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, 2017

OR

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

For the transition period from to

Commission file number: 001-35726

Radius Health, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**80-0145732**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
950 Winter Street Waltham, Massachusetts	**02451**
(Address of principal executive offices)	**(Zip Code)**

617-551-4000

(Registrant's telephone number, including area code)

Securities issued pursuant to Section 12(b) of the Act: Common Stock

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

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	**The NASDAQ Global Market**

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

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

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

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

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

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

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☐
	Emerging growth company ☐

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

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

The aggregate market value of the registrant's common stock, $0.0001 par value per share ("Common Stock"), held by non-affiliates of the registrant, based on the last sale price of the Common Stock at the close of business on June 30, 2017 was $1.3 billion. For the purpose of the foregoing calculation only, all directors and executive officers of the registrant are assumed to be affiliates of the registrant.

Number of shares outstanding of the registrant's common stock, par value $0.0001 per share, as of February 26, 2018: 45,076,508

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2018 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

Radius Health, Inc.
Annual Report on Form 10-K
For the Fiscal Year Ended December 31, 2017
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report, including in the sections titled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," contains, in addition to historical information, forward-looking statements. We may, in some cases, use words such as "project," "believe," "anticipate," "plan," "expect," "estimate," "intend," "continue," "should," "would," "could," "potentially," "will," "may" or similar words and expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements in this Annual Report on Form 10-K may include, among other things, statements about:

- *our expectations regarding commercialization of TYMLOS™ in the U.S. and our ability to successfully commercialize TYMLOS in the U.S.;*
- *the therapeutic benefits and effectiveness of TYMLOS and our investigational product candidates;*
- *our ability to obtain U.S. and foreign regulatory approval for our product candidates, and the timing thereof;*
- *our ability to compete with other companies that are or may be developing or selling products that are competitive with TYMLOS or our investigational product candidates;*
- *anticipated trends and challenges in the market in which TYMLOS will compete and in other potential markets in which we may compete;*
- *our plans with respect to collaborations and licenses related to the development, manufacture or sale of TYMLOS and our investigational product candidates;*
- *the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;*
- *the safety profile and related adverse events of TYMLOS and our investigational product candidates;*
- *the ability of our investigational product candidates to meet existing or future regulatory standards;*
- *our expectations regarding federal, state and foreign regulatory requirements;*
- *the success of our clinical studies for our investigational product candidates;*
- *our expectations as to future financial performance, expense levels, future payment obligations and liquidity sources;*
- *our ability to attract, motivate, and retain key personnel; and*
- *other factors discussed elsewhere in this report.*

The outcome of the events described in these forward-looking statements is subject to known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from the results anticipated by these forward-looking statements. These important factors include our financial performance, our ability to attract and retain customers, our development activities and those other factors we discuss in Item 1A of this Annual Report on Form 10-K under the caption "Risk Factors." You should read these factors and the other cautionary statements made in this report as being applicable to all related forward-looking statements wherever they appear in this report. These risk factors are not exhaustive and other sections of this report may include additional factors which could adversely impact our business and financial performance.

PART I

ITEM 1. BUSINESS.

Unless otherwise provided in this report, all references in this report to "we," "us," "Radius," "our company," "our," or the "Company" refer to Radius Health, Inc. and our subsidiaries.

Overview

We are a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics in the areas of osteoporosis and oncology. In April 2017, our first commercial product, TYMLOS™ (abaloparatide) injection, was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In May 2017, we commenced U.S. commercial sales of TYMLOS and, as of February 2018, TYMLOS was available and covered for approximately 259 million U.S. insured lives, representing approximately 86% of U.S. insured lives. In May 2017, we also announced positive top-line results from our completed 24-month ACTIVExtend clinical trial for TYMLOS, which met all of its primary and secondary endpoints. We submitted a labeling supplement to the FDA in connection with the results from our ACTIVExtend trial in December 2017. In July 2017, we entered into a license and development agreement with Teijin Limited ("Teijin") for abaloparatide for subcutaneous injection ("abaloparatide-SC") in Japan. Under this agreement, we are entitled to receive milestone payments upon the achievement of certain regulatory and sales milestones and a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term, and we have an option to negotiate for a co-promotion agreement with Teijin for abaloparatide-SC in Japan. Our European Marketing Authorisation Application ("MAA") for abaloparatide-SC is under review by the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") and we expect an opinion from the CHMP regarding the MAA during the first half of 2018. In the first quarter of 2018, we expect to initiate a clinical trial in men with osteoporosis which, if successful, will form the basis of a supplemental new drug application ("NDA") seeking to expand the use of TYMLOS to treat men with osteoporosis at high risk for fracture. In the first half of 2018, we plan to initiate a bone histomorphometry study, which would enroll approximately 25 postmenopausal women with osteoporosis to evaluate the early effects of TYMLOS on tissue-based bone remodeling and structural indices.

We are developing an abaloparatide transdermal patch, or abaloparatide-patch, for potential use in the treatment of postmenopausal women with osteoporosis. In January 2018, we met with the FDA and gained alignment with the agency on a single, pivotal BMD non-inferiority bridging study to support an NDA submission. The FDA agreed that, depending on the study results, a randomized, open label, active-controlled, non-inferiority Phase 3 study of up to 500 patients with postmenopausal osteoporosis at high risk of fracture would be sufficient to gain approval for abaloparatide-patch. The FDA confirmed that the primary endpoint will be change in lumbar spine BMD at 12 months and that the non-inferiority margin must preserve 75% of the active control (abaloparatide-SC) based on the lower bound of the 95% confidence interval. We expect to initiate this pivotal study in mid-2019 and to complete it in 2020. In February 2018, we entered into a scale-up and commercial supply agreement with 3M Company pursuant to which 3M has agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-patch.

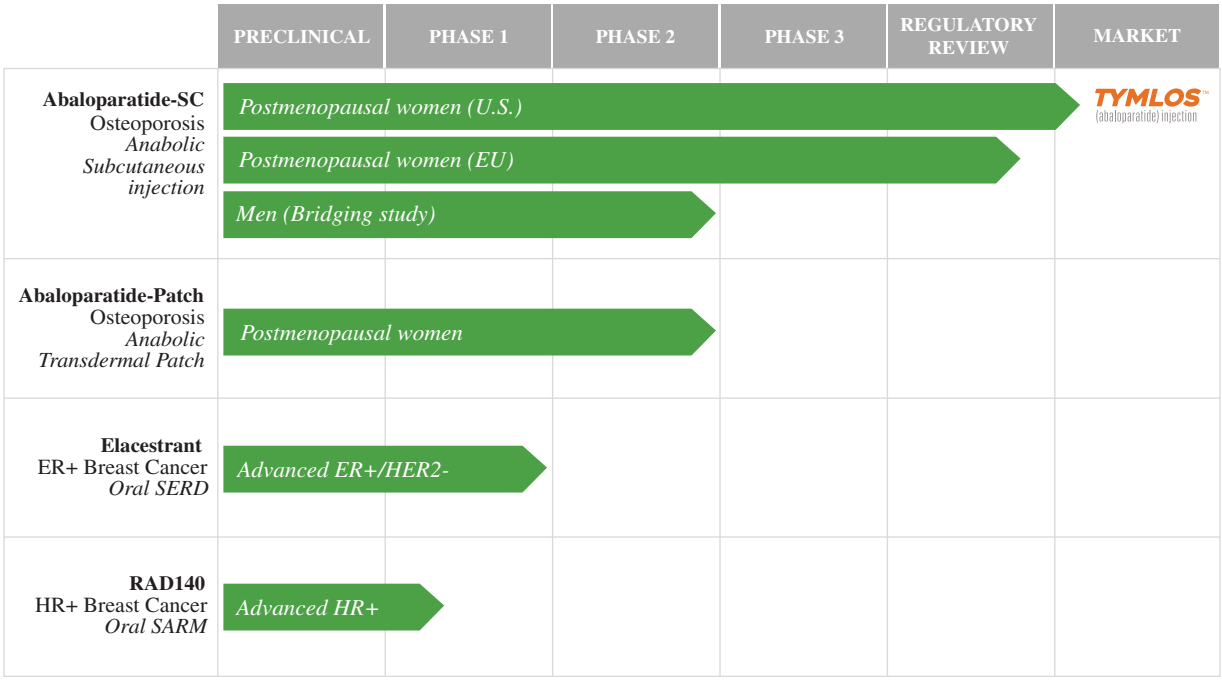
We are also developing our investigational product candidate, elacestrant (RAD1901), a selective estrogen receptor degrader ("SERD"), for potential use in the treatment of hormone-receptor positive breast cancer. We have completed enrollment in our ongoing dose escalation Part A, and dose expansion Part B and C, and in the ^{18}F fluoroestradiol positron emission tomography ("FES-PET") imaging Phase 1 studies of elacestrant in advanced metastatic breast cancer. In October 2017, the FDA granted Fast Track designation for our elacestrant breast cancer program. Based on feedback from the EMA and the FDA, we now intend to conduct a single, randomized, controlled Phase 2 trial of elacestrant as a third-line monotherapy in approximately 300 patients

with ER+/HER2- advanced/metastatic breast cancer. Patients in the study would be randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent and the primary endpoint of the study will be progression-free survival ("PFS"). The study would also include a planned interim PFS analysis. We believe that, depending on results, this single trial would support applications for global marketing approvals for elacestrant as a third-line monotherapy. In addition, depending on results of the interim analysis, the Company could seek accelerated approval for elacestrant in the United States. We will provide further study details when the Phase 2 study is started, which we expect will be in the second half of 2018.

We are developing our internally discovered investigational product candidate, RAD140, a non-steroidal selective androgen receptor modulator ("SARM") for potential use in the treatment of hormone-receptor positive breast cancer. In September 2017, we initiated a Phase 1 study of RAD140 in patients with locally advanced or metastatic breast cancer. We expect to provide an update on our RAD140 development program by the end of 2018.

Our Marketed Product and Investigational Product Candidates

The success of our business is primarily dependent upon our ability to commercialize TYMLOS and to develop and commercialize our current and future product candidates. The following table identifies our commercial product, TYMLOS, and the investigational product candidates in our current product portfolio, their potential indication and stage of development. We hold worldwide commercialization rights for all these product candidates, excluding abaloparatide-SC, for which we hold worldwide commercialization rights, except for Japan, where we have an option to negotiate a co-promotion agreement with Teijin.



Abaloparatide

In April 2017, the FDA approved TYMLOS for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. We are developing two formulations of abaloparatide: abaloparatide-SC, an injectable subcutaneous formulation of abaloparatide, and abaloparatide-patch, a short-wear-time patch formulation of abaloparatide.

