Revance Therapeutics, Inc.
Form 10-K
February 28, 2019
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

FORM 10-K

(Mark One)

ý **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	**77-0551645**
State or other jurisdiction of incorporation or organization	(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	**Name of Exchange on Which Registered**
Common Stock, par value $0.001 per share	The Nasdaq Stock Market LLC

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ý 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 ý
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 ý 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 ý No ¨
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this

Form 10-K or any amendment to this Form 10-K. ý

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	ý	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 pursuance 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 ý

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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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," "c or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-K, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. These forward-looking statements include, but are not limited to, statements concerning the following:

- our expectations regarding the results, 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 1:1:1:1:1 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 tretinoins, 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 (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