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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

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

(Address, including zip code, of principal executive offices)

(510) 742-3400

(Registrant's telephone number, including area code)

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

Title of Each Class

Trading Symbol(s)

Name of Exchange on Which Registered

Common Stock, par value \$0.001 per share

RVNC

The Nasdaq Stock Market LLC

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

None

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Emerging growth company

Non-accelerated filer

Smaller reporting 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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, was \$494 million, based on the closing price of the registrant's common stock on the Nasdaq Global Market of \$12.97 per share for such date.

Number of shares outstanding of the registrant's common stock, par value \$0.001 per share, as of February 13, 2020: 56,926,751

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 29, 2020, in connection with the registrant's 2020 Annual Meeting of the Stockholders are incorporated herein by reference into Part III of this Annual Report on Form 10-K.

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

Unless expressly indicated or the context requires otherwise, the terms “Revance,” “company,” “we,” “us,” and “our,” in this document refer to Revance Therapeutics, Inc., a Delaware corporation, and, where appropriate, its wholly owned subsidiaries.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Form 10-K, including the documents incorporated by reference herein, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Form 10-K and documents incorporated by reference herein, including statements regarding our future financial condition, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include, but are not limited to, statements concerning the following:

- our expectations regarding the results, timing, costs 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, upper facial lines (frown lines, forehead lines and lateral canthal lines combined), cervical dystonia, plantar fasciitis, and adult upper limb spasticity in the United States ("U.S."), Europe and other countries or for the approval of RHA® 1 in the U.S.;
- the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results, or that positive results would assure regulatory approval or commercial success of our product candidates;
- our expectations regarding our future development of DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates for other indications, including but not limited to, migraine;
- our ability to effectively and reliably manufacture supplies of DAXI, biosimilar or any future product candidates and to develop, validate and maintain a commercially viable manufacturing process, as well as our ability to acquire supplies of RHA® dermal fillers from Teoxane;
- our plans to research, develop and commercialize our product candidates, including 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;
- that we may not obtain the anticipated financial and other benefits of the distribution agreement (the "Teoxane Agreement") with Teoxane SA ("Teoxane"), including our ability to realize anticipated synergies and successfully commercialize Teoxane's Resilient Hyaluronic Acid® dermal fillers ("RHA® dermal fillers");
- the commercial acceptance and potential of Teoxane's RHA® dermal fillers, including market size and anticipated adoption rates;
- status of commercial collaborations, including collaboration agreement with Mylan's continuation decision with respect to our collaboration agreement and the timing thereof;
- 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 successfully commercialize our product candidates and the timing of commercialization activities;
- 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;

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- unanticipated costs or delays in research, development and commercialization efforts;
- estimates of our expenses, future revenue, and capital requirements;
- the timing or likelihood of regulatory filings and approvals;
- our ability to obtain and maintain regulatory approval of our product candidates;
- 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;
- our ability to achieve market acceptance of our product candidates;
- the rate and degree of market acceptance of our product candidates;
- the initiation, timing, progress and results of future preclinical studies and clinical trials and our research and development programs;
- unanticipated costs or delays in research;
- 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 funding for our operations;
- our financial performance, including future revenue targets; and
- developments and projections relating to our competitors and our industry.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions described under the section titled “[Risk factors](#)” in this Form 10-K and the documents incorporated by reference herein. We also operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances described in this in this Form 10-K and the documents incorporated by reference herein may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements contained or incorporated by reference in this offering memorandum and the documents incorporated by reference herein.

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

You should read this in this Form 10-K, together with the information incorporated herein by reference, with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

PART I

ITEM 1. BUSINESS

Overview

Revance Therapeutics is a biotechnology company, developing new innovations in neuromodulators for aesthetic and therapeutic indications. Our lead product candidate, DaxibotulinumtoxinA for Injection (DAXI), combines a proprietary stabilizing peptide excipient with a highly purified botulinum toxin that does not contain human or animal-based components. We have successfully completed a Phase 3 program for DAXI in glabellar (frown) lines. In November 2019, we submitted the Biologics License Application (“BLA”) to the U.S. Food and Drug Administration (the “FDA”) for DAXI in the treatment of moderate to severe glabellar (frown) lines. The FDA accepted the BLA on February 5, 2020, and the Prescription Drug User Fee Act (“PDUFA”) target action date is November 25, 2020. If the BLA is approved on or by the target action date, we plan to initiate commercialization activities for DAXI for the treatment of glabellar lines before year end 2020. We are also evaluating DAXI in upper facial lines - glabellar lines, forehead lines and crow’s feet combined - as well as in three therapeutic indications - cervical dystonia, adult upper limb spasticity and plantar fasciitis, with plans to study migraine. Beyond DAXI, we have begun development of a biosimilar to BOTOX®, which would compete in the existing short-acting neuromodulator marketplace. In January 2020, we entered into an exclusive distribution Agreement (the “Teoxane Agreement”) with Teoxane SA (“Teoxane”), pursuant to which Teoxane granted Revance with the exclusive right to import, market, promote, sell and distribute Teoxane’s line of Resilient Hyaluronic Acid® dermal fillers. Revance is dedicated to making a difference by transforming patient experiences.

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 a biosimilar to BOTOX® with Mylan.

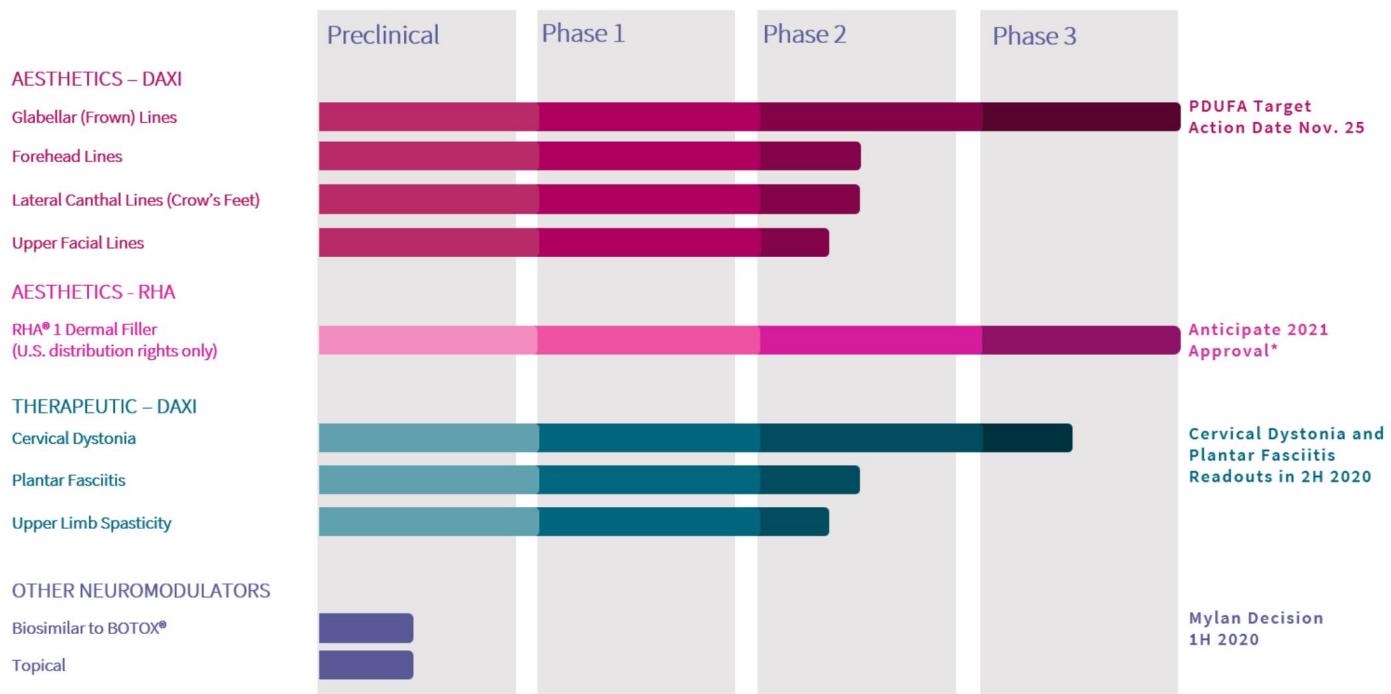
Key elements of our strategy are:

- *Complete DAXI clinical development and obtain marketing approval in glabellar lines in the U.S.* 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. We submitted the BLA in November 2019. The FDA accepted the BLA on February 5, 2020, and the PDUFA target action date is November 25, 2020. If the BLA is approved on or by the target action date, we plan to initiate commercialization activities for DAXI for the treatment of glabellar lines before year end 2020, pending approval. Furthermore, we completed enrollment of Phase 2 studies for the treatment of forehead lines and lateral canthal lines, and expect to release top-line results from these Phase 2 studies in the first half of 2020. In December 2019, we initiated an additional Phase 2 study for the full upper face (glabellar lines, forehead and crow’s feet). We expect preliminary results from this study in the fourth quarter of 2020.
- *Advance DAXI clinical development for therapeutic indications.* We have begun developing our commercial organization and have plans to build a specialty sales force upon U.S. Food and Drug Administration (“FDA”) approval for DAXI. Enrollment is complete in our ASPEN-1 Phase 3 pivotal trial for the treatment of isolated cervical dystonia and we expect to report topline results in the second half of 2020. Our Phase 2 placebo-controlled clinical trial of DAXI for the management of plantar fasciitis is also fully enrolled and we expect to announce topline results in the second half of 2020. Our JUNIPER Phase 2 randomized, double-blind, placebo-controlled trial for the treatment of upper limb spasticity in adults continues to enroll patients. We anticipated enrollment should be complete in the second half of 2020, with topline results to follow in the first half of 2021.

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- *Build our own sales and marketing capabilities in the U.S.* In connection with the Teoxane Agreement, we have accelerated the build out of our own, direct medical aesthetics sales organization in the U.S. In anticipation of the launch of Teoxane's RHA® dermal fillers in the second quarter of 2020, we have begun the process of hiring a field force of approximately 100 people. Specifically, we plan to build a specialty sales force to target key physicians who perform the majority of facial aesthetic injections, including dermatologists, plastic surgeons, facial plastic surgeons, and oculoplastic surgeons. Upon DAXI's approval, we may further increase the size of U.S. field organization.
- *Expand the opportunity for botulinum toxin products.* We believe DAXI has the ability to expand the botulinum toxin opportunity beyond the current patient base by appealing to patients who seek a long-lasting effect. We also believe DaxibotulinumtoxinA Topical and other possible formulations can expand the overall botulinum toxin market.
- *Establish selective strategic partnerships to maximize the commercial potential of our product candidates.* 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. 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, the Teoxane Agreement provides Teoxane with a right of first negotiation for DAXI, in aesthetic indications, in select markets where they have a direct affiliate.
- *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®.
- *Leverage DAXI's unique duration profile to build valuable franchises in aesthetics and therapeutics.* We will continue to selectively evaluate partnerships, distribution opportunities, joint development agreements and acquisitions as a way to expand our aesthetic and therapeutic franchises while enhancing our competitive position.

Pipeline Summary



- Revance has the exclusive right to commercialize RHA® 1 dermal filler in the U.S., however it is not our product candidate
- RHA is a trademark of TEOXANE SA; BOTOX is a registered trademark of Allergan, Inc.

Our Product Candidates

DaxibotulinumtoxinA for Injection (“DAXI”)

We are developing new innovations in neuromodulators for aesthetic and therapeutic indications. Our lead product candidate, DaxibotulinumtoxinA for Injection (“DAXI”), combines a proprietary stabilizing peptide excipient with a highly purified botulinum toxin that does not contain human or animal-based components. DAXI has demonstrated high response rates and long duration of effect. We are currently focusing on developing DAXI for the treatment of both aesthetic and therapeutic indications.

DAXI Aesthetics

DAXI for the Treatment of Glabellar Lines

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 neurotoxin is for the treatment of glabellar lines and currently available products provide an effect for at most three to four months.

Early Clinical Trials. DAXI was studied in two early clinical trials in Glabellar Lines that established the dose that was taken forward into the Phase 3 program. A Phase 1/2 dose escalation study was conducted outside the U.S. between 2012 and 2014, enrolling 48 subjects with moderate or severe Glabellar Lines assigned to one of 4 dose cohorts. In this trial, DAXI met its primary efficacy and safety endpoints and a long-lasting effect was demonstrated in the final cohort of the study.

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Based on the results of this study, a 36-week, Phase 2, randomized, double-blind, dose ranging, active and placebo controlled, multi-center study (BELMONT) was initiated in late 2014 to evaluate the safety, efficacy, and duration of effect of DAXI to treat glabellar lines. This study was conducted at nine investigational sites in Canada and enrolled a total of 268 subjects. The trial compared the safety, efficacy and duration of DAXI in subjects randomized to a 20 Units, 40 Units or 60 Units dose of DAXI, the labeled dose of BOTOX® Cosmetic or a placebo control in a 1:1:1:1:1 trial design. At the primary timepoint of week 24, all doses of DAXI showed statistically significant improvements from placebo based on the proportion of subjects achieving at least a one-point improvement in Glabellar Lines as assessed by Investigators. The 40 Units dose of DAXI demonstrated a 23.6-week median duration, compared to BOTOX® Cosmetic which demonstrated an 18.8-week median duration in this study. Across all cohorts, DAXI appeared to be generally safe and well-tolerated and no new safety signals were observed with DAXI at doses of up to 60 Units in Glabellar Lines. The 40 Units dose of DAXI was assessed as having the most favorable risk benefit profile and was selected as the dose for the Phase 3 Glabellar Lines program.

Phase 3 Clinical Trials. The Phase 3 clinical program for Glabellar Lines was conducted between December 2016 and October 2018 and included three studies: two 36-week, 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 (SAKURA 1 and SAKURA 2), and an 84-week, 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 (SAKURA 3).

The SAKURA 1 and SAKURA 2 trials enrolled 609 subjects with moderate or severe Glabellar Lines at 30 sites in the U.S. and Canada. In both trials, subjects were randomized in a 2:1 ratio to either the DAXI (40 Units) or placebo treatment groups, respectively. Subjects were followed for at least 24 weeks and up to 36 weeks. Both the SAKURA 1 and SAKURA 2 studies met their primary endpoints and with DAXI-treated subjects demonstrating highly statistically significant improvements in the severity of glabellar lines compared with subjects receiving placebo. The percentage of DAXI-treated patients who achieved at least a two-point improvement from baseline on both validated physician and patient scales at Week 4 was 73.6% in SAKURA 1 and 74.0% in SAKURA 2 ($p<0.0001$ compared to placebo). In assessing the duration of the clinical response, the median time to return to moderate or severe wrinkle severity on both the physician and patient scales for DAXI-treated patients was 24.0 weeks in SAKURA 1 and 23.9 weeks in SAKURA 2. The median time to return to baseline wrinkle severity on both scales for DAXI-treated patients was 27.7 weeks for SAKURA 1 and 26.0 weeks for SAKURA 2. The safety profile observed in SAKURA 1 and SAKURA 2 was consistent with the findings of the BELMONT study, with no new safety signals observed.

In December 2018, we announced top-line results for the SAKURA 3 open-label, long-term safety study. SAKURA 3 was conducted at 65 investigational sites in the U.S. and Canada and enrolled 2691 subjects, of whom 568 received three treatments with DAXI (40 Units). DAXI was generally well-tolerated, with no new safety concerns reported. The rate of treatment-related adverse events decreased over successive treatments. There were no treatment-related serious adverse events. Eyelid ptosis was reported in 0.9% of treatments, decreased in frequency with successive treatments and was lower than the rate observed in SAKURA 1 and SAKURA 2 (2.2% of treatments). A high degree of efficacy was seen consistently across all three treatment cycles and results were consistent with those seen in SAKURA 1 and SAKURA 2. As early as Week 1, over 90% of subjects across all three treatments had none or mild wrinkle severity on the IGA-FWS. At Week 4, the percentage of DAXI-treated patients who achieved a none or mild response on IGA-FWS was over 95% in each treatment cycle, closely aligned to the finding of 97.5% for both SAKURA 1 and SAKURA 2.

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. The median time to return to baseline wrinkle severity on both IGA-FWS and PFWS was 28.0 weeks and 28.1 weeks for the first and second treatments respectively in SAKURA 3. This is highly consistent with the findings from SAKURA 1 and SAKURA 2 of 27.7 weeks and 26.0 weeks respectively. The median time to loss of none or mild wrinkle severity on both IGA-FWS and PFWS was 24.0 weeks and 24.1 weeks for the first and second treatments in SAKURA 3; consistent with the findings of 24.0 weeks in SAKURA 1, and 23.9 weeks in SAKURA 2.

No subject in the SAKURA 1, 2 or 3 studies developed neutralizing antibodies against daxibotulinumtoxinA.

We submitted the BLA in November 2019. The FDA accepted the BLA on February 5, 2020, and the PDUFA target action date is November 25, 2020. If the BLA is approved on or by the target action date, we plan to initiate commercialization activities for DAXI for the treatment of glabellar lines before year end 2020.

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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.

DAXI for the Treatment of 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.

In January 2019, we initiated a Phase 2 multicenter, open-label, dose-escalation study to evaluate treatment of moderate or severe dynamic forehead lines in conjunction with treatment of the glabellar complex. The objective is to understand the potential dosing and injection patterns of DAXI in other areas of the upper face in addition to the lead indication in glabellar lines. We completed enrollment for the study in July 2019, and we expect to release top-line results in the second quarter of 2020.

DAXI for the Treatment of 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. 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 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 in the U.S., though other toxins are used off-label.

In March 2019, we initiated a Phase 2 multicenter, open-label, dose-escalation study to evaluate the treatment of moderate or severe lateral canthal lines. The objective is to understand the potential dosing of DAXI in the lateral canthal area. We completed enrollment for the study in August 2019, and we expect to release top-line results in second quarter of 2020.

DAXI for the Treatment of Upper Facial Lines

Upper Facial Lines (UFL) is the name commonly given to the combination of the three most commonly treated facial areas with botulinum toxins; specifically, glabellar lines, lateral canthal lines and forehead lines. In clinical practice a large proportion of patients seek treatment in all three areas to address signs of aging.

In November 2019, we initiated a Phase 2 multicenter, open-label study to evaluate the simultaneous treatment of UFL with DAXI. The objective is to understand the combined safety and efficacy of the treatment of all three areas together. We anticipate receiving top-line results in the fourth quarter of 2020.

DAXI Therapeutic

DAXI is being developed for a variety of therapeutic indications, including cervical dystonia, limb spasticity, plantar fasciitis, and migraine. 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 the Treatment of Cervical Dystonia

Cervical dystonia is a chronic neurologic disorder characterized by involuntary muscle contractions of the head, neck, and shoulders, resulting in pain, abnormal movements and/or postural changes. Cervical dystonia symptoms may negatively impact mood and emotions, resulting in depression, social withdrawal, impaired sleep, poor health outcomes, and diminished quality of life. The cause of cervical dystonia is often unknown, and treatment with botulinum toxin is the current standard of care.

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In December 2016, we completed a 37-subject, Phase 2 study of three sequential dosing cohorts. Subjects in the first cohort received a single dose of 100 to 200 Units, the second cohort 200 to 300 Units, and the third cohort 300 to 450 Units. In May 2017, we announced top-line data that demonstrated a median duration of at least 24 weeks in each of the cohorts.

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 two days. The most frequently reported events were dysphagia (14%, 5 subjects, all mild), injection site erythema (8%), injection site bruising (5%), injection site pain (5%), muscle tightness (5%) and muscular weakness (5%). For reference, trials for botulinum type A products approved to treat cervical dystonia have reported adverse events for dysphagia ranging from 13% to 39%.

The trial's four-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%, across all three cohorts at Week 4. This reduction continued to increase to 50% at Week 6 for all subjects, was 42% at Week 12 and was maintained at or above 30% through Week 24. Clinically meaningful mean reductions in the TWSTRS Severity, Disability and Pain subscales were consistent and observed at all follow-up visits across all subjects. For reference, placebo-controlled trials for botulinum toxin type A products approved to treat cervical dystonia had a reduction in the TWSTRS-Total score from baseline of 21% to 26% at Week 4 and 13% to 16% at Week 12.

In 2018, we initiated two Phase 3 clinical trials for cervical dystonia. ASPEN-1 Phase 3 is a 301-subject, randomized, double-blind, placebo-controlled trial comparing two doses of DAXI (125 Units and 250 Units) to placebo. We completed the ASPEN-1 Phase 3 pivotal trial enrollment in October 2019, and expect to release top-line results in the second half of 2020. ASPEN-OLS is a 350-subject, open-label study that includes subjects rolling over from ASPEN-1, plus additional newly enrolled subjects.

DAXI for the Treatment of Adult Upper Limb Spasticity

Spasticity is a motor symptom characterized by rigidity, muscle tightness, joint stiffness, involuntary jerky movements, exaggeration of reflexes, unusual posture, abnormal positioning of fingers, wrists, arms, or shoulders, and muscle spasms. 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. Botulinum toxin is one of several approved therapies for the treatment of Adult Upper Limb Spasticity.

In December 2018, we initiated the JUNIPER Phase 2 trial, a 128-subject, multi-center, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of DAXI in reducing muscle tone of adult patients with upper limb spasticity due to stroke or traumatic brain injury. Subjects are assigned to one of three doses of DAXI (250 Units, 375 Units, or 500 Units) or to placebo. Following treatment, patients will be followed for a maximum of 36 weeks. The co-primary efficacy endpoints of the trial are 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 scale at Week 6. Subjects are followed for 36 weeks. We expect to complete the JUNIPER Phase 2 trial enrollment in the second half of 2020 and expect top-line results in the second half of 2021.

DAXI for the Treatment of Plantar Fasciitis

Plantar fasciitis is a painful affliction caused by inflammation of the ligament running along the bottom of the foot, which causes 80% of reported cases of heel pain. Plantar fasciitis is estimated to affect 20 million individuals in the U.S. Risk factors include age, excessive weight, long distance running, abnormal foot posture, use of poor foot wear, and repetitive trauma. 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.

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In 2016, we initiated a 59-subject, Phase 2, randomized, double-blinded, placebo-controlled trial of DAXI for the treatment of plantar fasciitis. This study evaluated the safety and efficacy of a single administration of DAXI (240 Units) versus placebo in reducing the signs and symptoms. The study's primary efficacy endpoint was the improvement in the American Orthopedic Foot and Ankle Score.

The study completed in 2018. DAXI appeared to be generally safe and well-tolerated. 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% and 10.3%) and muscle weakness (3.3 % and 3.4%), all classified as mild in severity. The trial's primary endpoint, the reduction in the patient-reported visual analog scale ("VAS") for pain at Week 8, showed a robust impact on pain, with a greater than 50% reduction for patients treated with DAXI. In the intent-to-treat population, a mean reduction in the VAS score of 54.2% from baseline was achieved with DAXI, compared with a 42.6% reduction in the placebo group, which upon further subgroup analysis, was driven primarily by a strong placebo response in the control group at three of the five study sites. While the results are not statistically significant ($p=0.39$), DAXI provided patients with considerable pain relief. Similar numeric trends were seen in the secondary and exploratory endpoints. We completed the 16-week trial which showed a 58% reduction of pain from baseline along with a strong placebo response, with the difference between the treatment groups not being statistically significant.

Following discussions with the FDA, in December 2018 we initiated a second randomized, double-blind, placebo-controlled Phase 2 study. In this study 150 subjects have been randomized in equal numbers to receive 80 Units of DAXI or 120 Units of DAXI, or placebo. The study's primary efficacy endpoint is the change from baseline in Numeric Pain Rating Scale score at Week 8. Patients will be followed for up to 24 weeks post treatment to assess treatment response, tolerability and safety. We completed Phase 2 trial enrollment in December 2019 and expect to release top-line results in the second half of 2020.

DAXI for the Treatment of 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.

As part of our 2020 planning process, we decided to delay the initiation of migraine clinical trials this year and will re-evaluate the timing next year as part of our 2021 planning cycle.

Teoxane's Resilient Hyaluronic Acid® Technology

In January 2020, we entered into the Teoxane Agreement with Teoxane, pursuant to which Teoxane granted us with an exclusive right to import, market, promote, sell and distribute Teoxane's line of Resilient Hyaluronic Acid® dermal fillers, which include i) RHA® 2, RHA® 3 and RHA® 4 which have been approved by the FDA for the correction of moderate to severe dynamic facial wrinkles and folds, including RHA® 2, RHA® 3 and RHA® 4 in the currently approved indications, ii) RHA® 1, which we anticipate will be approved by the FDA in 2021 for the treatment of perioral rhytids, and is currently in ongoing clinical trials, and iii) future hyaluronic acid filler advancements and products by Teoxane (collectively the "RHA® dermal fillers") in the U.S. and U.S. territories and possessions, in exchange for 2,500,000 shares of our common stock and certain other commitments by us. The Teoxane Agreement will be effective for a term of ten years upon product launch and may be extended for a two-year period upon the mutual agreement of the parties.

We have begun to build out a U.S. commercial organization and plan to introduce the FDA approved RHA® dermal fillers in the U.S. in the second quarter of 2020.

OnabotulinumtoxinA Biosimilar

We entered into a collaboration and license agreement with Mylan ("Mylan Collaboration") in February 2018, under which the companies will collaborate exclusively, on a worldwide basis (excluding Japan), to develop, manufacture, and commercialize a biosimilar to the branded biologic product (onabotulinumtoxinA) marketed as BOTOX®. In February 2019, we had a biosimilar initial advisory meeting ("BIAM") with the FDA and Mylan on a proposed biosimilar to BOTOX®. Based on the FDA's feedback, the companies believe that a 351(k) pathway for the development of a biosimilar to onabotulinumtoxinA is viable. In April 2019, we received the official FDA minutes from the BIAM.

In August 2019, we entered into an amendment to the Mylan Collaboration (the “Mylan Amendment”) which, among other things, extended the period of time for Mylan to make a decision under the Mylan Collaboration (the “Continuation Decision”) as to whether to continue the biosimilar development program beyond the initial development plan and the BIAM. In accordance with the Mylan Amendment, Mylan is now required to notify us of the Continuation Decision on or before the later of (i) April 30, 2020 or (ii) 30 calendar days from the date that we provide Mylan with certain deliverables. Additionally, Mylan agreed and incrementally paid \$5.0 million to the previously agreed non-refundable upfront payment of \$25.0 million with contingent payments of up to \$100.0 million, in the aggregate, upon the achievement of specified clinical and regulatory milestones, tiered sales milestones of up to \$225.0 million, and royalties on sales of the biosimilar in the Mylan territories previously disclosed from the Mylan Collaboration.

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 may 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.

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. Four products, Allergan’s BOTOX® Cosmetic, Ipsen and Galderma’s Dysport®, Merz’s Xeomin®, and Evolus’s Jeuveau™, each of which is delivered in an injectable form, have been approved for the treatment of glabellar lines in the U.S.

According to Millennium Research Group, Inc. (“MRG”), the global opportunity for botulinum toxin was estimated to be \$5.1 billion in 2019 compared to \$4.6 billion in 2018. The market is projected to reach approximately \$9.7 billion by 2027, registering a compounded annual growth rate of approximately 9% over the analysis period of 2017 to 2027. We estimate the market opportunity split between therapeutics and aesthetics is approximately 60% and 40%, 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, 2019, there were more than 155 active clinical trials for a wide range of uses of botulinum toxin, with approximately 23% 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

Injectable botulinum toxin treatments are the single largest cosmetic procedure in the U.S. and globally. According to the American Society for Aesthetic Plastic Surgery, 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. Injectable botulinum toxin continued to be the most frequently performed non-surgical procedure in 2018, with 1.8 million procedures in the U.S., which represents a 16.3% increase over 2017.

According to our 2018 Harris Poll survey results, 86% of the physicians surveyed want a neuromodulator that offers longer-lasting results than is available today and 88% 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 longer duration than what is available today is a differentiating and desirable attribute, meeting the greatest unmet need. Most 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.

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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 most 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.

The Opportunity for Botulinum Toxins for Therapeutic Indications

While currently approved botulinum toxin products may be better known for their aesthetic applications, botulinum toxin's ability to affect neuromuscular junctions, muscle activity or the release of neuropeptides, neurotransmitters and neuromodulators in a controlled manner has enabled it to be developed and used in a wide range of therapeutic indications. According to MRG, the fastest-growing segment for botulinum toxin treatments globally is for therapeutic indications, including botulinum toxin products as a preventive treatment for chronic migraine headache and upper limb spasticity, urinary incontinence, overactive bladder, and lower limb spasticity. We estimate that the global opportunity for botulinum toxin for the treatment of migraine was approximately \$761 million in 2018.