TYMLOS (Abaloparatide-SC)

TYMLOS was approved in the United States in April 2017 for the treatment of postmenopausal women with osteoporosis at high risk for fracture. The efficacy of TYMLOS for the treatment of postmenopausal women with osteoporosis was evaluated in an 18-month, randomized, multicenter, double-blind, placebo controlled clinical trial. The study also had an open label teriparatide arm. TYMLOS resulted in a significant reduction in the incidence of new vertebral fractures compared to placebo at 18 months (0.6% TYMLOS compared to 4.2% placebo). The relative risk reduction in new vertebral fractures at 18 months compared to placebo was 86% ($p < 0.001$) for TYMLOS and 80% ($p < 0.001$) for teriparatide. TYMLOS also resulted in a significant reduction in the incidence of nonvertebral fractures at the end of the 18 months of treatment plus one month follow-up where no drug was administered (2.7% for TYMLOS compared to 4.7% for placebo). The relative risk reduction, compared to placebo, in nonvertebral fractures for TYMLOS was 43% ($p=0.049$) and 28% for teriparatide ($p=0.22$). There was a 43% ($p=0.02$) risk reduction in clinical fractures for TYMLOS and a 29% ($p=0.11$) for teriparatide; a 70% ($p<0.001$) risk reduction in major osteoporotic fractures for TYMLOS, and 33% ($p=0.14$) for teriparatide, compared with patients who received placebo. For major osteoporotic fractures, there was a 55% ($p=0.03$) risk reduction for TYMLOS-treated patients compared to teriparatide.

The first commercial sales of TYMLOS in the United States occurred in May 2017 and we are commercializing TYMLOS in the United States through our commercial organization. We have built a distribution network for TYMLOS in the United States, comprised of well-established distributors and specialty pharmacies. Under our distribution model, both the distributors and specialty pharmacies take physical delivery of TYMLOS and the specialty pharmacies dispense TYMLOS directly to patients. As of February 2018, TYMLOS was available and covered for approximately 259 million U.S. insured lives, representing approximately 86% of U.S. insured lives. We hold worldwide commercialization rights to abaloparatide-SC, except for Japan, where we have an option to negotiate a co-promotion agreement with Teijin for abaloparatide-SC.

The combined 25-month fracture data from our Phase 3 clinical trial program for TYMLOS formed the basis of our regulatory submissions in the United States and Europe. In November 2015, we submitted an MAA for abaloparatide-SC to the EMA, which was validated and is currently undergoing active regulatory assessment by the CHMP. In December 2017, the CHMP issued a third Day-180 List of Outstanding Issues. As part of its on-going risk-benefit assessment, the CHMP informed the Company that it intends to refer the MAA to a scientific advisory group for additional advice. We expect that the CHMP may adopt an opinion regarding our MAA during the first half of 2018. We intend to enter into a collaboration for the commercialization of abaloparatide-SC outside of the United States and Japan.

In May 2017, we announced positive top-line results from the completed 24-month ACTIVExtend clinical trial of TYMLOS, which met all of its primary and secondary endpoints. In ACTIVExtend, patients who had completed 18 months of TYMLOS injections or placebo in the ACTIVE Phase 3 trial were transitioned to receive 24 additional months of open-label alendronate. For the subset of ACTIVE trial patients ($n=1139$) that enrolled in the ACTIVExtend trial, the previous TYMLOS-treated patients had a significant 84% relative risk reduction ($p<0.0001$) in the incidence of new vertebral fractures compared with patients who received placebo followed by alendronate. They also demonstrated a 39% risk reduction in nonvertebral fractures ($p=0.038$), a 34% risk reduction clinical fractures ($p=0.045$) and a 50% risk reduction in major osteoporotic fractures ($p=0.011$) compared with patients who received placebo followed by alendronate. At the 43-month timepoint, for all patients ($n=1645$) that enrolled in the ACTIVE trial, TYMLOS-treated patients had a statistically significant risk reduction in new vertebral fractures ($p<0.0001$), nonvertebral fractures ($p=0.038$), clinical fractures ($p=0.045$), and major osteoporotic fractures ($p<0.001$), compared with patients who received placebo followed by alendronate. While not a pre-specified endpoint, there was also a statistically significant risk reduction in hip fractures ($p=0.027$) at the 43-month time point in the TYMLOS-treated patients, compared with patients who received placebo followed by alendronate. The adverse events reported during the alendronate treatment period were similar between the previous TYMLOS-treated patients and the previous placebo group. The incidences of cardiovascular adverse events including serious adverse events were similar between groups. There have been no

cases of osteonecrosis of the jaw or atypical femoral fracture in the entire TYMLOS development program. The results from the completed ACTIVExtend trial were presented at a major scientific meeting in September 2017 and we submitted a labeling supplement in connection with this data to the FDA in December 2017.

In July 2017, we entered into a license and development agreement with Teijin for abaloparatide-SC in Japan. Pursuant to the agreement, we may receive additional milestone payments upon the achievement of certain regulatory and sales milestones, and a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term. In addition, we have an option to negotiate for a co-promotion agreement with Teijin for abaloparatide-SC in Japan.

In late 2017, we gained agreement with the FDA on the design of a clinical trial in men with osteoporosis which, if successful, will form the basis of a supplemental NDA seeking to expand the use of TYMLOS to treat men with osteoporosis at high risk for fracture. The study will be a randomized, double-blind, placebo-controlled trial that will enroll approximately 225 men with osteoporosis. The primary endpoint is change in spine BMD at 12 months compared with placebo. In previous clinical trials, TYMLOS has demonstrated increases in BMD in postmenopausal women. The study will include specialized high-resolution imaging of bone structure in a subset of the study participants. We expect to initiate the trial in the first quarter of 2018.

In the first half of 2018, we plan to initiate a bone histomorphometry study, which would enroll approximately 25 postmenopausal women with osteoporosis to evaluate the early effects of TYMLOS on tissue-based bone remodeling and structural indices.

Abaloparatide-patch

We are also developing abaloparatide-patch, based on 3M's patented Microstructured Transdermal System technology, for potential use as a short wear-time transdermal patch. We hold worldwide commercialization rights to the abaloparatide-patch technology and we are developing abaloparatide-patch toward future global regulatory submissions to build upon the potential success of TYMLOS. Our development strategy for abaloparatide patch is to bridge to the established efficacy and safety of our approved abaloparatide-SC formulation.

We commenced a human replicative clinical evaluation of the optimized abaloparatide-patch in December 2015, with the goal of achieving comparability to abaloparatide-SC. In September 2016, we presented results from this evaluation of the first and second abaloparatide-patch prototypes, demonstrating that formulation technology can modify the pharmacokinetic profile of abaloparatide, including Tmax, half-life ("T1/2"), and area under the curve ("AUC"). In March 2018, we announced that through further optimization we had achieved comparability to the abaloparatide-SC profile with a third prototype (the "current abaloparatide-patch"). The current abaloparatide-patch optimized the drug-device combination through process improvements, a finalized formulation, selection of a dose (300 μg), and the introduction of a new clinical applicator. Together these changes, which were designed to improve the ease of use and patient experience, resulted in an increased half-life and AUC (915 pg.hr/ml for the current abaloparatide-patch, compared to 242 pg.hr/ml for the first patch prototype, 645 pg.hr/ml for the second patch prototype, and 936 pg.hr/ml for abaloparatide-SC).

In January 2018, we met with the FDA to align on a regulatory and development path for registration of abaloparatide-patch. We gained alignment with the agency on a single, pivotal BMD non-inferiority bridging study to support an NDA submission. The FDA agreed that, depending on the study results, a randomized, open label, active-controlled, non-inferiority Phase 3 study of up to 500 patients with postmenopausal osteoporosis at high risk of fracture would be sufficient to gain approval for abaloparatide-patch. The FDA confirmed that the primary endpoint will be change in lumbar spine BMD at 12 months and that the non-inferiority margin must preserve 75% of the active control (abaloparatide-SC) based on the lower bound of the 95% confidence interval. We expect to initiate this pivotal study in mid-2019 and to complete it in 2020. On February 27, 2018, we entered into a scale-up and commercial supply agreement with 3M Company pursuant to which 3M has agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-patch.

Elacestrant (RAD1901)

Elacestrant is a SERD that we are evaluating for potential use as an oral treatment for hormone-receptor positive breast cancer. We hold worldwide commercialization rights to elacestrant. Elacestrant is currently being investigated in women with advanced estrogen receptor positive ("ER-positive") and human epidermal growth factor receptor 2-negative ("HER2-negative") breast cancer, the most common subtype of the disease. Studies completed to date indicate that the compound has the potential for use as a single agent, or in combination with other therapies for the treatment of breast cancer. To date, no dose limiting toxicities have been reported in the elacestrant program. We believe that, subject to successful development, regulatory review and approval, elacestrant could have the potential to offer the following advantages compared to current standard of care treatments for ER-positive and HER2-negative breast cancer:

- ability to degrade the estrogen receptor;
- favorable efficacy and tolerability profile;
- ability to effectively combine with other agents;
- treatment of hormone-resistant breast cancers; and
- once a day oral administration.

We have completed enrollment in our elacestrant FES-PET imaging study and dose-escalation Part A and expansion study parts B and C Phase 1 breast cancer trials. In June 2017, we discussed the data from these ongoing Phase 1 studies with the FDA to gain alignment on defining the next steps for our elacestrant breast cancer program, including the design of a Phase 2 trial. In this meeting, the FDA agreed that a single-arm monotherapy Phase 2 study of up to 200 patients, could be appropriate with the primary endpoint being ORR, coupled with DOR. Depending on the study results, which must demonstrate an improvement over then available therapies, this study could be considered a pivotal study for accelerated approval as long as a confirmatory study is ongoing at the time of our NDA submission. In October 2017, the FDA granted Fast Track designation for our elacestrant breast cancer program. Fast Track is a process the FDA designed to facilitate the development and expedite the review of new therapies to treat serious conditions and fill unmet medical needs.

In February 2018, we received scientific advice from the European Medicines Agency ("EMA") regarding a potential single-arm monotherapy Phase 2 trial of elacestrant in patients with ER+, HER2- advanced or metastatic breast cancer. In addition, we had a further meeting in February 2018 with the FDA regarding the registrational pathway for elacestrant at which we confirmed FDA's guidance for a single-arm study and gained alignment with the agency on an alternative potential comparator study design for our monotherapy program. Based on feedback from the EMA and the FDA, we now intend to conduct a single, randomized, controlled Phase 2 trial of elacestrant as a third-line monotherapy in approximately 300 patients with ER+/HER2- advanced/metastatic breast cancer. Patients in the study would be randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent and the primary endpoint of the study will be progression-free survival ("PFS"). The study would also include a planned interim PFS analysis. We believe that, depending on results, this single trial would support applications for global marketing approvals for elacestrant as a third-line monotherapy. In addition, depending on results of the interim analysis, the Company could seek accelerated approval for elacestrant in the United States. We will provide further study details when the Phase 2 study is started, which we expect will be in the second half of 2018.

Phase 1—Dose-Escalation and Expansion Study

In December 2014, we commenced a Phase 1, multicenter, open-label, multiple-part, dose-escalation study of elacestrant in postmenopausal women with ER-positive and HER2-negative advanced breast cancer in the United States to determine the recommended dose for a Phase 2 clinical trial and to make a preliminary evaluation of the potential anti-tumor effect of elacestrant. Part A of this Phase 1 study was designed to evaluate escalating doses of elacestrant. The Part B expansion cohort was initiated at 400-mg daily dosing in March 2016

to allow for an evaluation of additional safety, tolerability and preliminary efficacy. The patients enrolled in this study are heavily pretreated ER-positive, HER2-negative advanced breast cancer patients who have received a median of 3 prior lines of therapy including fulvestrant and CDK4/6 inhibitors, and about 50% of the patients had ESR1 mutations. We have completed enrollment in the ongoing dose-escalation Part A and expansion study parts B and C. In December 2017, we initiated enrollment of a Part D cohort in this study to provide additional data on a more homogeneous and genetically defined patient population to support our overall elacestrant clinical development program and anticipated regulatory submissions.

