property and equipment, net	14,449	9,250
Restricted cash	730	580
Other non-current assets	3,247	658
<b>TOTAL ASSETS</b>	<b>\$226,348</b>	<b>\$295,699</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$8,434	\$6,805
Accruals and other current liabilities	14,948	12,225
Deferred revenue, current portion	8,588	—
Financing obligations	—	1,872
Total current liabilities	31,970	20,902
Derivative liability associated with the Medicis settlement	2,753	2,613
Deferred revenue, net of current portion	42,684	—
Deferred rent	3,319	3,339
<b>TOTAL LIABILITIES</b>	<b>80,726</b>	<b>26,854</b>
Commitments and Contingencies (Note 10)		
<b>STOCKHOLDERS' EQUITY</b>		
Common stock, par value \$0.001 per share — 95,000,000 shares authorized both as of December 31, 2018 and 2017; 36,975,203 and 36,516,075 shares issued and outstanding as of December 31, 2018 and 2017, respectively	37	37
Additional paid-in capital	830,368	810,975
Accumulated other comprehensive loss	(8	) —
Accumulated deficit	(684,775	) (542,167 )
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>145,622</b>	<b>268,845</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$226,348</b>	<b>\$295,699</b>

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

Table of Contents**REVANCE THERAPEUTICS, INC.****Consolidated Statements of Operations and Comprehensive Loss  
(In thousands, except share and per share amounts)**

	Year Ended December 31,		
	2018	2017	2016
Revenue	\$3,729	\$262	\$300
Operating expenses:			
Research and development	92,500	80,361	50,381
General and administrative	53,863	37,398	29,075
Loss on impairment	—	2,927	9,059
Total operating expenses	146,363	120,686	88,515
Loss from operations	(142,634 )	(120,424 )	(88,215 )
Interest income	4,023	1,410	1,170
Interest expense	(44 )	(457 )	(1,082 )
Changes in fair value of derivative liability associated with the Medicis settlement	(140 )	(591 )	(608 )
Other expense, net	(773 )	(525 )	(535 )
Loss before income taxes	(139,568 )	(120,587 )	(89,270 )
Income tax provision	(3,000 )	—	—
Net loss	(142,568 )	(120,587 )	(89,270 )
Unrealized gain (loss) and adjustment on securities included in net loss	(8 )	45	(5 )
Comprehensive loss	\$(142,576 )	\$(120,542 )	\$(89,275 )
Basic and Diluted net loss attributable to common stockholders	\$(142,568 )	\$(120,587 )	\$(89,270 )
Basic and Diluted net loss per share attributable to common stockholders	\$(3.94 )	\$(4.01 )	\$(3.18 )
Basic and Diluted weighted-average number of shares used in computing net loss per share attributable to common stockholders	36,171,582	30,101,125	28,114,784

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

**REVANCE THERAPEUTICS, INC.**  
**Consolidated Statements of Stockholders' Equity**  
(In thousands, except share and per share amounts)