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.

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.

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 and upper or lower limb spasticity. 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 three to four 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.

The Opportunity Dermal Fillers for Aesthetic Indications

According to ASAPA Cosmetic (Aesthetic) Surgery National Data Bank, Hyaluronic Acid dermal fillers are the second top non-surgical procedure performed in aesthetic medicine. In 2018, they estimate 810,240 procedures were performed in the U.S., which represented a 12.2% increase over 2017. According to the Medical Insight, Inc., Global Facial Injectables Market Study, dermal fillers are a \$1.1 billion market in the U.S., and projected to reach \$2.1 billion sales in 2025, around 10% annually.

Our Technology

Our Proprietary Peptide Excipient Technology

Combining our proprietary peptide excipient technology with active drug macromolecules such as daxibotulinumtoxinA may help address currently unmet medical needs. Employing our proprietary peptide excipient technology may deliver improved performance when combined with other active drug macromolecules, as demonstrated with our lead candidate DAXI.

DAXI Delivery of Botulinum Toxin

The DAXI formulation incorporates our proprietary stabilizing peptide excipient along with the other excipients: polysorbate-20, buffers and a sugar. DAXI will be supplied as a lyophilized powder which will require reconstitution with saline prior to injection. The highly positively charged peptide excipient has been shown to bind non-covalently to the daxibotulinumtoxinA molecule. The unique formulation of DAXI has permitted us to create a drug product without human serum albumin, found in all other FDA approved botulinum toxin products. Preclinical and clinical data taken together suggest that DAXI may provide long duration of effect at the target muscle with a safety profile consistent with currently approved botulinum toxin products.

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. dba Ajinomoto Bio-Pharma Services (“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 DAXI. The additional components required for our product lines and the peptide for DAXI are manufactured by third parties under contract with us. Please refer to “[Outsourced Components](#)” section below for additional information.

Drug Substance Manufacturing

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 Manufacturing

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.

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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 Bachem Americas, Inc. (formerly known as American Peptide Company, Inc.) (“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 Bachem will remain in effect until 2020 and may be terminated earlier by either party following advance notice or a material breach by either party. We expect to renew our agreement with Bachem in 2020.

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. As of December 31, 2019, our agreement with Althea will remain in effect for four years and may be terminated earlier by either party following advance notice or a material breach by either party.

The Teoxane Agreement granted us the exclusive right to import, market, promote, sell, and distribute Teoxane’s RHA® dermal fillers, which include (i) RHA® 2, RHA® 3 and RHA® 4 which have been approved by the FDA for the correction of moderate to severe dynamic facial wrinkles and folds, (ii) RHA® 1, once approved, in the indication currently in ongoing clinical trials, and (iii) future hyaluronic acid filler advancements and products by Teoxane in the U.S. and U.S. territories and possessions. The agreement is effective for a term of ten years and may be extended for two additional years upon mutual agreement, provided that agreed upon annual purchase and commercialization spend minimums are maintained.

Sales and Marketing

We have begun building out a U.S. commercial organization for the distribution of Teoxane RHA® dermal fillers in the U.S. in the second quarter of 2020 and for the potential launch of DAXI in the fourth quarter of 2020, if the BLA is approved on or by the PDUFA target action date.

Intellectual Property

Our success depends in large part on our ability to obtain and maintain intellectual property protection for our drug candidates, novel biological discoveries, and drug development technology and other know-how, to operate without infringing on the proprietary or intellectual property rights of others and to prevent others from infringing our proprietary and intellectual property rights. We seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on know-how, copyright, trademarks and trade secret laws, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. Such protection is also maintained using confidential disclosure agreements. Protection of our technologies is important for us to offer our customers proprietary services and products unavailable from our competitors, and to exclude our competitors from using technology that we have developed. If competitors in our industry have access to the same technology, our competitive position may be adversely affected.

It is possible that our current patents, or patents which we may later acquire or develop, may be successfully challenged or invalidated in whole or in part. It is also possible that we may not obtain issued patents from our pending patent applications or other inventions we seek to protect. Due to uncertainties inherent in prosecuting patent applications, sometimes patent applications are rejected and we subsequently abandon them. It is also possible that we may develop proprietary products or technologies in the future that are not patentable or that the patents of others will limit or altogether preclude our ability to do business. In addition, any patent issued to us, or any of our pending patent applications, may provide us with little or no competitive advantage, in which case we may abandon such patent, or patent applications, or license them to another entity. 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 December 31, 2019, we held approximately 418 issued patents and approximately 124 pending patent applications, including foreign counterparts of U.S. patents and applications. 38 of our patents are issued in the U.S., with the rest issued in Australia, Brazil, Canada, China, Colombia, various countries in Europe, Hong Kong, India, Israel, Japan, 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, Colombia, Europe, Hong Kong, Israel, India, Japan, Korea, Mexico, and Singapore. The earliest that any of our U.S. patents will expire is July 20, 2021 for U.S. Patent No. 7807780. 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 DAXI, we continue to take appropriate measures to defend the patent. On May 10, 2019 our European Patent No. EP 2 490 986 B1 for “Methods and Systems For Purifying Non-Complexed Botulinum Neurotoxin” was opposed. We are vigorously defending this patent in the European Patent Office. We were informed in May 2019 that our patent application NC2018/0005351 pending in Colombia for “Injectable Botulinum Toxin Formulations And Methods of Use Thereof Having Long Duration of Therapeutic Effect” was opposed. We have responded to this pre-grant opposition. Furthermore, even if our patents and applications are unchallenged, they may not adequately protect our intellectual property or prevent others from designing around our claims.

Our registered U.S. trademarks include REVANCE®, MOTISTE®, “Remarkable Science Changes Everything®”, Relastin®, “Remarkable Science. Enduring Performance®”, and R Logo®.

Competition

We expect to enter highly competitive pharmaceutical and medical device markets. Successful competitors 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. Numerous companies are engaged in the development, financial, research, manufacture and marketing of healthcare products competitive with those that we are developing. Our competitors may also have more experience and expertise in obtaining marketing approvals from the FDA and other regulatory authorities. 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.

Based on our ongoing clinical trials and submission of our BLA to the FDA for DAXI in the treatment of glabellar lines, we will continue to pursue additional regulatory approvals for the indications supported in these trials. Initially, we expect to compete directly with competitors that sell an injectable neuromodulator product in the markets where we have a labeled indication and/or regulatory clearance.

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. Allergan is also currently in the process of being acquired by AbbVie which may have unknown impacts.

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- 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.

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 current good manufacturing practice standards ("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.

Dermal Fillers

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 Restylane® family of fillers. 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, 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.

Government Regulations

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:

- 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, 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 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.

Clinical Trials

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

- *Phase 1.* The product candidate is initially introduced into a limited population of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for some diseases, or when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients with the disease or condition for which the product candidate is intended to gain an early indication of its effectiveness.
- *Phase 2.* The product candidate is evaluated in a limited patient population, but larger than in Phase 1, to identify possible adverse events and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted indications and to assess dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, and provide substantial evidence of clinical efficacy and safety in an expanded patient population, such as several hundred to several thousand, at geographically dispersed clinical trial sites. Phase 3 clinical trials are typically conducted when Phase 2 clinical trials demonstrate that a dose range of the product candidate is effective and has an acceptable safety profile. These trials typically have at least 2 groups of patients who, in a blinded fashion, receive either the product or a placebo. Phase 3 clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

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

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

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

U.S. Review and Approval Processes

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

Once the FDA receives a BLA, it has 60 days to review the BLA to determine if it is substantially complete and the data are readable, before it accepts the BLA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the BLA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act (“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.

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 and other agencies closely regulate 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. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products. 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.

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.

The federal false claims laws, including the False Claims Act, and civil and monetary penalties laws prohibit, among other things, 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

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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.

The federal transparency requirements under ACA , commonly referred to as the Physician Payments Sunshine Act, 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, as defined by such law, and teaching hospitals and ownership and investment interests held by physicians and their immediate family members.

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

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. HIPAA, as amended by the Health Information Technology and Clinical Health Act ("HITECH"), and its implementing regulations, imposes certain standards and obligations on covered entities, including certain healthcare providers, health plans and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain, or transmit individually identifiable health information for or on behalf of a covered entity relating to the privacy, security, transmission and breach reporting of individually identifiable health information. 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 significant 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.

Medical Device Distribution

As the distributor of Teoxane's RHA® dermal fillers, we will be subject to state permitting requirements for distribution of medical devices, and must cooperate with Teoxane in the event of any medical device reports (adverse events) or product recalls. As we have no prior experience in the distribution of medical devices, it will take time and expense to build the necessary compliance infrastructure to support these activities.

Coverage and Reimbursement

Patients in the United States and elsewhere generally rely on third-party payors to reimburse part or all of the costs associated with their prescription drugs. Accordingly, our ability to commercialize DAXI or any future product candidates for therapeutic indications such as cervical dystonia, adult upper limb spasticity, plantar fasciitis or migraine will depend in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not obtain adequate third-party coverage or reimbursement for DAXI or any future product candidates for therapeutic indications, or we may be required to sell them at a discount.

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

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

Healthcare Reform

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was passed in March 2010, and substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U.S. biotechnology industry. There remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2020 contained further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and, at the same, has implemented others under its existing authority. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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.

Customers

For the years ended December 31, 2019 and 2018, all of our revenue was from Mylan under the Mylan Collaboration. For the years ended December 31, 2017, all of our revenue represented royalty revenue from Precision Dermatology, Inc., which was subsequently acquired by Valeant Pharmaceuticals International Inc., now known as Bausch Health Companies Inc.

Employees

As of December 31, 2019, we had 193 employees. Of these employees, 129 employees were engaged in research and development and 64 employees were engaged in finance, marketing, human resources, facilities, information technology, and other 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.

Corporate Information

We were incorporated in Delaware in August 1999, under the name Essentia Biosystems, Inc. We commenced operations in June 2002 and, in April 2005, changed our name to Revance Therapeutics, Inc. Our principal executive offices are located at 7555 Gateway Boulevard, Newark, California 94560, and our telephone number is (510) 742-3400.

Available Information

We make available, free of charge through our website, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, and any amendments to those reports, filed or furnished pursuant to Sections 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after they have been electronically filed with or furnished to the Securities and Exchange Commission (“SEC”) at www.sec.gov. Our website address is www.revance.com. Information contained on or accessible through these websites is not incorporated by reference nor otherwise included in this report, and any references to these websites are intended to be inactive textual references only.

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 completed 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 submitted our BLA to the U.S. FDA for DAXI for the treatment of glabellar lines in November 2019. In February 2020, the FDA accepted the BLA filing. If the BLA is approved on or by the PDUFA target action date, we plan to initiate commercialization activities for DAXI for the treatment of glabellar lines before the end of 2020.

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 October 2019, we completed the ASPEN Phase 3 pivotal trial enrollment, and plan to release topline results in the second half of 2020.

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 American Orthopedic Foot and Ankle Score. In January 2018, we announced interim 8-week results from this study. We completed the 16-week trial which showed a 58% 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. We completed Phase 2 trial enrollment in December 2019 and expect to release topline results in the second half of 2020.

In April 2018, we announced two new clinical programs for DAXI, including adult upper limb spasticity and migraine. We initiated the JUNIPER Phase 2 study in adult upper limb spasticity in the fourth quarter of 2018 and we expect to complete Phase 2 trial enrollment in mid-2020. In 2021, we may initiate a study with DAXI for the treatment of migraine.

In July 2019, we completed the enrollment in the Phase 2 clinical study of DAXI for forehead lines. In August 2019, we completed Phase 2 study enrollment of DAXI for lateral canthal lines (crow’s feet). Topline results for both studies are expected in the first half of 2020. In December 2019, we initiated an additional study of upper facial lines, which includes glabellar (frown), lateral canthal (crow’s feet), and forehead lines combined. This trial is being conducted to understand the safety and efficacy of DAXI, including potential dosing and injection patterns for covering upper facial lines. We expect completion of enrollment in first quarter of 2020, with topline results in fourth quarter of 2020.

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Our near-term prospects, including our ability to finance our company and generate revenue, will depend heavily on the successful development, regulatory approval and commercialization of 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:

- 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 effectively and reliably 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 ("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;

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- the willingness of patients to pay out of pocket for DAXI and any future products we may commercialize for aesthetic indications; and
- 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.

We are substantially dependent on the clinical and commercial success of the Teoxane Resilient Hyaluronic Acid® dermal fillers.

In January 2020, we entered into an exclusive distribution agreement with Teoxane SA (“Teoxane”) (such agreement, the “Teoxane Agreement”), pursuant to which Teoxane granted us the exclusive right to import, market, promote, sell and distribute Teoxane’s line of Resilient Hyaluronic Acid® dermal fillers, which have been approved by the FDA for the correction of moderate to severe dynamic facial wrinkles and folds, including RHA® 2, RHA® 3 and RHA® 4 in the currently approved indications, as well as RHA® 1 in the indication currently in ongoing clinical trials, if approved by the FDA for the treatment of perioral rhytids and future Hyaluronic Acid filler advancements by Teoxane (collectively, the “RHA® dermal fillers”) in the U.S., U.S. territories and possessions.

Our success as a company is substantially dependent on our ability to successfully and timely commercialize the RHA® dermal fillers, which will depend on many factors including, but not limited to, our ability to:

- develop and execute our sales and marketing strategies for the RHA® dermal fillers;
- develop, maintain and manage the necessary sales, marketing and other capabilities and infrastructure that are required to successfully integrate and commercialize the RHA® dermal fillers, including in connection with our marketing and sale of DAXI;
- achieve, maintain and grow market acceptance of, and demand for, the RHA® dermal fillers;
- establish or demonstrate in the medical community the safety and efficacy of the RHA® dermal fillers and their potential advantages over and side effects compared to existing dermal fillers and products currently in clinical development;
- the relative price of the RHA® dermal fillers as compared to alternative options, and our ability to achieve a suitable profit margin on our sales of the RHA® dermal fillers;
- collaborate with Teoxane to obtain necessary approvals from the FDA and similar regulatory authorities for the RHA® dermal fillers;
- adapt to additional changes to the label for the RHA® dermal fillers, that could place restrictions on how we market and sell the RHA® dermal fillers, including as a result of adverse events observed in these or other studies;
- obtain adequate and timely supply of the RHA® dermal fillers under the Teoxane Agreement;
- comply with the terms of the Teoxane Agreement, including our obligations with respect to purchase quantities and marketing efforts;
- comply with applicable legal and regulatory requirements, including medical device compliance as the RHA® dermal fillers are Class III Premarket Approval (“PMA”) devices under the Food, Drug and Cosmetic Act, as amended (the “FDCA”);

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- register as the initial importer of the RHA® dermal fillers with FDA and obtain necessary state prescription medical device distribution permits and hire and operationalize complaint and medical device vigilance services in support of the RHA® dermal fillers; and
- establish agreements with third party logistics providers to distribute the RHA® dermal fillers to customers.

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 the RHA® dermal fillers, which may materially impact the success of our business. If we fail to comply with the terms of the Teoxane Agreement, including by failing to meet certain obligations in connection with purchase and marketing of RHA® dermal fillers, Teoxane may terminate the Teoxane Agreement, and we would have no further rights to distribute the RHA® dermal fillers. In addition, the lack of, or limited, complementary products to be offered by sales personnel in marketing the RHA® dermal fillers may put us at a competitive disadvantage relative to companies with more extensive product lines. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of the RHA® dermal fillers to continue our business.

Reports of adverse events or safety concerns involving the RHA® dermal fillers could delay or prevent Teoxane from obtaining or maintaining regulatory approval for, or could negatively impact our sales of, the RHA® dermal fillers.

Reports of adverse events or safety concerns involving the RHA® dermal fillers could result in the FDA or other regulatory authorities withdrawing approval of the RHA® dermal fillers for any or all indications that have approval, including the use of the RHA® dermal fillers for specified aesthetic indications. We cannot assure you that patients receiving the RHA® dermal fillers will not experience serious adverse events in the future that require submission of medical device reports to the FDA. Adverse events may also negatively impact the sales of the RHA® dermal fillers. Teoxane may also be required to further update package inserts and patient information brochures of the RHA® dermal fillers based on reports of adverse events or safety concerns, which could adversely affect acceptance of the RHA® dermal fillers in the market, make competition easier or make it more difficult or expensive for us to commercialize the RHA® dermal fillers.

The Teoxane Agreement requires us to make specified annual minimum purchases of RHA® dermal fillers and to meet specified expenditure levels in connection with our marketing of RHA® dermal fillers in furtherance of the commercialization of the RHA® dermal fillers, regardless of whether our commercialization efforts are successful. Such expenditure requirements may adversely affect our cash flow and our ability to operate our business and our prospects for future growth, or may result in the termination of the Teoxane Agreement.

The Teoxane Agreement requires us to make specified annual minimum purchases of RHA® dermal fillers, and to meet an annual minimum expenditure on marketing and other areas related to the commercialization of the RHA® dermal fillers, regardless of whether our commercialization efforts are successful. If we fail to meet the annual minimum purchase amount or the annual minimum marketing spending requirements specified in the Teoxane Agreement, Teoxane has the right to terminate the Teoxane Agreement.

If our commercialization efforts of the RHA® dermal fillers are unsuccessful, there can be no assurance that we will have sufficient cash flow to comply with such minimum purchase and expenditure requirements. Our obligation to Teoxane to meet such requirements could:

- make it more difficult for us to satisfy obligations with respect to our indebtedness, including the Notes (as defined in Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations—[Liquidity and Capital Resources](#).”) and any failure to comply with the obligations of any of our debt instruments, including financial and other restrictive covenants, could result in an event of default under the agreements governing such indebtedness;
- require us to dedicate a substantial portion of available cash flow to meet the minimum expenditure requirements, which will reduce the funds available for working capital, capital expenditures, acquisitions and other general corporate purposes;
- limit flexibility in planning for and reacting to changes in our business and in the industry in which we operate;
- limit our ability to engage in strategic transactions or implement our business strategies;

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- limit our ability to borrow additional funds; and
- place us at a disadvantage compared to our competitors.

Any of the factors listed above could materially and adversely affect our business and our results of operations.

We may be unable to obtain regulatory approval for DAXI, Daxibotulinumtoxin A Topical product candidates, biosimilar product candidates or future product candidates, and Teoxane may be unable to do the same for RHA® 1 and future hyaluronic acid filler advancements, 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. Teoxane must do the same with its PMAs to the FDA for the RHA® dermal fillers. The development of such 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 “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.

Currently, the only products for which we have the rights to commercialize and that have been approved for sale by the applicable regulatory authorities are RHA® 2, RHA® 3, and RHA® 4. We may never obtain regulatory approval to commercialize DAXI, DaxibotulinumtoxinA Topical, biosimilar, or future rights to commercialize RHA® 1 or any hyaluronic acid filler products developed pursuant to the Teoxane Agreement. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug, biologic and medical device 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 biologic product candidates, including DAXI, DaxibotulinumtoxinA Topical, biosimilar product candidate, any hyaluronic acid filler products, such RHA® 1 or future advancements developed by Teoxane, or future product candidates, in the U.S. until we receive approval of a BLA from the FDA. We are also not permitted to market the RHA® dermal fillers for additional indications for use unless and until Teoxane receives approval of a PMA supplement for such new indication for use. 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.

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, RHA® 1 or any future hyaluronic acid filler products developed pursuant to the Teoxane Agreement or any future product candidates are safe and effective for the requested indication;

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- Teoxane's inability to satisfy FDA approval requirements with respect to the RHA® dermal fillers or any future hyaluronic acid filler products developed pursuant to the Teoxane Agreement;
- our inability to demonstrate proof of concept of DaxibotulinumtoxinA Topical, biosimilar, RHA® 1 or any future hyaluronic acid filler products developed pursuant to the Teoxane Agreement 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, RHA® 1 or any future hyaluronic acid filler products developed pursuant to the Teoxane Agreement, 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, RHA® 1 or any future hyaluronic acid filler products developed pursuant to the Teoxane Agreement 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.

Our business currently depends substantially on the successful development, regulatory approval and commercialization of our product candidates. Of the large number of drugs, including biologics, and medical devices 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, RHA® 1 or any future hyaluronic acid filler products developed pursuant to the Teoxane Agreement 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, RHA® 1 or any future hyaluronic acid filler products developed pursuant to the Teoxane Agreement, 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.

All of the RHA® dermal fillers and any of our approved products and product candidates in the future 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 cGMP 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. The RHA® dermal fillers are subject to the FDA's Quality Systems Regulation ("QSR"), for medical devices. 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 cGMP and QSR, as applicable. 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 (for example, Teoxane, with respect to the RHA® dermal fillers), 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.

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. As such, any failure of Teoxane to maintain compliance with the applicable regulations and standards for RHA® dermal fillers could increase our costs, cause us to lose revenue, prevent the import and/or export of the RHA® dermal fillers, cause the RHA® dermal fillers to be recalled or withdrawn and prevent us from successfully commercializing the RHA® dermal fillers.

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. Our clinical programs for DAXI, DaxibotulinumtoxinA Topical or biosimilar will require substantial additional funds to complete. In addition, in connection with the Teoxane Agreement, we must make specified annual minimum purchases of RHA® dermal fillers and build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services in order to successfully commercialize the RHA® dermal fillers.

We had an accumulated deficit through December 31, 2019 of \$844.2 million and a working capital surplus of \$255.6 million as of December 31, 2019. Our recorded net losses were \$159.4 million, \$142.6 million and \$120.6 million for the years ended December 31, 2019, 2018, and 2017, respectively.

We have funded our operations primarily through the sale and issuance of common stock. As of December 31, 2019, we had capital resources consisting of cash and cash equivalents and investments of \$290.1 million. We believe that we will continue to expend substantial resources for the foreseeable future for the commercialization of the RHA® dermal fillers (including the establishment of our sales and marketing function) and 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, and marketing and selling the RHA® dermal fillers and any other 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 commercialize the RHA® dermal fillers and complete the development and commercialization of DAXI and any future product candidates. In addition, we have formed strategic collaborations, licensing and similar arrangements with third parties, such as the Teoxane Agreement, the Mylan Collaboration (as defined below) and Fosun License Agreement (as defined below), that we believe can complement or augment our product offerings, and may continue to do so in the foreseeable future.

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

Our future capital requirements depend on many factors, including:

- our ability to successfully commercialize the RHA® dermal fillers;
- our ability to establish our marketing, sales, and distribution functions;
- the results of our clinical trials for DAXI and preclinical studies and clinical trials of DaxibotulinumtoxinA Topical, biosimilar, RHA® 1 or any future hyaluronic acid filler products developed pursuant to the Teoxane Agreement 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, biosimilar, RHA® 1 or any future hyaluronic acid filler products developed pursuant to the Teoxane Agreement or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the scope, progress, results and costs of researching and developing and conducting preclinical and clinical trials of DAXI, DaxibotulinumtoxinA Topical, biosimilar, RHA® 1 or any future hyaluronic acid filler products developed pursuant to the Teoxane Agreement or any future product candidates;
- the cost of commercialization activities if DAXI or any future product candidates, including DaxibotulinumtoxinA Topical, biosimilar or any hyaluronic acid filler products developed pursuant to the Teoxane Agreement, are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing DAXI, DaxibotulinumtoxinA Topical, biosimilar, any hyaluronic acid filler products developed pursuant to the Teoxane Agreement, 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 Agreement, 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;

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- 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 the RHA® dermal fillers, DAXI, DaxibotulinumtoxinA Topical, biosimilar, any hyaluronic acid filler products developed pursuant to the Teoxane Agreement 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.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

We may not have the ability to raise the funds necessary to settle conversions of the Notes in cash or to repurchase the Notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Notes.

Holders of the Notes will have the right to require us to repurchase all or a portion of their notes upon the occurrence of a fundamental change (as defined in the indenture for the Notes) at a fundamental change repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Notes being converted. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of notes surrendered therefor or notes being converted. In addition, our ability to repurchase the Notes or to pay cash upon conversions of the Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase notes at a time when the repurchase is required by the indenture or to pay any cash payable on future conversions of the Notes as required by the indenture would constitute a default under the indenture. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes or make cash payments upon conversions thereof.

The conditional conversion feature of the Notes, if triggered, may adversely affect our financial condition and operating results.

In the event the conditional conversion feature of the Notes is triggered, holders of notes will be entitled to convert the Notes at any time during specified periods at their option. If one or more holders elect to convert their notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital.

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, the RHA® dermal fillers 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, the RHA® dermal fillers 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, 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, the RHA® dermal fillers and any future products we may commercialize for therapeutic indications;
- the willingness of patients to pay out of pocket for DAXI, the RHA® dermal fillers 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, the RHA® dermal fillers 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.

In addition, DAXI has only been used in clinical trials to date. Therefore, the commercial or real-world experience may yield different outcomes or patient experiences due to variations in injection techniques, dilution approaches and dosing levels employed by different physician and nurse injectors. As a result, these market-based approaches may differ from our clinical trial design and could negatively impact adoption.

If our competitors develop and market products that are safer, more effective or more convenient or less expensive than DAXI or the RHA® dermal fillers, our commercial opportunity will be reduced or eliminated.

Our commercial opportunity with respect to DAXI or the RHA® dermal fillers will be reduced or eliminated if our competitors develop and market dermal filler products that are more effective, have fewer side effects, are more convenient or are less expensive than DAXI or the RHA® dermal fillers. Our competitors include large, fully-integrated pharmaceutical companies and more established biotechnology and medical device companies, including companies offering injectable dose forms of botulinum toxin procedures and companies offering procedures such as laser treatments, face lifts, chemical peels, fat injections and cold therapy, all of which have significant resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals and marketing. It is possible that competitors will succeed in developing technologies that are safer, more effective, more convenient or with a lower cost of goods and price than those used in the RHA® dermal fillers and in our product candidates or being developed by us, or that would render our technology obsolete or noncompetitive.

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 DAXI, DaxibotulinumtoxinA Topical, or biosimilar 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, our BLA seeks 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.

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 a Technology Transfer, Validation and Commercial Fill/Finish Services Agreement (the “Althea Services Agreement”) with Ajinomoto Althea, Inc. dba Ajinomoto Bio-Pharma Services (“Althea”), a contract development and manufacturing organization. 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.

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

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

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

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

There were no indicators of impairment for the years ended December 31, 2019 and 2018. Under U.S. generally accepted accounting principles (“GAAP”), long-lived assets, such as our fill/finish line, are required to be reviewed for impairment whenever adverse events or changes in circumstances indicate a possible impairment. If business conditions or other factors indicate that the carrying value of the asset may not be recoverable, we may be required to record additional non-cash impairment charges. Additionally, if the carrying value of our capital equipment exceeds current fair value as determined based on the discounted future cash flows of the related product, the capital equipment would be considered impaired and would be reduced to fair value by a non-cash charge to earnings, which could negatively affect our operating results. Events and conditions that could result in impairment in the value of our long-lived assets include adverse clinical trial results, changes in operating plans, unfavorable changes in competitive landscape, adverse changes in the regulatory environment, or other factors leading to reduction in expected long-term sales or profitability. We will evaluate the recoverability and fair value of our long-lived assets, including those related to other components of the fill/finish line, each reporting period to determine the extent to which further non-cash charges to earnings are appropriate. Additional impairment in the value of our long-lived assets may materially and negatively impact our operating results.

We have incurred significant losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future. In January 2020, we entered into the Teoxane Agreement pursuant to which we obtained the right to import, market, promote, sell and distribute the RHA® dermal fillers in the United States, its territories and possessions. We have not yet had any commercial sales, and aside from our rights to the RHA® dermal fillers, only have one product candidate in clinical trials, which makes it difficult to assess our future viability.

Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We are not profitable and have incurred losses in each year since we commenced operations in 2002. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry. We have not yet made any sales of the RHA® dermal fillers and have not demonstrated the ability to successfully commercialize the RHA® dermal fillers. To date, we have not obtained any regulatory approvals for any of our product candidates or generated any revenue from product sales relating to DAXI, DaxibotulinumtoxinA Topical or biosimilar. We continue to incur significant research and development and other expenses related to our ongoing clinical trials and operations, and expect to incur substantial expenses in building out our sales, marketing and distribution function as we pursue commercialization of DAXI, if approved, and the RHA® dermal fillers. As of December 31, 2019, we had a working capital surplus of \$255.6 million and an accumulated deficit of \$844.2 million. Our recorded net losses were \$159.4 million, \$142.6 million and \$120.6 million for the years ended December 31, 2019, 2018 and 2017, respectively. We have funded our operations primarily through the sale and issuance of common stock. Our capital requirements to implement our business strategy are substantial, including our capital requirements to commercialize the RHA® dermal fillers and to develop and commercialize DAXI. We believe that our currently available capital is sufficient to fund our operations through at least the next 12 months following the filing of this Form 10-K.

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

Even if DAXI, DaxibotulinumtoxinA Topical, biosimilar, any RHA® dermal fillers or any future product candidates obtain regulatory approval, they may never achieve market acceptance or commercial success.

Even if we obtain FDA or other regulatory approvals, DAXI, DaxibotulinumtoxinA Topical, biosimilar, any hyaluronic acid filler products developed pursuant to the Teoxane Agreement or any future product candidates may not achieve market acceptance among physicians and patients, and may not be commercially successful.

The degree and rate of market acceptance of DAXI, DaxibotulinumtoxinA Topical, biosimilar, any hyaluronic acid filler products developed pursuant to the Teoxane Agreement or any future product candidates for which we receive approval depends on a number of factors, including:

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

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- the willingness of patients to pay for DAXI, DaxibotulinumtoxinA Topical, any hyaluronic acid filler products developed pursuant to the Teoxane Agreement and other aesthetic treatments in general, relative to other discretionary items, especially during economically challenging times;
- the willingness of third-party payors to reimburse physicians or patients for DAXI and any future products we may commercialize for therapeutic indications;
- the relative convenience and ease of administration;
- the prevalence and severity of adverse events; and
- the effectiveness of our sales and marketing efforts.

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

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

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

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

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

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

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- add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of product candidate for use in clinical trials.

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

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

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

We have no experience manufacturing DAXI, DaxibotulinumtoxinA Topical, biosimilar, or any other product candidates at full commercial scale. If any of these product candidates are approved, we will face certain risks associated with scaling up our manufacturing capabilities to support commercial production.

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

We rely on Teoxane for the manufacture and supply of the RHA® dermal fillers pursuant to the Teoxane Agreement, and our dependence on Teoxane may impair our ability to commercialize of the RHA® dermal fillers.

Pursuant to the Teoxane Agreement, we are not entitled to manufacture the RHA® dermal fillers. Instead, Teoxane is responsible for supplying all of our requirements for the RHA® dermal fillers. If Teoxane were to cease production or otherwise fail to timely supply us with an adequate supply of the RHA® dermal fillers, our ability to commercialize the RHA® dermal fillers would be adversely affected.

Teoxane is required to produce the RHA® dermal fillers under QSR in order to meet acceptable standards for commercial sale. If such standards change, the ability of Teoxane to produce the RHA® dermal fillers on the schedule we require to meet commercialization goals may be affected. Teoxane is subject to pre-approval inspections and periodic unannounced inspections by the FDA and corresponding state and foreign authorities to ensure strict compliance with QSR and other applicable government regulations and corresponding foreign standards. We do not have control over Teoxane's compliance with these regulations and standards. Any difficulties or delays in Teoxane's manufacturing and supply of the RHA® dermal fillers or any failure of Teoxane to maintain compliance with the applicable regulations and standards could increase our costs, cause us to lose revenue, prevent the import and/or export of the RHA® dermal fillers, or cause the RHA® dermal fillers to be the subject of field alerts, recalls or market withdrawals.

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

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

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

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

We and our manufacturers purchase the materials necessary to produce DAXI for our clinical trials from single-source third-party suppliers. There are a limited number of suppliers for the raw materials that we use to manufacture our product candidates, and we may need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials and, if approved, ultimately for commercial sale. In particular, we outsource the manufacture of bulk peptide through our agreement with Bachem Americas, Inc, which provides for the development, manufacture and supply of peptide in accordance with certain specifications.

We do not have any control over the process or timing of the acquisition of raw materials by our manufacturers. Although we generally do not begin a clinical trial unless we believe that we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of DAXI or any future product candidates, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party supplier could considerably delay completion of our clinical trials, product testing and potential regulatory approval of DAXI or any future product candidates. If we or our manufacturers are unable to purchase these raw materials on acceptable terms and at sufficient quality levels or in adequate quantities if at all, the development of DAXI and any future product candidates, or the commercial launch of any approved products, would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our product candidates or generate revenues from the sale of any approved products.

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

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

We currently have limited marketing and sales capabilities and no field sales organization. To commercialize DAXI, the RHA® dermal fillers, or any other future product candidates, if approved, in the U.S., Europe and other jurisdictions we seek to enter, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In connection with the Teoxane Agreement, we will have to build out our marketing and sales capabilities sooner than we initially anticipated. We expect to market DAXI and the RHA® dermal fillers, as applicable, through our own sales force in North America, and in Europe and other countries through either our own sales force or a combination of our internal sales force and distributors or partners, which may be expensive and time consuming.

We have no prior experience in the marketing, sale and distribution of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products, and may result in a breach of our obligations to Teoxane under the Teoxane Agreement. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize the RHA® dermal fillers, DAXI or any future product candidates. We also have to compete with other pharmaceutical and life sciences companies to recruit, hire, train and retain sales and marketing personnel, and turnover in our sales force and marketing personnel could negatively affect the commercialization of RHA® dermal fillers and, if it receives regulatory approval, DAXI. If we are not successful in commercializing the RHA® dermal fillers, DAXI or any future product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

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

In order to successfully commercialize our products, we need to expand our organization, including adding marketing, managerial, operational and sales capabilities, or contracting with third parties to provide these capabilities for us. If we are successful in advancing DAXI or any other product candidates through the development stage towards commercialization, we may need to expand such capabilities even further. Our management, personnel, systems and facilities currently in place are not adequate to support the commercialization of the RHA® dermal fillers and the potential commercialization of DAXI and any other product candidates, if they are approved. Effectively executing our growth strategy requires that we:

- identify recruit, train, integrate, incentivize and retain adequate numbers of effective sales and marketing personnel;
- generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team;
- achieve, maintain and grow market, physician, patient and healthcare payor acceptance of, and demand for our products;
- manage our clinical trials and manufacturing operations effectively;

- manage our internal development efforts effectively while carrying out our contractual obligations to Teoxane under the Teoxane Agreement and to other third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

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

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

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

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

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

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

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

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

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

Even if we obtain regulatory approval for DAXI, the RHA® dermal fillers, DaxibotulinumtoxinA Topical, biosimilar, or any other product candidates and are able to commercialize them, these products may not gain market acceptance among physicians, patients, healthcare payors and the medical community.

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

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

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

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

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

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

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

If there is not sufficient physician and patient demand for and acceptance of the RHA® dermal fillers, or, if approved for commercialization, DAXI and any future product candidates, our financial results and future prospects will be harmed.

Use of the RHA® dermal fillers, and, if approved for commercialization, DAXI for aesthetic indications are elective procedures, the cost of which must be borne by the patient, and we do not expect it to be reimbursable through government or private health insurance. The decision by a patient to elect to undergo the treatment of aesthetic indications with the RHA® dermal fillers or, if approved for commercialization, DAXI may pursue may be influenced by a number of factors, including:

- the success of any sales and marketing programs that we, or any third parties we engage, undertake, and as to which we have limited experience;
- the extent to which physicians recommend the RHA® dermal fillers or DAXI to their patients;
- the extent to which the RHA® dermal fillers or DAXI satisfies patient expectations;
- our ability to properly train physicians in the use of the RHA® dermal fillers and DAXI or such that their patients do not experience excessive discomfort during treatment or adverse side effects;
- the cost, safety and effectiveness of the RHA® dermal fillers and DAXI versus other treatments;
- consumer sentiment about the benefits and risks of aesthetic procedures generally and the RHA® dermal fillers and DAXI in particular;
- the success of any direct-to-consumer marketing efforts we may initiate; and

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

Our business, financial results and future prospects will be materially harmed if we cannot generate sufficient demand for the RHA® dermal fillers or, if approved for commercialization, DAXI or for any other future product candidate.

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

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

We expect that third-party payors will consider the efficacy, cost effectiveness and safety of DAXI in determining whether to approve reimbursement for DAXI for therapeutic indications and at what level. Our business would be materially adversely affected if we do not receive coverage and adequate reimbursement of DAXI for therapeutic indications from private insurers on a timely or satisfactory basis. No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States; therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, coverage under certain government programs, such as Medicare and Medicaid, may not be available for certain of our product candidates. As a result, the coverage determination process will likely be a time-consuming and costly process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our business could also be adversely affected if third-party payors limit the indications for which DAXI will be reimbursed to a smaller patient set than we believe they are effective in treating.

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

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

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

- decreased demand for the RHA® dermal fillers, DAXI or any future product candidates or products we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- costs to defend the related litigation;

- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- an increase in product liability insurance premiums or an inability to maintain product liability insurance coverage; and
- the inability to commercialize the RHA® dermal fillers, DAXI or any other products we develop.

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

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

We have been, and may in the future be, the target of securities class actions or stockholder derivative claims. On May 1, 2015, a securities class action complaint was filed on behalf of City of Warren Police and Fire Retirement System against us and certain of our directors and executive officers at the time of our follow-on public offering, and the investment banking firms that acted as the underwriters in our follow-on public offering. The Court granted final approval of the settlement, as set forth in the Stipulation of Settlement, on July 28, 2017. While the litigation has ended, we may be subject to future securities class action and shareholder derivation actions, which may adversely impact our business, results of operations, financial position or cash flows and divert management's time and attention from the business.

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

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We believe that our future success is highly dependent upon the contributions of our senior management, particularly Mark J. Foley, our President and Chief Executive Officer, Abhay Joshi, Ph.D., our Chief Operating Officer, Tobin C. Schilke, our Chief Financial Officer, and Dustin Sjuts, our Chief Commercial Officer, Aesthetics & Therapeutics, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, the completion of our planned clinical trials or the commercialization of the RHA® dermal fillers, DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future products we develop.

Leadership transitions can be inherently difficult to manage. Resignations of executive officers may cause disruption in our business, strategic and employee relationships, which may significantly delay or prevent the achievement of our business objectives. Leadership changes may also increase the likelihood of turnover in other key officers and employees and may cause declines in the productivity of existing employees. The search for a replacement officer may take many months or more, further exacerbating these factors. Identifying and hiring an experienced and qualified executive officer are typically

difficult. Periods of transition in senior management leadership are often difficult as the new executives gain detailed knowledge of our operations and may result in cultural differences and friction due to changes in strategy and style. During the transition periods, there may be uncertainty among investors, employees, creditors and others concerning our future direction and performance.

We could experience problems attracting and retaining qualified employees. Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense and the turnover rate can be high due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire a significant number of additional personnel as we begin building out a U.S. commercial organization for the distribution of RHA® dermal fillers in the U.S. in the second quarter of 2020 and, if the BLA is approved on or by the PDUFA target action date, the planned initiation of commercialization activities for DAXI for the treatment of glabellar lines before the end of 2020. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their previous research output.

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

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

Even if we identify an appropriate collaboration or product acquisition, we may not be successful in negotiating the terms of the collaboration or acquisition, or effectively integrating the collaboration or acquired product into our existing business and operations. Moreover, we may not be able to pursue such opportunities if they fall within the non-compete provision of the Teoxane Agreement, which prohibits us from developing, manufacturing, marketing, selling, detailing or promoting any cross-linked hyaluronic acid dermal filler (other than the RHA® dermal fillers) in the U.S. during the term of the Teoxane Agreement. We have limited experience in successfully acquiring and integrating products and technologies into our business and operations, and even if we are able to consummate an acquisition or other investment, we may not realize the anticipated benefits of such acquisitions or investments. We may face risks, uncertainties and disruptions, including difficulties in the integration of the operations and services of these acquisitions. If we fail to successfully integrate collaborations, assets, products or technologies that we enter into or acquire, or if we fail to successfully exploit acquired product distribution rights and maintain acquired relationships with customers, our business could be harmed. Furthermore, we may have to incur debt or issue equity securities in connection with proposed collaborations or to pay for any product acquisitions or investments, the issuance of which could be dilutive to our existing shareholders. Identifying, contemplating, negotiating or completing a collaboration or product acquisition and integrating an acquired product or technology could significantly divert management and employee time and resources.

While DAXI is in the clinical development stage, DaxibotulinumtoxinA Topical and all of our other potential product candidates remain in the discovery or preclinical stage. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

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

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

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

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

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or (the "Exchange Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), The Nasdaq Stock Market LLC listing rules and other applicable securities rules and regulations. Compliance with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly, and increase demand on our systems and resources. The Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Although we have hired additional employees to comply with these requirements, we may need to hire more employees in the future, which will increase our costs and expenses.

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

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

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

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

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

In the second quarter of 2019, we implemented a new enterprise resource planning (“ERP”) system and expect to continue with additional ERP implementations, including those in preparation of potential product launches. ERP implementations are complex and time-consuming, and involve substantial expenditures on system software and implementation activities. The ERP system will be critical to our ability to provide important information to our management, obtain and deliver our products, provide services and customer support, send invoices and track payments, fulfill contractual obligations, accurately maintain books and records, provide accurate, timely and reliable reports on our financial and operating results or otherwise operate our business. ERP implementations also require transformation of business and financial processes in order to reap the benefits of the ERP system; any such transformation involves risks inherent in the conversion to a new computer system, including loss of information and potential disruption to our normal operations. The implementation and maintenance of the new ERP system has required, and will continue to require, the investment of significant financial and human resources. Any disruptions, delays or deficiencies in the design or the ongoing maintenance of the new ERP system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations, accurately maintain books and records, provide accurate, timely and reliable reports on our financial and operating results, or otherwise operate our business. Additionally, if the system does not operate as intended, the effectiveness of our internal control over financial reporting could be adversely affected or our ability to assess it adequately could be delayed.

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

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

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

We may continue to license or selectively pursue strategic collaborations for the development, validation and commercialization of DAXI, DaxibotulinumtoxinA Topical, biosimilar, hyaluronic acid filler products, and any future product candidates. For instance, in February 2018, we and Mylan entered into the Mylan Collaboration, pursuant to which we and Mylan will collaborate exclusively, on a world-wide basis (excluding Japan), to develop, manufacture and commercialize our biosimilar product candidate. In December 2018, we and Fosun entered into the Fosun License Agreement pursuant to which we have granted Fosun the exclusive rights to develop and commercialize DAXI in the Fosun Territory and certain sublicense rights. In addition, we entered into the Teoxane Agreement in January 2020, pursuant to which Teoxane granted us the exclusive right to import, market, promote, sell and distribute the RHA® dermal fillers in the U.S., its territories and possessions. In any third-party collaboration, we are dependent upon the success of the collaborators to perform their responsibilities with continued cooperation. Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to performing their responsibilities under our agreements with them. Our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us. The development, validation and commercialization of our product candidates will be delayed if collaborators fail to conduct their responsibilities in a timely manner or in accordance with applicable regulatory requirements or if they breach or terminate their collaboration agreements with us. Disputes with our collaborators could also impair our reputation or result in development delays, decreased revenues and litigation expenses. Our collaboration with Mylan is for the development of a biosimilar product, which is subject to risks inherent with the relatively short history of biosimilar product approvals in the United States. The biosimilar product would be subject to similar commercial risks as our DAXI and Daxibotulinumtoxin A Topical product candidates. In February 2019, we and Mylan participated in a BIAM with the FDA to discuss the feasibility of a 351(k) biosimilar submission and the necessary development pathway for the biosimilar product candidate. While we believe that such a pathway is viable, the successful development and commercialization of a biosimilar product in any indications of BOTOX® or BOTOX Cosmetic® would be subject to FDA requirements that would need to be assessed by us and Mylan in determining the development of the biosimilar product candidate. In August 2019, we announced an amendment to the Mylan Collaboration pursuant to which, among other things, we agreed to extend the period of time for Mylan to make a decision under the collaboration agreement as to whether to continue the development and commercialization of a biosimilar to the branded biologic product (onabotulinumtoxinA) marketed as BOTOX® beyond the initial development plan to prepare for and conduct the BIAM with the FDA. Such amendment to the Mylan Collaboration and the FDA requirements may also limit our ability to begin development of the biosimilar in 2020, as presently planned or at all. Even if successfully developed, the biosimilar product would be subject to similar commercial risks as our DAXI and DaxibotulinumtoxinA Topical product candidates.

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

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

In addition, changes in U.S. and foreign trade policies could trigger retaliatory actions by affected countries, resulting in "trade wars", which may reduce customer demand for goods exported out of the United States if the parties having to pay those retaliatory tariffs increase their prices, or if trading partners limit their trade with the United States. If these consequences are realized, the price to the consumer of aesthetic or therapeutic medical procedures from products exported out of the United States may increase, resulting in a material reduction in the demand for our future product candidates. Such a reduction may materially and adversely affect our potential sales and our business. In particular, under our Fosun License Agreement, we are responsible for manufacturing DAXI and supplying it to Fosun, which would then develop, commercialize, market and sell it in mainland China, Hong Kong and Macau. If this arrangement is restricted in any way due

to the US-China trade relation, the contingent payments we are entitled to receive under the agreement, which are based on product sales, among other things, may be adversely affected. In addition, under the Teoxane Agreement, we are responsible for the commercialization of the RHA® dermal fillers in the U.S., and rely on Teoxane for our entire supply of the RHA® dermal fillers.

Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current or future economic climate and financial market conditions could adversely impact our business.

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

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

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

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

In December 2017, the Tax Cuts and Jobs Act of 2017 (the “Tax Act”) was signed into law. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years, and could increase our future U.S. tax expense. The foregoing items, as well as any other future changes in tax laws, could have a material adverse effect on our business, cash flow, financial condition, or results of operations. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation.

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

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. Breaches and other inappropriate access can be difficult to detect and any delay in identifying them could increase their harm. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events. Any such breaches of security and inappropriate access could disrupt our operations, harm our reputation or otherwise have a material adverse effect on our business, financial condition and results of operations.

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

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

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

In the U.S., HIPAA imposes, among other things, certain standards and obligations on covered entities including certain healthcare providers, health plans and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain, or transmit individually identifiable health information for or on behalf of a covered entity relating to the privacy, security, transmission and breach reporting of individually identifiable health information. Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. We may become subject to new privacy or cybersecurity regulations. Such laws and regulations could affect our ability to process personal data (in particular, our ability to use certain data for purposes such as risk or fraud avoidance, marketing or advertising), our ability to control our costs by using certain vendors or service providers, or impact our ability to offer certain services in certain jurisdictions. For example, the California Consumer Privacy Act ("CCPA") became effective on January 1, 2020. The CCPA establishes a privacy framework for covered businesses, including an expansive definition of personal information and data privacy rights for California residents. The CCPA includes a framework with potentially severe statutory damages and private rights of action. The CCPA requires covered companies to provide new disclosures to California consumers (as that word is broadly defined in the CCPA), provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. As we expand our operations, the CCPA will likely impact our business activities and may increase our compliance costs and potential liability. If we fail to comply with the CCPA, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Other states are beginning to pass similar laws, and some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. In the event that we are subject to HIPAA, the CCPA or other U.S. privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. Many countries in these regions have established or are in the process of establishing privacy and data security legal frameworks with which we, our customers, or our vendors must comply. For example, the EU has adopted the GDPR, which went into effect in May 2018 and introduces strict requirements for processing the personal information of EU subjects, including clinical trial data. The GDPR is likely to increase compliance burdens on us, including by mandating potentially burdensome documentation requirements and granting certain rights to individuals to control how we collect, use, disclose, retain and process information about them. The processing of sensitive personal data, such as physical health condition, may impose heightened compliance burdens under the GDPR and is a topic of active interest among foreign regulators. In addition, the GDPR provides for more robust regulatory enforcement and fines of up to €20 million or 4 percent of the annual global revenue of the noncompliant company, whichever is greater. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Risks Related to Our Intellectual Property

If Teoxane fails to obtain and maintain patent, licensing arrangements or other protection for the proprietary intellectual property that we have exclusive distribution rights to, we could lose our rights related to the RHA® dermal fillers, which would have a material adverse effect on our potential to generate revenue, our business prospects, and our results of operations.

If Teoxane fails to obtain and maintain patent, licensing arrangements or other protection for the proprietary intellectual property that we have exclusive distribution rights to, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. The intellectual property underlying the RHA® dermal fillers is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise regarding intellectual property subject to the Teoxane Agreement, including:

- the scope of rights granted under the Teoxane Agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of Teoxane that is not subject to the Teoxane Agreement;
- the sublicensing of patent and other rights under our collaborative development relationships; and
- the ownership of inventions and know-how resulting from the development of intellectual property under the Teoxane Agreement.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected products or product candidates.

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

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

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of issued patents. The patent applications that we own or license may fail to result in issued patents in the U.S. or foreign countries. Competitors in the field of cosmetics, pharmaceuticals, and botulinum toxin have created a substantial amount of prior art, including scientific publications, patents and patent applications. Our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope of such issued patents or any other issued patents we own or license, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant. Our European Patent EP 2 661 276 for “Topical composition comprising botulinum toxin and a dye” was opposed in the European Patent Office by Allergan plc on May 2, 2018, and although this patent is not material to our business, we continue to take appropriate measures to defend the patent. On May 10, 2019 our European Patent No. EP 2 490 986 B1 for “Methods and Systems For Purifying Non-Complexed Botulinum Neurotoxin” was opposed. We are vigorously defending this patent in the European Patent Office. We were informed in May 2019 that our patent application NC2018/0005351 pending in Colombia for “Injectable Botulinum Toxin Formulations And Methods of Use Thereof Having Long Duration of Therapeutic Effect” was opposed. We have responded to this pre-grant opposition. Furthermore, even if our patents and applications are unchallenged, they may not adequately protect our intellectual property or prevent others from designing around our claims.

In addition, the patent laws of the U.S. provide procedures for third parties to challenge the validity of issued patents. Patents issued from applications filed after March 15, 2013 may be challenged by third parties using the post-grant review procedure which allows challenges for a number of reasons, including prior art, sufficiency of disclosure, and subject matter eligibility. Under the inter partes review procedure, any third party may challenge the validity of any issued U.S. Patent in the U.S. Patent and Trademark Office (“USPTO”) on the basis of prior art patents or printed publications. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings as compared to the evidentiary standard relied on in U.S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates is challenged, then it could threaten our ability to commercialize DAXI, DaxibotulinumtoxinA Topical, biosimilar or any future product candidates, and could threaten our ability to prevent competitive products from being marketed. Further, if we encounter delays in our clinical trials, the period of time during which we could market DAXI, or any future product candidates under patent protection would be reduced. The results of our REALISE 1 Phase 3 clinical trial may be relevant to our patent strategy for our DaxibotulinumtoxinA Topical program.

Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the U.S. transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the United States resulting from the Leahy-Smith America Invents Act signed into law on September 16, 2011. Among some of the other changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Government Regulation

Our business and products are subject to extensive government regulation.

We are subject to extensive, complex, costly and evolving regulation by federal and state governmental authorities in the U.S., principally by the FDA, the U.S. Drug Enforcement Administration, the CDC, and foreign regulatory authorities. Failure to comply with all applicable regulatory requirements, including those promulgated under FDCA, the Public Health Service Act, and Controlled Substances Act, may subject us to operating restrictions and criminal prosecution, monetary penalties and other disciplinary actions, including, sanctions, warning letters, product seizures, recalls, fines, injunctions, suspension, revocation of approvals, or exclusion from future participation in the Medicare and Medicaid programs.

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

The regulatory approval process is highly uncertain and we or any collaboration partner may not obtain regulatory approval for the commercialization of DAXI, the RHA® dermal fillers or any future product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug and biologic products are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and other countries, which regulations differ from country to country. Neither we nor any collaboration partner are permitted to market DAXI or any future product candidates in the U.S. until we receive approval of a BLA from the FDA. Even though filed with the FDA, our BLA may receive a Complete Response Letter identifying deficiencies that must be addressed, rather than an approval. Obtaining regulatory approval of a BLA can be a lengthy, expensive and uncertain process. Similarly, Teoxane must do the same with its PMAs to the FDA for the RHA® dermal fillers.

In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions or other actions, including:

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

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

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

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

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- If DAXI, the RHA® dermal fillers or any future product candidates fail to demonstrate safety and efficacy in clinical trials or do not gain approval, our business and results of operations will be materially and adversely harmed.

The RHA® dermal fillers are Class III medical devices that require PMA approval before they may be commercialized in the U.S. Although Teoxane has received PMA for RHA® 2, RHA® 3 and RHA® 4 dermal fillers, we and Teoxane will be subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, registration, and listing of these devices. For example, periodic reports must be submitted to the FDA as a condition of PMA approval. These reports include safety and effectiveness information about the device after its approval. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation. Any failure to comply with the conditions of approval could result in the withdrawal of PMA approval and the inability to continue to market the device. The medical device regulations to which we are subject are complex and have become more stringent over time, and we have no history of operating as a distributor of Class III medical devices. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, including recalls, Dear Doctor letters and negative publicity which would negatively affect our business, financial condition and results of operations.

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

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

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us or our strategic collaborators, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

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

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

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

The RHA® dermal fillers, and, if approved, DAXI or any other products, may cause or contribute to adverse medical events that we are required to report to regulatory agencies and if we fail to do so, we could be subject to sanctions that would materially harm our business.

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

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

While we do not expect that DAXI, if approved for the treatment of glabellar lines, or the RHA® dermal fillers will subject us to all of the various U.S. federal and state laws intended to prevent healthcare fraud and abuse, we may be subject to, or in the future become subject to, such laws for treatment of other indications. The federal anti-kickback statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal healthcare programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “ACA”) to a stricter standard such that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Further, the ACA codified case law 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 False Claims Act (“FCA”). Many states have similar laws that apply to their state healthcare programs as well as private payors.

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The federal false claims and civil monetary penalties laws, including the FCA impose liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal healthcare program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims.

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

HIPAA also imposes, among other things, certain standards and obligations on covered entities including certain healthcare providers, health plans and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain, or transmit individually identifiable health information for or on behalf of a covered entity relating to the privacy, security, transmission and breach reporting of individually identifiable health information.

The federal Physician Payments Sunshine Act, and its implementing regulations, require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to Centers for Medicare & Medicaid Services information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Beginning in 2022, covered manufacturers will also be required to report annually regarding payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives and report ownership or investment interests held by such healthcare professionals and their immediate family members.

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

State and federal authorities have aggressively targeted pharmaceutical manufacturers for alleged violations of these anti-fraud statutes for a range of activities, such as those based on improper research or consulting contracts with physicians and other healthcare professionals, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans, and have often become subject to consent decrees severely restricting the manner in which they conduct business. Further, defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. If we become the target of such an investigation or prosecution based on our activities such as contractual relationships with providers or institutions, or our marketing and promotional practices, we could be subject to significant civil, criminal, and administrative sanctions, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, imprisonment, additional reporting requirements, and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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

Legislative or regulatory healthcare reforms in the U.S. may make it more difficult and costly for us to obtain regulatory clearance or approval of DAXI, topical, or any future product candidates and to produce, market, and distribute the RHA® dermal fillers and, if clearance or approval is obtained, DAXI and our other products.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture, and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. For example, the ACA was passed in March 2010, and substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the U.S. biotechnology industry. There remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress has considered legislation that would repeal or replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2020 contained further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services has solicited feedback on some of these measures and, at the same, has implemented others under its existing authority. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of, or affect the price that we may charge for, DAXI, or any future product candidates including DaxibotulinumtoxinA Topical or biosimilar. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs on our commercialization efforts for the RHA® dermal fillers. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could require, among other things:

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

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

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

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

Risks Related to the Ownership of Our Common Stock

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

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

- regulatory or legal developments in the U.S. and foreign countries;
- our success or lack of success in commercializing the RHA® dermal fillers;
- results from or delays in clinical trials of our product candidates, including our ongoing ASPEN Phase 3 clinical program in cervical dystonia and our Phase 2 programs in plantar fasciitis, adult upper limb spasticity, forehead lines, and lateral canthal lines all with DAXI;
- announcements of regulatory approval or disapproval of DAXI, the RHA® dermal fillers or any future product candidates;
- FDA or other U.S. or foreign regulatory actions or guidance affecting us or our industry;
- introductions and announcements of new products by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of securities analysts' reports or recommendations;
- quarterly variations in our results of operations or those of our future competitors;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- sales of substantial amounts of our stock by insiders and large stockholders, or the expectation that such sales might occur;
- general economic, industry and market conditions;

- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- expiration or termination of our potential relationships with customers and strategic partners;
- the occurrence of trade wars or barriers, or the perception that trade wars or barriers will occur; and
- other factors described in this “Risk Factors” section.