In December 2016 and June 2017, we reported positive results from this ongoing Phase 1 dose-escalation and expansion study. As of the study cut-off date of April 28, 2017, the elacestrant single agent ORR, was 23% with five confirmed partial responses in heavily pre-treated patients with advanced ER-positive breast cancer and in the 400-mg patient group of 26 patients with mature data, the median progression free survival was 4.5 months. These results showed that elacestrant was well-tolerated with the most commonly reported adverse events being low grade nausea and dyspepsia. In December 2017, we reported additional updated data from this ongoing Phase 1 dose-escalation and expansion study, which included mature data from 40 patients treated at the 400 mg dose in this study. As of the study cut-off date of October 30, 2017, the elacestrant single agent ORR, was 27.3% with six confirmed partial responses out of 22 patients with response evaluation criteria in solid tumors ("RECIST") measurable disease. The median progression free survival was 5.4 months and clinical benefit rate at 24 weeks was 47.4%. These results showed that elacestrant was well-tolerated with the most commonly reported adverse events being low grade nausea, dyspepsia and vomiting.

Phase 1—FES-PET Study

In December 2015, we commenced a Phase 1 FES-PET study in patients with metastatic breast cancer in the European Union, which includes the use of FES-PET imaging to assess estrogen receptor occupancy in tumor lesions following elacestrant treatment. In December 2016, we reported positive results from the Phase 1 FES-PET study. The first three enrolled patients dosed at the 400-mg cohort had a tumor FES-PET signal intensity reduction ranging from 79% to 91% at day 14 compared to baseline. This study enrolled five additional patients in the 400-mg daily oral cohort, followed by eight patients in the 200-mg daily oral cohort.

In December 2017, we reported updated data from the Phase 1 FES-PET study that elacestrant demonstrated robust reduction in tumor ER availability in patients with advanced ER+ breast cancer who progressed on prior endocrine therapy. Seven out of eight patients dosed at the 400-mg cohort, and four out of seven patients dosed at the 200-mg cohort, had a tumor FES-PET signal intensity reduction equal to, or greater than, 75% at day 14 compared to baseline. The reduction in FES uptake supports flexibility for both 200-mg and 400-mg elacestrant dose selection for further clinical development in combination studies with various targeted agents and was similar in patients harboring mutant or wild-type ESR1. The most commonly reported adverse events reported were grade 1 and 2 nausea and dyspepsia.

Potential for use in Combination Therapy

In July 2015, we announced that early but promising preclinical data showed that our investigational drug elacestrant, in combination with Pfizer's palbociclib, a cyclin-dependent kinase ("CDK 4/6 inhibitor") or Novartis' everolimus, an mTOR inhibitor, was effective in shrinking tumors. In preclinical patient-derived xenograft breast cancer models with either wild type or mutant ESR1, treatment with elacestrant resulted in marked tumor growth inhibition, and the combination of elacestrant with either agent, palbociclib or everolimus, showed anti-tumor activity that was significantly greater than either agent alone. We believe that this preclinical data suggests that elacestrant has the potential to overcome endocrine resistance, is well-tolerated, and has a profile that is well suited for use in combination therapy.

In December 2017, we announced additional preclinical data that continues to demonstrate elacestrant anti-tumor activity, as a single agent and in combination, in multiple models. In these preclinical models, elacestrant

demonstrated marked tumor growth inhibition, as a single agent in models treated with multiple rounds of fulvestrant and in combination with CDK 4/6 inhibitors such as palbociclib and abemaciclib and with a phosphoinositide 3-kinase inhibitor, alpelisib.

Collaborations

In July 2016, we entered into a preclinical collaboration with Takeda Pharmaceutical Company Limited to evaluate the combination of elacestrant with Takeda's investigational drug TAK-228, an oral mTORC 1/2 inhibitor in Phase 2b development for the treatment of breast, endometrial and renal cancer, with the goal of potentially exploring such combination in a clinical study. We and Takeda have each agreed to contribute resources and supply compound material necessary for studies to be conducted under the collaboration and will share third party out-of-pocket research and development expenses. Activities under this collaboration are ongoing. Upon completion, both parties will agree upon the appropriate communication of the results.

In January 2016, we entered into a worldwide clinical collaboration with Novartis Pharmaceuticals to evaluate the safety and efficacy of combining elacestrant with Novartis' investigational agent LEE011 (ribociclib), a CDK 4/6 inhibitor, and BYL719 (alpelisib), an investigational phosphoinositide 3-kinase inhibitor. In January 2018, we terminated this collaboration following the completion of preclinical studies. We are evaluating additional opportunities to collaborate with companies to evaluate the safety and efficacy of combining elacestrant with other agents for the treatment of breast cancer. We believe that such combinations may be suitable in earlier lines of treatment for patients with advanced disease.

Vasomotor Symptoms

In December 2017, following a strategic review, we announced that we decided to discontinue further evaluation of elacestrant for vasomotor symptoms to focus instead on the continued clinical development of the compound as a potential treatment option in breast cancer.

RAD140

RAD140 is an internally discovered SARM. The androgen receptor ("AR") is highly expressed in many ER-positive, ER-negative, and triple-negative receptor breast cancers. Due to its receptor and tissue selectivity, potent activity, oral bioavailability, and long half-life, we believe RAD140 could have clinical potential in the treatment of breast cancer. We hold worldwide commercialization rights to RAD140.

In July 2016, we reported that RAD140 in preclinical xenograft models of breast cancer demonstrated potent tumor growth inhibition when administered alone or in combinations with CDK4/6 inhibitors. It is estimated that approximately 70% of breast cancers express the androgen receptor. Our data suggest that RAD140 activity at the androgen receptor leads to activation of AR signaling pathways including an AR-specific tumor suppressor and suppression of ER signaling. In April 2017, we presented these RAD140 preclinical results at a major scientific congress.

In September 2017, we initiated a Phase 1 study of RAD140 in patients with hormone receptor positive locally advanced or metastatic breast cancer. The clinical trial is designed to evaluate the safety and maximum tolerated dose of RAD140 in approximately 40 patients. Primary safety outcomes from the trial include rate of dose-limiting toxicities, adverse events related to treatment, and tolerability as measured by dose interruptions or adjustments. In addition, pharmacokinetics, pharmacodynamics and tumor response will also be evaluated. We expect to provide an update on our RAD140 development program by the end of 2018.

Our Strategy

To achieve our goal of becoming a leading provider of innovative endocrine therapeutics in the areas of osteoporosis and oncology, we plan to:

- **Become a market leader for anabolic osteoporosis therapies.** TYMLOS was approved by the FDA in April 2017, with U.S. commercial sales commencing in May 2017, and are focused on growing our market share in anabolic appropriate patients. We are conducting additional clinical research towards potential additional indications for TYMLOS, including a clinical trial in men with osteoporosis that we expect to initiate in the first quarter of 2018, and which, if successful, will form the basis of a supplemental NDA seeking to expand the use of TYMLOS to treat men with osteoporosis at high risk for fracture. In the first half of 2018, we plan to initiate a bone histomorphometry study, which would enroll approximately 25 postmenopausal women with osteoporosis to evaluate the early effects of TYMLOS on tissue-based bone remodeling and structural indices.
- **Selectively pursue partnerships or collaborations to commercialize abaloparatide-SC outside the U.S.** In July 2017, we entered into a license and development agreement with Teijin for abaloparatide-SC in Japan. Under this agreement, we received an upfront payment and may receive up to an aggregate of $40.0 million upon the achievement of certain regulatory and sales milestones, and a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term. In addition, we have an option to negotiate for a co-promotion agreement with Teijin for abaloparatide-SC in Japan. We intend to enter into a collaboration for the commercialization of abaloparatide-SC outside of the United States and Japan.
- **Expand abaloparatide's market potential through the continued development of abaloparatide-patch.** We are developing our investigational abaloparatide-patch as a short-wear-time transdermal patch. In January 2018, we met with the FDA and gained alignment with the agency on a single, pivotal BMD non-inferiority bridging study to support an NDA submission. The FDA agreed that, depending on the study results, a randomized, open label, active-controlled, non-inferiority Phase 3 study of up to 500 patients with postmenopausal osteoporosis at high risk of fracture would be sufficient to gain approval for abaloparatide-patch. The FDA confirmed that the primary endpoint will be change in lumbar spine BMD at 12 months and that the non-inferiority margin must preserve 75% of the active control (abaloparatide-SC) based on the lower bound of the 95% confidence interval. We expect to initiate this pivotal study in mid-2019 and to complete it in 2020. In February 2018, we entered into a scale-up and commercial supply agreement with 3M Company pursuant to which 3M has agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-patch.
- **Become a leader in the field of hormone-receptor driven cancers.** We are developing our investigational product candidate elacestrant as a potential treatment for hormone-receptor positive breast cancer as a single agent and in combination with other therapies. Based on feedback from the EMA and the FDA, we intend to conduct a single, randomized, controlled Phase 2 trial of elacestrant as a third-line monotherapy in approximately 300 patients with ER+/HER2- advanced/metastatic breast cancer. We believe that, depending on results, this single trial would support applications for global marketing approvals for elacestrant as a third-line monotherapy. In addition, depending on results of the interim analysis, the Company could seek accelerated approval for elacestrant in the United States. We will provide further study details when the Phase 2 study is started, which we expect will be in the second half of 2018. We are exploring potential strategic collaborations to broaden development to potentially address earlier lines of treatment in combination with other anti-cancer agents. In addition, we are leveraging our experience with elacestrant to develop a next generation SERD for potential use in the treatment of hormone-drive cancers. We are advancing the development of RAD140 as a potential treatment for hormone-receptor positive breast cancer and in September 2017 we initiated a Phase 1 study of RAD140 in patients with locally advanced or metastatic breast cancer.
- **Continue to expand our product portfolio.** We plan to leverage our drug development expertise to discover and develop additional investigational product candidates focused on osteoporosis, oncology

and endocrine diseases and conditions. We may also consider opportunistically expanding our product portfolio within these areas through in-licensing, acquisitions or partnerships.

Our Opportunity

Osteoporosis

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, which leads to greater fragility and an increase in fracture risk. All bones become more fragile and susceptible to fracture as the disease progresses. People tend to be unaware that their bones are getting weaker, and a person with osteoporosis can fracture a bone from even a minor fall. The debilitating effects of osteoporosis have substantial costs. Loss of mobility, admission to nursing homes and dependence on caregivers are all common consequences of osteoporosis. The prevalence of osteoporosis is growing and, per the National Osteoporosis Foundation ("NOF"), is significantly under-recognized and under-treated in the population. While the aging of the population is a primary driver of an increase in cases, osteoporosis is also increasing from the use of drugs that induce bone loss, such as chronic use of glucocorticoids and aromatase inhibitors that are increasingly used for breast cancer and hormone therapies used for prostate cancer.

The NOF has estimated that 10 million people in the United States, composed of eight million women and two million men, already have osteoporosis, and another approximately 44 million have low bone mass placing them at increased risk for osteoporosis. In addition, the NOF has estimated that osteoporosis is responsible for more than two million fractures in the United States each year resulting in an estimated $19 billion in costs annually. The NOF expects that the number of fractures in the United States due to osteoporosis will rise to three million by 2025, resulting in an estimated $25.3 billion in costs each year. Worldwide, osteoporosis affects an estimated 200 million women according to the International Osteoporosis Foundation ("IOF") and causes more than 8.9 million fractures annually, which is equivalent to an osteoporotic fracture occurring approximately every three seconds.