	Common Stock		Additional	Other	Accumulated	Accumulated	Total
	Shares	Amount	Paid-In	Accumulated	Comprehensive	Deficit	Stockholders'
			Capital	Gain (Loss)			Equity
Balance — December 31, 2015	28,288,464	\$ 28	\$ 585,537	\$ (40 )	\$ (332,273 )		\$ 253,252
Issuance of common stock relating to employee stock purchase plan	21,064	—	243	—	—		243
Stock-based compensation expense	—	—	11,953	—	—		11,953
Issuance of common stock upon exercise of stock options	131,752	—	1,405	—	—		1,405
Issuance of restricted stock awards, net of cancellation	234,567	1	(1 )	—	—		—
Net settlement of restricted stock awards for employee taxes	(26,893 )	—	(507 )	—	—		(507 )
Unrealized loss and adjustment on securities included in net loss	—	—	—	(5 )	—		(5 )
Net loss	—	—	—	—	(89,270 )		(89,270 )
Balance — December 31, 2016	28,648,954	29	598,630	(45 )	(421,543 )		177,071
Cumulative-effect adjustment from adoption of ASU 2016-09	—	—	37	—	(37 )		—
Issuance of common stock relating to employee stock purchase plan	28,135	—	583	—	—		583
Stock-based compensation expense	—	—	13,230	—	—		13,230
Issuance of common stock in connection with at-the-market offering, net of issuance costs of \$603	1,802,651	2	38,155	—	—		38,157
Issuance of common stock in connection with the 2017 follow-on offering, net of issuance costs of \$535	5,389,515	5	156,928	—	—		156,933
Issuance of common stock upon net exercise of warrants	9,878	—	—	—	—		—
Issuance of common stock upon exercise of stock options	309,341	1	3,985	—	—		3,986
Issuance of restricted stock awards, net of cancellation	353,620	—	—	—	—		—
Net settlement of restricted stock awards for employee taxes	(26,019 )	—	(573 )	—	—		(573 )
Unrealized gain and adjustment on securities included in net loss	—	—	—	45	—		45
Net loss	—	—	—	—	(120,587 )		(120,587 )
Balance — December 31, 2017	36,516,075	37	810,975	—	(542,167 )		268,845
Cumulative-effect adjustment from adoption of ASU 2018-07	—	—	40	—	(40 )		—
Issuance of common stock relating to employee stock purchase plan	37,894	—	765	—	—		765
Stock-based compensation expense	—	—	16,273	—	—		16,273
Issuance of common stock upon exercise of stock options	293,100	—	4,527	—	—		4,527
Issuance of restricted stock awards, net of cancellation	201,032	—	—	—	—		—
Net settlement of restricted stock awards for employee taxes	(72,898 )	—	(2,212 )	—	—		(2,212 )
Unrealized loss and adjustment on securities included in net loss	—	—	—	(8 )	—		(8 )
Net loss	—	—	—	—	(142,568 )		(142,568 )
Balance — December 31, 2018	36,975,203	\$ 37	\$ 830,368	\$ (8 )	\$ (684,775 )		\$ 145,622

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

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

	<b>Year Ended December 31,</b>		
	<b>2018</b>	<b>2017</b>	<b>2016</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net loss	\$(142,568)	\$(120,587)	\$(89,270)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,726	1,468	1,445
Amortization of premium (discount) on investments	(1,103)	) 410	1,212
Stock-based compensation expense	16,273	13,230	11,953
Gain on disposal of fixed assets	(1,466)	) —	—
Impairment of long-lived assets	—	2,927	9,059
Acquisition of in-process research and development	—	—	2,000
Other non-cash operating activities	175	767	1,013
Changes in operating assets and liabilities:			
Accounts and other receivables	(26,952)	) 80	30
Prepaid expenses and other current assets	(2,911)	) 4,849	(5,621)
Other non-current assets	(1,871)	) (403)	) (151)
Accounts payable	1,691	2,607	953
Accruals and other liabilities	1,609	(565)	) 7,502
Deferred revenue	51,272	—	—
Deferred rent	(121)	) (125)	) 48
<b>Net cash used in operating activities</b>	<b>(104,246)</b>	<b>) (95,342)</b>	<b>) (59,827)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Purchases of property and equipment	(6,991)	) (2,525)	) (1,670)
Proceeds from sale of property and equipment	1,541	—	2
Purchases of short-term investments	(314,911)	) (36,028)	) (280,681)
Proceeds from maturity of short-term investments	146,000	157,445	207,650
Proceeds from sale of short-term investments	67,435	—	1,000
Purchase of in-process research and development	(100)	) (100)	) (1,800)
<b>Net cash provided by (used in) investing activities</b>	<b>(107,026)</b>	<b>) 118,792</b>	<b>(75,499)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Proceeds from issuance of common stock in connection with the 2017 follow-on offering, net of commissions and discount	—	157,468	—
Proceeds from issuance of common stock in connection with at-the-market offerings, net of commissions	—	38,760	—
Proceeds from the exercise of stock options and common stock warrants, and purchases under the employee stock purchase plan	5,292	4,569	1,649
Principal payments made on financing obligations	(932)	) (3,636)	) (3,541)
Net settlement of restricted stock awards for employee taxes	(2,212)	) (573)	) (507)
Payment of offering costs	(366)	) (644)	) (243)
<b>Net cash provided by (used in) financing activities</b>	<b>1,782</b>	<b>195,944</b>	<b>(2,642)</b>
<b>NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH</b>	<b>(209,490)</b>	<b>) 219,394</b>	<b>(137,968)</b>
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH — Beginning of period	283,476	64,082	202,050
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH — End of period	\$73,986	\$283,476	\$64,082
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>			
Cash paid for interest	\$16	\$299	\$676
<b>SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:</b>			
Deferred offering costs	\$354	\$251	\$134
Property and equipment purchases included in accounts payable and accruals and other current liabilities	\$642	\$718	\$200

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Holdback related to acquisition of in-process research and development	\$—	\$—	\$200
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The accompanying notes are an integral part of these Consolidated Financial Statements.