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

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

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

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. In March 2018, we entered into the 2018 At-the-Market Agreement (“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. As of December 31, 2019, 687,189 shares of our common stock have been sold under the 2018 ATM Agreement. In January 2019, we completed the 2019 follow-on public offering, pursuant to which we issued 6,764,705 shares of common stock at a public offering price of \$17.00 per share, including the exercise of the underwriters’ over-allotment option to purchase 882,352 additional shares of common stock, for aggregate net proceeds of \$107.6 million, after deducting underwriting discounts, commissions and other offering expenses. During December 2019 and January 2020, we completed a follow-on public offering of an aggregate of 7,475,000 shares of common stock at a public offering price of \$17.00 per share, including the exercise of the underwriters’ over-allotment option to purchase 975,000 additional shares of common stock, for aggregate net proceeds of \$119.2 million, after deducting underwriting discounts, commissions and other offering expenses.

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

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

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

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

- only one of our three classes of directors will be elected each year;
- no cumulative voting in the election of directors;
- the ability of our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- the exclusive right of our board of directors to elect a director to fill a vacancy or newly created directorship;
- stockholders will not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders;
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- the ability of our board of directors, by a majority vote, to amend the bylaws; and
- the requirement for the affirmative vote of at least 66 2/3 percent or more of the outstanding common stock to amend many of the provisions described above.

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

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

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

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

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

- We will indemnify our directors and officers for serving us in those capacities, or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person’s conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- We will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification.

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- The rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.
- We may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

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

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

Conversion of the Notes may dilute the ownership interest of our stockholders or may otherwise depress the price of our common stock.

The conversion of some or all of the Notes may dilute the ownership interests of our stockholders. Upon conversion of the Notes, we have the option to pay or deliver, as the case may be, cash, shares of our common stock, or a combination of cash and shares of our common stock. If we elect to settle our conversion obligation in shares of our common stock or a combination of cash and shares of our common stock, any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Notes may encourage short selling by market participants because the conversion of the Notes could be used to satisfy short positions, or anticipated conversion of the Notes into shares of our common stock could depress the price of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our headquarters are located in Newark, California, where we occupy approximately 109,000 square feet of office, laboratory and manufacturing space. The current term of our lease expires in January 2027. We have options to extend the leases for up to 14 years, which would extend our lease through January 2041. We believe that our current facilities are adequate for our needs and for the immediate future and that, should it be needed, additional space can be leased to accommodate any future growth.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

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

Our common stock has been trading on the Nasdaq under the symbol “RVNC” since our IPO on February 6, 2014. Prior to this date, there was no public market for our common stock.

Holders of Record

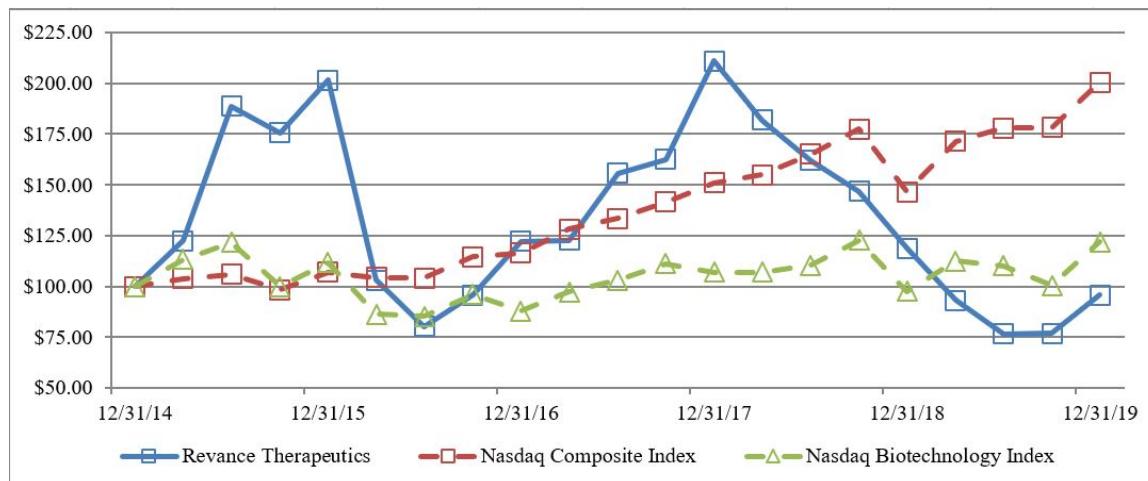
As of February 13, 2020, there were approximately 18 holders of record of our common stock, one of which was Cede & Co., a nominee for Depository Trust Company (“DTC”). All of the shares of our common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC and are therefore considered to be held of record by Cede & Co. as one stockholder.

Dividend Policy

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

Stock Price Performance Graph

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



This graph shows a comparison of the cumulative total return on our common stock, Nasdaq Biotechnology Index (“NBI”), and the Nasdaq Composite Index (“CCMP”) for the five years ended December 31, 2019. The graph assumes that \$100 was invested at the market close on the last trading day for the year ended December 31, 2014 in our common stock, the NBI, and CCMP, and assumes the reinvestment of any dividends. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

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| Company/Index | 12/31/2014 | 12/31/2015 | 12/31/2016 | 12/31/2017 | 12/31/2018 | 12/31/2019 |
|----------------------------|------------|------------|------------|------------|------------|------------|
| Revance Therapeutics, Inc. | \$ 100.00 | \$ 201.65 | \$ 122.20 | \$ 211.04 | \$ 118.83 | \$ 95.81 |
| Nasdaq Biotechnology Index | \$ 100.00 | \$ 111.77 | \$ 87.91 | \$ 106.92 | \$ 97.45 | \$ 121.91 |
| Nasdaq Composite Index | \$ 100.00 | \$ 106.96 | \$ 116.45 | \$ 150.96 | \$ 146.67 | \$ 200.49 |

Recent Sales of Unregistered Securities

On January 10, 2020, we issued 2,500,000 shares of our common stock to Teoxane SA in consideration of their granting exclusive distribution rights to Revance pursuant to the Teoxane Agreement. As the issuance did not involve a public offering of securities, the transaction was exempt from the registration requirements of the Securities Act of 1933, as amended, pursuant to Section 4(a)(2) thereof.

Issuer Purchases of Equity Securities

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

ITEM 6. SELECTED FINANCIAL DATA

The information set forth below for the five years ended December 31, 2019 is not necessarily indicative of results of future operations, and should be read in conjunction with Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations.” and Part II, Item 8. “Financial Statements and Supplementary Data.” to fully understand the factors that may affect the comparability of the information presented below.

| | Year Ended December 31, | | | | |
|--|-------------------------|--------------|--------------|--------------|--------------|
| | 2019 | 2018 | 2017 | 2016 | 2015 |
| Consolidated Statements of Operations Data: | | | | | |
| Revenue | \$ 413 | \$ 3,729 | \$ 262 | \$ 300 | \$ 300 |
| Total operating expenses | \$ 164,872 | \$ 146,363 | \$ 120,686 | \$ 88,515 | \$ 72,617 |
| Loss from operations | \$ (164,459) | \$ (142,634) | \$ (120,424) | \$ (88,215) | \$ (72,317) |
| Loss before income taxes | \$ (159,429) | \$ (139,568) | \$ (120,587) | \$ (89,270) | \$ (73,476) |
| Basic and diluted net loss | \$ (159,429) | \$ (142,568) | \$ (120,587) | \$ (89,270) | \$ (73,476) |
| Basic and diluted net loss per share | \$ (3.67) | \$ (3.94) | \$ (4.01) | \$ (3.18) | \$ (3.02) |
| | | | | | |
| | | | | | |
| | As of December 31, | | | | |
| | 2019 | 2018 | 2017 | 2016 | 2015 |
| Consolidated Balance Sheet Data: | | | | | |
| Cash and cash equivalents | \$ 171,160 | \$ 73,256 | \$ 282,896 | \$ 63,502 | \$ 201,615 |
| Short-term investments | \$ 118,955 | \$ 102,556 | \$ — | \$ 122,026 | \$ 52,439 |
| Working capital | \$ 255,623 | \$ 175,952 | \$ 264,309 | \$ 173,048 | \$ 241,926 |
| Total Assets | \$ 340,287 | \$ 226,348 | \$ 295,699 | \$ 204,360 | \$ 275,822 |
| Financing obligation, net of current portion | \$ — | \$ — | \$ — | \$ 1,872 | \$ 5,346 |
| Accumulated deficit | \$ (844,204) | \$ (684,775) | \$ (542,167) | \$ (421,543) | \$ (332,273) |

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

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

Overview

Revance Therapeutics is a biotechnology company, developing new innovations in neuromodulators for aesthetic and therapeutic indications. Revance's lead product candidate, DaxibotulinumtoxinA for Injection (DAXI), combines a proprietary stabilizing peptide excipient with a highly purified botulinum toxin that does not contain human or animal-based components. We have successfully completed a Phase 3 program for DAXI in glabellar (frown) lines. In November 2019, we submitted the BLA to the U.S. FDA for DAXI in the treatment of moderate to severe glabellar (frown) lines. The FDA accepted the BLA on February 5, 2020, and the PDUFA target action date is November 25, 2020. If the BLA is approved on or by the target action date, we plan to initiate commercialization activities for DAXI for the treatment of glabellar lines before the end of 2020. We are also evaluating DAXI in upper facial lines - glabellar lines, forehead lines and crow's feet combined - as well as in three therapeutic indications - cervical dystonia, adult upper limb spasticity and plantar fasciitis, with plans to study migraine. Beyond DAXI, Revance has begun development of a biosimilar to BOTOX®, which would compete in the existing short-acting neuromodulator marketplace. In January 2020, we entered into the Teoxane Agreement with Teoxane, pursuant to which Teoxane granted Revance with the exclusive right to import, market, promote, sell and distribute Teoxane's line of RHA® dermal fillers. Revance is dedicated to making a difference by transforming patient experiences.

Neuromodulator Pipeline

DAXI Aesthetics

Glabellar lines. In November 2019, we submitted a BLA to the FDA for DAXI in the treatment of moderate-to-severe glabellar (frown) lines. In the Phase 3 pivotal program, the median time to loss of none or mild wrinkle severity was 24 weeks and the median time to return to baseline wrinkle severity was approximately 28 weeks. The FDA accepted the BLA on February 5, 2020. If the BLA is approved on or by the PDUFA target action date, we plan to initiate commercialization activities for DAXI for the treatment of glabellar lines before the end of 2020.

Forehead lines. In January 2019, we initiated a Phase 2 multicenter, open-label, dose-escalation trial to evaluate treatment of moderate or severe dynamic forehead lines (also known as "frontalis") in conjunction with treatment of the glabellar complex. The objective is to understand the potential dosing and injection patterns of DAXI in other areas of the upper face in addition to the lead indication in glabellar lines. We completed enrollment for the study in July 2019 and we expect to release top-line results in the second quarter of 2020.

Lateral canthal lines. In March 2019, we initiated a Phase 2 multicenter, open-label, dose-escalation study to evaluate the treatment of moderate or severe lateral canthal lines (also known as "crow's feet"). The objective is to understand the potential dosing of DAXI in the lateral canthal area. We completed enrollment for the study in August 2019 and we expect to release top-line results in second quarter of 2020.

Upper Facial Lines. In December 2019, we initiated a new multicenter, open-label Phase 2 trial for treatment of the upper facial lines -- glabellar (frown), lateral canthal (crow's feet), and forehead lines combined -- to understand the safety and efficacy, including potential dosing and injection patterns, of DAXI, covering the upper facial lines. We expect to complete enrollment in first quarter of 2020, with topline results in fourth quarter of 2020. This trial is in addition to the existing open-label Phase 2 clinical trials that the company has already fully enrolled in forehead lines and crow's feet.

DAXI Therapeutics

Cervical dystonia. In 2018, we initiated two Phase 3 clinical trials for cervical dystonia. ASPEN-1 Phase 3 is a 301-subject, randomized, double-blind, placebo-controlled trial comparing two doses of DAXI (125 Units and 250 Units) to placebo. We completed the ASPEN-1 Phase 3 pivotal trial enrollment in October 2019 and expect to release top-line results in the third quarter of 2020. ASPEN-OLS is a 350-subject, open-label study that includes subjects rolling over from ASPEN-1, plus additional newly enrolled subjects. We expect to complete the ASPEN-OLS trial enrollment in the second half of 2020.

Adult upper limb spasticity. In December 2018, we initiated a Phase 2 trial for the treatment of adult upper limb spasticity (JUNIPER). This is a randomized, double-blind, placebo-controlled, parallel group, dose-ranging trial to evaluate the efficacy and safety of DAXI for the treatment of upper limb spasticity in adults after stroke or traumatic brain injury. We expect to complete the JUNIPER Phase 2 trial enrollment by mid-2020.

Plantar fasciitis. In September 2018, we completed a Type C meeting with the 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. We completed the Phase 2 trial enrollment in December 2019. We expect to release topline results in the second half of 2020.

Migraine. As part of our 2020 planning process, we decided to delay the initiation of migraine clinical trials this year and will re-evaluate the timing next year as part of our 2021 planning cycle.

Follow-On Public Offering

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

During December 2019 and January 2020, we completed a follow-on public offering of an aggregate of 7,475,000 shares of common stock at \$17.00 per share including the exercise of the underwriters' over-allotment option to purchase 975,000 additional shares of common stock, for net proceeds of \$119.2 million, after underwriting discounts, commissions and other offering expenses.

Teoxane Exclusive Distribution Agreement

In January 2020, we entered into the Teoxane Agreement with Teoxane, pursuant to which Teoxane granted us with the exclusive right to import, market, promote, sell and distribute Teoxane's line of Resilient Hyaluronic Acid® dermal fillers, which include i) RHA® 2, RHA® 3 and RHA® 4 which have been approved by the FDA for the correction of moderate to severe dynamic facial wrinkles and folds, including RHA® 2, RHA® 3 and RHA® 4 in the currently approved indications, ii) RHA® 1, which we anticipate will be approved by the FDA in 2021 for the treatment of perioral rhytids, the indication currently in ongoing clinical trials, and iii) future hyaluronic acid filler advancements and products by Teoxane (collectively the "RHA® dermal fillers") in the U.S. and U.S. territories and possessions, in exchange for 2,500,000 shares of our common stock and certain other commitments by us. The Teoxane Agreement will be effective for a term of ten years upon product launch and may be extended for a two-year period upon the mutual agreement of the parties.

We have begun to build out a U.S. commercial organization and plan to introduce the FDA approved RHA® dermal fillers in the U.S. in the second quarter of 2020.

OnabotulinumtoxinA Biosimilar

In February 2019, we had a BIAM with the FDA and Mylan on a proposed biosimilar to BOTOX®. Based on the FDA's feedback, the companies believe that a 351(k) pathway for the development of a biosimilar to onabotulinumtoxinA is viable. In April 2019, we received the official FDA minutes from the BIAM.

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In August 2019, we entered into the Mylan Amendment and agreed, among other things, to extend the period of time for Mylan to make a decision under the Mylan Collaboration (“Continuation Decision”) as to whether to continue the biosimilar development program beyond the initial development plan and the BIAM. Mylan is now required to notify us of the Continuation Decision on or before the later of (i) April 30, 2020 or (ii) 30 calendar days from the date that we provide Mylan with certain deliverables. Additionally, Mylan agreed and incrementally paid \$5.0 million to the previously agreed non-refundable upfront payment of \$25.0 million with contingent payments of up to \$100.0 million, in the aggregate, upon the achievement of specified clinical and regulatory milestones, tiered sales milestones of up to \$225.0 million, and royalties on sales of the biosimilar in the Mylan territories previously disclosed from the Mylan Collaboration.

Fosun License Agreement

In January 2019, in connection with the Fosun License Agreement executed in December 2018, we received from Fosun a non-refundable upfront payment of \$30.0 million, net of foreign withholding tax of \$3.0 million.

Results of Operations

A discussion regarding our financial condition and results of operations for the year ended December 31, 2019 compared to the same period in 2018 is presented below. For a discussion regarding our financial condition and results of operations for the year ended December 31, 2018 compared to the same period in 2017, see Part II, Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations” of our Annual Report on Form 10-K for the year ended December 31, 2018, as filed with the SEC on February 28, 2019 (File No. 001-36297).

Revenue

| (in thousands, except percentages) | Year Ended December 31, | | | 2019 vs. 2018 |
|------------------------------------|-------------------------|-----------------|---------------|---------------|
| | 2019 | 2018 | 2017 | |
| Milestone | \$ 413 | \$ 3,729 | \$ — | (89)% |
| Relastin Royalty | — | — | 262 | — % |
| Total revenue | \$ 413 | \$ 3,729 | \$ 262 | (89)% |

Our total revenue for the year ended December 31, 2019 decreased \$3.3 million or 89% compared to the same period in 2018, primarily due to the timing of the initial development activities from the Mylan Collaboration which was completed in February 2019.

Operating Expenses

Our operating expenses consist of research and development expenses and general and administrative expenses. The largest component of our operating expenses is our personnel costs including stock-based compensation. We expect our operating expenses to increase in the near term as we prepare to commercialize the Teoxane RHA® dermal fillers in the U.S. and, if the BLA is approved on or before the PDUFA target action date, DAXI for treatment of glabellar lines, initiate and complete additional clinical trials and associated programs related to DAXI for the treatment of facial wrinkles, cervical dystonia, plantar fasciitis, adult upper limb spasticity, and any future new indications, and our biosimilar product candidate.

Research and Development Expenses

We recognize research and development expenses as they are incurred. Since our inception, we have focused on our clinical development programs and the related research and development. Since 2002, we have been developing one or more of DAXI, DaxibotulinumtoxinA Topical, and our biosimilar product candidate and have typically shared our employees, consultants and infrastructure resources across all programs. We believe that the strict allocation of costs by product candidate would not be meaningful, therefore, we generally do not track these costs by product candidates.

Research and development expenses consist primarily of:

- salaries and related expenses for personnel in research and development functions, including stock-based compensation;

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- expenses related to the initiation and completion of clinical trials and studies for DAXI, DaxibotulinumtoxinA Topical and our biosimilar candidate, including expenses related to production of clinical supplies;
- fees paid to clinical consultants, contract research organizations (“CROs”) and other vendors, including all related fees for investigator grants, patient screening fees, laboratory work and statistical compilation and analysis;
- other consulting fees paid to third parties;
- expenses related to establishment and maintenance of our own manufacturing facilities;
- expenses related to the manufacture of drug substance and drug product supplies for ongoing and future preclinical and clinical trials and other pre-commercial supplies;
- expenses to support our product development and establish manufacturing capabilities to support potential future commercialization of any products for which we may obtain regulatory approval;
- expenses related to license fees and milestone payments under in-licensing agreements;
- expenses related to compliance with drug development regulatory requirements in the U.S., the European Union and other foreign jurisdictions; and
- depreciation and other allocated expenses.

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

Our research and development expenses fluctuate as projects transition from one development phase to the next. Depending on the stage of completion and level of effort related to each development phase undertaken, we may reflect variations in our research and development expenses. We expense both internal and external research and development expenses as they are incurred.

Our research and development expenses are summarized as follows:

| (in thousands, except percentages) | Year Ended December 31, | | 2019 vs. 2018 |
|---|-------------------------|------------------|---------------|
| | 2019 | 2018 | |
| Clinical and regulatory | \$ 52,191 | \$ 47,777 | 9 % |
| Manufacturing and quality | 32,226 | 25,857 | 25 % |
| Other research and development expenses | 9,932 | 11,386 | (13)% |
| Stock-based compensation | 8,512 | 7,480 | 14 % |
| Total research and development expenses | <u>\$ 102,861</u> | <u>\$ 92,500</u> | 11 % |

Clinical and regulatory

Clinical and regulatory expenses include personnel costs, external clinical trial costs for clinical sites, clinical research organizations, central laboratories, data management, contractors and regulatory activities associated with the development of DAXI. For the years ended December 31, 2019, and 2018, clinical and regulatory expenses totaled \$52.2 million, or 51%, and \$47.8 million, or 52% of the total research and development expenses in 2019 and 2018, respectively.

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Clinical and regulatory expenses for the year ended December 31, 2019 increased by 9%, compared to the same period in 2018, primarily due to increased expenses related to hiring additional personnel and outside services to support BLA preparation activities. We expect to maintain our clinical and regulatory expenses in the near term as we initiate and complete clinical trials and other associated programs related to DAXI for the treatment forehead lines, lateral canthal lines, cervical dystonia, plantar fasciitis, adult upper limb spasticity, and migraine.

Manufacturing and quality

Manufacturing and quality expenses include personnel and occupancy expenses, external contract manufacturing costs and pre-approval manufacturing of drug product used in our research and development of DAXI. Manufacturing and quality expenses also include raw materials, lab supplies, and storage and shipment of our product to support quality control and assurance activities. These expenses do not include clinical expenses associated with the development of DAXI. For the years ended December 31, 2019 and 2018, our manufacturing and quality expenses were \$32.2 million, or 31%, and \$25.9 million, or 28% of the total research and development expenses in 2019 and 2018, respectively.

Manufacturing and quality expenses for the year ended December 31, 2019 increased by 25%, compared to the same period in 2018, primarily due to increased expenses related to pre-BLA manufacturing and quality activities, hiring additional personnel and outside services to address compliance requirements, and infrastructure build-out. We expect to increase our manufacturing and quality efforts as we approach commercialization.

Other research and development expenses

Other research and development expenses include expenses for personnel, contract research organizations, consultants, raw materials, and lab supplies used to conduct preclinical research and development of DAXI and our biosimilar product candidate. Other research and development expenses were \$9.9 million, or 10%, and \$11.4 million, or 12% for the years ended on December 31, 2019 and 2018, respectively.

Other research and development expenses for the year ended December 31, 2019 decreased by 13%, compared to the same period in 2018, primarily due to the expenses related to the initial development activities from the Mylan Collaboration, which was completed in February 2019. The level of efforts related to the biosimilar development program in 2020 may depend on Mylan's Continuation Decision, expected by end of April 2020.

Stock-based compensation

Stock-based compensation included in research and development increased by \$1.0 million, or 14%, for the year ended December 31, 2019 compared to the same period in 2018, primarily due to an increase in employee headcount, offset by an average decrease in the fair value of stock option granted during those periods.

General and Administrative Expenses

General and administrative expenses consist primarily the following:

- pre-activities including market research, public relations, promotion and advertising;
- personnel and service costs in our finance, information technology, commercial, investor relations, legal, human resources, and other administrative functions, including stock-based compensation; and
- professional fees for accounting and legal services, including legal services associated with obtaining and maintaining patents and litigation.

We expect that our general and administrative expenses will increase with the launch of the RHA® dermal fillers and the continued development of, and if approved, the commercialization of DAXI.

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Our general and administration expenses are summarized as follows:

| (in thousands, except percentages) | Year Ended December 31, | | 2019 vs. 2018 |
|---|-------------------------|------------------|---------------|
| | 2019 | 2018 | |
| General and administrative expenses before stock-based compensation | \$ 52,601 | \$ 45,070 | 17% |
| Stock-based compensation | 9,410 | 8,793 | 7% |
| Total general and administrative expenses | \$ 62,011 | \$ 53,863 | 15% |

General and administrative expenses before stock-based compensation

General and administrative expenses for the year ended December 31, 2019 increased by 17%, compared to the same period in 2018, primarily due to ramp up in pre-commercial activities, increased personnel in commercial and administrative functions, and costs related to infrastructure build-out.

Stock-based compensation

Stock-based compensation included in general and administrative expenses for the year ended December 31, 2019 increased by \$0.6 million, or 7%, compared to the same period in 2018, primarily due to stock-based award modifications in connection with certain employees' termination and increased employee headcount, offset by an average decrease in fair value of stock option granted during the period.

Net Non-Operating Income and Expense

Interest Income

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

Interest Expense

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

Change in Fair Value of Derivative Liability

The derivative liability on our consolidated balance sheet is remeasured to fair value at each balance sheet date with the corresponding gain or loss recorded. We will continue to record adjustments to the fair value of derivative liability until we make the payment.

Other Expense, net

Other expense, net primarily consists of miscellaneous tax and other expense items.

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Our net non-operating income and expense are summarized as follows:

| (in thousands, except percentages) | Year Ended December 31, | | 2019 vs. 2018 |
|---|-------------------------|-----------------|---------------|
| | 2019 | 2018 | |
| Interest income | \$ 5,532 | \$ 4,023 | 38% |
| Interest expense | — | (44) | (100)% |
| Changes in fair value of derivative liability | (199) | (140) | 42 % |
| Other expense, net | (303) | (773) | (61)% |
| Total net non-operating income | \$ 5,030 | \$ 3,066 | 64 % |

Our total net non-operating income for the year ended December 31, 2019 increased by \$2.0 million, compared to the same period in 2018, primarily due to our higher cash balances available for investment activities and higher net interest rates in 2019.

Income Tax Provision

Since inception, we have incurred net losses and have not recorded any U.S. federal or state income tax and the tax benefits of our operating losses have been fully offset by valuation allowances. There was no provision or benefit from income taxes for the year ended December 31, 2019. The tax provision of \$3.0 million for the year ended December 31, 2018 was a foreign withholding tax associated with the Fosun License Agreement.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

| (in thousands) | Year Ended December 31, | | |
|--|-------------------------|------------|---------------------|
| | 2019 | 2018 | Increase (Decrease) |
| Cash, cash equivalents, and short-term investments | \$ 290,115 | \$ 175,812 | \$ 114,303 |
| Working Capital | \$ 255,623 | \$ 175,952 | \$ 79,671 |
| Stockholders' Equity | \$ 225,490 | \$ 145,622 | \$ 79,868 |

Sources and Uses of Cash

We hold our cash, cash equivalents, and short-term investments in a variety of non-interest bearing bank accounts and interest-bearing instruments subject to investment guidelines allowing for certain lower-risk holdings such as, but not limited to, money market accounts, U.S. treasury securities, U.S. government and agency securities, overnight purchase agreements, and commercial paper. Our investment portfolio is structured to provide for investment maturities and access to cash to fund our anticipated working capital needs.

Our cash, cash equivalents and short-term investments totaled \$290.1 million as of December 31, 2019 compared to \$175.8 million as of December 31, 2018, representing an increase of \$114.3 million, which was primarily due to the proceeds from issuance of common stock (net of commissions and discount) of \$212.0 million in connection with the 2019 follow-on offerings, the proceeds from issuance of common stock in connection with at-the-market offerings, net of commissions of \$10.9 million, and the upfront payment (net of withholding tax) received under the Fosun License Agreement of \$27.0 million, and the incremental payment received from the Mylan of \$5 million. These increases were primarily offset by cash used in other operating activities of \$138.2 million.

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We derived the following summary of our consolidated statement of cash flows for the periods indicated from our audited consolidated financial statements included elsewhere in this Form 10-K:

| (in thousands) | Year Ended December 31, | |
|---------------------------------|--------------------------------|--------------|
| | 2019 | 2018 |
| Net cash provided by (used in): | | |
| Operating activities | \$ (106,161) | \$ (104,246) |
| Investing activities | \$ (17,592) | \$ (107,026) |
| Financing activities | \$ 221,657 | \$ 1,782 |

Cash Flows from Operating Activities

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

Net cash used in operating activities for the year ended December 31, 2019 of \$106.2 million, which was primarily due to clinical spend of approximately \$35 million to advance our clinical programs toward commercialization; investing in our personnel and talent retention, which represents approximately \$43 million; professional services and consulting of approximately \$39 million; and rent, supplies and utilities of \$18 million; offset by the upfront payment, net with withholding tax, received under the Fosun License Agreement of \$27 million, and the incremental payment received from Mylan of \$5 million. The remaining balance of operating activities related primarily to other supplies.