The IOF has estimated that 1.6 million hip fractures occur worldwide each year, and by 2050 this number could reach between 4.5 million and 6.3 million. The IOF estimates that in Europe alone, the annual cost of osteoporotic fractures could surpass €76 billion by 2050. The IOF, in its 2013 Asia-Pacific audit, estimated that osteoporosis affects 10% of the population in Japan over age 40; composed of 9.8 million women and 3 million men. By 2025, it is expected that 25% of Japan's population will be over 70 years old with an average life expectancy of 87 years, and this is predicted to increase to 32% of Japan's population in 2050 with an average life expectancy of 92 years. In 2050, it is also expected that over half of the Japanese population will be over 50 years old. The expected increase in the age of its population presents Japan with a significant need to focus on the health of its elderly, including osteoporosis.

In 2017, total sales of branded osteoporosis drugs approximated $7.3 billion, worldwide, of which more than $4.3 billion was attributable to injectable therapies. There are two main types of osteoporosis drugs currently available in the United States, anti-resorptive agents and anabolic agents. Anti-resorptive agents act to prevent further bone loss by inhibiting the breakdown of bone, whereas anabolic agents stimulate bone formation to build new bone.

We believe there is a large unmet need in the market for osteoporosis treatment because existing therapies have been reported to have shortcomings in efficacy, tolerability and convenience. For example, one current standard of care, bisphosphonates, which are anti-resorptive agents, have been associated with infrequent but serious adverse events, such as osteonecrosis of the jaw and atypical fractures, especially of long bones. These side effects, although uncommon, reportedly have created increasing concern with physicians and patients. We believe many physicians are seeking alternatives to bisphosphonates. Forteo/Forsteo® (teriparatide) marketed by Eli Lilly and Company ("Lilly") and Prolia® (denosumab) marketed by Amgen Inc. ("Amgen") are two alternatives to bisphosphonates that are approved for the treatment of osteoporosis. Prolia has also been

associated with infrequent but serious adverse events, such as osteonecrosis of the jaw and atypical fractures. In 2017, Forteo/Forsteo had reported worldwide sales of approximately $1.8 billion, $1.0 billion in the United States and $0.8 billion outside of the United States, and Prolia had reported worldwide sales of approximately $2.0 billion, $1.3 billion in the United States and $0.7 billion outside of the United States. In 2016, IMS (now IQVIA) estimated that sales for osteoporosis medicines in Japan were 292 billion yen, or approximately $2.7 billion, of which aggregate sales for anabolic agents (Lilly's Forteo and Asahi Kasei's Teribone) comprised 77 billion yen, or $720 million.

We believe there is a significant opportunity for TYMLOS (abaloparatide), an anabolic agent which is approved in the U.S. for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. With the potential addition of new guidelines, expanding research, increased diagnosis effort, greater awareness of the long-term risk associated with osteoporotic fracture, and new, more effective therapies we believe osteoporosis treatment will expand and likewise our potential commercial opportunity. We also believe that there is a significant opportunity for abaloparatide outside the U.S., particularly in Japan, where we have a license and development agreement with Teijin for abaloparatide-SC under which we are entitled to receive payments up to an aggregate of $40.0 million upon the achievement of certain regulatory and sales milestones, a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term, and have an option to negotiate for a co-promotion agreement with Teijin for abaloparatide-SC in Japan.

Abaloparatide

In April 2017, the FDA approved TYMLOS for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. We are developing two formulations of abaloparatide: abaloparatide-SC and abaloparatide-patch.

Abaloparatide-SC

TYMLOS was approved in the United States in April 2017 for the treatment of postmenopausal women with osteoporosis at high risk for fracture. The first commercial sales of TYMLOS in the United States occurred in May 2017. We are commercializing TYMLOS in the United States through our commercial organization. We have a distribution network of well-established distributors and specialty pharmacies for TYMLOS in the United States. Under our distribution model, both the distributors and specialty pharmacies take physical delivery of TYMLOS and the specialty pharmacies dispense TYMLOS directly to patients. We hold worldwide commercialization rights to abaloparatide-SC, except for Japan, where we have an option to negotiate a co-promotion agreement with Teijin for abaloparatide-SC.

The combined 25-month fracture data from our Phase 3 clinical trial program for TYMLOS formed the basis of our regulatory submissions in the United States and Europe. In November 2015, we submitted an MAA for abaloparatide-SC to the EMA, which was validated and is currently undergoing active regulatory assessment by the CHMP. In December 2017, the CHMP issued a third Day-180 List of Outstanding Issues. As part of its on-going risk-benefit assessment, the CHMP informed the Company that it intends to refer the MAA to a scientific advisory group for additional advice. We expect that the CHMP may adopt an opinion regarding our MAA during the first half of 2018. We intend to enter into a collaboration for the commercialization of abaloparatide-SC outside of the United States and Japan.

In May 2017, we announced positive top-line results from the completed 24-month ACTIVExtend clinical trial of TYMLOS, which met all its primary and secondary endpoints. In ACTIVExtend, patients who had completed 18 months of TYMLOS (abaloparatide) injections or placebo in the ACTIVE Phase 3 trial were transitioned to receive 24 additional months of open-label alendronate. For the subset of ACTIVE trial patients

(n=1139) that enrolled in the ACTIVExtend trial, the previous TYMLOS-treated patients had a significant 84% relative risk reduction ($p<0.0001$) in the incidence of new vertebral fractures compared with patients who received placebo followed by alendronate. They also demonstrated a 39% risk reduction in nonvertebral fractures ($p=0.038$), a 34% risk reduction clinical fractures ($p=0.045$) and a 50% risk reduction in major osteoporotic fractures ($p=0.011$) compared with patients who received placebo followed by alendronate. At the 43-month timepoint, for all patients (n=1645) that enrolled in the ACTIVE trial, TYMLOS-treated patients had a statistically significant risk reduction in new vertebral fractures ($p<0.0001$), nonvertebral fractures ($p=0.038$), clinical fractures ($p=0.045$), and major osteoporotic fractures ($p<0.001$), compared with patients who received placebo followed by alendronate. While not a pre-specified endpoint, there was also a statistically significant risk reduction in hip fractures ($p=0.027$) at the 43-month time point in the TYMLOS-treated patients, compared with patients who received placebo followed by alendronate. The adverse events reported during the alendronate treatment period were similar between the previous TYMLOS-treated patients and the previous placebo group. The incidences of cardiovascular adverse events including serious adverse events were similar between groups. There have been no cases of osteonecrosis of the jaw or atypical femoral fracture in the entire TYMLOS development program. The results from the completed ACTIVExtend trial were presented at a major scientific meeting in September 2017 and we submitted a labeling supplement in connection with this data to the FDA in December 2017.

In July 2017, we entered into a license and development agreement with Teijin for abaloparatide-SC in Japan. Pursuant to the agreement, we may receive additional milestone payments upon the achievement of certain regulatory and sales milestones, and a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term. In addition, we have an option to negotiate for a co-promotion agreement with Teijin for abaloparatide-SC in Japan.

In late 2017, we gained agreement with the FDA on the design of a clinical trial in men with osteoporosis which, if successful, will form the basis of a supplemental NDA seeking to expand the use of TYMLOS to treat men with osteoporosis at high risk for fracture. The study will be a randomized, double-blind, placebo-controlled trial that will enroll approximately 225 men with osteoporosis. The primary endpoint is change in lumbar spine BMD at 12 months compared with placebo. In previous clinical trials, TYMLOS has demonstrated increases in BMD in postmenopausal women. The study will include specialized high-resolution imaging of bone structure in a subset of the study participants. We expect to initiate the trial in the first quarter of 2018.

In the first half of 2018, we plan to initiate a bone histomorphometry study, which would enroll approximately 25 postmenopausal women with osteoporosis to evaluate the early effects of TYMLOS on tissue-based bone remodeling and structural indices.

Abaloparatide-patch

We are also developing abaloparatide-patch, based on 3M's patented Microstructured Transdermal System technology, for potential use as a short wear-time transdermal patch. We hold worldwide commercialization rights to the abaloparatide-patch technology and we are developing abaloparatide-patch toward future global regulatory submissions to build upon the potential success of TYMLOS. Our development strategy for abaloparatide patch is to bridge to the established efficacy and safety of our approved abaloparatide-SC formulation.

We commenced a human replicative clinical evaluation of the optimized abaloparatide-patch in December 2015, with the goal of achieving comparability to abaloparatide-SC. In September 2016, we presented results from this evaluation of the first and second abaloparatide-patch prototypes, demonstrating that formulation technology can modify the pharmacokinetic profile of abaloparatide, including Tmax, half-life ("T1/2"), and area under the curve ("AUC"). In March 2018, we announced that through further optimization we had achieved comparability to the abaloparatide-SC profile with a third prototype (the "current abaloparatide-patch"). The current abaloparatide-patch optimized the drug-device combination through process improvements,

a finalized formulation, selection of a dose (300 µg), and the introduction of a new clinical applicator. Together these changes, which were designed to improve the ease of use and patient experience, resulted in an increased half-life and AUC (915 pg.hr/ml for the current abaloparatide-patch, compared to 242 pg.hr/ml for the first patch prototype, 645 pg.hr/ml for the second patch prototype, and 936 pg.hr/ml for abaloparatide-SC).

In January 2018, we met with the FDA to align on a regulatory and development path for registration of abaloparatide-patch. We gained alignment with the agency on a single, pivotal BMD non-inferiority bridging study to support an NDA submission. The FDA agreed that, depending on the study results, a randomized, open label, active-controlled, non-inferiority Phase 3 study of up to 500 patients with postmenopausal osteoporosis at high risk of fracture would be sufficient to gain approval for abaloparatide-patch. The FDA confirmed that the primary endpoint will be change in lumbar spine BMD at 12 months and that the non-inferiority margin must preserve 75% of the active control (abaloparatide-SC) based on the lower bound of the 95% confidence interval. We expect to initiate this pivotal study in mid-2019. On February 27, 2018, we entered into a scale-up and commercial supply agreement with 3M Company pursuant to which 3M has agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-patch.

Breast Cancer

According to the World Health Organization, breast cancer is the most common cancer in women and the global incidence is expected to increase in the coming years. The major cause of death from breast cancer is metastases, most commonly to the bone, liver, lung and brain. Approximately 30% of early-stage breast cancer patients develop metastatic disease, and of those patients 90% relapse during the course of their treatment. About 5% of breast cancer patients have distant metastases at the time of diagnosis. Patients with metastatic breast cancer have a five-year survival rate of only 25%, compared with a greater than 90% five-year survival rate for patients with only local disease at diagnosis. Importantly, even patients without metastases at diagnosis are at risk for developing metastases over time.

Approximately 70% of breast cancers express the ER and depend on estrogen signaling for growth and survival. The standard of care for ER+ advanced/metastatic breast cancer calls for endocrine therapy at all stages of treatment, with patients typically cycling through multiple anti-estrogen therapies, such as aromatase inhibitors ("AIs"), selective estrogen receptor modulators ("SERMs"), and selective estrogen receptor degraders ("SERDs").