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Table of Contents**REVANCE THERAPEUTICS, INC.****Notes to Consolidated Financial Statements****1. The Company and Basis of Presentation**

Revance Therapeutics, Inc. (“the Company”) is a clinical-stage biotechnology company focused on the development, manufacturing, and commercialization of novel neuromodulators for multiple aesthetic and therapeutic indications. The Company is leveraging its proprietary portfolio of botulinum toxin type A compounds, formulated with its patented and proprietary peptide excipient technology, to address unmet needs in large and growing neuromodular markets. The Company's initial focus is on developing daxibotulinumtoxinA, our highly purified botulinum toxin Type A, for a broad spectrum of aesthetic and therapeutic indications, including facial wrinkles, muscle disorders, and chronic migraine.

The Company's lead drug candidate is DaxibotulinumtoxinA for Injection (“DAXI”). The Company used its unique proprietary peptide excipient technology to formulate DAXI. The noncovalent bond formed between the proprietary peptide excipient technology and the botulinum toxin may enable longer residence time of botulinum toxin Type A, which could explain DAXI’s long duration of effect. The process binds a highly purified botulinum toxin Type A with a unique proprietary stabilizing excipient peptide. The Company does not use human serum albumin (“HSA”) and other animal-sourced ingredients, which carry the risk of transmission of pathogens, to stabilize our product.

The Company is currently studying DAXI for the treatment of facial wrinkles, cervical dystonia, plantar fasciitis, adult upper limb spasticity, and chronic migraine. The Company believes DAXI has the potential to expand into additional aesthetic and therapeutic indications. The Company also is developing a topically applied neuromodulator for aesthetic and therapeutic indications, DaxibotulinumtoxinA Topical, and have a collaboration and license agreement with Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V. (“Mylan”), to develop and commercialize a biosimilar to BOTOX®.

Since inception, the Company has devoted substantially all of its efforts to identifying and developing product candidates for the aesthetic and therapeutic pharmaceutical markets, recruiting personnel, raising capital, conducting preclinical and clinical development of, and manufacturing development for DAXI and DaxibotulinumtoxinA Topical. The Company has incurred losses and negative cash flows from operations. The Company has not yet commenced commercial operations, has not generated product revenue to date, and will continue to incur significant research and development and other expenses related to its ongoing operations. The Company has recorded net losses of \$142.6 million, \$120.6 million, and \$89.3 million for the years ended December 31, 2018, 2017, and 2016, respectively. As of December 31, 2018, the Company had a working capital surplus of \$176.0 million and an accumulated deficit of \$684.8 million. The Company has funded its operations primarily through the sale and issuance of common stock, convertible preferred stock, notes payable, and convertible notes. As of December 31, 2018, the Company had capital resources consisting of cash, cash equivalents, and short-term investments of \$175.8 million. In January 2019, the Company completed a follow-on public offering (the “2019 follow-on offering”) for net proceeds of \$107.6 million after underwriting discounts, commissions and other offering expenses (Note 11). In January 2019, the Company received \$27.0 million for an upfront payment net of foreign withholding tax from Shanghai Fosun Pharmaceutical (Group) Co., Ltd (“Fosun”) (Note 3). The Company believes that its existing cash and cash equivalents will allow the Company to fund its operating plan through at least the next 12 months following the issuance of this Form 10-K and may identify additional capital resources to fund its operations.

**Basis of Presentation**

The Consolidated Financial Statements of the Company include the Company’s accounts and those of its wholly-owned subsidiaries, Revance Therapeutics Limited and Revance International Limited, and have been prepared in conformity with U.S. generally accepted accounting principles (“GAAP”). The Company operates in one segment.

**2. Summary of Significant Accounting Policies**

**Principles of consolidation**

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

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**REVANCE THERAPEUTICS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

**Use of Estimates**

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

**Risks and Uncertainties**

The product candidates developed by the Company require approvals from the U.S. Food and Drug Administration (“FDA”) or foreign regulatory agencies prior to commercial sales. There can be no assurance that the Company’s current and future product candidates will meet desired efficacy and safety requirements to obtain the necessary approvals. If approval is denied or delayed, it may have a material adverse impact on the Company’s business and its Consolidated Financial Statements.