Net cash used in operating activities for the year ended December 31, 2018 of \$104.2 million was primarily due to clinical spend of approximately \$38.5 million to advance our clinical programs toward commercialization; investing in our personnel and talent retention, which represents approximately \$31.0 million; and professional services and consulting of approximately \$32.0 million, offset by the \$25.0 million upfront payment received from the Mylan Collaboration. The remaining balance of operating activities related primarily to rent, utilities, and other supplies.

Cash Flows from Investing Activities

Net cash used in investing activities for the year ended December 31, 2019 and 2018 was primarily due to purchases of property and equipment, proceeds from sale of property and equipment, and fluctuations in the timing of purchases, sales and maturities of short-term investments.

Cash Flows from Financing Activities

Net cash provided by financing activities for the year ended December 31, 2019 are primarily driven by proceeds from the issuance of our common stock in connection with follow-on offerings (as described below), ATM offering (as described below), and proceeds from the exercise of stock options and employee stock purchase plan, offset by net settlement of restricted stock awards for employee taxes and payment of offering costs. Net cash provided by financing activities for the year ended December 31, 2018 are primarily driven by proceeds from stock option exercises and employee stock plan purchases, offset by net settlement of restricted stock awards for employee taxes, principal payments made on financing obligations, and payment of offering costs.

Follow-On Public Offerings

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

During December 2019 and January 2020, we completed a follow-on public offering of an aggregate of 7,475,000 shares of common stock at \$17.00 per share including the exercise of the underwriters' over-allotment option to purchase 975,000 additional shares of common stock, for net proceeds of \$119.2 million, after underwriting discounts, commissions and other offering expenses, of which \$103.6 million was received in December 2019.

ATM Offering

Under 2018 ATM Agreement, we may offer and sell common stock having aggregate proceeds of up to \$125.0 million from time to time through Cantor Fitzgerald as our sales agent. As of December 31, 2019, we issued 687,189 shares for net proceeds of \$10.9 million after underwriting discounts, commissions and other offering expenses, under the 2018 ATM Agreement.

Convertible Senior Notes Due 2027

On February 14, 2020, we issued an aggregate of \$287.5 million principal amount of notes, pursuant to an Indenture, dated February 14, 2020, between Revance and U.S. Bank National Association, as trustee (the "Notes"). The Notes are senior unsecured obligations of Revance and will bear interest at a rate of 1.75% per year, payable semiannually in arrears on February 15 and August 15 of each year, beginning on August 15, 2020. The Notes will mature on February 15, 2027, unless earlier converted, redeemed or repurchased. The Notes are convertible into cash, shares of our common stock, or a combination of cash and shares of our common stock, at our election. We received approximately \$278.4 million in net proceeds, after deducting the initial purchasers' discount, commissions, and estimated expenses payable by us, from the issuance of the Notes. We may not redeem the Notes prior to February 20, 2024, and 0 sinking fund is provided for the Notes.

We used approximately \$28.9 million of the net proceeds from the Notes to pay the cost of certain capped call transactions. The capped call transactions are expected generally to reduce potential dilution to our common stock upon any conversion of Notes and/or offset any cash payments we are required to make in excess of the principal amount of converted Notes.

Common Stock and Common Stock Equivalents

As of February 13, 2020, outstanding shares of common stock were 56,926,751, outstanding stock options were 5,246,837, and unvested restricted stock awards, including unvested performance stock awards, were 2,804,720.

Operating and Capital Expenditure Requirements

We have not achieved profitability on a quarterly or annual basis since our inception and we expect to continue to incur net losses for the foreseeable future. We expect to make additional capital outlays to increase operating expenditures over the next several years to support the completion of the clinical trials and other associated programs relating to DAXI for the treatment of glabellar lines, cervical dystonia, plantar fasciitis, adult upper limb spasticity, migraine headache, and other indications, seek regulatory approval, prepare for and, if approved, proceed to commercialization, as well as efforts to introduce and sell the Teoxane RHA® dermal fillers in the U.S. in 2020. We believe that our existing capital resources will be sufficient to fund our operations for at least the next 12 months following the filing of this Form 10-K. However, we anticipate that we may need to raise substantial additional financing in the future to fund our operations. In order to meet these additional cash requirements, we may seek to sell additional equity or issue debt, convertible debt or other securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of debt or convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring debt, making capital expenditures or declaring dividends. Our failure to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on our business, results of operations, and financial condition.

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

- the results of our clinical trials for DAXI and preclinical trials of DaxibotulinumtoxinA Topical, biosimilar or any future product candidates;
- the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results, or that positive results would assure regulatory approval or commercial success of our 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;
- our plans to research, develop and commercialize the RHA® dermal fillers and our other product candidates, including the potential for commercialization by us of DAXI, if approved;
- the cost of commercialization activities for the RHA® dermal fillers and, if approved for sale, DAXI or any future product candidates including DaxibotulinumtoxinA Topical or biosimilar, 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 successfully commercialize the RHA® dermal fillers and our other product candidates and the timing of commercialization activities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements, including the Mylan collaboration, and the terms of and timing such arrangements;
- that we may not obtain the anticipated financial and other benefits of the Teoxane Agreement, including our ability to realize anticipated synergies and successfully commercialize the RHA® dermal fillers
- the commercial acceptance and potential of the RHA® dermal fillers, including market size and anticipated adoption rates;
- 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;
- our ability to establish our marketing, sales, and distribution functions if we receive regulatory approval for our product candidates;
- our ability to effectively and reliably manufacture supplies of DAXI, biosimilar or any future product candidates and to develop, validate and maintain a commercially viable manufacturing processes, as well as our ability to acquire supplies of RHA® dermal fillers from Teoxane;
- any product liability or other lawsuits related to our products;

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

Please read Part I, Item 1A. "Risk Factors" for additional risks associated with our substantial capital requirements.

Since inception, we have devoted substantially all of our efforts to identifying and developing product candidates for the aesthetic and therapeutic pharmaceutical markets, recruiting personnel, raising capital, conducting preclinical and clinical development of, and manufacturing development for DAXI and DaxibotulinumtoxinA Topical. We have incurred losses and negative cash flows from operations. We have not yet commenced commercial operations, have not generated product revenue to date, and will continue to incur significant research and development and other expenses related to our ongoing operations. We have recorded net losses of \$159.4 million and \$142.6 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had a working capital surplus of \$255.6 million and an accumulated deficit of \$844.2 million. In recent years, we have funded our operations primarily through the sale and issuance of common stock and, in February 2020, convertible senior notes. As of December 31, 2019, we had capital resources consisting of cash, cash equivalents, and short-term investments of \$290.1 million. In January 2019, we received \$27.0 million for an upfront payment net of foreign withholding tax from Fosun. In January 2019, we completed the 2019 follow-on offering for net proceeds of \$107.6 million after underwriting discounts, commissions and other offering expenses. During December 2019 and January 2020, we completed a follow-on public offering of an aggregate of 7,475,000 shares of common stock at \$17.00 per share including the exercise of the underwriters' over-allotment option to purchase 975,000 additional shares of common stock, for net proceeds of \$119.2 million, after underwriting discounts, commissions and other offering expenses. As of December 31, 2019, we issued 687,189 shares for net proceeds of \$10.9 million after underwriting discounts, commissions and other offering expenses, under the 2018 ATM Agreement. In February 2020, we issued Notes and certain capped call transaction for aggregate net proceeds of approximately \$249.5 million after discounts, commissions, estimated offering expenses payable by us, and costs of the capped call transactions. We believe that our existing cash and cash equivalents will allow us to fund our operating plan through at least the next 12 months following the issuance of this Form 10-K, and may identify additional capital resources to fund our operations.

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires our management to make estimates, assumptions and judgments that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the applicable periods. We base our estimates, assumptions and judgments on historical experience and on various other factors that we believe to be reasonable under the circumstances. Different assumptions and judgments would change the estimates used in the preparation of our consolidated financial statements, which, in turn, could change the results from those reported. We evaluate our estimates, assumptions and judgments on an ongoing basis.

The critical accounting estimates, assumptions and judgments that we believe have the most significant impact on our consolidated financial statements are described below.

Revenue

Effective January 1, 2018, we adopted Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606), using the full retrospective transition method. We elected to use certain practical expedients permitted related to adoption (Note 3) and the adoption of ASC 606 had no impact on our financial position, results of operations or liquidity. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services.

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

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

Clinical Trial Accruals

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

The CRO contracts generally include pass-through fees including, but not limited to, regulatory expenses, investigator fees, travel costs and other miscellaneous costs, including shipping and printing fees. We estimate our clinical accruals based on reports from and discussion with clinical personnel and outside services providers as to the progress or state of completion of trials, or the services completed. We estimate accrued expenses as of each balance sheet date based on the facts and circumstances known at that time. Our clinical trial accrual is dependent, in part, upon the receipt of timely and accurate reporting from the CROs and other third-party vendors. As of December 31, 2019, there have not been any material adjustments to our estimated accrued clinical expenses.

Stock-Based Compensation

We have an equity compensation plan under which various types of stock-based awards including, but not limited to, stock option, restricted stock awards, and performance stock awards, may be granted to employees, non-employee directors, and non-employee consultants. We also have an inducement plan under which various types of stock-based awards, including stock options, restricted stock awards, and performance stock awards, may be granted to new employees.

We measure our stock-based awards using the estimated grant-date fair values. For stock options issued under the 2014 Equity Incentive Plan (“2014 EIP”) and the 2014 Inducement Plan (“2014 IN”), and shares purchased under the 2014 Employee Stock Purchase Plan (the “2014 ESPP”), fair values are determined using the Black-Scholes option pricing model. For restricted stock awards including performance stock awards subject to performance-based vesting conditions, the grant-date fair values are based on the closing prices of our common stock on the grant dates. For performance stock awards subject to market conditions, fair values are determined using the Monte Carlo simulation model.

For stock-based awards other than performance stock awards subject to performance-based vesting conditions, the value of the stock-based awards is recognized as compensation expense over the requisite service period (generally the vesting period). For performance stock awards subject to performance-based vesting conditions, the value of the stock-based awards is recognized as compensation expense when the performance condition is probable of achievement. Stock-based compensation expenses are classified in the consolidated statements of operations and comprehensive loss based on the functional area to which the related recipients belong. Forfeitures are recognized when they occur.

The estimated grant date fair values of the stock options granted to all employees and non-employees during the year ended December 31, 2019 were calculated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

| | Year Ended December 31, 2019 |
|--------------------------|---|
| Expected term (in years) | 6.0 |
| Expected volatility | 60.2% |
| Risk-free interest rate | 2.1% |
| Expected dividend rate | —% |

The estimated grant date fair values of the stock options granted to all employees and non-employees directors during the year ended December 31, 2018 were calculated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

| | Year Ended December 31, 2018 |
|--------------------------|---|
| Expected term (in years) | 6.0 |
| Expected volatility | 60.2% |
| Risk-free interest rate | 2.7% |
| Expected dividend rate | —% |

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

- *Expected Term.* For stock options, the expected term is based on the simplified method, as our stock options have the following characteristics: (i) granted at-the-money; (ii) exercisability is conditioned upon service through the vesting date; (iii) termination of service prior to vesting results in forfeiture; (iv) limited exercise period following termination of service; and (v) options are non-transferable and non-hedgeable, or “plain vanilla” options, and we have limited history of exercise data. For stock options granted to non-employees before adoption of ASU 2018-07 on July 1, 2018, the expected term is based on the remaining contractual term. For ESPP, the expected term is based on the term of the purchase period under the 2014 ESPP.

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- *Expected Volatility.* The expected volatility is based on the historical volatilities of a group of similar entities combined with the historical volatility of us. In evaluating similarity, we considered factors such as industry, stage of life cycle, capital structure, and company size.
- *Risk-Free Interest Rate.* The risk-free interest rate is based on U.S. Treasury constant maturity rates with remaining terms similar to the expected term of the stock options.
- *Expected Dividend Rate.* We use an expected dividend rate of zero because we have never paid any dividends and do not plan to pay dividends in the foreseeable future.

Effective July 1, 2018, we adopted ASU 2018-07, *Compensation - Stock Compensation (Topic 718)* using a retroactive approach. All non-employee stock-based awards granted prior to adoption were remeasured at fair value as of July 1, 2018. Before adoption, compensation expense for stock options granted to non-employee consultants was recognized based on the fair value of the stock options, determined using the Black-Scholes option pricing model, as they are earned. The stock-based awards vest over the time period we expect to receive services from the non-employee consultants. After adoption, all non-employee stock-based awards granted are measured at grant-date fair value, and such grant-date fair value is recognized as compensation expense over the requisite service period (generally the vesting period). Refer to consolidated statements of stockholders' equity for cumulative adjustments from adoption ASU 2018-07.

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

Performance Stock Awards Subject to Market-based Vesting Conditions

Certain performance stock awards granted in 2019 include market-based vesting conditions (“market-based PSAs”). These market-based PSAs vest upon the earlier of i) the date that the closing share price of our common stock meet certain minimum share prices on a volume-weighted basis for a specified period of time or ii) upon a change in control in which the purchase price of our common stock is at or above the same minimum share prices as determined in the award agreement.

We determined the fair value of the market-based PSAs using the Monte Carlo simulation model. The following weighted-average assumptions were used in the Monte Carlo simulation model in determining fair value of these performance stock awards:

| | Year Ended December 31, 2019 |
|---|---|
| Expected term (in years) ⁽¹⁾ | 10.0 |
| Expected volatility ⁽²⁾ | 60.0% |
| Risk-free interest rate | 1.8% |
| Expected dividend rate | —% |

(1) Expected term was based on the expiration period of the performance stock awards in the award agreement.

(2) Expected volatility was based on the historical volatilities of a group of similar entities combined with our historical volatility.

For the year ended December 31, 2019, we recognized stock-based compensation expense of \$0.5 million for the market-based PSAs.

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Unrecognized Compensation Cost

| | As of December 31, | | | |
|--------------------------------------|--|--|--|--|
| | 2019 | | 2018 | |
| | Unrecognized Compensation Cost (in thousands) | Weighted Average Expected Recognize Period (in years) | Unrecognized Compensation Cost (in thousands) | Weighted Average Expected Recognize Period (in years) |
| Stock options | \$ 18,487 | 2.9 | \$ 20,202 | 2.7 |
| Restricted stock awards | 11,891 | 2.3 | 10,591 | 2.4 |
| Performance stock awards | 8,839 | 2.4 | — | — |
| Total unrecognized compensation cost | <u>\$ 39,217</u> | 2.6 | <u>\$ 30,793</u> | 2.6 |

Contractual Obligations

Our contractual commitments will have an impact on our future liquidity. The following table, which summarizes our contractual obligations as of December 31, 2019, represents material expected or contractually committed future obligations, with terms in excess of one year. We believe that we will be able to fund these obligations through cash generated from funding activities and from our existing cash balances.

| Contractual Obligations | Payment due by period | | | | |
|-----------------------------|-----------------------|------------------|-----------------|-----------|-------------------|
| | Total | Less than 1 year | 1-3 years | 3-5 years | More than 5 years |
| | | | (In thousands) | | |
| Operating lease obligations | \$ 42,657 | \$ 6,735 | \$ 12,406 | \$ 11,290 | \$ 12,226 |

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

- We are obligated to pay milestone and royalties to List Laboratories on future sales of botulinum toxin products.
- We also have one future milestone payment of \$4.0 million due to certain settlement agreement in 2012 upon the achievement of regulatory approval for DAXI or DaxibotulinumtoxinA Topical.
- In June 2016, we entered into BTRX Purchase Agreement in which we agreed to pay up to an additional \$16.0 million in aggregate upon the satisfaction of specified milestones relating to our sales revenue, intellectual property, and clinical and regulatory events. In exchange, we acquired all rights, title and interest in a portfolio of botulinum toxin-related patents and patent applications from BTRX and were granted the right of first negotiation and first refusal with respect to other botulinum toxin-related patents owned or controlled by BTRX.
- In April 2016, we entered into an agreement with BioSentinel, Inc. to in-license their technology and expertise for research and development and manufacturing purposes. In addition to minimum quarterly use fees, we are obligated to make a one-time future milestone payment of \$0.3 million payable to BioSentinel, Inc. upon the achievement of regulatory approval.
- In March 2017, we entered into the Althea Services Agreement, under which Althea has agreed to provide us with a future source of commercial fill/finish services for our neuromodulator products. The Althea Services Agreement has an initial term that will expire in 2024, unless terminated sooner by either party. In accordance with the Althea Services Agreement, and we have minimum purchase obligations based on our production forecasts.

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- In January 2020, we entered into the Teoxane Agreement. Pursuant to the Teoxane Agreement, if Teoxane pursues regulatory approval for the RHA® dermal fillers for certain new indications or filler technologies, including innovations with respect to existing products in the U.S., we will be subject to certain specified cost-sharing arrangements for third party expenses incurred in achieving regulatory approval for such products. We are required to meet certain minimum purchase obligations during each year of the term. We are also required to meet certain minimum expenditure requirements in connection with commercialization efforts.

Off-Balance Sheet Arrangements

As of December 31, 2019, we did not have any material off-balance-sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

Recent Accounting Pronouncements

Please read Part IV, Item 15. “Exhibits and Financial Statement Schedules—Notes to consolidated financial statements—Note 2—Summary of Significant Accounting Policies” in this Annual Report on Form 10-K.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Sensitivity

Our exposure to market risk for changes in interest rates relates primarily to our cash, cash equivalents, and short-term investments. We had cash, cash equivalents, and short-term investments of \$290.1 million and \$175.8 million as of December 31, 2019 and 2018, respectively. As of December 31, 2019, our cash, cash equivalents, and short-term investments were held in deposit, money market funds, U.S. treasury securities, U.S. government agency obligations, commercial paper, and overnight repurchase agreements. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates in the U.S. A hypothetical 10% movement in interest rates would not be expected to have a material impact on our consolidated financial statements. We mitigate market risk for changes in interest rates by holding our short-term investments in U.S. treasury securities, U.S. government agency obligations, commercial paper, and overnight repurchase agreements to maturity.

Foreign Exchange

Our operations are primarily conducted in the U.S. using the U.S. Dollar. However, we conduct limited operations in foreign countries, primarily for clinical and regulatory services, whereby settlement of our obligations are denominated in the local currency. Transactional exposure arises when transactions occur in currencies other than the U.S. Dollar. Transactions denominated in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction with the resulting liabilities being translated into the U.S. Dollar at exchange rates prevailing at the balance sheet date. The resulting gains and losses, which were insignificant for the years ended December 31, 2019, and 2018, are included in other expense in the consolidated statement of operations and comprehensive loss. We do not use currency forward exchange contracts to offset the related effect on the underlying transactions denominated in a foreign currency.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements are set forth beginning on page [F-5](#) in this Annual Report on Form 10-K and are incorporated herein by reference.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial and accounting officer) of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, our principal executive officer and principal financial and accounting officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of December 31, 2019, the end of the period covered by this report.

Management's Report on Internal Control Over Financial Reporting

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

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

Under the supervision and with the participation of our management, including our principal executive officer and principal financial and accounting officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2019 based on the criteria established in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Based on our evaluation, our management concluded our internal control over financial reporting was effective as of December 31, 2019.

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report on pages [F2 to F4](#) in Part IV, Item 15 in this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

For the three months ended December 31, 2019, there were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be included in our proxy statement for the 2020 Annual Meeting of the Stockholders (“2020 Proxy Statement”), which will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates, and is incorporated by reference.

Code of Business Conduct.

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

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be included in our 2020 Proxy Statement, which will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates, and is incorporated by reference.

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

The information required by this item will be included in our 2020 Proxy Statement, which will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates, and is incorporated by reference.

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

The information required by this item will be included in our 2020 Proxy Statement, which will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates, and is incorporated by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be included in our 2020 Proxy Statement, which will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates, and is incorporated by reference.

PART IV**ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

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

- (1) Financial Statements. The financial statements required by this item are set forth beginning at F-1 in this Annual Report on Form 10-K and are incorporated herein by reference.
- (2) Financial Statement Schedules. None. Financial statement schedules have been omitted because they are not applicable.
- (3) Exhibits: See Item 15(b) below.

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

EXHIBIT INDEX

| Exhibit Number | Exhibit Description | Incorporated by Reference | | | | Filed Herewith |
|----------------|--|---------------------------|------------|---------|-------------------|----------------|
| | | Form | File No. | Exhibit | Filing Date | |
| 3.1 | Amended and Restated Certificate of Incorporation | 8-K | 001-36297 | 3.1 | February 11, 2014 | |
| 3.2 | Amended and Restated Bylaws | S-1 | 333-193154 | 3.4 | December 31, 2013 | |
| 4.1 | Form of Common Stock Certificate | S-1/A | 333-193154 | 4.4 | February 3, 2014 | |
| 4.2 | Indenture, dated as of February 14, 2020, by and between Revance Therapeutics, Inc. and U.S. Bank National Association, as Trustee | 8-K | 001-36297 | 4.1 | February 14, 2020 | |
| 4.3 | Form of Global Note, representing Revance Therapeutics, Inc.'s 1.75% Convertible Senior Notes due 2027 (included as Exhibit A to the Indenture filed as Exhibit 4.2) | 8-K | 001-36297 | 4.2 | February 14, 2020 | |
| 4.4 | Description of Registrant's Securities | — | — | — | — | X |
| 10.1* | Revance Therapeutics, Inc. 2002 Equity Incentive Plan | S-1 | 333-193154 | 10.1 | December 31, 2013 | |
| 10.2* | Form of Stock Option Agreement and Option Grant Notice for Revance Therapeutics, Inc. 2002 Equity Incentive Plan | S-1 | 333-193154 | 10.2 | December 31, 2013 | |
| 10.3* | Revance Therapeutics, Inc. Amended and Restated 2012 Equity Incentive Plan | S-1 | 333-193154 | 10.3 | December 31, 2013 | |
| 10.4* | Form of Stock Option Agreement and Option Grant Notice for Revance Therapeutics, Inc. Amended and Restated 2012 Equity Incentive Plan | S-1 | 333-193154 | 10.4 | December 31, 2013 | |
| 10.5* | Revance Therapeutics, Inc. 2014 Equity Incentive Plan | S-1/A | 333-193154 | 10.5 | January 27, 2014 | |
| 10.6* | Form of Restricted Stock Unit Award Agreement and Grant Notice for Revance Therapeutics, Inc. 2014 Equity Incentive Plan | 10-K | 001-36297 | 10.6 | March 4, 2016 | |
| 10.7* | Form of Stock Option Agreement and Grant Notice for Revance Therapeutics, Inc. 2014 Equity Incentive Plan | 10-Q | 001-36297 | 10.3 | November 10, 2015 | |
| 10.8* | Form of Restricted Stock Bonus Agreement and Grant Notice for Revance Therapeutics, Inc. 2014 Equity Incentive Plan | 10-K | 001-36297 | 10.8 | March 4, 2016 | |

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| Exhibit Number | Exhibit Description | Incorporated by Reference | | | | Filed Herewith |
|----------------|--|---------------------------|------------|---------|-------------------|----------------|
| | | Form | File No. | Exhibit | Filing Date | |
| 10.9* | Revance Therapeutics, Inc. 2014 Employee Stock Purchase Plan | S-1/A | 333-193154 | 10.7 | January 27, 2014 | |
| 10.10* | Form of Indemnity Agreement by and between Revance Therapeutics, Inc. and each of its officers and directors | S-1/A | 333-193154 | 10.8 | January 27, 2014 | |
| 10.11* | Revance Therapeutics, Inc. Amended and Restated 2014 Inducement Plan | 8-K | 001-36297 | 99.1 | December 14, 2015 | |
| 10.12* | Form of Stock Option Agreement and Grant Notice under Amended and Restated Revance Therapeutics, Inc. 2014 Inducement Plan | 10-Q | 001-36297 | 10.5 | November 10, 2015 | |
| 10.13* | Form of Restricted Stock Agreement and Grant Notice under Amended and Restated Revance Therapeutics, Inc. 2014 Inducement Plan | 10-K | 001-36297 | 10.31 | March 4, 2016 | |
| 10.14 | Lease Agreement dated March 31, 2008 by and between Revance Therapeutics, Inc. and BMR-Gateway Boulevard LLC | S-1 | 333-193154 | 10.9 | December 31, 2013 | |
| 10.15 | First Amendment to Office Lease dated April 7, 2008 by and between Revance Therapeutics, Inc. and BMR-Gateway Boulevard LLC | S-1 | 333-193154 | 10.10 | December 31, 2013 | |
| 10.16 | Second Amendment to Office Lease and Lease dated May 17, 2010 by and between Revance Therapeutics, Inc. and BMR-Gateway Boulevard LLC | S-1 | 333-193154 | 10.11 | December 31, 2013 | |
| 10.17 | Third Amendment to Lease, dated February 26, 2014 by and between Revance Therapeutics, Inc. and BMR-Gateway Boulevard LLC | 8-K | 001-36297 | 10.35 | March 4, 2014 | |
| 10.18 | Fourth Amendment to Lease, dated May 10, 2018, by and between Revance Therapeutics, Inc. and BMR-Pacific Research Center L.P. | 8-K | 001-36297 | 10.1 | May 11, 2018 | |
| 10.19+ | License and Service Agreement dated February 8, 2007 between Revance Therapeutics, Inc. and List Biological Laboratories, Inc. | S-1 | 333-193154 | 10.15 | December 31, 2013 | |
| 10.20+ | First Addendum to the License and Service Agreement dated April 21, 2009 between Revance Therapeutics, Inc. and List Biological Laboratories, Inc. | S-1 | 333-193154 | 10.16 | December 31, 2013 | |
| 10.21+ | Development and Supply Agreement dated December 11, 2009 between Revance Therapeutics, Inc. and Hospira Worldwide, Inc. | S-1 | 333-193154 | 10.18 | December 31, 2013 | |
| 10.22+ | First Amendment to Development and Supply Agreement dated May 29, 2013 between Revance Therapeutics, Inc. and Hospira Worldwide, Inc. | S-1 | 333-193154 | 10.20 | December 31, 2013 | |
| 10.23+ | Second Amendment to Development and Supply Agreement dated August 31, 2015 between Revance Therapeutics, Inc. and Hospira Worldwide, Inc. | 10-Q | 001-36297 | 10.1 | November 10, 2015 | |
| 10.24+ | Manufacture and Development Agreement dated May 20, 2013 between Revance Therapeutics, Inc. and American Peptide Company, Inc. | S-1 | 333-193154 | 10.19 | December 31, 2013 | |
| 10.25 | First Amendment to Manufacture and Development Agreement dated April 13, 2018 between Revance Therapeutics, Inc. and Bachem Americas, Inc. | 10-Q | 001-36297 | 10.3 | August 3, 2018 | |

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| Exhibit Number | Exhibit Description | Incorporated by Reference | | | | Filed Herewith |
|----------------|--|---------------------------|------------|---------|-------------------|----------------|
| | | Form | File No. | Exhibit | Filing Date | |
| 10.26* | Revance Therapeutics, Inc. Executive Severance Benefit Plan, Amended and Restated effective October 13, 2019 | 10-Q | 001-36297 | 10.3 | November 4, 2019 | |
| 10.27* | Revance Therapeutics, Inc. Amended and Restated Non-Employee Director Compensation Policy | — | — | — | — | X |
| 10.28* | Revance Therapeutics, Inc. 2020 Management Bonus Plan | — | — | — | — | X |
| 10.29* | Executive Employment Agreement dated December 30, 2013 by and between Revance Therapeutics, Inc. and L. Daniel Browne | S-1/A | 333-193154 | 10.25 | January 27, 2014 | |
| 10.30* | Executive Employment Agreement dated December 14, 2015 by and between Revance Therapeutics, Inc. and Abhay Joshi. | 10-K | 001-36297 | 10.34 | March 4, 2016 | |
| 10.31* | Executive Employment Agreement dated May 1, 2018 by and between Company and Caryn G. McDowell | 10-Q | 001-36297 | 10.1 | August 3, 2018 | |
| 10.32* | Executive Employment Agreement dated November 5, 2018 by and between Revance Therapeutics, Inc. and Tobin Schilke | 10-K | 001-36291 | 10.37 | February 28, 2019 | |
| 10.33 | Technology Transfer, Validation and Commercial Fill/Finish Services Agreement dated March 14, 2017 between Revance Therapeutics, Inc. and Ajinomoto Althea, Inc. | 10-Q | 001-36297 | 10.4 | May 9, 2017 | |
| 10.34 | Controlled Equity Offering Sales Agreement, dated March 13, 2018, by and between Revance Therapeutics, Inc. and Cantor Fitzgerald & Co. | 8-K | 001-36297 | 99.1 | March 13, 2018 | |
| 10.35+ | Collaboration and License Agreement, dated February 28, 2018, by and between Revance Therapeutics, Inc. and Mylan Ireland Ltd | 10-Q | 001-36297 | 10.1 | May 9, 2018 | |
| 10.36++ | Amendment #1 to the Collaboration and License Agreement dated August 22, 2019 between Revance Therapeutics, Inc. and Mylan Ireland Ltd. | 10-Q | 001-36297 | 10.1 | November 4, 2019 | |
| 10.37+ | License Agreement, dated December 4, 2018, by and between Revance Therapeutics, Inc. and Shanghai Fosun Pharmaceutical Industrial Development Co., Ltd. | 10-K | 001-36291 | 10.42 | February 28, 2019 | |
| 10.38* | Separation Agreement effective October 11, 2019 by and between Revance Therapeutics, Inc. and L. Daniel Browne | 10-Q | 001-36297 | 10.2 | November 4, 2019 | |
| 10.39* | Executive Employment Agreement effective October 13, 2019 by and between Revance Therapeutics, Inc. and Mark J. Foley | 10-Q | 001-36297 | 10.4 | November 4, 2019 | |
| 10.40* | Executive Employment Agreement effective December 1, 2019 and between Revance Therapeutics, Inc. and Dustin Sjuts | — | — | — | — | X |
| 10.41* | Separation Agreement effective January 8, 2020 by and between Revance Therapeutics, Inc. and Caryn G. McDowell | — | — | — | — | X |
| 10.42* | Executive Employment Agreement dated February 17, 2020 by and between Revance Therapeutics, Inc. and Dwight Moxie | — | — | — | — | X |

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| Exhibit Number | Exhibit Description | Incorporated by Reference | | | | Filed Herewith |
|----------------|---|---------------------------|----------|---------|-------------|----------------|
| | | Form | File No. | Exhibit | Filing Date | |
| 10.43++ | Exclusive Distribution Agreement, dated January 10, 2020, by and between Revance Therapeutics, Inc. and Teoxane SA | — | — | — | — | X |
| 21.1 | List of Subsidiaries of the Registrant | — | — | — | — | X |
| 24.1 | Power of Attorney (contained in the signature page to this Annual Report on Form 10-K) | — | — | — | — | X |
| 31.1 | Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) promulgated under the Exchange Act | — | — | — | — | X |
| 31.2 | Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) promulgated under the Exchange Act | — | — | — | — | X |
| 32.1† | Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | — | — | — | — | X |
| 32.2† | Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | — | — | — | — | X |
| 101.INS | XBRL Instance Document | — | — | — | — | X |
| 101.SCH | XBRL Taxonomy Extension Schema Document | — | — | — | — | X |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document | — | — | — | — | X |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document | — | — | — | — | X |
| 101.LAB | XBRL Taxonomy Extension Labels Linkbase Document | — | — | — | — | X |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document | — | — | — | — | X |
| 104 | Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibits 101) | — | — | — | — | X |

* Indicates a management contract or compensatory plan or arrangement.