These therapies inhibit the ER pathway either by inhibiting estrogen synthesis (AIs) or by directly inhibiting the estrogen receptor (SERMs and SERDs). While both SERMs and SERDs antagonize the estrogen receptor, SERDs function to degrade the receptor. Although many patients initially respond to AIs and SERMs, a majority of patients will have progressive disease and the dependence on ER for tumor growth and sensitivity to other ER-targeting agents is often retained. On the basis of this continued dependence on ER, novel SERDs have gained widespread attention as a means of delivering more durable responses and increasing progression-free survival in this setting. Indeed, SERDs have demonstrated clinical efficacy in patients who have progressed on AIs or SERMs.

Currently only one SERD, fulvestrant, an intramuscular injection, is approved for the treatment of ER-positive metastatic breast cancer. We believe a significant opportunity may exist for new oral therapies that can more effectively treat ER-positive breast cancer.

Elacestrant (RAD1901)

Elacestrant (RAD1901) is a SERD that we are evaluating for potential use as a once daily oral treatment for hormone-receptor positive breast cancer. We hold worldwide commercialization rights to elacestrant, which we licensed from Eisai Co. Ltd. ("Eisai"). Elacestrant is currently being investigated in women with ER-positive and HER2-negative breast cancer, the most common subtype of the disease. Studies completed to date indicate that

the compound has the potential for use as a single agent or in combination with other therapies for the treatment of breast cancer. To date, no dose limiting toxicities have been reported in the elacestrant program.

We believe that, subject to successful development, regulatory review and approval, elacestrant could have the potential to offer the following advantages over other current standard of care treatments for ER-positive breast cancer:

- ability to degrade the estrogen receptor;
- favorable efficacy and tolerability profile;
- ability to effectively combine with other agents;
- treatment of hormone-resistant breast cancers; and
- once a day oral administration.

We have completed enrollment in our 18-F fluoroestradiol positron emission tomography ("FES-PET") imaging study and dose-escalation Part A and expansion study parts B and C Phase 1 breast cancer trials. In June 2017, we discussed the data from these ongoing Phase 1 studies with the FDA to gain alignment on defining the next steps for our elacestrant breast cancer program, including the design of a Phase 2 trial. In this meeting, the FDA agreed that a single-arm monotherapy Phase 2 study of up to 200 patients, could be appropriate with the primary endpoint being ORR, coupled with DOR. Depending on the study results, which must demonstrate an improvement over then available therapies, this study could be considered a pivotal study for accelerated approval as long as a confirmatory study is ongoing at the time of our NDA submission. In October 2017, the FDA granted Fast Track designation for our elacestrant breast cancer program.

In February 2018, we received scientific advice from the European Medicines Agency ("EMA") regarding a potential single-arm monotherapy Phase 2 trial of elacestrant in patients with ER+, HER2- advanced or metastatic breast cancer. In addition, we had a further meeting in February 2018 with the FDA regarding the registrational pathway for elacestrant at which we confirmed FDA's guidance for a single-arm study and gained alignment with the agency on an alternative potential comparator study design for our monotherapy program. Based on feedback from the EMA and the FDA, we now intend to conduct a single, randomized, controlled Phase 2 trial of elacestrant as a third-line monotherapy in approximately 300 patients with ER+/HER2- advanced/metastatic breast cancer. Patients in the study would be randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent and the primary endpoint of the study will be progression-free survival ("PFS"). The study would also include a planned interim PFS analysis. We believe that, depending on results, this single trial would support applications for global marketing approvals for elacestrant as a third-line monotherapy. In addition, depending on results of the interim analysis, the Company could seek accelerated approval for elacestrant in the United States. We will provide further study details when the Phase 2 study is started, which we expect will be in the second half of 2018.

Phase 1—Dose-Escalation and Expansion Study

In December 2014, we commenced a Phase 1, multicenter, open-label, multiple-part, dose-escalation study of elacestrant in postmenopausal women with ER-positive and HER2-negative advanced breast cancer in the United States to determine the recommended dose for a Phase 2 clinical trial and to make a preliminary evaluation of the potential anti-tumor effect of elacestrant. Part A of this Phase 1 study was designed to evaluate escalating doses of elacestrant. The Part B expansion cohort was initiated at 400-mg daily dosing in March 2016 to allow for an evaluation of additional safety, tolerability and preliminary efficacy. The patients enrolled in this study are heavily pretreated ER-positive, HER2-negative advanced breast cancer patients who have received a median of 3 prior lines of therapy including fulvestrant and CDK4/6 inhibitors, and about 50% of the patients had ESR1 mutations. We have completed enrollment in the ongoing dose-escalation Part A and expansion study parts B and C. In December 2017, we opened a Part D cohort in this study to provide additional data on a more homogeneous and genetically defined patient population to support our overall elacestrant clinical development program and anticipated regulatory submissions.

In December 2016, we reported positive results from this ongoing Phase 1 dose-escalation and expansion study. These results showed that elacestrant was well-tolerated with the most commonly reported adverse events being low grade nausea and dyspepsia. Enrollment in the Part C tablet dosage form cohort was completed in November 2016.

In June 2017, we reported additional positive data from this ongoing Phase 1 dose-escalation and expansion study. As of the study cut-off date of April 28, 2017, the elacestrant single agent ORR, was 23% with five confirmed partial responses in heavily pre-treated patients with advanced ER-positive breast cancer. In the 400-mg patient group of 26 patients with mature data, the median progression free survival was 4.5 months. These results showed that elacestrant was well-tolerated with the most commonly reported adverse events being low grade nausea and dyspepsia.

In December 2017, we reported updated data from this ongoing Phase 1 dose-escalation and expansion study, which included mature data from 40 patients treated at the 400 mg dose in this study. As of the study cut-off date of October 30, 2017, the elacestrant single agent ORR, was 27.3% with six confirmed partial responses out of 22 patients with RECIST measurable disease. The median progression free survival was 5.4 months and clinical benefit rate at 24 weeks was 47.4%. These results showed that elacestrant was well-tolerated with the most commonly reported adverse events being low grade nausea, dyspepsia and vomiting.

Phase 1—FES-PET Study

In December 2015, we commenced a Phase 1 18-F fluoroestradiol positron emission tomography ("FES-PET") study in patients with metastatic breast cancer in the European Union, which includes the use of FES-PET imaging to assess estrogen receptor occupancy in tumor lesions following elacestrant treatment. In December 2016, we reported positive results from the Phase 1 FES-PET study. The first three enrolled patients dosed at the 400-mg cohort had a tumor FES-PET signal intensity reduction ranging from 79% to 91% at day 14 compared to baseline. This study enrolled 5 additional patients in the 400-mg daily oral cohort, followed by 8 patients in the 200-mg daily oral cohort.

In December 2017, we reported updated data from the Phase 1 FES-PET study that elacestrant demonstrated robust reduction in tumor ER availability in patients with advanced ER+ breast cancer who progressed on prior endocrine therapy. Seven out of eight patients dosed at the 400-mg cohort, and four out of seven patients dosed at the 200-mg cohort, had a tumor FES-PET signal intensity reduction equal to, or greater than, 75% at day 14 compared to baseline. The reduction in FES uptake supports flexibility for both 200-mg and 400-mg elacestrant dose selection for further clinical development in combination studies with various targeted agents and was similar in patients harboring mutant or wild-type ESR1. The most commonly reported adverse events reported were grade 1 and 2 nausea and dyspepsia.

Potential for use in Combination Therapy

In July 2015, we announced that early but promising preclinical data showed that our investigational drug elacestrant, in combination with Pfizer's palbociclib, a cyclin-dependent kinase 4/6 inhibitor, or Novartis' everolimus, an mTOR inhibitor, was effective in shrinking tumors. In preclinical patient-derived xenograft breast cancer models with either wild type or mutant ESR1, treatment with elacestrant resulted in marked tumor growth inhibition, and the combination of elacestrant with either agent, palbociclib or everolimus, showed anti-tumor activity that was significantly greater than either agent alone. We believe that this preclinical data suggests that elacestrant has the potential to overcome endocrine resistance, is well-tolerated, and has a profile that is well suited for use in combination therapy.

In December 2017, we announced additional preclinical data that continues to demonstrate elacestrant anti-tumor activity, as a single agent and in combination, in multiple models. In these preclinical models, elacestrant demonstrated marked tumor growth inhibition, as a single agent in models treated with multiple rounds of

fulvestrant and in combination with CDK 4/6 inhibitors such as palbociclib and abemaciclib and with a phosphoinositide 3-kinase inhibitor, alpelisib.

Collaborations

In July 2016, we entered into a preclinical collaboration with Takeda Pharmaceutical Company Limited to evaluate the combination of elacestrant with Takeda's investigational drug TAK-228, an oral mTORC 1/2 inhibitor in Phase 2b development for the treatment of breast, endometrial and renal cancer, with the goal of potentially exploring such combination in a clinical study. We and Takeda have each agreed to contribute resources and supply compound material necessary for studies to be conducted under the collaboration and will share third party out-of-pocket research and development expenses. Activities under this collaboration are ongoing. Upon completion, both parties will agree upon the appropriate communication of the results.

In January 2016, we entered into a worldwide clinical collaboration with Novartis Pharmaceuticals to evaluate the safety and efficacy of combining elacestrant with Novartis' investigational agent LEE011 (ribociclib), a CDK 4/6 inhibitor, and BYL719 (alpelisib), an investigational phosphoinositide 3-kinase inhibitor. In January 2018, we terminated this collaboration following the completion of pre-clinical studies. We are evaluating additional opportunities to collaborate with companies to evaluate the safety and efficacy of combining elacestrant with other agents for the treatment of breast cancer. We believe that such combinations may be suitable in earlier lines of treatment for patients with advanced disease.

Our Investigational Drug—RAD140

RAD140 is an internally discovered SARM. The androgen receptor is highly expressed in many ER-positive, ER-negative, and triple-negative receptor breast cancers. Due to its receptor and tissue selectivity, potent activity, oral bioavailability, and long half-life, we believe RAD140 could have clinical potential in the treatment of breast cancer. We hold worldwide commercialization rights to RAD140.

In September 2017, we initiated a Phase 1 study of RAD140 in patients with hormone receptor positive locally advanced or metastatic breast cancer. The clinical trial is designed to evaluate the safety and maximum tolerated dose of RAD140 in approximately 40 patients. Primary safety outcomes from the trial include rate of dose-limiting toxicities, adverse events related to treatment, and tolerability as measured by dose interruptions or adjustments. In addition, pharmacokinetics, pharmacodynamics and tumor response will also be evaluated. We expect to provide an update on our RAD140 development program by the end of 2018.

In July 2016, we reported that RAD140 in preclinical xenograft models of breast cancer demonstrated potent tumor growth inhibition when administered alone or in combinations with CDK4/6 inhibitors. It is estimated that approximately 70% of breast cancers express the androgen receptor. Our data suggest that RAD140 activity at the androgen receptor leads to activation of AR signaling pathways including an AR-specific tumor suppressor and suppression of ER signaling. In April 2017, we presented these RAD140 preclinical results at a major scientific congress.

Manufacturing

We do not own or operate manufacturing facilities for the production of our commercial product, TYMLOS, or any of our investigational product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future.