The Company is subject to risks common to companies in the development stage including, but not limited to, dependency on the clinical and commercial success of its product candidates, ability to obtain regulatory approval of its product candidates, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and consumers, significant competition and untested manufacturing capabilities.

**Concentration of Credit Risk**

Financial instruments that potentially subject the Company to a concentration of credit risk consist of short-term investments. Under the Company’s investment policy, the Company limits its credit exposure by investing in highly liquid funds and debt obligations of the United States (“U.S.”) government and its agencies with high credit quality. The Company’s cash, cash equivalents, and short-term investments are held in the U.S. Such deposits may, at times, exceed federally insured limits. The Company has not experienced any significant losses on its deposits of cash, cash equivalents, and short-term investments.

**Cash and Cash Equivalents**

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

**Restricted Cash**

As of December 31, 2018 and 2017, a deposit totaling \$0.7 million was restricted from withdrawal. The Company has a deposit balance of approximately \$0.5 million that relates to securing the Company’s facility lease and will remain until the end of the lease. The remaining \$0.2 million deposit balance relates to a letter of credit. These balances are included in restricted cash on the accompanying Consolidated Balance Sheets and within the cash, cash equivalents, and restricted cash balance on the Consolidated Statement of Cash Flows.

## Investments

Investments generally consist of securities with original maturities greater than three months and remaining maturities of less than one year, while long-term investments generally consist of securities with remaining maturities greater than one year. The Company determines the appropriate classification of its investments at the time of purchase and reevaluates such determination at each balance sheet date. All of its investments are classified as available-for-sale and carried at fair value, with the change in unrealized gains and losses reported as a separate component of other comprehensive income (loss) on the Consolidated Statements of Operations and Comprehensive Loss and accumulated as a separate component of stockholders' equity on the Consolidated Balance Sheets. Interest income, net includes interest, dividends, amortization of purchase premiums and discounts, realized gains and losses on sales of securities and other-than-temporary declines in the fair value of investments, if any. The cost of securities sold is based on the specific-identification method. The Company monitors its investment portfolio for potential impairment on a quarterly basis. If the carrying amount of an investment in debt securities

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**REVANCE THERAPEUTICS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

exceeds its fair value and the decline in value is determined to be other-than-temporary, the carrying amount of the security is reduced to fair value and a loss is recognized in operating results for the amount of such decline. In order to determine whether a decline in value is other-than-temporary, the Company evaluates, among other factors, the cause of the decline in value, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, and its intent and ability to hold the security to maturity or forecast recovery. The Company mitigates its credit risk by investing in money market funds, U.S. treasury securities, and U.S. government agency obligations which limits the amount of investment exposure as to credit quality and maturity.

Of the Company's total cash, cash equivalents, and short-term investments of \$175.8 million and \$282.9 million as of December 31, 2018 and 2017, respectively, the Company held cash, cash equivalents, and short-term investments with a total fair value of \$87.7 million and \$150.7 million as of December 31, 2018 and 2017, respectively, in an investment account with a related party, J.P. Morgan Securities LLC. As of December 31, 2018 and 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 approximately 3.8 million shares and 3.6 million shares, respectively, of the Company's common stock, which represents approximately 10.30% and 9.75% of the Company's outstanding common stock, respectively. J.P. Morgan Securities LLC, who acts as a custodian and trustee for certain Company investments, is an affiliate of JPMorgan Chase Bank, NA.

**Fair Value of Financial Instruments**

The Company uses fair value measurements to record fair value adjustments to certain financial and non-financial assets and liabilities to determine fair value disclosures. The accounting standards define fair value, establish a framework for measuring fair value, and require disclosures about fair value measurements. Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required to be recorded at fair value, the principal or most advantageous market in which the Company would transact are considered along with assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions, and risk of nonperformance. The accounting standard for fair value establishes a fair value hierarchy based on three levels of inputs, the first two of which are considered observable and the last unobservable, that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. A financial instrument's categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

The three levels of inputs that may be used to measure fair value are as follows:

Level 1—Observable inputs, such as quoted prices in active markets for identical assets or liabilities.

Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other Level 2—inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Valuations based on unobservable inputs to the valuation methodology and including data about assumptions Level 3—market participants would use in pricing the asset or liability based on the best information available under the circumstances.