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

++ Portions of this exhibit (indicated by asterisks) have been omitted as the registrant has determined that (i) the omitted information is not material and (ii) the omitted information would likely cause competitive harm to the registrant if publicly disclosed.

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

ITEM 16. FORM 10-K SUMMARY

None.

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REVANCE THERAPEUTICS, INC.

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Report of Independent Registered Public Accounting Firm

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

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Revance Therapeutics, Inc. and its subsidiaries (the “Company”) as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, of stockholder’s equity and of cash flows for each of the three years in the period ended December 31, 2019, including the related notes (collectively referred to as the “consolidated financial statements”). We also have audited the Company’s internal control over financial reporting as of December 31, 2019 based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Changes in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

Basis for Opinions

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

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

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

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP
San Jose, California
February 26, 2020

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

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REVANCE THERAPEUTICS, INC.

Consolidated Balance Sheets
(In thousands, except share and per share amounts)

| | As of December 31, | |
|--|--------------------|-------------------|
| | 2019 | 2018 |
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | \$ 171,160 | \$ 73,256 |
| Short-term investments | 118,955 | 102,556 |
| Accounts and other receivables | — | 27,000 |
| Prepaid expenses and other current assets | 6,487 | 5,110 |
| Total current assets | 296,602 | 207,922 |
| Property and equipment, net | 14,755 | 14,449 |
| Operating lease right of use assets | 26,531 | — |
| Restricted cash | 730 | 730 |
| Other non-current assets | 1,669 | 3,247 |
| TOTAL ASSETS | \$ 340,287 | \$ 226,348 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| CURRENT LIABILITIES | | |
| Accounts payable | \$ 8,010 | \$ 8,434 |
| Accruals and other current liabilities | 18,636 | 14,948 |
| Deferred revenue, current portion | 7,911 | 8,588 |
| Operating lease liabilities, current portion | 3,470 | — |
| Derivative liability, current | 2,952 | — |
| Total current liabilities | 40,979 | 31,970 |
| Deferred revenue, net of current portion | 47,948 | 42,684 |
| Operating lease liabilities, net of current portion | 25,870 | — |
| Deferred rent | — | 3,319 |
| Derivative liability, non-current | — | 2,753 |
| TOTAL LIABILITIES | 114,797 | 80,726 |
| Commitments and Contingencies (Note 9) | | |
| STOCKHOLDERS' EQUITY | | |
| Convertible preferred stock, par value \$0.001 per share — 5,000,000 shares authorized, and no shares issued and outstanding as of December 31, 2019 and 2018 | — | — |
| Common stock, par value \$0.001 per share — 95,000,000 shares authorized both as of December 31, 2019 and 2018; 52,374,735 and 36,975,203 shares issued and outstanding as of December 31, 2019 and 2018, respectively | 52 | 37 |
| Additional paid-in capital | 1,069,639 | 830,368 |
| Accumulated other comprehensive income (loss) | 3 | (8) |
| Accumulated deficit | (844,204) | (684,775) |
| TOTAL STOCKHOLDERS' EQUITY | 225,490 | 145,622 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | \$ 340,287 | \$ 226,348 |

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

REVANCE THERAPEUTICS, INC.

Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

| | Year Ended December 31, | | |
|--|--------------------------------|---------------------|---------------------|
| | 2019 | 2018 | 2017 |
| Revenue | \$ 413 | \$ 3,729 | \$ 262 |
| Operating expenses: | | | |
| Research and development | 102,861 | 92,500 | 80,361 |
| General and administrative | 62,011 | 53,863 | 37,398 |
| Loss on impairment | — | — | 2,927 |
| Total operating expenses | <u>164,872</u> | <u>146,363</u> | <u>120,686</u> |
| Loss from operations | (164,459) | (142,634) | (120,424) |
| Interest income | 5,532 | 4,023 | 1,410 |
| Interest expense | — | (44) | (457) |
| Changes in fair value of derivative liability | (199) | (140) | (591) |
| Other expense, net | <u>(303)</u> | <u>(773)</u> | <u>(525)</u> |
| Loss before income taxes | (159,429) | (139,568) | (120,587) |
| Income tax provision | — | (3,000) | — |
| Net loss | <u>(159,429)</u> | <u>(142,568)</u> | <u>(120,587)</u> |
| Unrealized gain (loss) and adjustment on securities included in net loss | 11 | (8) | 45 |
| Comprehensive loss | <u>\$ (159,418)</u> | <u>\$ (142,576)</u> | <u>\$ (120,542)</u> |
| Basic and diluted net loss | <u>\$ (159,429)</u> | <u>\$ (142,568)</u> | <u>\$ (120,587)</u> |
| Basic and diluted net loss per share | <u>\$ (3.67)</u> | <u>\$ (3.94)</u> | <u>\$ (4.01)</u> |
| Basic and diluted weighted-average number of shares used in computing net loss per share | <u>43,460,804</u> | <u>36,171,582</u> | <u>30,101,125</u> |

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

REVANCE THERAPEUTICS, INC.

Consolidated Statements of Stockholders' Equity
(In thousands, except share and per share amounts)

| | Common Stock | | Additional Paid-In Capital | Other Accumulated Comprehensive Gain (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|--|-------------------|--------------|----------------------------------|--|------------------------|----------------------------------|
| | Shares | Amount | | | | |
| Balance — December 31, 2016 | 28,648,954 | \$ 29 | \$ 598,630 | \$ (45) | \$ (421,543) | \$ 177,071 |
| Cumulative-effect adjustment from adoption of ASU 2016-09 | — | — | 37 | — | (37) | — |
| Issuance of common stock relating to employee stock purchase plan | 28,135 | — | 583 | — | — | 583 |
| Stock-based compensation expense | — | — | 13,230 | — | — | 13,230 |
| Issuance of common stock in connection with at-the-market offering, net of issuance costs of \$603 | 1,802,651 | 2 | 38,155 | — | — | 38,157 |
| Issuance of common stock in connection with the 2017 offering, net of issuance costs of \$535 | 5,389,515 | 5 | 156,928 | — | — | 156,933 |
| Issuance of common stock upon net exercise of warrants | 9,878 | — | — | — | — | — |
| Issuance of common stock upon exercise of stock options | 309,341 | 1 | 3,985 | — | — | 3,986 |
| Issuance of restricted stock awards, net of cancellation | 353,620 | — | — | — | — | — |
| Net settlement of restricted stock awards for employee taxes | (26,019) | — | (573) | — | — | (573) |
| Unrealized gain and adjustment on securities included in net loss | — | — | — | 45 | — | 45 |
| Net loss | — | — | — | — | (120,587) | (120,587) |
| Balance — December 31, 2017 | 36,516,075 | 37 | 810,975 | — | (542,167) | 268,845 |
| Cumulative-effect adjustment from adoption of ASU 2018-07 | — | — | 40 | — | (40) | — |
| Issuance of common stock relating to employee stock purchase plan | 37,894 | — | 765 | — | — | 765 |
| Stock-based compensation expense | — | — | 16,273 | — | — | 16,273 |
| Issuance of common stock upon exercise of stock options | 293,100 | — | 4,527 | — | — | 4,527 |
| Issuance of restricted stock awards, net of cancellation | 201,032 | — | — | — | — | — |
| Net settlement of restricted stock awards for employee taxes | (72,898) | — | (2,212) | — | — | (2,212) |
| Unrealized loss and adjustment on securities included in net loss | — | — | — | (8) | — | (8) |
| Net loss | — | — | — | — | (142,568) | (142,568) |
| Balance — December 31, 2018 | 36,975,203 | 37 | 830,368 | (8) | (684,775) | 145,622 |
| Issuance of common stock relating to employee stock purchase plan | 74,935 | — | 818 | — | — | 818 |
| Stock-based compensation expense | — | — | 17,922 | — | — | 17,922 |
| Issuance of common stock in connection with at-the-market offering, net of issuance costs of \$265 | 687,189 | 1 | 10,604 | — | — | 10,605 |
| Issuance of common stock in connection with the 2019 offerings, net of issuance costs of \$770 | 13,264,705 | 13 | 211,187 | — | — | 211,200 |
| Issuance of common stock upon exercise of stock options | 10,135 | — | 119 | — | — | 119 |
| Issuance of restricted stock awards, net of cancellation | 1,447,544 | 1 | (1) | — | — | — |
| Net settlement of restricted stock awards for employee taxes | (84,976) | — | (1,378) | — | — | (1,378) |
| Unrealized loss and adjustment on securities included in net loss | — | — | — | 11 | — | 11 |
| Net loss | — | — | — | — | (159,429) | (159,429) |
| Balance — December 31, 2019 | <u>52,374,735</u> | <u>\$ 52</u> | <u>\$ 1,069,639</u> | <u>\$ 3</u> | <u>\$ (844,204)</u> | <u>\$ 225,490</u> |

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

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

| | Year Ended December 31, | | |
|---|-------------------------|------------------|-------------------|
| | 2019 | 2018 | 2017 |
| CASH FLOWS FROM OPERATING ACTIVITIES | | | |
| Net loss | \$ (159,429) | \$ (142,568) | \$ (120,587) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation | 2,909 | 1,726 | 1,468 |
| Amortization of premium (discount) on investments | (2,637) | (1,103) | 410 |
| Stock-based compensation expense | 17,922 | 16,273 | 13,230 |
| Gain on disposal of property and equipment | (8) | (1,466) | — |
| Impairment of property and equipment | — | — | 2,927 |
| Other non-cash operating activities | 810 | 175 | 767 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | 27,000 | (26,952) | 80 |
| Prepaid expenses and other current assets | (1,377) | (2,911) | 4,849 |
| Operating lease right of use assets | (1,868) | — | — |
| Other non-current assets | 1,578 | (1,871) | (403) |
| Accounts payable | (360) | 1,691 | 2,607 |
| Accruals and other liabilities | 3,565 | 1,488 | (690) |
| Deferred revenue | 4,587 | 51,272 | — |
| Operating lease liabilities | 1,147 | — | — |
| Net cash used in operating activities | (106,161) | (104,246) | (95,342) |
| CASH FLOWS FROM INVESTING ACTIVITIES | | | |
| Purchases of investments | (331,362) | (314,911) | (36,028) |
| Purchases of property and equipment | (3,238) | (6,991) | (2,525) |
| Proceeds from maturities of investments | 317,000 | 146,000 | 157,445 |
| Proceeds from sale of property and equipment | 8 | 1,541 | — |
| Proceeds from sale of investments | — | 67,435 | — |
| Payment for acquisition of in-process research and development | — | (100) | (100) |
| Net cash provided by (used in) investing activities | (17,592) | (107,026) | 118,792 |
| CASH FLOWS FROM FINANCING ACTIVITIES | | | |
| Proceeds from issuance of common stock in connection with offerings, net of commissions and discount | 211,970 | — | 157,468 |
| Proceeds from issuance of common stock in connection with at-the-market offerings, net of commissions | 10,870 | — | 38,760 |
| Proceeds from the exercise of stock options and common stock warrants, and purchases under the employee stock purchase plan | 937 | 5,292 | 4,569 |
| Net settlement of restricted stock awards for employee taxes | (1,378) | (2,212) | (573) |
| Payment of offering costs | (742) | (366) | (644) |
| Principal payments made on financing obligations | — | (932) | (3,636) |
| Net cash provided by financing activities | 221,657 | 1,782 | 195,944 |
| NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH | 97,904 | (209,490) | 219,394 |
| CASH, CASH EQUIVALENTS, AND RESTRICTED CASH — Beginning of period | 73,986 | 283,476 | 64,082 |
| CASH, CASH EQUIVALENTS, AND RESTRICTED CASH — End of period | \$ 171,890 | \$ 73,986 | \$ 283,476 |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION: | | | |
| Cash paid for income taxes | \$ 3,000 | \$ — | \$ — |
| Cash paid for interest | \$ — | \$ 16 | \$ 299 |
| SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION: | | | |
| Property and equipment purchases included in accounts payable and accruals | \$ 619 | \$ 642 | \$ 718 |
| Accrued offering costs | \$ 293 | \$ 354 | \$ 251 |

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

REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements

1. The Company

Revance Therapeutics is a biotechnology company, developing new innovations in neuromodulators for aesthetic and therapeutic indications. Our lead product candidate, DaxibotulinumtoxinA for Injection (DAXI), combines a proprietary stabilizing peptide excipient with a highly purified botulinum toxin that does not contain human or animal-based components. We have successfully completed a Phase 3 program for DAXI in glabellar (frown) lines. In November 2019, we submitted the Biologics License Application (“BLA”) to the U.S. Food and Drug Administration (the “FDA”) for DAXI in the treatment of moderate to severe glabellar (frown) lines. The FDA accepted the BLA on February 5, 2020, and the Prescription Drug User Fee Act (“PDUFA”) target action date is November 25, 2020. If the BLA is approved on or by the target action date, we plan to initiate commercialization activities for DAXI for the treatment of glabellar lines before the end of 2020. We are also evaluating DAXI in upper facial lines - glabellar lines, forehead lines and crow’s feet combined - as well as in three therapeutic indications - cervical dystonia, adult upper limb spasticity and plantar fasciitis, with plans to study migraine. Beyond DAXI, we have begun development of a biosimilar to BOTOX®, which would compete in the existing short-acting neuromodulator marketplace. In January 2020, the company entered into an exclusive distribution Agreement (the “Teoxane Agreement”) with Teoxane SA (“Teoxane”), pursuant to which Teoxane granted Revance with the exclusive right to import, market, promote, sell and distribute Teoxane’s line of Resilient Hyaluronic Acid® dermal fillers. Revance is dedicated to making a difference by transforming patient experiences.

Since inception, we have devoted substantially all of our efforts to identifying and developing product candidates for the aesthetic and therapeutic pharmaceutical markets, recruiting personnel, raising capital, conducting preclinical and clinical development of, and manufacturing development for DAXI, DaxibotulinumtoxinA Topical, and the biosimilar to BOTOX®. We have incurred losses and negative cash flows from operations. We have not commenced commercial operations, have not generated product revenue to date, and will continue to incur significant research and development and other expenses related to our ongoing operations.

For the year ended December 31, 2019, we had a net loss of \$159.4 million. As of December 31, 2019, we had a working capital surplus of \$255.6 million and an accumulated deficit of \$844.2 million. In recent years, we have funded our operations primarily through the issuance and sale of common stock. As of December 31, 2019, we had capital resources of \$290.1 million consisting of cash, cash equivalents, and investments. We believe that our existing capital resources will fund the operating plan through at least the next 12 months following the issuance of this Form 10-K, and may identify additional capital resources to fund our operations.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

Our consolidated financial statements include our accounts and those of our wholly-owned subsidiaries, Revance Therapeutics Limited and Revance International Limited, and have been prepared in conformity with United States (“U.S.”) generally accepted accounting principles (“GAAP”). We operate in one segment. All intercompany transactions have been eliminated.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Such management estimates include revenue recognition, deferred revenue, accruals including clinical trial accruals, stock-based compensation, fair value of derivative liability, impairment of long-lived assets and the valuation of deferred tax assets. We base our estimates on historical experience and also on assumptions that we believe are reasonable; however, actual results could significantly differ from those estimates.

REVANCE THERAPEUTICS, INC.**Notes to Consolidated Financial Statements — (Continued)****Risks and Uncertainties**

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

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

Concentration of Credit Risk

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

Cash and Cash Equivalents

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

Restricted Cash

As of December 31, 2019 and 2018, a deposit totaling \$0.7 million was restricted from withdrawal. We have a deposit balance of \$0.5 million that relates to securing our facility lease and will remain until the end of the lease. The remaining \$0.2 million deposit balance relates to a letter of credit. These balances are included in restricted cash on the accompanying consolidated balance sheets and within the cash, cash equivalents, and restricted cash balance on the consolidated statement of cash flows.

Investments

Investments generally consist of securities with original maturities greater than three months and remaining maturities of less than one year, while long-term investments generally consist of securities with remaining maturities greater than one year. We determine the appropriate classification of our investments at the time of purchase and reevaluate such determination at each balance sheet date. All of our investments are classified as available-for-sale and carried at fair value, with the change in unrealized gains and losses reported as a separate component of other comprehensive income (loss) on the consolidated statements of operations and comprehensive loss and accumulated as a separate component of stockholders' equity on the consolidated balance sheets. Interest income includes interest, amortization of purchase premiums and discounts, realized gains and losses on sales of securities and other-than-temporary declines in the fair value of investments, if any. The cost of securities sold is based on the specific-identification method. We monitor our investment portfolio for potential impairment on a quarterly basis. If the carrying amount of an investment in debt securities exceeds its fair value and the decline in value is determined to be other-than-temporary, the carrying amount of the security is reduced to fair value and a loss is recognized in operating results for the amount of such decline. In order to determine whether a decline in value is other-than-temporary, we evaluate, among other factors, the cause of the decline in value, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, and our intent and ability to hold the security to maturity or forecast recovery. We mitigate our credit risk by investing in money market funds, U.S. treasury securities, U.S. government agency obligations, commercial paper and overnight repurchase agreement which limit the amount of investment exposure as to credit quality and maturity.

REVANCE THERAPEUTICS, INC.**Notes to Consolidated Financial Statements — (Continued)****Fair Value of Financial Instruments**

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

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

- Level 1 — Observable inputs, such as quoted prices in active markets for identical assets or liabilities;
- Level 2 — Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3 — Valuations based on unobservable inputs to the valuation methodology and including data about assumptions market participants would use in pricing the asset or liability based on the best information available under the circumstances.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Computer equipment and software, lab equipment and furniture and fixtures, and manufacturing equipment is depreciated generally over 3, 5, and 7 years, respectively. Leasehold improvements are depreciated over the lesser of 15 years or the term of the lease. The cost of maintenance and repairs is expensed as incurred.

When property and equipment are retired or otherwise disposed of, the costs and accumulated depreciation are removed from the consolidated balance sheets and any resulting gain or loss is reflected in the consolidated statements of operations and comprehensive loss in the period realized.

REVANCE THERAPEUTICS, INC.**Notes to Consolidated Financial Statements — (Continued)****Impairment of Long-lived Assets**

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

Clinical Trial Accruals and Prepaid Expenses

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

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

Revenue

Effective January 1, 2018, we adopted Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* (ASC 606), using the full retrospective transition method. We elected to use certain practical expedients permitted related to adoption ([Note 3](#)) and the adoption of ASC 606 had no impact on our financial position, results of operations or liquidity. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services.

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

REVANCE THERAPEUTICS, INC.**Notes to Consolidated Financial Statements — (Continued)*****Licenses of intellectual property***

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

Milestone payments

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

Royalties

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

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

Research and Development Expense

Research and development expense are charged to operations as incurred. Research and development expense include, but are not limited to, personnel expenses, clinical trial supplies, fees for clinical trial services, manufacturing costs, consulting costs and allocated overhead, including rent, equipment, depreciation, and utilities. Assets acquired that are utilized in research and development that have no alternative future use are also expensed as incurred.

REVANCE THERAPEUTICS, INC.**Notes to Consolidated Financial Statements — (Continued)****Income Taxes**

We account for income taxes under the asset and liability method. We estimate actual current tax exposure together with assessing temporary differences resulting from differences in accounting for reporting purposes and tax purposes for certain items, such as accruals and allowances not currently deductible for tax purposes. These temporary differences result in deferred tax assets and liabilities, which are included in our consolidated balance sheets. In general, deferred tax assets represent future tax benefits to be received when certain expenses previously recognized in our consolidated statements of operations and comprehensive loss become deductible expenses under applicable income tax laws or when net operating loss or credit carryforwards are utilized. Accordingly, realization of our deferred tax assets is dependent on future taxable income against which these deductions, losses and credits can be utilized.

We must assess the likelihood that our deferred tax assets will be recovered from future taxable income, and to the extent we believe that recovery is not likely, we establish a valuation allowance. Based on the available evidence, we are unable, at this time, to support the determination that it is more likely than not that our deferred tax assets will be utilized in the future. Accordingly, we recorded a full valuation allowance as of December 31, 2019 and 2018. We intend to maintain valuation allowances until sufficient evidence exists to support our reversal.

Stock-Based Compensation

We have an equity compensation plan under which various types of stock-based awards including, but not limited to, stock option, restricted stock awards, and performance stock awards, may be granted to employees, non-employee directors, and non-employee consultants. We also have an inducement plan under which various types of stock-based awards, including stock options, restricted stock awards, and performance stock awards, may be granted to new employees.

We measure our stock-based awards using the estimated grant-date fair values. For stock options issued under the 2014 Equity Incentive Plan (“2014 EIP”) and the 2014 Inducement Plan (“2014 IN”), and shares purchased under the 2014 Employee Stock Purchase Plan (the “2014 ESPP”), fair values are determined using the Black-Scholes option pricing model. For restricted stock awards including performance stock awards subject to performance-based vesting conditions, the grant-date fair values are the closing prices of our common stocks on the grant dates. For performance stock awards subject to market-based vesting conditions, fair values are determined using the Monte Carlo simulation model.

For stock-based awards other than performance stock awards subject to performance-based vesting conditions, the value of the stock-based awards is recognized as compensation expense over the requisite service period (generally the vesting period). For performance stock awards subject to performance-based vesting conditions, the value of the stock-based awards is recognized as compensation expense when the performance condition is probable of achievement. Stock-based compensation expenses are classified in the consolidated statements of operations and comprehensive loss based on the functional area to which the related recipients belong. Forfeitures are recognized when they occur.

Effective July 1, 2018, we adopted ASU 2018-07, *Compensation - Stock Compensation (Topic 718)* using a retroactive approach. All non-employee stock-based awards granted prior to adoption were remeasured at fair value as of July 1, 2018. Before adoption, stock-based compensation expense related to stock options granted to non-employee consultants was recognized as the stock options are earned. All non-employee stock-based awards granted after adoption are measured at grant-date fair value. Refer to consolidated statements of stockholders’ equity for cumulative adjustments from adoption ASU 2018-07.

Derivative Liability

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

REVANCE THERAPEUTICS, INC.**Notes to Consolidated Financial Statements — (Continued)****Contingencies**

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

Net Loss per Share

Our basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of common stock outstanding for the period, which includes the vested restricted stock awards. The diluted net loss per share is calculated by giving effect to all potential dilutive common stock equivalents outstanding for the period. For purposes of this calculation, outstanding stock options, outstanding common stock warrants, unvested restricted stock awards including unvested performance stock awards are considered common stock equivalents, which were excluded from the computation of diluted net loss per share because including them would have been antidilutive.

Common stock equivalents that were excluded from the computation of diluted net loss per share are presented as below:

| | As of December 31, | | |
|-----------------------------------|--------------------|-----------|-----------|
| | 2019 | 2018 | 2017 |
| Outstanding common stock options | 4,734,616 | 3,605,333 | 3,210,400 |
| Outstanding common stock warrants | 34,113 | 34,113 | 34,113 |
| Unvested restricted stock awards | 1,808,518 | 605,012 | 639,287 |

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

In February 2016, the Financial Accounting Standards Board (“FASB”) issued ASU 2016-02, *Leases (Topic 842)* which requires an entity to recognize right-of-use asset and lease liabilities arising from a lease for both financing and operating leases with terms greater than twelve months. In July 2018, the FASB issued ASU 2018-10, *Leases (Topic 842), Codification Improvements* and ASU 2018-11, *Leases (Topic 842), Targeted Improvements*, to provide additional guidance for the Topic 842 adoption. ASU 2018-10 clarifies certain provisions and corrects unintended applications of the guidance such as the application of implicit rate, lessee reassessment of lease classification, and certain transition adjustments that should be recognized to earnings rather than to stockholders’ equity. ASU 2018-11 provides an alternative transition method to allow entities initially applying Topic 842 at the adoption date, rather than at the beginning of the earliest comparative period presented, and recognizing the cumulative effect of applying the new standard as an adjustment to beginning retained earnings in the year of adoption while continuing to present all prior periods under previous lease accounting guidance. ASU 2018-11 also provides a number of optional practical expedients in transition. In March 2019, the FASB issued ASU 2019-01, *Leases (Topic 842): Codification Improvements*. We evaluated ASU 2019-01 in its entirety and determined that Issue 3, *Transition disclosures related to Topic 250, Accounting Changes and Error Corrections*, is the only provision that currently applies to us. Issue 3 of ASU 2019-01 exempts certain interim disclosures in the fiscal year of adoption. ASU 2018-11, ASU 2018-10, ASU 2016-02, and Issue 3 of ASU 2019-01 (collectively, “the new lease standards”) are effective for fiscal years beginning after December 15, 2018, with early adoption permitted. We have elected the transition method under ASU 2018-11 at the adoption date of January 1, 2019 on a modified retrospective basis and will not restate comparative periods. We have also elected all of the available practical expedients except the practical expedient allowing the use of hindsight in determining the lease term and assessing impairment of right-of-use assets based on all facts and circumstances through the effective date of the new standard. We have elected the recognition exemption for short-term leases for all leases that qualify. Under this exemption, we will not recognize right-of-use assets or lease liabilities for those leases that qualify as a short-term lease. For real estate leases, we did not elect the practical expedient to combine lease and non-lease components, therefore we account for lease and non-lease components separately. For equipment leases, lease and non-lease components are accounted for as a single lease component. We recognized \$24.7 million and \$28.2 million as total right-of-use assets and total lease liabilities, respectively, on our consolidated balance sheet as of January 1, 2019 for our existing operating lease agreements for the office and manufacturing spaces in Newark, California and equipment leases. The existing deferred rent liabilities of \$3.5 million associated with the same lease agreements was reversed as of January 1, 2019.