Abaloparatide, the active pharmaceutical ingredient ("API") for both TYMLOS and abaloparatide-patch, is manufactured for us on a contract basis by Polypeptide Laboratories Holding (PPL) AB ("PPL"), as successor-in-interest to Lonza Group Ltd., using a solid phase peptide synthesis assembly process, and purification by high pressure liquid chromatography. Abaloparatide for TYMLOS is supplied as a liquid in a multi-dose cartridge for

use in a pen delivery device. The components of the pen delivery device are manufactured by Ypsomed AG ("Ypsomed"). The multi-dose cartridges and pen delivery device are filled, assembled and packaged by Vetter International GmbH ("Vetter").

Abaloparatide-patch drug product is manufactured by 3M Company and 3M Innovative Properties Company, (together "3M"), based on their patented microneedle technology to administer drugs through the skin, as an alternative to subcutaneous injection.

Elacestrant API and drug product are manufactured for us on a contract basis by Patheon, Inc.

RAD140 API and drug product are manufactured for us on a contract basis by Alcami Corporation.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, which govern the methods used in, and the facilities and controls used for, the manufacture, processing, packing and holding of drugs. FDA and International Conference on Harmonisation ("ICH") current Good Manufacturing Practice ("cGMP") requirements include those pertaining to record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our contract manufacturing organizations are required to manufacture TYMLOS and our investigational product candidates under cGMP conditions. cGMP is a regulatory standard for the production of human pharmaceuticals that imposes extensive substantive, procedural and record keeping requirements on the manufacturing processes, testing methodology, and associated production and testing facilities.

Intellectual Property

As of December 31, 2017, we owned or co-owned 11 issued U.S. patents, as well as 15 pending U.S. patent applications, 4 pending Patent Cooperation Treaty ("PCT") applications, 55 pending foreign patent applications in the European Patent Office and 14 other jurisdictions, and 99 granted foreign patents. As of December 31, 2017, we had licenses to 3 U.S. patents related to compositions and related uses thereof, as well as numerous foreign counterparts to many of these patents and patent applications. We own the federal trademark registration in the United States for Radius® in association with pharmaceuticals. In addition, we have received notices of allowance in the U.S. and in Canada for TYMLOS and for trademarks on potential brand names for our product candidates in the U.S. and in other countries.

We strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining patents intended to cover our investigational product candidates and compositions, their methods of use and processes for their manufacture and any other inventions that are commercially important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will significantly depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology and inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how and continuing technological innovation to develop and maintain our proprietary position.

Abaloparatide

We acquired and maintain exclusive worldwide rights, excluding development and commercialization rights for Japan, to certain patents, data and technical information related to abaloparatide through a license agreement with an affiliate of Ipsen Pharma SAS ("Ipsen"). Composition of matter of abaloparatide was claimed in the United States (U.S. Patent No. 5,969,095), Europe, Australia, Canada, China, Hong Kong, South Korea, New Zealand, Poland, Russia, Singapore, Mexico, Hungary, and Taiwan. These patents and European Patent

No. 0847278, which was included in the license from Ipsen and claimed the composition of matter of abaloparatide, expired in 2016. The subcutaneous formulation of abaloparatide for use in treating osteoporosis is covered by Patent No. 7,803,770 until the statutory term expires October 3, 2027, which we expect will be extended to March 26, 2028 (statutory term that may be extended with 175 days of patent term adjustment due to delays in patent prosecution by the United States Patent and Trademark Office, or USPTO) in the United States (not including any patent term extension under the Hatch-Waxman Act). The intended therapeutic formulation for abaloparatide-SC is covered by Patent No. 8,148,333 until 2027 in the United States (not including any patent term extension under the Hatch-Waxman Act). Related patents granted in Europe, Australia, China, Israel, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, and Ukraine, and additional patent applications pending in Brazil, Canada, Europe, Hong Kong, India, South Korea, and Norway, will have a patent expiration date of 2027, not taking into account extension under any applicable laws. A notice to grant the intended therapeutic formulation for abaloparatide-SC and its use for osteoporosis treatment has been received from the European Patent Office in February 2018. When granted, this patent and the granted European Patent No. 2957278 will have a normal expiry of October 3, 2027, not including any issued supplementary patent certificates ("SPC"). We are aware of two oppositions to European Patent No. 2957278 filed before the opposition period expired on February 19, 2018. One opposition was filed on February 16, 2018 by Teva Pharmaceutical Industries Ltd and the other opposition was filed on February 19, 2018 in the name of a patent law firm, Isenbruck Bosl Horschler LLP. Patent applications covering various aspects of abaloparatide for microneedle application have been granted in Australia, Europe, Japan, and New Zealand, and additional patent applications are currently pending in the United States, Europe, Hong Kong, and Japan. The issued patents and any patents that might issue from the pending applications will have statutory expiration dates ranging from 2032 to 2037, not taking into account extension under any applicable laws. We have worldwide rights to commercialize abaloparatide-patch, including in Japan.

Elacestrant (RAD1901)

We exclusively licensed the worldwide rights to elacestrant from Eisai. U.S. Patent No. 7,612,114 (statutory term expires December 25, 2023 which may be extended up to August 18, 2026 with 967 days of patent term adjustment not taking into account any Hatch-Waxman patent term extensions) that covers elacestrant as a composition of matter as well as the use of elacestrant for treatment of estrogen-dependent breast cancer. Corresponding patents issued in Australia, Canada, Japan, Poland, and Europe and pending in India will have a statutory expiration date in 2023, not taking into account extension under any applicable laws. We exclusively licensed US 9,421,264 (statutory term expires October 10, 2034) covering the treatment of ER+, SERM-resistant (such as tamoxifen and fulvestrant) breast cancer brain metastasis with elacestrant and related applications covering, more broadly, the use of elacestrant for the treatment of ER+ cancers, such as SERM-resistant ER+ breast cancer (statutory term expires October 10, 2034). Corresponding applications pending in Europe and Canada will have a statutory expiration date in 2035. Polymorphic forms of elacestrant are covered in a U.S. application and a PCT application (filed January 2018) having a projected statutory expiration date in 2038, not taking into account any extension under any applicable laws. Elacestrant combination therapies with a CDK4/6 inhibitor (e.g., palbociclib) or an mTOR inhibitor (e.g., everolimus) for treatment of cancers that are drug-resistant and/or expressing mutant ERα+ are covered by applications pending in the U.S., Australia, Brazil, Canada, China, Europe, Israel, Japan, South Korea, Mexico, New Zealand, Russia, and Singapore (statutory expiration date in 2036, not taking into account any extension under any applicable laws).

RAD140

The composition of matter of, and methods of using, RAD140 are covered by U.S. Patent No. 8,067,448 (statutory term expires February 19, 2029, which we expect will be extended to September 25, 2029, with potentially 218 days of patent term adjustment due to delays by the USPTO, not taking into account any Hatch Waxman patent term extensions) and U.S. Patent No. 8,268,872 (statutory term expires February 19, 2029 which may be extended to September 25, 2029 with patent term adjustment, subject to a terminal disclaimer of Patent Nos. 8,067,448 and 8,455,525). Related patents have been granted in Australia, Canada, Europe, Japan and

Mexico and additional patent applications are pending in Brazil and India. Any patents issued from these filings will have a statutory expiration date in 2029. RAD140 for the treatment of breast cancer expressing the androgen receptor ("AR+ breast cancer") is covered in a PCT application (projected statutory expiration date in 2037, not taking into account extension under any applicable laws). The PCT application covers the use of RAD140 alone or in combination with a CDK4/6 inhibitor (e.g., palbociclib) or an mTOR inhibitor (e.g., everolimus) for the treatment of the AR+ breast cancer.

There can be no assurance that an issued patent will remain valid and enforceable in a court of law through the entire patent term. Should the validity of a patent be challenged, the legal process associated with defending the patent can be costly and time consuming. Issued patents can be subject to oppositions, interferences and other third-party challenges that can result in the revocation of the patent or that can limit patent claims such that patent coverage lacks sufficient breadth to protect subject matter that is commercially relevant. Competitors may be able to circumvent our patents. Development and commercialization of pharmaceutical products can be subject to substantial delays and it is possible that at the time of commercialization any patent covering the product has expired or will be in force for only a short period of time following commercialization. We cannot predict with any certainty if any third-party U.S. or foreign patent rights, or other proprietary rights, will be deemed infringed by the use of our technology. Nor can we predict with certainty which, if any, of these rights will or may be asserted against us by third-parties. Should we need to defend ourselves and our partners against any such claims, substantial costs may be incurred. Furthermore, parties making such claims may be able to obtain injunctive or other equitable relief, which could effectively block our ability to develop or commercialize some or all our products in the United States and abroad and could result in the award of substantial damages. In the event of a claim of infringement, we or our partners may be required to obtain one or more licenses from a third party. There can be no assurance that we can obtain a license on a reasonable basis should we deem it necessary to obtain rights to an alternative technology that meets our needs. The failure to obtain a license may have a material adverse effect on our business, results of operations and financial condition.

We also rely on trade secret protection for our confidential and proprietary information. No assurance can be given that we can meaningfully protect our trade secrets on a continuing basis. Others may independently develop substantially equivalent confidential and proprietary information or otherwise gain access to our trade secrets.

It is our policy to require our employees and consultants, outside scientific collaborators, sponsored researchers and other advisors who receive confidential information from us to execute confidentiality agreements upon the commencement of employment or consulting relationships. These agreements provide that all confidential information developed or made known to these individuals during the course of the individual's relationship with us is to be kept confidential and is not to be disclosed to third parties except in specific circumstances. The agreements provide that all inventions conceived by an employee shall be our property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Our success will depend in part on our ability to obtain and maintain patent protection, preserve trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others, both in the United States and other territories worldwide.

Competition

The development and commercialization of new products to treat the targeted indications of our investigational product candidates is highly competitive, and TYMLOS faces, and our product candidates if approved, will face considerable competition from major pharmaceutical, biotechnology and specialty pharmaceutical companies, including Lilly, Amgen, UCB S.A., Merck & Co, Novartis, Pfizer, Roche, Asahi Kasei, and Corium, that currently market and/or are seeking to develop products for similar indications. Many of our competitors have substantially more resources than we do, including financial, manufacturing, marketing,

research and drug development resources. In addition, many of these companies have longer operating histories and more experience than us in preclinical and clinical development, manufacturing, regulatory and global commercialization.

Abaloparatide

There are two main types of osteoporosis drugs currently available in the United States, anti-resorptive agents and anabolic agents. Anti-resorptive agents including bisphosphonates, estrogen, SERMs and Amgen's Prolia are the most common treatments for osteoporosis. Teriparatide, marketed by Lilly under the name Forteo/Forsteo (outside the U.S.), is the only other anabolic drug approved in the United States and the only anabolic drug approved Europe for the treatment of osteoporosis. We are aware of companies pursuing development of biosimilar and/or generic versions of teriparatide through various regulatory pathways, including Pfenex, Inc. in the United States; Teva Pharmaceutical Industries, Ltd., approved in various European Union member states and under U.S. regulatory review; and STADA Arzneimittel AG and Gedeon Richter, approved in the European Union (in each case, with launch not expected until expiration of the applicable patents covering teriparatide, or if earlier, invalidation of such patents in connection with currently pending patent litigation and/or challenges). Other companies are in earlier stages of development of a generic version of teriparatide. Other organizations are also working to develop new therapies to treat osteoporosis. For example, Amgen and UCB are co-developing romosozumab, a humanized monoclonal antibody that inhibits the action of sclerostin, for which an MAA has recently been filed and validated in the European Union.