**Property and Equipment**

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Computer equipment, lab equipment and furniture and fixtures, and manufacturing equipment is depreciated generally over 3, 5, and 7 years, respectively. Repairs and maintenance that do not extend the life or improve an asset are expensed in the period incurred.

Leasehold improvements are depreciated over the lesser of 15 years or the term of the lease. Repairs and maintenance are charged to operations as incurred. When assets are retired or otherwise disposed of, the costs and accumulated depreciation are removed from the Consolidated Balance Sheets and any resulting gain or loss is reflected in the Consolidated Statements of Operations and Comprehensive Loss in the period realized.

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**REVANCE THERAPEUTICS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

**Impairment of Long-Lived Assets**

The Company evaluates long-lived assets, such as property and equipment subject to depreciation, for impairment whenever events or changes in circumstances indicate that the carrying value of long-lived assets may not be recoverable. Events and changes in circumstances considered important that could result in an impairment review of long-lived assets include (i) a significant decrease in the market price of a long-lived asset; (ii) a significant adverse change in the extent or manner in which a long-lived asset is being used or in its physical condition; (iii) 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; (iv) an accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction of a long-lived asset; (v) a 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 (vi) a current expectation that, more likely than not (more than 50 percent), a long-lived asset will be sold or otherwise disposed of significantly before the end of its previously estimated useful life. The impairment evaluation of long-lived assets includes an analysis of estimated future undiscounted net cash flows expected to be generated by the long-lived assets over their remaining estimated useful lives. If the estimate of future undiscounted net cash flows is insufficient to recover the carrying value of the long-lived assets over the remaining estimated useful lives, the Company records an impairment loss in the amount by which the carrying value of the long-lived assets exceeds the fair value. Fair value is generally measured based on discounted cash flow analysis.

**Clinical Trial Accruals**

Clinical trial costs are charged to research and development expense as incurred. The Company accrues for expenses resulting from contracts with clinical research organizations (CROs), consultants, and clinical site 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 to the Company under such contracts. The Company's objective is to reflect the appropriate 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 expense, 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. The Company determines accrual estimates through 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. The Company estimates accrued expenses as of each balance sheet date based on the facts and circumstances known to the Company at that time. The Company's clinical trial accrual is dependent, in part, upon the receipt of timely and accurate reporting from the CROs and other third-party vendors.

**Revenue**

Effective January 1, 2018, the Company adopted Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606), using the full retrospective transition method. The Company evaluated its prior contractual revenue arrangement with Precision Dermatology, Inc., which was acquired by Valeant Pharmaceuticals International Inc. ("Valeant") in 2014. After Valeant notified the Company that it intended to terminate the asset purchase and royalty agreement in 2015, the Company continued to receive royalties of \$75,000 each quarter until

November 2017 when the Company and Valeant entered into an asset transfer agreement to finalize the termination of the asset purchase and royalty agreement and Valeant returned the Relastin® intellectual property rights to the Company. Based on its evaluation, the Company determined that the new guidance had no impact to the revenue recognized prior to January 1, 2018 and, accordingly, had no impact on the accumulated deficit as of January 1, 2018.

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

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Table of Contents**REVANCE THERAPEUTICS, INC.****Notes to Consolidated Financial Statements — (Continued)**

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

***Licenses of intellectual property***

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

***Milestone payments***

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

***Royalties***

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Up-front payments and fees are recorded as deferred revenue upon receipt or when due, and may require deferral of revenue recognition to a future period until the Company performs its obligations under these arrangements. Amounts payable to the Company are recorded as accounts receivable when the Company's right to consideration is unconditional. As a practical expedient, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.



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**REVANCE THERAPEUTICS, INC.**

**Notes to Consolidated Financial Statements — (Continued)**

**Research and Development Expenditures**

Research and development expenditures are charged to operations as incurred. Research and development expenditures include, but are not limited to, personnel expenses, clinical trial supplies, fees for clinical trial services, manufacturing costs, consulting costs and allocated overhead, including rent, equipment, depreciation, and utilities.

**Income Taxes**

The Company accounts for income taxes under the asset and liability method. The Company estimates 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 the Company's Consolidated Balance Sheets. In general, deferred tax assets represent future tax benefits to be received when certain expenses previously recognized in the Company's 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 the Company's deferred tax assets is dependent on future taxable income against which these deductions, losses and credits can be utilized.