Recent Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40) Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. The amendments in ASU 2018-15 align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). Accordingly, the amendments require an entity (customer) in a hosting arrangement that is a service contract to follow the guidance in Subtopic 350-40 to determine which implementation costs to capitalize as an asset related to the service contract and which costs to expense. ASU 2018-15 is effective for fiscal years beginning after December 15, 2019 with early adoption permitted. We adopted ASU 2018-15 on January 1, 2020, on a prospective approach.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The amendments in ASU 2019-12 are intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. ASU 2019-12 is effective for us beginning January 1, 2021 with early adoption permitted. We adopted ASU 2019-12 on December 31, 2019 and the adoption did not have a material impact on our consolidated financial statements.

REVANCE THERAPEUTICS, INC.**Notes to Consolidated Financial Statements — (Continued)****3. Revenue****Mylan Collaboration and License Agreement*****Agreement Terms***

We entered into a collaboration agreement with Mylan Ireland Limited, a wholly-owned indirect subsidiary of Mylan N.V. (“Mylan”) in February 2018 (the “Mylan Collaboration”), pursuant to which we will collaborate with Mylan exclusively, on a world-wide basis (excluding Japan), to develop, manufacture, and commercialize a biosimilar to the branded biologic product (onabotulinumtoxinA) marketed as BOTOX®. In August 2019, we entered into an amendment with Mylan (the “Mylan Amendment”) to the Mylan Collaboration, pursuant to which, among other things, we have agreed to extend the period of time for Mylan to decide whether to continue the development and commercialization of the biosimilar beyond the initial development plan (the “Continuation Decision”), for which both parties prepared and conducted the Biosimilar Initial Advisory Meeting (“BIAM”) with the U.S. FDA. In accordance with the Mylan Amendment, Mylan is required to notify us of the Continuation Decision on or before the later of (i) April 30, 2020 or (ii) 30 calendar days from the date that we provide Mylan with certain deliverables.

Pursuant to the Mylan Collaboration, we formed a joint steering committee with Mylan, consisting of an equal number of members from both parties, to oversee and manage the development, manufacturing and commercialization of the biosimilar. We were responsible for conducting initial non-clinical development activities with the goal of preparing for and conducting the BIAM with the FDA to receive feedback as to whether a biosimilar pathway to BOTOX® is feasible. These activities were completed as the BIAM took place in February 2019. If Mylan chooses to continue the program upon the Continuation Decision, we will be primarily responsible for (a) non-clinical development activities, (b) clinical development activities in North America, and (c) manufacturing and supply of clinical drug substance and drug product; and Mylan will be primarily responsible for (a) clinical development activities outside of North America (excluding Japan) (the “ex-U.S. Mylan territories”), (b) regulatory activities, and (c) commercialization for any approved product. The cost incurred for the biosimilar program after the Continuation Decision are subject to certain cost-sharing arrangements.

Under the Mylan Collaboration, Mylan paid us a non-refundable upfront payment of \$25 million with additional contingent payments of up to \$100 million in the aggregate, upon the achievement of specified clinical and regulatory (i.e., biosimilar biological pathway) milestones and of specified, tiered sales milestones of up to \$225 million. In connection with the Mylan Amendment, Mylan made an incremental payment of \$5 million to us. The upfront payment does not represent a financing component for the transfer of goods or services. The contingent payments would be payable after the Continuation Decision and upon meeting certain milestones. 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 areas excluding Japan. 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.

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

REVANCE THERAPEUTICS, INC.**Notes to Consolidated Financial Statements — (Continued)*****Revenue Recognition***

As of the Mylan Amendment date in August 2019, we have the following unfulfilled non-distinct performance obligations within the Mylan Collaboration: (1) Intellectual property license for technology and know-how related to the biosimilar, (2) the performance of development services after the Initial Phase for the biosimilar through the filing of an IND application by us, and (3) manufacturing services to provide drug substance or drug product during the development and commercialization periods. The performance obligation related to the initial development services for the biosimilar up to the BIAM was completed in February 2019.

We considered that the license has standalone functionality and is capable of being distinct. However, we determined that the license is not distinct from the development and manufacturing services within the context of the agreement because the development and manufacturing services significantly increase the utility of the intellectual property.

Our development, manufacturing and commercialization license can only provide benefit to Mylan in combination with our development services during initial development and subsequent studies. The intellectual property related to the biosimilar platform, which is proprietary to us, is the foundation for the development activities related to the treatment for all indications. The manufacturing services are a necessary and integral part of the development services as they could only be conducted utilizing the outcomes of these services. Given the development services under the Mylan Collaboration are expected to involve significant further development of the initial intellectual property, we have concluded that the development and compound supply services are not distinct from the license, and thus the license, development services and compound supply services are combined into a single performance obligation. The nature of the combined performance obligation is to provide development and manufacturing services to Mylan under the arrangement.

We determined that the Continuation Decision represents a material right, because it includes consideration for the intellectual property license, and provides economic value for the duration of the entire development period, defined as the initial development through regulatory approval. Further, in accordance with ASC 606, we elected to use a practical alternative to estimate the standalone fair value selling price of the material right, which is based on the cost of expected services to be provided for the duration of the contract.

In accordance with ASC 606, transaction price is defined as the amount of consideration to which an entity expects to be entitled in exchange for promised goods or services to a customer. We estimated the transaction price for the Mylan Collaboration using the most likely amount method. In order to determine the transaction price, we evaluated all of the payments to be received during the duration of the contract, which included milestones and consideration payable by Mylan. Other than the upfront payment, all other milestones and consideration we may earn under the Mylan Collaboration are subject to uncertainties related to development achievements, Mylan's rights to terminate the agreement, and estimated effort for cost-sharing payments. Components of such estimated effort for cost-sharing payments include both internal and external costs. Consequently, the transaction price does not include any milestones and considerations that, if included, could result in a probable significant reversal of revenue when related uncertainties become resolved. Sales-based milestones and royalties are not included in the transaction price until the sales occur because as the underlying value relates to the license, the license is the predominant feature in the Mylan Collaboration. The initial estimated transaction price of \$81.0 million included the \$25.0 million upfront payment, \$40.0 million of development milestones, and estimated variable consideration for cost-sharing payments from Mylan. We re-evaluate the transaction price at each reporting period. As of December 31, 2019, the transaction price allocated to the unfulfilled performance obligations is \$106.9 million, which incorporates the impact from the incremental payment of \$5.0 million and estimated variable consideration for cost-sharing payments resulting from the Mylan Amendment.

We recognize revenue and estimate deferred revenue based on the cost of services incurred over the total estimated cost of services to be provided for the development period. As a result of the extended period of time for Mylan to make the Continuation Decision provided in the Mylan Amendment, both short-term and long-term deferred revenue have been adjusted accordingly to reflect the impact of the extension. For revenue recognition purposes, the development period is estimated to extend through 2024. However, it is possible that this period will change and is assessed at each reporting date.

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

For the year ended December 31, 2019 and 2018, we recognized revenue related to development services of \$0.4 million and \$3.7 million, respectively. As of December 31, 2019 and 2018, we estimated short-term deferred revenue of \$7.9 million and \$8.6 million, respectively; and long-term deferred revenue of \$18.0 million and \$12.7 million, respectively.

Fosun License Agreement*Agreement Terms*

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 Revance has 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.

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

Under the Fosun License Agreement, Fosun will have the right to import, develop, commercialize, market and sell the product in the Fosun Territory or engage service providers for such activities, and we will be responsible for manufacturing the product and supplying it to Fosun for the clinical and commercial activities in the Fosun Territory, subject to the terms of a supply agreement and a quality assurance agreement, each to be entered into between the parties in the six months following the date of the Fosun License Agreement. Except as provided in the Fosun License Agreement, each party has retained all of its intellectual property rights.

During the term of the Fosun License Agreement and an additional two years from the termination date if Fosun terminates the Fosun License Agreement, Fosun will not engage in any research, development, manufacture or commercialization of any product competitive with the product; provided that such non-compete restrictions will expire if we fail to submit a BLA for the product in the U.S. by the end of 2020. Under the Fosun License Agreement, the parties will also establish a joint development committee, which will oversee the development and commercialization of the product as well as all clinical and pre-clinical studies to be conducted by Fosun for the product in the Fosun Territory.

The term of the Fosun License Agreement will continue until Fosun’s payment obligations have been performed or have expired, unless sooner terminated by either party pursuant to the terms of the Fosun License Agreement. Either party may terminate the Fosun License Agreement for material breach by, or bankruptcy of, the other party. In addition, we may terminate the Fosun License Agreement if Fosun challenges our patents, and Fosun may terminate the Fosun License Agreement upon 120 days notice. In the event of a change of control of us, our successor will have the option to terminate the Agreement by paying Fosun a variable payment that depends on the stage of development of the product.

Revenue Recognition

We identified the following material promises within the Fosun License Agreement: (1) license to certain intellectual property and know-how related to DAXI, (2) development supplies to achieve regulatory approvals in the Fosun Territory, and (3) future commercial product supplies. We retained all manufacturing rights and know-how due to complexities associated with the risks and management of toxins and transferability of the underlying technology. Since the manufacturing rights and know-how, which are highly specialized and complex, do not transfer, Fosun cannot benefit from the license on its own or together with other readily available resources without the supplies provided by Revance. Accordingly, the license is not distinct from the other material promises and are bundled into a single performance obligation.

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

In accordance with ASC 606, transaction price is defined as the amount of consideration to which an entity expects to be entitled in exchange for promised goods or services to a customer. We estimated the transaction price for the Fosun License Agreement using the most likely amount method. We evaluated all of the variable payments to be received during the duration of the contract, which included payments from specified milestones, royalties, and estimated supplies to be delivered, and concluded only a certain milestone of \$1.0 million was included in the transaction price. We will re-evaluate the transaction price at each reporting period and upon a change in circumstances. As of December 31, 2019, the transaction price allocated to unfulfilled performance obligation is \$31.0 million.

We will recognize revenue on the single performance obligation as control of the manufactured product is supplied to Fosun. As of December 31, 2019, no revenue has been recognized as no supply has been provided under the agreement. Upon commencement of the transfer of control, revenue will be recognized in a pattern consistent with estimated deliveries of the product through the term of the arrangement, which is estimated to extend through 2039. However, it is possible that this period will change and is assessed at each reporting date. The estimated contract term for revenue recognition purposes is not limited or impacted by Fosun's ability to terminate the agreement due to a substantive significant termination penalty from non-refundable payments.

No revenue has been recognized from the Fosun License Agreement for the year ended December 31, 2019. Substantially all of the \$30 million non-refundable upfront payment was included in long-term deferred revenue as of December 31, 2019.

4. Derivative Liability

Due to an existing settlement agreement which we entered in 2012, we are obligated to pay \$4.0 million upon our achievement of regulatory approval for DAXI or DaxibotulinumtoxinA Topical. We determined that such payment was a derivative instrument that requires fair value accounting as a liability and periodic fair value remeasurements until settled. The fair value of the derivative liability was determined by estimating the timing and probability of the related regulatory approval and multiplying the payment amount by this probability percentage and a discount factor.

As of December 31, 2018, the fair value of the derivative liability was \$2.7 million, which was measured using a term of 1.5 years based on an expected BLA approval in 2020, a risk-free rate of 2.6% and a credit risk adjustment of 8.0%. As of December 31, 2019, the fair value of the derivative liability was \$3.0 million, which was measured using a term of 0.9 years based on an expected BLA approval in 2020, a risk-free rate of 1.6% and a credit risk adjustment of 7.5%.

As a result of the fair value remeasurements during the years ended December 31, 2019, 2018, and 2017, we recognized aggregate losses of \$0.2 million, \$0.1 million, and \$0.6 million, respectively.

5. Cash Equivalents and Short-Term Investments

Our cash equivalents and short-term investments consist of money market funds, U.S. treasury securities, U.S. government agency obligations, commercial paper, and overnight repurchase agreements which are classified as available-for-sale securities.

REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

The following table is a summary of amortized cost, unrealized gains and losses, and fair value:

| (in thousands) | December 31, 2019 | | | | December 31, 2018 | | | |
|--|-------------------|-------------|---------------|-------------------|-------------------|-------------|----------------|-------------------|
| | Unrealized | | | Fair Value | Unrealized | | | Fair Value |
| | Cost | Gains | Losses | | Cost | Gains | Losses | |
| Money market funds | \$ 136,258 | \$ — | \$ — | \$ 136,258 | \$ 38,354 | \$ — | \$ — | \$ 38,354 |
| U.S. treasury securities | 48,349 | 6 | — | 48,355 | 80,844 | 5 | (5) | 80,844 |
| U.S. government agency obligations | 5,993 | 2 | (5) | 5,990 | 52,586 | — | (8) | 52,578 |
| Commercial paper | 77,082 | — | — | 77,082 | — | — | — | — |
| Overnight repurchase agreements | 15,001 | — | — | 15,001 | — | — | — | — |
| Total cash equivalents and available-for-sale securities | <u>\$ 282,683</u> | <u>\$ 8</u> | <u>\$ (5)</u> | <u>\$ 282,686</u> | <u>\$ 171,784</u> | <u>\$ 5</u> | <u>\$ (13)</u> | <u>\$ 171,776</u> |
| Classified as: | | | | | | | | |
| Cash equivalents | | | | \$ 163,731 | | | | \$ 69,220 |
| Short-term investments | | | | <u>118,955</u> | | | | <u>102,556</u> |
| Total cash equivalents and available-for-sale securities | | | | <u>\$ 282,686</u> | | | | <u>\$ 171,776</u> |

As of December 31, 2019 and 2018, we have no other-than-temporary impairments on our available-for-sale securities, and the contractual maturities of the available-for-sale securities are less than one-year.

REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

6. Fair Value Measurement

The following table summarizes, for assets and liabilities measured at fair value, the respective fair value and the classification by level of input within the fair value hierarchy:

| (in thousands) | As of December 31, 2019 | | | |
|--|-------------------------|-------------------|------------------|-----------------|
| | Fair Value | Level 1 | Level 2 | Level 3 |
| Assets | | | | |
| Money market funds | \$ 136,258 | \$ 136,258 | \$ — | \$ — |
| U.S. treasury securities | 48,355 | 48,355 | — | — |
| Commercial paper | 77,082 | — | 77,082 | — |
| Overnight repurchase agreements | 15,001 | — | 15,001 | — |
| U.S. government agency obligations | 5,990 | — | 5,990 | — |
| Total assets measured at fair value | <u>\$ 282,686</u> | <u>\$ 184,613</u> | <u>\$ 98,073</u> | <u>\$ —</u> |
| Liabilities | | | | |
| Derivative liability | \$ 2,952 | \$ — | \$ — | \$ 2,952 |
| Total liabilities measured at fair value | <u>\$ 2,952</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 2,952</u> |
| As of December 31, 2018 | | | | |
| (in thousands) | Fair Value | Level 1 | Level 2 | Level 3 |
| Assets | | | | |
| Money market funds | \$ 38,354 | \$ 38,354 | \$ — | \$ — |
| U.S. treasury securities | 80,844 | 80,844 | — | — |
| U.S. government agency obligations | 52,578 | — | 52,578 | — |
| Total assets measured at fair value | <u>\$ 171,776</u> | <u>\$ 119,198</u> | <u>\$ 52,578</u> | <u>\$ —</u> |
| Liabilities | | | | |
| Derivative liability | \$ 2,753 | \$ — | \$ — | \$ 2,753 |
| Total liabilities measured at fair value | <u>\$ 2,753</u> | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 2,753</u> |

For Level 1 investments, we use quoted prices in active markets for identical assets to determine the fair value. For Level 2 investments, we use quoted prices for similar assets sourced from certain third-party pricing services. The third-party pricing services generally utilize industry standard valuation models for which all significant inputs are observable, either directly or indirectly, to estimate the price or fair value of the securities. The primary input generally includes reported trades of or quotes on the same or similar securities. We do not make additional judgments or assumptions made to the pricing data sourced from the third-party pricing services.

REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

The following table summarizes the change in the fair value of our Level 3 financial instrument:

| (in thousands) | Derivative liability |
|------------------------------------|-----------------------------|
| Fair value as of December 31, 2018 | \$ 2,753 |
| Change in fair value | 199 |
| Fair value as of December 31, 2019 | <u><u>\$ 2,952</u></u> |

The fair value of the derivative liability was determined by estimating the timing and probability of the related regulatory approval and multiplying the payment amount by this probability percentage and a discount factor based primarily on the estimated timing of the payment and a credit risk adjustment ([Note 4](#)). Generally, increases or decreases in these unobservable inputs would result in a directionally similar impact to the fair value measurement of this derivative instrument. The significant unobservable inputs used in the fair value measurement of the product approval payment derivative are the expected timing and probability of the payments at the valuation date and the credit risk adjustment.

7. Balance Sheet Components

Property and Equipment, net

Property and equipment, net consists of the following:

| | As of December 31, | |
|--------------------------------|-------------------------|-------------------------|
| (in thousands) | 2019 | 2018 |
| Manufacturing equipment | \$ 19,113 | \$ 11,307 |
| Leasehold improvements | 5,374 | 4,752 |
| Construction in progress | 2,386 | 8,925 |
| Computer software | 2,040 | 1,299 |
| Computer equipment | 1,505 | 1,351 |
| Furniture and fixtures | 1,203 | 787 |
| Total property and equipment | 31,621 | 28,421 |
| Less: Accumulated depreciation | (16,866) | (13,972) |
| Property and equipment, net | <u><u>\$ 14,755</u></u> | <u><u>\$ 14,449</u></u> |

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REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

Accruals and Other Current Liabilities

Accruals and other current liabilities consist of the following:

| (in thousands) | As of December 31, | |
|---|--------------------|-----------|
| | 2019 | 2018 |
| Accruals related to: | | |
| Compensation | \$ 7,933 | \$ 6,743 |
| Clinical trials | 4,746 | 4,021 |
| Professional service | 2,732 | 2,272 |
| Nonrecurring milestone payment | 1,000 | 1,000 |
| Manufacturing and quality control | 1,798 | 260 |
| Property and equipment (including construction in progress) | 221 | 111 |
| Other current liabilities | 206 | 541 |
| Total accruals and other current liabilities | \$ 18,636 | \$ 14,948 |

(1) We recorded \$5.5 million and \$5.3 million for bonus accruals as of December 31, 2019 and 2018, respectively.

8. Leases

We have non-cancelable operating leases for facilities for research, manufacturing, and administrative functions, and equipment operating leases. One of the facility operating leases commenced in February 2019. As of December 31, 2019, the weighted average remaining lease term is 7.0 years. The monthly payments for the facility lease escalate over the facility lease term with the exception of a decrease in payments at the beginning of 2022. We have options to extend the facility operating leases for up to 14.0 years. Our lease contracts do not contain termination options, residual value guarantees or restrictive covenants.

The operating lease costs are summarized as follows:

| (in thousands) | Year Ended | |
|------------------------------------|-------------------|-------|
| | December 31, 2019 | |
| Operating lease cost | \$ 5,618 | |
| Variable lease cost ⁽¹⁾ | | 1,184 |
| Total operating lease costs | \$ 6,802 | |

(1) Variable lease cost includes management fees, common area maintenance, property taxes, and insurance, which are not included in the lease liabilities and are expensed as incurred.

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REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

As of December 31, 2019, maturities of our operating lease liabilities are as follows:

| <u>Year Ending December 31,</u> | <u>(in thousands)</u> |
|---|-----------------------|
| 2020 | \$ 6,735 |
| 2021 | 6,942 |
| 2022 | 5,464 |
| 2023 | 5,557 |
| 2024 | 5,733 |
| 2025 and thereafter | 12,226 |
| Total operating lease payments | 42,657 |
| Less imputed interest ⁽¹⁾ | (13,317) |
| Present value of operating lease payments | \$ 29,340 |

- (1) Our lease contracts do not provide a readily determinable implicit rate. The imputed interest was based on a weighted average discount rate of 12.0%, which represents the estimated incremental borrowing based on the information available at the adoption or commencement dates.

As of December 31, 2018, the aggregate total future minimum lease payments under non-cancelable operating leases were as follows:

| <u>Year Ending December 31,</u> | <u>(in thousands)</u> |
|---------------------------------|-----------------------|
| 2019 | \$ 5,826 |
| 2020 | 6,011 |
| 2021 | 6,196 |
| 2022 | 4,696 |
| 2023 and thereafter | 20,173 |
| Total payments | \$ 42,902 |

Supplemental cash flow information related to the operating leases was as follows:

| | <u>Year Ended</u> |
|--|--------------------------|
| | <u>December 31, 2019</u> |
| Cash paid for amounts included in the measurement of operating lease liabilities | \$ 6,339 |
| Right-of-use assets obtained in exchange for operating lease liabilities | \$ 3,890 |

9. Commitments and Contingencies

Purchase Commitments

We are parties to a Technology Transfer, Validation and Commercial Fill/Finish Services Agreement with Ajinomoto Althea, Inc. dba Ajinomoto Bio-Pharma Services (“Althea”) (the “Althea Services Agreement”), under which Althea provides us a contract development and manufacturing organization, which allows us to have expanded capacity and a second source for drug product manufacturing in order to support a global launch of DAXI. Under the Althea Services Agreement, the initial term is to 2024, unless terminated sooner by either company, and we have minimum purchase obligations based on our production forecasts. As of December 31, 2019, non-refundable advanced payments of \$1.5 million under the Althea Services Agreement have been recorded in prepaid expense on our consolidated balance sheets. The remaining services can be canceled at any time, with us required to pay costs incurred through the cancellation date.

REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

Contingencies

We are obligated to pay a \$2.0 million milestone payment to a developer of botulinum toxin, List Biological Laboratories, Inc. (“List Laboratories”), when a certain regulatory milestone is achieved. As of December 31, 2019, the milestone has not been achieved. We are also obligated to pay royalties to List Laboratories on future sales of botulinum toxin products.

We entered into an asset purchase agreement (the “BTRX Purchase Agreement”) with Botulinum Toxin Research Associates, Inc. (“BTRX”), under which we are obligated to pay up to \$16.0 million to BTRX upon the satisfaction of milestones relating to our product revenue, intellectual property, and clinical and regulatory events. As of December 31, 2019, a one-time intellectual property development milestone liability of \$1.0 million has been recorded in accruals on our consolidated balance sheets.

We entered into an agreement with BioSentinel, Inc. (“BioSentinel”), under which we in-license BioSentinel’s technology and expertise for research, development and manufacturing purposes. We are obligated to pay BioSentinel minimum quarterly use fees and a one-time milestone payment of \$0.3 million when regulatory approval is achieved. As of December 31, 2019, the milestone has not been achieved.

Indemnification

We have standard indemnification agreements in the ordinary course of business. Under these indemnification agreements, we indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party, in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to our technology. The term of these indemnification agreements is generally perpetual after the execution of the agreements. The maximum potential amount of future payments we are obligated to pay under these indemnification agreements is not determinable because it involves claims that may be made against us in the future, but have not been made. We have not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

We have indemnification agreements with our directors and officers that may require us to indemnify them against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of the individual.

For the year ended December 31, 2019, no amounts associated with the indemnification agreements have been recorded.

10. Stock-Based Compensation

Equity Compensation Plans

We maintain three equity compensation plans: 2014 Equity Incentive Plan (the “2014 EIP”), 2014 Inducement Plan (the “2014 IN”) and 2014 Employee Stock Purchase Plan (the “2014 ESPP”). Under the 2014 EIP and 2014 IN, stock options may be granted with different vesting terms with maximum contractual term of 10 years from the grant dates. Under the 2014 EIP and the 2014 IN, stock options typically vest over four years, either with 25% of the total grant vesting on the first anniversary of the grant date and 1/36th of the remaining grant vesting each month thereafter or 1/48th vesting monthly; restricted stock awards typically vest annually over 1, 3, or 4 years. The 2014 EIP is the successor of the 2012 and 2002 Equity Incentive Plans, and any canceled or forfeited common stock shares under the 2012 and 2002 Equity Incentive Plans were retired upon the effectiveness of the 2014 EIP.

2014 EIP

The 2014 EIP was effective on February 5, 2014, and the plan provides for the issuance of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, and other forms of equity compensation to qualified employees, directors and consultants. The common stock shares reserved for issuance under the

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

2014 EIP will automatically increase each year on January 1st from January 1, 2015 to January 1, 2024 by 4% of our total common stock shares outstanding on December 31st of the preceding calendar year or a lesser number of shares determined by our Board of Directors. On January 1, 2019, the common stock shares reserved for issuance under the 2014 EIP increased by 1,479,008 shares, and on January 1, 2020, the common stock shares reserved for issuance under the 2014 EIP increased by 2,094,989 shares. For the year ended December 31, 2019, 1,976,750 stock options and 1,640,275 restricted stock awards, including 865,000 performance stock awards, were granted under the 2014 EIP. As of December 31, 2019, 641,813 common stock shares were available for issuance under the 2014 EIP.

2014 IN

The 2014 IN was effective on August 29, 2014, and the plan provides for the issuance of stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, and other forms of equity compensation exclusively to individuals that were not previously employees or directors of us, as an inducement material to the individual's entry into employment with us Stockholder approval of the 2014 IN was not required pursuant to Rule 5635 (c)(4) of the Nasdaq Listing Rules. For the year ended December 31, 2019, no stock options or restricted stock awards were granted under the 2014 IN. As of December 31, 2019, 174,546 common stock shares were available for issuance under the 2014 IN.

2014 ESPP

The 2014 ESPP was effective on February 5, 2014, and the plan provides employees with an opportunity to purchase our common stock through accumulated payroll deductions. The common stock shares reserved for issuance under the 2014 ESPP will automatically increase each year on January 1st from January 1, 2015 to January 1, 2024 by the lesser of (i) 1% of the total common stock shares outstanding on December 31st of the preceding calendar year, (ii) 300,000 common stock shares or (iii) a lesser number of common stock shares determined by our Board of Directors. On January 1, 2019, the number of shares of common stock reserved for issuance under the 2014 ESPP increased by 300,000 shares, and on January 1, 2020, the common stock shares reserved for issuance under the 2014 ESPP increased by 300,000 shares. For the year ended December 31, 2019, 74,935 common stock shares were issued to employees under the 2014 ESPP. As of December 31, 2019, 1,404,005 common stock shares were available for issuance under the 2014 ESPP.

REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

Stock Options

The following table summarizes our stock option activities:

| | Shares | Weighted Average Exercise Price Per Share | Weighted Average Remaining Contractual Term (in Years) | Weighted-Average Grant-Date Fair Value Per Share | Aggregate Intrinsic Value ⁽¹⁾ (in thousands) |
|-------------------------------------|------------------|---|--|--|---|
| Balance as of December 31, 2016 | 2,790,646 | \$ 19.31 | | | |
| Granted | 960,525 | \$ 21.75 | | \$ 13.59 | |
| Exercised | (309,341) | \$ 12.88 | | | \$ 7,073 |
| Forfeited | <u>(231,430)</u> | <u>\$ 22.76</u> | | | |
| Balance as of December 31, 2017 | 3,210,400 | \$ 20.41 | | | |
| Granted | 1,136,650 | \$ 28.30 | | \$ 16.35 | |
| Exercised | (293,100) | \$ 15.45 | | | \$ 1,519 |
| Forfeited | <u>(448,617)</u> | <u>\$ 25.59</u> | | | |
| Balance as of December 31, 2018 | 3,605,333 | \$ 22.66 | | | |
| Granted | 1,976,750 | \$ 14.53 | | \$ 8.29 | |
| Exercised | (10,135) | \$ 11.76 | | | \$ 45 |
| Forfeited | <u>(837,332)</u> | <u>\$ 22.40</u> | | | |
| Balance as of December 31, 2019 | <u>4,734,616</u> | <u>\$ 19.34</u> | 6.2 | | \$ 7,762 |
| Exercisable as of December 31, 2019 | <u>2,659,741</u> | <u>\$ 21.31</u> | | 3.9 | \$ 3,433 |

(1) The total intrinsic values of options exercised as of December 31, 2019, 2018 and 2017 were determined by multiplying the number of shares by the difference between exercise price of the stock options and the fair value of the common stock as of December 31, 2019, 2018 and 2017 of \$16.23, \$20.13 and \$35.75 per share, respectively. The intrinsic values of outstanding and exercisable options were determined by multiplying the number of shares by the difference in exercise price of the options and the fair value of the common stock as of December 31, 2019.

REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

Restricted Stock Awards

The following table summarizes our activities of restricted stock awards, including performance stock awards:

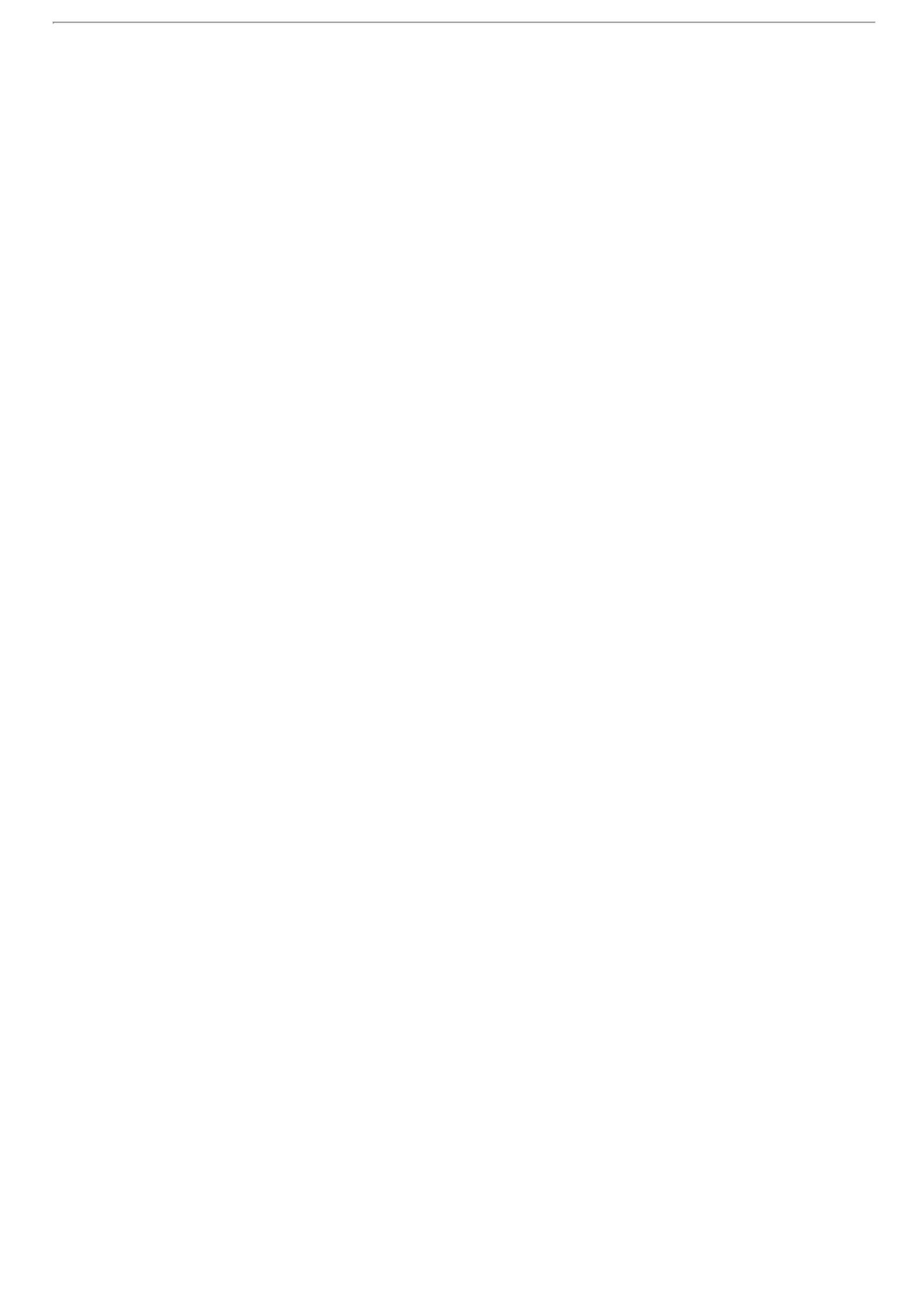
| | Shares | Weighted-Average Grant-Date Fair Value Per Share |
|--|------------------|--|
| Unvested balance as of December 31, 2016 | 416,229 | \$ 20.02 |
| Granted | 435,525 | \$ 22.08 |
| Vested | (130,562) | \$ 23.25 |
| Forfeited | <u>(81,905)</u> | <u>\$ 19.32</u> |
| Unvested balance as of December 31, 2017 | 639,287 | \$ 20.86 |
| Granted | 373,500 | \$ 28.37 |
| Vested | (235,307) | \$ 20.25 |
| Forfeited | <u>(172,468)</u> | <u>\$ 24.83</u> |
| Unvested balance as of December 31, 2018 | 605,012 | \$ 24.61 |
| Granted | 1,640,275 | \$ 12.78 |
| Vested | (244,038) | \$ 23.80 |
| Forfeited | <u>(192,731)</u> | <u>\$ 21.47</u> |
| Unvested balance as of December 31, 2019 | <u>1,808,518</u> | <u>\$ 14.32</u> |

For the year ended December 31, 2019, we granted 865,000 shares of performance stock awards with weighted-average grant-date fair value of \$10.78 per share. The performance stock awards will vest based on certain market and performance conditions, and all 865,000 shares were unvested as of December 31, 2019. There were no performance stock awards granted prior to 2019.

Stock-based Awards Valuation**Stock Option and 2014 ESPP Shares**

The fair value of both stock options and the option component of shares purchased under our 2014 ESPP was estimated using the Black-Scholes option pricing model. The description of the significant assumptions used in the model are as follows:

- *Fair Value of Common Stock.* The fair value of the common stock shares is based on our stock price as quoted by the Nasdaq.
- *Expected Term.* For stock options, the expected term is based on the simplified method, as our stock options have the following characteristics: (i) granted at-the-money; (ii) exercisability is conditioned upon service through the vesting date; (iii) termination of service prior to vesting results in forfeiture; (iv) limited exercise period following termination of service; and (v) options are non-transferable and non-hedgeable, or “plain vanilla” options, and we have limited history of exercise data. For stock options granted to non-employees before adoption of ASU 2018-07 on July 1, 2018 ([Note 2](#)), the expected term is based on the remaining contractual term. For ESPP, the expected term is based on the term of the purchase period under the 2014 ESPP.
- *Expected Volatility.* The expected volatility is based on the historical volatilities of a group of similar entities combined with the historical volatility of us. In evaluating similarity, we considered factors such as industry, stage of life cycle, capital structure, and company size.
- *Risk-Free Interest Rate.* The risk-free interest rate is based on U.S. Treasury constant maturity rates with remaining terms similar to the expected term of the stock options.



REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

- *Expected Dividend Rate.* We use an expected dividend rate of zero because we have never paid any dividends and do not plan to pay dividends in the foreseeable future.
- *Forfeitures.* We account for forfeitures as they occur.

The fair values of stock options were estimated using the Black-Scholes option pricing model with the following weighted-average assumptions in 2019:

| | Year Ended December 31, 2019 |
|--------------------------|---------------------------------|
| Expected term (in years) | 6.03 |
| Expected volatility | 60.2% |
| Risk-free interest rate | 2.1% |
| Expected dividend rate | —% |

The fair values of the option component of the shares purchased under the 2014 ESPP were estimated using the Black-Scholes option pricing model with the following weighted-average assumptions for years presented:

| | Year Ended December 31, | | |
|--------------------------|-------------------------|-------|-------|
| | 2019 | 2018 | 2017 |
| Expected term (in years) | 0.5 | 0.5 | 0.5 |
| Expected volatility | 43.4% | 50.9% | 59.2% |
| Risk-free interest rate | 2.3% | 1.9% | 0.9% |
| Expected dividend rate | —% | —% | —% |

Stock Option Assumptions Before 2019

Effective July 1, 2018, we adopted ASU 2018-07 ([Note 2](#)). All non-employee consultants stock options granted prior to adoption were remeasured at fair value as of July 1, 2018. Before adoption, stock-based compensation expense related to stock options granted to non-employee consultants is recognized as the stock options are earned. For non-employees, the fair values of the stock options vested were remeasured at each reporting date using the Black-Scholes option pricing model with the following weighted-average assumptions:

| | Year Ended December 31, | |
|--------------------------|-------------------------|-------|
| | 2018 | 2017 |
| Expected term (in years) | 5.5 | 8.9 |
| Expected volatility | 59.4% | 67.9% |
| Risk-free interest rate | 2.8% | 2.3% |
| Expected dividend rate | —% | —% |

REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

ASU 2018-07 did not impact valuation of stock options for employees and non-employee directors. The fair values of the employee and non-employee director stock options were estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

| | Year Ended December 31, | |
|--------------------------|-------------------------|-------|
| | 2018 | 2017 |
| Expected term (in years) | 6.0 | 6.0 |
| Expected volatility | 60.2% | 67.7% |
| Risk-free interest rate | 2.7% | 2.1% |
| Expected dividend rate | —% | —% |

Performance Stock Awards Subject to Market-based Vesting Conditions

Certain performance stock awards granted in 2019 include market-based vesting conditions (“market-based PSAs”). These market-based PSAs vest upon the earlier of i) the date that the closing share price of our common stock meet certain minimum share prices on a volume-weighted basis for a specified period of time or ii) upon a change in control in which the purchase price of our common stock is at or above the same minimum share prices as determined in the award agreement.

We determined the fair value of the market-based PSAs using the Monte Carlo simulation model. The following weighted-average assumptions were used in the Monte Carlo simulation model in determining fair value of these performance stock awards:

| | Year Ended December 31, 2019 |
|---|---------------------------------|
| Expected term (in years) ⁽¹⁾ | 10.0 |
| Expected volatility ⁽²⁾ | 60.0% |
| Risk-free interest rate | 1.8% |
| Expected dividend rate | —% |

(1) Expected term was based on the expiration period of the performance stock awards in the award agreement.

(2) Expected volatility was based on the historical volatilities of a group of similar entities combined with our historical volatility.

For the year ended December 31, 2019, we recognized stock-based compensation expense of \$0.5 million for the market-based PSAs.

Stock-based compensation expense was allocated as follows:

| (in thousands) | Year Ended December 31, | | |
|---|-------------------------|------------------|------------------|
| | 2019 | 2018 | 2017 |
| Research and development | \$ 8,512 | \$ 7,480 | \$ 5,902 |
| General and administrative | 9,410 | 8,793 | 7,328 |
| Total stock-based compensation expense | \$ 17,922 | \$ 16,273 | \$ 13,230 |

REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

Unrecognized Compensation Cost

| | As of December 31, | | | |
|--------------------------------------|--|--|--|--|
| | 2019 | | 2018 | |
| | Unrecognized Compensation Cost (in thousands) | Weighted Average Expected Recognize Period (in years) | Unrecognized Compensation Cost (in thousands) | Weighted Average Expected Recognize Period (in years) |
| Stock options | \$ 18,487 | 2.9 | \$ 20,202 | 2.7 |
| Restricted stock awards | 11,891 | 2.3 | 10,591 | 2.4 |
| Performance stock awards | 8,839 | 2.4 | — | — |
| Total unrecognized compensation cost | <u>\$ 39,217</u> | <u>2.6</u> | <u>\$ 30,793</u> | <u>2.6</u> |

11. Stockholders' Equity**Common Stock Warrants**

As of both December 31, 2019 and December 31, 2018, 34,113, common stock warrants were outstanding at an exercise price of \$14.95 per share, which expire in 2020.

Follow-On Public Offerings

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

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

In December 2019, we completed a follow-on public offering (the “December 2019 follow-on offering”), pursuant to which we issued 6,500,000 shares of common stock at \$17.00 per share for net proceeds of \$103.6 million, after underwriting discounts, commissions and other offering expenses. In January 2020, the underwriters of the December 2019 follow-on offering exercised their over-allotment option to purchase 975,000 additional shares of common stock for net proceeds of \$15.6 million, after underwriting discounts, commissions and other offering expenses.

At-The-Market Offerings

In March 2016, we entered into the 2016 At-The-Market (“ATM”) agreement (the “2016 ATM Agreement”) under which we may offer and sell common stock having aggregate proceeds of up to \$75.0 million from time to time through Cowen, our sales agent. Sales of common stock through Cowen under the 2016 ATM agreement would be made by means of ordinary brokers’ transactions on the Nasdaq or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by us and Cowen. Cowen will sell the common stock from time to time, based upon instructions from us (including any price, time or size limits or other customary parameters or conditions we may impose). We agreed to pay Cowen a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Cowen under the 2016 ATM Agreement. For the year ended December 31, 2017, we sold 1,802,651 shares of common stock under the 2016 ATM Agreement at a weighted average price of \$22.17 per share resulting in net proceeds of \$38.2 million after underwriting discounts, commissions and other offering expenses.

REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

In March 2018, we terminated the 2016 ATM Agreement and entered into a separate ATM agreement with 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. Sales of common stock through Cantor Fitzgerald under the 2018 ATM Agreement will be made by means of ordinary brokers’ transactions on the Nasdaq or otherwise at market prices prevailing at the time of sale, in block transactions, or as otherwise agreed upon by us and Cantor Fitzgerald. Cantor Fitzgerald will sell the common stock from time to time, based upon instructions from us. We agreed to pay Cantor Fitzgerald a commission of up to 3.0% of the gross sales proceeds of any common stock sold through Cantor Fitzgerald under the 2018 ATM Agreement. For the year ended December 31, 2019, we sold 687,189 shares of common stock under the 2018 ATM Agreement at a weighted average price of \$15.82 per share resulting in net proceeds of \$10.9 million after underwriting discounts, commissions and other offering expenses.

12. Income Taxes

From inception through December 31, 2019, we have only generated pretax losses. Loss before income taxes were as follows:

| (in thousands) | Year Ended December 31, | | |
|---------------------------------|-------------------------|---------------------|---------------------|
| | 2019 | 2018 | 2017 |
| Domestic | \$ (159,429) | \$ (139,568) | \$ (118,331) |
| Foreign | — | — | (2,256) |
| Loss before income taxes | \$ (159,429) | \$ (139,568) | \$ (120,587) |

Statutory Federal Income Tax Provision (Benefit)

Reconciliations of the statutory federal income tax provision (benefit) to our effective tax are as follows:

| (in thousands) | Year Ended December 31, | | |
|--|-------------------------|-----------------|-------------|
| | 2019 | 2018 | 2017 |
| Tax benefit at statutory federal rate ⁽¹⁾ | \$ (33,480) | \$ (29,309) | \$ (40,999) |
| Research and development credits | (4,723) | (4,064) | (1,858) |
| Other changes in valuation allowance | 36,379 | 42,902 | (35,783) |
| Nondeductible/nontaxable items | 1,429 | 108 | 738 |
| Other | 395 | (153) | 224 |
| Sale of intellectual property ⁽²⁾ | — | (14,008) | 14,008 |
| Foreign rate differential and withholding taxes | — | 2,370 | 767 |
| Impact of the Tax Reform Act | — | 5,154 | 62,903 |
| Income tax provision | \$ — | \$ 3,000 | \$ — |

(1) U.S. federal statutory rate was 21%, for the years ended December 31, 2019 and 2018, and 35% for the year ended December 31, 2017.

(2) This represents the tax effect of an intra-entity sale between us and our wholly owned subsidiary, Revance International Limited, which was eliminated for financial reporting purposes (discussed below).

REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

Deferred Tax Assets, Net

Components of our deferred tax assets, net were as follows:

| (in thousands) | Year Ended December 31, | |
|--|-------------------------|------------|
| | 2019 | 2018 |
| Deferred tax assets | | |
| Net operating loss carryforward | \$ 184,879 | \$ 146,618 |
| Accruals and reserves | 1,537 | 2,191 |
| Stock-based compensation | 6,241 | 5,173 |
| Tax credits | 17,449 | 12,230 |
| Fixed and intangible assets | 2,803 | 3,328 |
| Deferred revenue | 10,703 | — |
| Operating lease liabilities | 6,174 | — |
| Other | 19 | — |
| Total deferred tax assets | 229,805 | 169,540 |
| Less: valuation allowance ⁽¹⁾ | (224,222) | (169,540) |
| Deferred tax assets, gross | 5,583 | — |
| Deferred tax liabilities | | |
| Operating lease right of use assets | (5,583) | — |
| Deferred tax assets, net | \$ — | \$ — |

(1) The valuation allowance for the year ended December 31, 2019 increased by \$54.7 million, compared to the same period in 2018, primarily due to net operating losses and credits generated in those years.

Valuation Allowance

We have evaluated the positive and negative evidence bearing upon our ability to realize the deferred tax assets. We have considered our history of cumulative net losses incurred since inception and have concluded that it is more likely than not that we will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets due to the uncertainty of realizing future tax benefits from our net operating loss (“NOL”) carryforwards and other deferred tax assets as of December 31, 2019 and 2018. We reevaluate the positive and negative evidence at each reporting period.

Net Operation Loss and Tax Credits Carryforwards

As of December 31, 2019, we had NOL carryforwards available to reduce future taxable income, if any, for federal, California, and other states income tax purposes of \$734.6 million, \$398.2 million, and \$281.7 million, respectively. The California NOL carryforwards will begin to expire in 2028. If not utilized, the federal and the other states NOL carryforwards will begin expiring in 2020 and 2030, respectively.

As of December 31, 2019, we had research and development credit carryforwards of \$9.1 million and \$7.6 million available to reduce future taxable income, if any, for federal and California income tax purposes, respectively. The federal research and development credit carryforwards will begin expiring in 2023 if they are not utilized, and the California research and development credit carryforwards have no expiration date.

As of December 31, 2019, we had orphan drug credit carryforwards of \$7.7 million available to reduce future taxable income, if any, for federal income tax purposes. The federal orphan drug credit carryforwards will begin expiring in 2038 if they are not utilized.

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

In general, if we experience a greater than 50% aggregate change in ownership over a 3-year period (a Section 382 ownership change), utilization of our pre-change NOL carryforwards are subject to an annual limitation under Internal Revenue Code Section 382 (California and the other states have similar laws). The annual limitation generally is determined by multiplying the value of our stock at the time of such ownership change (subject to certain adjustments) by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization. We determined that an ownership change occurred on April 7, 2004 but that all carryforwards can be utilized prior to the expiration. We also determined that an ownership change occurred in February 2014, and as a result, we reduced the deferred tax assets and the corresponding valuation allowance to account for this limitation. Since the research and development credits for California carry over indefinitely, there was no change to the California research and development credits. We have reviewed our Internal Revenue Code Section 382 limitation through December 31, 2019 and have not identified any ownership changes resulting in a limitation. Our ability to use our remaining NOL carryforwards may be further limited if we experience a Section 382 ownership change as a result of future changes in our stock ownership.

California State Apportionment

In 2018, we petitioned the California Franchise Tax Board for an alternative apportionment percentage due to the insignificant apportionment percentage derived from the single sales factor methodology for California. In January 2019, the California Franchise Tax Board approved the use of an alternative apportionment method. Our NOL in California is estimated to increase by approximately \$219 million as a result of the change in apportionment model. We have increased our deferred tax assets by \$15 million with a corresponding offsetting adjustment to its valuation allowance. There is no impact to the our net loss in the period as a result of the adjustment.

Tax Cuts and Jobs Act

In December 2017, the U.S. government enacted Tax Cuts and Jobs Act (the “Tax Reform Act”). The Tax Reform Act includes but not limited to, reducing the U.S. federal corporate tax rate from 35% to 21%, allowing for federal NOL to be carried over indefinitely for NOL generated after December 31, 2017 with statutory limitations to the annual utilization, and creating a new limitation on deductible interest expense. We have completed our assessment of the accounting impact resulting from the Tax Reform Act in December 2018, and the aggregated impact to deferred taxes is \$68.1 million, which continues to be fully offset by a valuation allowance.

In October 2017, we created a wholly owned subsidiary, Revance International Limited, which was incorporated in the Cayman Islands, and transferred the economic rights to certain intellectual property for \$41.2 million to the newly formed subsidiary. Under the tax laws prior to the Tax Reform Act in December 2017, the transaction had no financial statement impact to us other than to decrease the current NOL by the amount of the consideration. As a result of the Tax Reform Act, we did not complete the accounting with regard to the tax effects associated with this intra-entity transfer as of December 31, 2017. In October 2018, we received notification that the Internal Revenue Service (IRS) had approved our request to disregard the Cayman subsidiary by treating it as a U.S. branch for federal income tax purposes, effectively eliminating any tax effects from the transaction. As a result of the finalization of our assessment of the Tax Reform Act, we have reversed the usage of the NOLs from this transaction as of December 31, 2018.

Unrecognized Tax Benefits

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

We do not expect that our uncertain tax positions will materially change in the next twelve months. For year ending December 31, 2019, the amount of unrecognized tax benefits increased due to additional research and development credits generated. The additional uncertain tax benefits would not impact our effective tax rate to the extent that we continue to maintain a full valuation allowance against our deferred tax assets.

REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

The unrecognized tax benefit was as follows:

| (in thousands) | Year Ended December 31, | | |
|--|-------------------------|-----------------|-----------------|
| | 2019 | 2018 | 2017 |
| Balance at the beginning of the period | \$ 4,200 | \$ 2,577 | \$ 1,819 |
| Additions for prior years | — | 333 | — |
| Additions for current year | 1,498 | 1,290 | 758 |
| Balance at the end of the period | <u>\$ 5,698</u> | <u>\$ 4,200</u> | <u>\$ 2,577</u> |

We file income tax returns in the U.S., California, and other states. We are not currently under examination by income tax authorities in any federal, state or other jurisdictions. All tax returns will remain open for examination by the federal and state authorities for three and four years, respectively, from the date of utilization of any NOL or tax credits.

13. Subsequent Events

Stock Options and Restricted Stock Awards Grants under the 2014 EIP

In January 2020, we granted 568,675 stock options and 1,027,825 restricted stock awards including performance stock awards under the 2014 EIP to existing employees.

Teoxane Exclusive Distribution Agreement

In January 2020, we entered into the Teoxane Agreement with Teoxane, pursuant to which Teoxane granted us with the exclusive right to import, market, promote, sell and distribute Teoxane's line of Resilient Hyaluronic Acid® dermal fillers, which include i) RHA® 2, RHA® 3 and RHA® 4 which have been approved by the FDA for the correction of moderate to severe dynamic facial wrinkles and folds, including RHA® 2, RHA® 3 and RHA® 4 in the currently approved indications, ii) RHA® 1, which we anticipate will be approved by the FDA in 2021 for the treatment of perioral rhytids, the indication currently in ongoing clinical trials, and iii) future hyaluronic acid filler advancements and products by Teoxane (collectively the "RHA® dermal fillers") in the U.S. and U.S. territories and possessions, in exchange for 2,500,000 shares of our common stock and certain other commitments by us. The Teoxane Agreement will be effective for a term of ten years upon product launch and may be extended for a two-year period upon the mutual agreement of the parties.

We have begun to build out a U.S. commercial organization and plan to introduce the FDA approved RHA® dermal fillers in the U.S. in the second quarter of 2020.

If Teoxane pursues regulatory approval for RHA® dermal fillers for certain new indications or filler technologies, including innovations with respect to existing products in the U.S., we will be subject to certain specified cost-sharing arrangements for third party expenses incurred in achieving regulatory approval for such products. We will also have a right of first negotiation with respect to any cosmeceutical products that Teoxane wishes to distribute in the U.S. and Teoxane will have a right of first negotiation in connection with the distribution of DAXI for aesthetic use, outside the U.S. and U.S. territories where Teoxane has an affiliate. We are required to meet certain minimum purchase obligations during each year of the term. We are also required to meet certain minimum expenditure requirements in connection with commercialization efforts.

We are currently assessing the accounting impact of the Teoxane Agreement.

Convertible Senior Notes Due 2027

On February 14, 2020, we issued an aggregate of \$287.5 million principal amount of notes, pursuant to an Indenture (Exhibit 4.2) between Revance and U.S. Bank National Association, as trustee (the "Notes"). The Notes are senior unsecured obligations of Revance and will bear interest at a rate of 1.75% per year, payable semiannually in arrears on February 15 and August 15 of each year, beginning on August 15, 2020. The Notes will mature on February 15, 2027, unless earlier converted,

REVANCE THERAPEUTICS, INC.

Notes to Consolidated Financial Statements — (Continued)

redeemed or repurchased. The Notes are convertible into cash, shares of our common stock, or a combination of cash and shares of our common stock, at our election. We received approximately \$278.4 million in net proceeds, after deducting the initial purchasers' discount, commissions, and estimated expenses payable by us, from the issuance of the Notes. We may not redeem the Notes prior to February 20, 2024, and no sinking fund is provided for the Notes.

We used approximately \$28.9 million of the net proceeds from the Notes to pay the cost of certain capped call transactions. The capped call transactions are expected generally to reduce potential dilution to our common stock upon any conversion of Notes and/or offset any cash payments we are required to make in excess of the principal amount of converted Notes.

We are currently assessing the accounting impact of the Notes and the capped call transactions.

14. Quarterly Results of Operations (Unaudited)

The following table presents our unaudited consolidated quarterly financial data. This information has been prepared on a basis consistent with that of the audited consolidated financial statements. We believe that all necessary adjustments, consisting of normal recurring accruals and adjustments, have been included to present fairly the quarterly financial data. The results of historical periods are not necessarily indicative of the results of operations for any future period.

| | Three Months Ended | | | | | | | |
|---|--------------------|---------------|-------------|-------------|--------------|---------------|-------------|-------------|
| | 2019 | | | | 2018 | | | |
| | December 31, | September 30, | June 30, | March 31, | December 31, | September 30, | June 30, | March 31, |
| (in thousands, except per share amounts) | | | | | | | | |
| Revenue | \$ 89 | \$ 46 | \$ — | \$ 278 | \$ 487 | \$ 2,362 | \$ 686 | \$ 193 |
| Loss from operations | \$ (46,170) | \$ (42,540) | \$ (39,122) | \$ (36,627) | \$ (38,412) | \$ (33,641) | \$ (34,919) | \$ (35,662) |
| Net loss | \$ (45,326) | \$ (41,409) | \$ (37,390) | \$ (35,304) | \$ (40,616) | \$ (32,834) | \$ (34,080) | \$ (35,037) |
| Basic and diluted net loss | \$ (45,326) | \$ (41,409) | \$ (37,390) | \$ (35,304) | \$ (40,616) | \$ (32,834) | \$ (34,080) | \$ (35,037) |
| Basic and diluted net loss per share ⁽¹⁾ | \$ (0.99) | \$ (0.96) | \$ (0.86) | \$ (0.85) | \$ (1.12) | \$ (0.91) | \$ (0.94) | \$ (0.97) |

(1) Net loss per share amounts are calculated discretely and therefore may not add up to the total due to rounding.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Newark, State of California on the 26th day of February, 2020.

REVANCE THERAPEUTICS, INC.

By: /s/ Mark J. Foley

Mark J. Foley

President and Chief Executive Officer

(Duly Authorized Principal Executive Officer)

By: /s/ Tobin C. Schilke

Tobin C. Schilke

Chief Financial Officer

*(Duly Authorized Principal Financial Officer and
Principal Accounting Officer)*

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POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Mark J. Foley and Tobin C. Schilke, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution for him, and in his name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

| Signatures | Title | Date |
|---|---|-------------------|
| /s/ Mark J. Foley Mark J. Foley | President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i> | February 26, 2020 |
| /s/ Tobin C. Schilke Tobin C. Schilke | Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i> | February 26, 2020 |
| /s/ Angus C. Russell Angus C. Russell | Director, Chairman | February 26, 2020 |
| /s/ Jill Beraud Jill Beraud | Director | February 26, 2020 |
| /s/ Robert Byrnes Robert Byrnes | Director | February 26, 2020 |
| /s/ Julian S. Gangolli Julian S. Gangolli | Director | February 26, 2020 |
| /s/ Phyllis Gardner Phyllis Gardner, M.D. | Director | February 26, 2020 |
| /s/ Chris Nolet Chris Nolet | Director | February 26, 2020 |
| /s/ Philip J. Vickers Philip J. Vickers, Ph.D. | Director | February 26, 2020 |