In addition, we are aware that Corium is developing a transdermal form of PTH (1-34) that would compete with abaloparatide-patch.

Elacestrant (RAD1901)

Elacestrant for the treatment of hormone receptor positive breast cancer will face competition from SERDs, CNS-penetrant anti-cancer agents and from chemotherapy derivatives. AstraZeneca's Faslodex is the only SERD currently approved in the United States for the treatment of metastatic breast cancer. In addition, there are other organizations working to develop new therapies to treat metastatic breast cancer, including Roche, which is developing two oral SERD's which are currently in Phase 1 and Phase 2 clinical development.

RAD140

RAD140 is being developed for women with hormone receptor positive breast cancer. While no SARMs are currently approved as therapeutics in the United States, there are select competitive molecules in development across a range of indications, including in oncology (GTx), hip fractures (Viking Therapeutics), and cachexia (GSK).

We cannot assure you that any of our current investigational product candidates, if successfully developed and approved, will be able to compete effectively against these, or any other competing therapeutics that may become available on the market.

Collaborations and License Agreements

3M

On February 27, 2018 we entered into a Scale-Up And Commercial Supply Agreement (the "Supply Agreement") with 3M, pursuant to which 3M has agreed to exclusively manufacture Phase 3 and global commercial supplies of an abaloparatide-coated transdermal patch product ("Product") and associated applicator devices ("Applicator"). Under the Supply Agreement, 3M will manufacture Product and Applicator for us according to agreed-upon specifications in sufficient quantities to meet our projected supply requirements. 3M

will manufacture commercial supplies of Product at unit prices that decrease with an increase in the quantity we order. We will pay 3M a mid-to-low single digit royalty on worldwide net sales of Product and reimburse 3M for certain capital expenditures incurred to establish commercial supply of Product. We are responsible for providing, at our expense, supplies of abaloparatide drug substance to be used in manufacturing Product. During the term of the Supply Agreement, 3M and Radius have agreed to work exclusively with each other with respect to the delivery of abaloparatide, parathyroid hormone ("PTH"), and/or PTH related proteins via active transdermal, intradermal, or microneedle technology.

The initial term of the Supply Agreement began on its effective date and will continue for five years after the first commercial sale of Product. The Supply Agreement then automatically renews for successive three-year terms, unless earlier terminated pursuant to its terms or upon either party's notice of termination to the other 24 months prior to the end of the then-current term. The Supply Agreement may be terminated by either party upon an uncured material breach of its terms by the other party, or due to the other party's bankruptcy, insolvency, or dissolution. Radius may terminate the Supply Agreement upon the occurrence of certain events, including for certain clinical, technical, or commercial reasons impacting Product, if we are unable to obtain U.S. regulatory approval for Product within a certain time period, or if we cease development or commercialization of Product. 3M may terminate the Supply Agreement upon the occurrence of certain events, including if there are certain safety issues related to Product, if we are unable to obtain U.S. regulatory approval for Product within a certain time period, or if we fail to order Product for a certain period of time after commercial launch of the Product in the U.S. Upon certain events of termination, 3M is required to transfer the manufacturing processes for Product and Applicator to us or a mutually agreeable third party and continue supplying Product and Applicator for a period of time pursuant to our projected supply requirements.

In June 2009, we entered into a Development and Clinical Supplies Agreement with 3M, as amended (the "Development Agreement"), under which Product and Applicator development activities occur and 3M has manufactured phase 1 and 2 clinical trial supplies for us on an exclusive basis. The term of the Development Agreement runs until June 2019 and then automatically renews for additional one-year terms, unless earlier terminated, until the earliest of (i) the expiration or termination of the Supply Agreement, (ii) the mutual written agreement of the parties, or (iii) prior written notice by either party to the other party at least ninety days prior to the end of the then-current term of the Development Agreement that such party declines to extend the term. Either party may terminate the agreement in the event of an uncured material breach by the other party. We pay 3M for services delivered pursuant to the agreement on a fee-for-service or a fee-for-deliverable basis as specified in the agreement. We have paid 3M approximately $20.9 million, in the aggregate, through December 31, 2017 with respect to services and deliverables delivered pursuant to the 3M Agreement.

Ipsen Pharma

In September 2005, we entered into a license agreement with Ipsen, as amended (the "License Agreement") under which we exclusively licensed certain Ipsen compound technology and related patents covering abaloparatide to research, develop, manufacture and commercialize certain compounds and related products in all countries, except Japan (where we have an option to negotiate a co-promotion agreement for abaloparatide-SC) and France (where our commercialization rights were subject to certain co-marketing and co-promotion rights exercisable by Ipsen, provided that certain conditions included in the License Agreement were met). We believe that Ipsen's co-marketing and co-promotion rights in France have permanently expired. Ipsen also granted us an exclusive right and license under the Ipsen compound technology and related patents to make and have made compounds or product in Japan. Ipsen further granted us an exclusive right and license under certain Ipsen formulation technology and related patents solely for purposes of enabling us to develop, manufacture and commercialize compounds and products covered by the compound technology license in all countries, except Japan and France (as discussed above).

In consideration for the rights to abaloparatide, and in recognition of certain milestones having been met to date, we have paid to Ipsen an aggregate amount of $13.0 million. The license agreement further requires us to

make payments upon the achievement of certain future clinical and regulatory milestones. Total additional milestone payments that could be payable under the agreement as of December 31, 2017 are €24.0 million (approximately $28.7 million). The agreement provides that we or our sublicensees are obligated to pay to Ipsen a fixed five percent royalty based on net sales of products containing abaloparatide on a country-by-country basis until the later of the last to expire of the licensed patents or for a period of 10 years after the first commercial sale of the licensed products in such country. The date of the last to expire of the abaloparatide patents licensed from or co-owned with Ipsen, barring any extension thereof, is expected to be March 26, 2028. In the event that we sublicense abaloparatide to a third party, the agreement provides that we would pay a percentage of certain payments received from such sublicensee (in lieu of milestone payments not achieved at the time of such sublicense). The applicable percentage is in the low double digit range. In addition, if we or our sublicensees commercialize a product that includes a compound discovered by us based on or derived from confidential Ipsen know-how, the agreement provides that we would pay to Ipsen a fixed low single digit royalty on net sales of such product on a country-by-country basis until the later of the last to expire of our patents that cover such product or for a period of 10 years after the first commercial sale of such product in such country.

The License Agreement expires on a country-by-country basis on the later of (1) the date the last remaining valid claim in the licensed patents expires in that country, or (2) a period of 10 years after the first commercial sale of the licensed products in such country, unless it is sooner terminated in accordance with its terms.

The License Agreement may be terminated by us with prior notice to Ipsen. The License Agreement may be terminated by Ipsen upon notice to us with immediate effect, if we, in any country of the world, bring an action or proceeding to challenge any Ipsen patent. The License Agreement can also be terminated by Ipsen if we fail to use reasonable commercial efforts to develop the licensed product for sale and commercialization in those countries within the territory where it is commercially reasonable to do so as contemplated by the License Agreement, or fail to use reasonable commercial efforts to perform our obligations under the latest revised version of the development plan approved by the joint steering committee, or fail to use reasonable commercial efforts to launch and sell one licensed product in those countries within the territory where it is commercially reasonable to do so. Either party may also terminate the License Agreement upon an uncured material breach by the other party. Ipsen may terminate the License Agreement if the License Agreement is assigned or sublicensed, if a third party acquires us, or if we acquire control over a PTH or a PTHrP compound that is in clinical development or is commercially available in the territory, and if following such assignment, sublicense, acquisition, or acquisition of control by us, such assignee, sublicensee, acquirer or we, fail to meet the timetable under the latest revised version of the development plan approved by the joint steering committee under the License Agreement.

Prior to executing the License Agreement for abaloparatide with Radius, Ipsen licensed the Japanese rights for abaloparatide to Teijin Limited (“Teijin”) a Japanese pharmaceutical company. Teijin has initiated a Phase 3 clinical study of abaloparatide in Japan for the treatment of postmenopausal osteoporosis.

We are currently in arbitration proceedings with Ipsen in connection with the License Agreement. See “Legal Proceedings” for more information.

Eisai

In June 2006, we exclusively licensed the worldwide rights to research, develop, manufacture and commercialize elacestrant and related products from Eisai (the “Eisai Agreement”). Our license with Eisai did not originally include rights for Japan, however, on March 9, 2015, we entered into an amendment to the Eisai Agreement in which Eisai granted us an exclusive right and license to research, develop, manufacture and commercialize elacestrant in Japan (the “Eisai Amendment”). Specifically, we licensed the patent application that subsequently issued as U.S. Patent No. 7,612,114 (statutory term expires December 25, 2023 which we expect will be extended to August 18, 2026 with 967 days of patent term adjustment due to delays by the USPTO), entitled “Selective Estrogen Receptor Modulator,” the corresponding foreign patent applications and

continuing patent applications. In consideration for the worldwide rights to elacestrant and in recognition of certain milestones having been met to date, we have paid to Eisai an aggregate amount of $1.9 million. We have also agreed to pay Eisai additional fees of up to $22.3 million, payable upon the achievement of certain clinical and regulatory milestones.

Under the Eisai Agreement as amended, should a product covered by the licensed technology be commercialized, we will be obligated to pay to Eisai royalties in a variable mid-single digit range based on net sales of the product on a country-by-country basis. The royalty rate will be reduced, on a country-by-country basis, at such time as the last remaining valid claim in the licensed patents expires, lapses or is invalidated and the product is not covered by data protection clauses. In addition, the royalty rate will be reduced, on a country-by-country basis, if, in addition to the conditions specified in the previous sentence, lawful generic versions of such product account for more than a specified minimum percentage of the total sales of all products that contain the licensed compound during a calendar quarter. The latest licensed patent may expire, barring any patent term extension under any applicable laws, on August 18, 2026.

We were also granted the right to sublicense with prior written approval from Eisai. If we sublicense the licensed technology to a third party, we will be obligated to pay Eisai, in addition to the milestone fees referenced above, a fixed low double digit percentage of certain fees we receive from such sublicensee in addition to royalties in the low single digit range based on net sales of the sublicensee.

The license agreement expires on a country-by-country basis on the later of (1) the date the last remaining valid claim in the licensed patents expires, lapses or is invalidated in that country, the product is not covered by data protection clauses, and the sales of lawful generic versions of the product account for more than a specified percentage of the total sales of all pharmaceutical products containing the licensed compound in that country, or (2) a period of 10 years after the first commercial sale of the licensed products in such country, unless it is sooner terminated.

We can terminate the license agreement, with respect to the entire territory, with prior notice to Eisai if we reasonably determine that the medical/scientific, technical, regulatory or commercial profile of the licensed product does not justify continued development or marketing.

Eisai can terminate the license agreement, on a country-by-country basis, at any time prior to the date on which we have submitted for either an NDA approval or EMA marketing approval with respect to a licensed product, upon prior written notice to us, if Eisai makes a good faith determination, in accordance with certain provisions specified in the agreement, that we have not used commercially reasonable efforts to develop the licensed product in the territory. Either party may also terminate the agreement upon an uncured material breach by the other party or upon the bankruptcy or insolvency of the other party. Eisai may terminate the license agreement, with prior written notice, in the event of certain changes of control involving us, if Eisai reasonably determines that the entity assuming control of us is not able to perform under the license agreement with the same degree of skill and diligence that we would use. Eisai shall further have the right to terminate if the acquiring entity has any material and active litigations with Eisai or is a hostile takeover bidder against us.