The Company must assess the likelihood that the Company's deferred tax assets will be recovered from future taxable income, and to the extent the Company believes that recovery is not likely, the Company establishes a valuation allowance. Based on the available evidence, the Company is unable, at this time, to support the determination that it is more likely than not that its deferred tax assets will be utilized in the future. Accordingly, the Company recorded a full valuation allowance as of December 31, 2018 and 2017. The Company intends to maintain valuation allowances until sufficient evidence exists to support its reversal.

**Stock-Based Compensation**

The Company has equity incentive plans under which various types of equity-based awards including, but not limited to, incentive stock options, non-qualified stock options, and restricted stock awards, may be granted to employees, non-employee directors, and non-employee consultants. The Company also has an inducement plan under which various types of equity-based awards, including non-qualified stock options and restricted stock awards, may be granted to new employees.

For all equity-based awards granted to employees, non-employee directors, and non-employee consultants, the Company recognizes compensation expense based on the estimated grant-date fair values. The grant-date fair value of stock options is determined using the Black-Scholes option pricing model. The grant-date fair value of restricted stock awards is based on the closing price of the Company's common stock on the date of grant. As of January 1, 2017, the Company adopted the forfeiture rate methodology change in accordance with ASU 2016-09 to account for forfeitures as they occur. Prior to the adoption of ASU 2016-09, the Company was required to estimate forfeitures at the time of grant and revised those estimates in subsequent periods if actual forfeitures differed from those estimates. The Company used historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that were expected to vest. To the extent actual forfeitures differed from the estimates, the difference was recorded as a cumulative adjustment in the period that the estimates were revised.

For employees and non-employee directors, the value of the portion of the equity-based award that is ultimately expected to vest is recognized as expense ratably over the requisite service period. The value of the portion of the

equity-based award for non-employee consultants prior to July 1, 2018 that is ultimately expected to vest was recognized in the same period and in the same manner as if the Company had paid cash for the goods or services received, which is generally over the period the Company expects to receive services from the non-employee consultant. As of July 1, 2018, the Company adopted ASU 2018-07, under which the equity-classified share-based payment awards to non-employees are measured at fair value on the grant date.

### **Warrants**

The Company has issued freestanding warrants to purchase shares of common stock in connection with certain debt and lease transactions. The warrants are recorded at fair value using the Black-Scholes option pricing model. Common stock warrants classified as equity at inception are recorded to additional paid-in capital at fair value upon issuance.

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Table of Contents**REVANCE THERAPEUTICS, INC.****Notes to Consolidated Financial Statements — (Continued)****Derivative Liability**

The Company bifurcated and separately accounted for derivative instruments related to payment provisions underlying the Medicis settlement. This derivative is accounted for as a liability, which will be remeasured to fair value as of each balance sheet date, with changes in fair value recognized in the Consolidated Statements of Operations and Comprehensive Loss. The Company will continue to record adjustments to the fair value of the derivative liability associated with the Medicis settlement until the remaining settlement payment has been paid.

**Contingencies**

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

**Comprehensive Loss**

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. For the years ended December 31, 2018, 2017 and 2016, the other comprehensive gain or loss in the Consolidated Statements of Operations and Comprehensive Loss was the immaterial unrealized gain or loss on its short-term investments.

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

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

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

	As of December 31,		
	2018	2017	2016
Outstanding common stock options	3,605,333	3,210,400	2,790,646
Outstanding common stock warrants	34,113	34,113	61,595
Unvested restricted stock awards	605,012	639,287	416,229

**Interest Expense**

Interest expense includes cash and non-cash components with the non-cash components consisting of interest capitalized for assets constructed for use in operations and effective interest recognized on the financing obligation.

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Table of Contents**REVANCE THERAPEUTICS, INC.****Notes to Consolidated Financial Statements — (Continued)****Recently Adopted Accounting Pronouncements**

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

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

In May 2017, the FASB issued ASU 2017-09, *Scope of Modification Accounting (Topic 718)*, which amends the scope of modification accounting for share-based payment arrangements. The amendment provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. ASU 2017-09 is effective for fiscal years beginning after December 15, 2017, with early adoption permitted. The adoption of this standard on January 1, 2018 had no material impact to the Company's Consolidated Financial Statements.

In March 2018, the FASB issued ASU 2018-05, *Income Taxes (Topic 740) - Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118 (“SAB 118”)*. This standard amends Accounting Standards Codification 740, Income Taxes (ASC 740) to provide guidance on accounting for the tax effects of the Tax Cuts and Jobs Act passed in December 2017 (the “Tax Reform Act”) pursuant to SAB 118, which allows companies to complete the accounting under ASC 740 within a one-year measurement period from the Tax Reform Act enactment date. This standard is effective upon issuance. The Company has completed its assessment of the accounting impact resulting from the Tax Reform Act in December 2018. The impact of the Tax Reform Act includes:

- a decrease in deferred tax assets resulting from the change in tax rate in the amount of \$62.9 million;
  - an increase of net operating loss of \$43.5 million as a result of the reversal of the intra-entity transfer of certain intellectual properties, refer to Note 12. Income Taxes for further information related to this transaction;
  - a decrease in net operating loss of \$3.8 million related to a research and development credit adjustment.
- The aggregated impact resulting from the Tax Reform Act to deferred taxes is \$68.1 million, which continues to be fully offset by a valuation allowance.

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, to expand the scope of Topic 718 to include share-based payment

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

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Table of Contents**REVANCE THERAPEUTICS, INC.****Notes to Consolidated Financial Statements — (Continued)**

In July 2018, the FASB issued ASU 2018-09, *Codification Improvements*. The amendments in ASU 2018-09 affect a wide variety of Topics in the FASB Codification and apply to all reporting entities within the scope of the affected accounting guidance. The Company has evaluated ASU 2018-09 in its entirety and determined that the amendments related to Topic 718-740, *Compensation-Stock Compensation-Income Taxes*, are the only provisions that currently apply to the Company. The amendments in ASU 2018-09 related to Topic 718-740, *Compensation-Stock Compensation-Income Taxes*, clarify that an entity should recognize excess tax benefits related to stock compensation transactions in the period in which the amount of the deduction is determined. This is consistent with how the Company has historically reported and accounted for windfall/shortfall amounts. The amendments in ASU 2018-09 related to Topic 718-740 are effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company adopted this standard and determined it has no impact to the Company's Consolidated Financial Statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurements (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement*. ASU 2018-13 modifies the disclosure requirements for fair value measurements in Topic 820 based on the objectives of the FASB Concepts Statement, *Conceptual Framework for Financial Reporting - Chapter 8: Notes to Financial Statements* which aims to improve the effectiveness of notes to financial statements while allowing for the appropriate exercise of discretion by reporting entities based on materiality. The main provisions of ASU 2018-13 include the removal or modification of certain non-essential disclosure requirements and the addition of new disclosure requirements for public companies related to the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period, and the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019 with early adoption permitted. The Company adopted ASU 2018-13 and determined it has no material impact to the Company's Consolidated Financial Statements.

**Recent Accounting Pronouncements**

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* which requires an entity to recognize right-of-use asset and lease liabilities arising from a lease for both financing and operating leases with terms greater than 12 months. In July 2018, the FASB issued ASU 2018-10, *Leases (Topic 842), Codification Improvements* and ASU 2018-11, *Leases (Topic 842), Targeted Improvements, to provide additional guidance for the adoption of Topic 842*. ASU 2018-10 clarifies certain provisions and correct unintended applications of the guidance such as the application of implicit rate, lessee reassessment of lease classification, and certain transition adjustments that should be recognized to earnings rather than to stockholders' equity. ASU 2018-11 provides an alternative transition method to allow entities initially applying Topic 842 at the adoption date, rather than at the beginning of the earliest comparative period presented, and recognizing the cumulative effect of applying the new standard as an adjustment to beginning retained earnings in the year of adoption while continuing to present all prior periods under previous lease accounting guidance. ASU 2018-11 also provides a number of optional practical expedients in transition. ASU 2018-11, ASU 2018-10, and ASU 2016-02 (collectively, "the new lease standards") are effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company has elected the transition method under ASU 2018-11 at the adoption date of January 1, 2019 on a modified retrospective basis and will not restate comparative periods. The Company has also elected all of the available practical expedients except the practical expedient allowing the use of hindsight in determining the lease term and assessing impairment of right-of-use assets based on all facts and circumstances through the effective date of the new standard. The Company currently estimates that approximately \$25 million and \$28 million would be recognized as total right-of-use assets and total lease liabilities, respectively, on its Consolidated Balance Sheet as of January 1, 2019 for its existing operating lease

agreements for the office and manufacturing spaces in Newark, California. The existing deferred rent liabilities of \$3.5 million