Duke (RAD1901)

In December 2017, the Company entered into a License Agreement with Duke University ("Duke") (collectively "Duke License Agreement") pursuant to which Radius acquired the exclusive worldwide license to certain Duke patents associated with elacestrant (RAD1901) related to the use of elacestrant in the treatment of breast cancer as a monotherapy and in a combination therapy (collectively "Duke Patents").

In consideration for these rights, the Company incurred non-refundable, non-creditable obligations to pay Duke, totaling $1.3 million, which were expensed as research and development during 2017. The Duke License Agreement provides for further payments upon the achievement of certain future regulatory and commercial

milestones totaling up to $3.8 million. The agreement provides that the Company would pay Duke a fixed low single-digit royalty based on net sales, on a country-by-country basis, beginning in August 2029 and ending upon expiration of the last patent rights to expire.

If the Company sublicenses the Duke Patents to a third party, the agreement provides that the Company will pay Duke a percentage of certain payments received by it from such sublicensee(s). The applicable percentage is in the high single-digit range on certain payments received in excess a pre-specified amount. The License Agreement may be terminated by Duke upon a material uncured breach of the License Agreement. The Company may terminate the License Agreement upon 60 days written notice.

Teijin Limited

In July 2017, we entered into a license and development agreement with Teijin for abaloparatide-SC in Japan (the "Teijin Agreement"). Teijin is developing abaloparatide-SC in Japan under an agreement with Ipsen and has initiated a Phase 3 trial in Japanese patients with osteoporosis. Pursuant to the Teijin Agreement, we granted Teijin (i) an exclusive payment bearing license under certain of our intellectual property to develop and commercialize abaloparatide-SC in Japan, (ii) a non-exclusive payment bearing license under certain of our intellectual property to manufacture abaloparatide-SC for commercial supply in Japan, (iii) a right of reference to certain of our regulatory data related to abaloparatide-SC for purposes of developing, manufacturing and commercializing abaloparatide-SC in Japan, (iv) a manufacture transfer package, upon Teijin's request, consisting of information and the Company's know-how that is necessary for the manufacture of active pharmaceutical ingredient and abaloparatide-SC, (v) an obligation, at Teijin's request, to manufacture (or arrange for a third party to manufacture) and supply (or arrange for a third party to supply) the active pharmaceutical ingredient for the clinical supply of abaloparatide-SC in sufficient quantities to enable Teijin to conduct its clinical trials in Japan, and (vi) an obligation, at Teijin's request, to arrange for Teijin to directly enter into commercial supply agreements with the Company's existing contract manufacturers on the same pricing terms and on substantially similar commercial terms to those set forth in the Company's existing agreements with such contract manufacturers.

In consideration for these rights, we received an upfront payment of $10.0 million. The Teijin Agreement also provides for additional payments to us of up to an aggregate of $40.0 million upon the achievement of certain regulatory and sales milestones and requires Teijin to pay us a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term, as defined below. In addition, we have an option to negotiate a co-promotion agreement with Teijin for abaloparatide-SC in Japan.

We maintain full global rights to its development program for abaloparatide-patch, which is not part of the Teijin Agreement. Pursuant to the Teijin Agreement, the parties may further collaborate on new indications for abaloparatide-SC.

Unless earlier terminated, the Teijin Agreement expires on the later of the (i) date on which the use, sale or importation of abaloparatide-SC is no longer covered by a valid claim under our patent rights licensed to Teijin in Japan, (ii) expiration of marketing or data exclusivity for abaloparatide-SC in Japan, or (iii) 10th anniversary of the first commercial sale of abaloparatide-SC in Japan.

Supply and Manufacturing Agreements

In June 2016, we entered into a Supply Agreement with Ypsomed (the "Ypsomed Supply Agreement") pursuant to which Ypsomed agreed to supply commercial and clinical supplies of a disposable pen injection device customized for subcutaneous injection of abaloparatide (the "Device"). We agreed to purchase a minimum number of Devices at prices per Device that decrease with an increase in quantity supplied. In addition, we agreed to make milestone payments for Ypsomed's capital developments in connection with the initiation of the commercial supply of the Device and to pay a one-time capacity fee. All costs and payments under the Ypsomed Supply Agreement are delineated in Swiss Francs.

The Ypsomed Supply Agreement has an initial term of three years from the earlier of the date of delivery of the first commercial batch of Devices after regulatory approval or June 1, 2017, after which, it automatically renews for two-year terms until terminated. We or Ypsomed may terminate the agreement at any time by providing notice to the other party 18 months prior to the end of the then-current term. The agreement may also be terminated by either party upon material breach of the agreement, due to a party's bankruptcy, insolvency, or dissolution, or due to a change of control of either party under certain circumstances. We may terminate the agreement in the event that Ypsomed is unable to obtain regulatory or other approval for the manufacture and sale of Devices or if such approval is revoked. During the initial term of the agreement, we estimate that we will be obligated to make total minimum payments to Ypsomed of approximately CHF 3.9 million (approximately $4.0 million) in the aggregate, including the milestone payments and one-time capacity fee.

In June 2016, we entered into a Commercial Supply Agreement (the "Vetter Supply Agreement") with Vetter Pharma International, GmbH ("Vetter") pursuant to which Vetter has agreed to formulate the finished abaloparatide-SC drug product containing the API of abaloparatide, to fill cartridges with the drug product, to assemble the pen delivery device, and to package and label the pen for commercial distribution. We agreed to purchase the cartridges and pens in specified batch sizes at a price per unit. For labeling and packaging services, we agreed to pay a per unit price dependent upon the number of pens loaded with cartridges that are labeled and packaged. These prices are subject to an annual price adjustment. The Vetter Supply Agreement has an initial term of five years, which began on January 1, 2016, after which, it automatically renews for two-year terms unless either party notifies the other party two years before the end of the then-current term that it does not intend to renew.

Vetter may terminate the Vetter Supply Agreement effective upon written notice to us if we fail to maintain certain insurance required under the agreement, or breach provisions regarding ethical business practices, laws, and regulations. We may terminate the agreement effective upon written notice to Vetter if: (1) Vetter fails to obtain or maintain any material governmental licenses or approvals, (2) Vetter has breached provisions regarding ethical business practices, laws, and regulations, or (3) we fail to obtain certain regulatory approvals. Either party may terminate the agreement due to: (1) the other party's bankruptcy or insolvency, (2) the other party's uncured breach of the agreement, (3) a continuing force majeure event, or (4) a failure to reach mutual agreement on a change in the scope of work or services that Vetter reasonably believes it cannot perform because the change is in violation of applicable law.

In July 2016, we entered into a Manufacturing Services Agreement (the "Manufacturing Agreement") with PPL, as successor-in-interest to Lonza, pursuant to which PPL has agreed to manufacture the commercial and clinical supplies of the API for abaloparatide. We agreed to purchase the API in batches at a price per gram in euros, subject to an annual increase by PPL. We are also required to purchase a minimum number of batches annually beginning in 2018. The Manufacturing Agreement has an initial term of six years, after which, it automatically renews for three-year terms unless either party provides notice of non-renewal 24 months before the end of the then-current term.

PPL may terminate the agreement for any reason upon 30-months' notice. We may terminate the Manufacturing Agreement for any reason upon 24-months' notice, if we fail to obtain regulatory marketing approval for abaloparatide upon 12-months' notice to PPL, or if abaloparatide is withdrawn from the market upon 12-months' notice to PPL. Either party may terminate the agreement for the other's uncured breach of the agreement due to a party's bankruptcy, insolvency, or dissolution, or due to certain force majeure events.

Government Regulation

United States—FDA Product Approval Process

The research, development, testing, manufacture, labeling, promotion, marketing, advertising, and distribution, among other things, of our product candidates are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food,

Drug, and Cosmetic Act (the "FDCA") and its implementing regulations. Failure to comply with the applicable United States requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, imposition of clinical holds, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution. We expect abaloparatide-patch, elacestrant and RAD140 will each be subject to review by the FDA as a drug pursuant to the NDA process, and we currently only have active investigational new drug ("IND") applications in relation to abaloparatide, elacestrant and RAD140 in the United States.

Approval Process—None of our drugs may be marketed in the United States until the drug has received FDA approval of an NDA. The steps required to be completed before a drug may be marketed in the United States include, among others:

- preclinical laboratory tests, animal studies, and formulation studies, all performed in accordance with the FDA's Good Laboratory Practice ("GLP") regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin and must be updated annually;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each proposed indication to FDA's satisfaction;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA pre-approval inspection of one or more clinical trial site(s) at which the drug was studied in a clinical trial(s) to assess compliance with Good Clinical Practices ("GCP") regulations;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP regulations; and
- FDA review and approval of the NDA based on a determination that the drug is safe and effective for the proposed indication(s).

Preclinical tests include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application, which must become effective before human clinical trials may begin. An IND application will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND application. In such a case, the IND application sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND application will result in the FDA allowing clinical trials to begin.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under GCP pursuant to protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND application. Detailed information about many clinical trials must be submitted to the National Institutes of Health ("NIH") for public disclosure on the government website ClinicalTrials.gov.

Clinical trials necessary for product approval are typically conducted in three sequential phases, but the Phases may overlap. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board ("IRB") for each institution where the trials will be conducted, and each IRB must monitor the study until completion. Study subjects must provide informed consent and sign an informed consent form before participating in a clinical trial. Clinical testing also must satisfy the extensive GCP regulations for informed consent and privacy of individually identifiable information.

Phase 1 usually involves the initial introduction of the investigational drug into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase 1 studies are usually conducted in healthy individuals and are not intended to treat disease or illness. However, Phase 1b studies are conducted in healthy volunteers or in patients diagnosed with the disease or condition for which the study drug is intended, who present some biomarker, surrogate, or possibly clinical outcome that could be considered for "proof of concept." Proof of concept in a Phase 1b study typically confirms the hypothesis that the current prediction of biomarker, or outcome benefit is compatible with the mechanism of action.

Phase 2 usually involves trials in a limited patient population to: (1) evaluate dosage tolerance and appropriate dosage, (2) identify possible adverse effects and safety risks, and (3) evaluate preliminarily the efficacy of the drug for specific target indications. Several different doses of the drug may be looked at in Phase 2 to see which dose has the desired effects. Patients are monitored for side effects and for any improvement in their illness, symptoms, or both.

Phase 3 trials usually further evaluate clinical efficacy and test further for safety by using the drug in its planned commercial form in an expanded patient population. A Phase 3 trial usually compares how well the study drug works compared with an inactive placebo and/or another approved medication. One group of patients may receive the investigational new drug being tested, while another group of patients may receive the comparator drug (already approved drug for the disease being studied), or placebo. Phase 3 trials typically are relied upon as the primary basis for approval because they provide the safety and effectiveness information needed to evaluate the overall benefit-risk relationship of the drug and to create the physician labeling.

There can be no assurance that Phase 1, Phase 2 or Phase 3 testing will be completed successfully within any specified period of time, if at all. Furthermore, we, the FDA, or an Institutional Review Board (with respect to a particular study site) may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

In addition, clinical trial sponsors are required to register and report results from certain applicable clinical trials for publication on www.clinicaltrials.gov. Until recently, disclosure of clinical trial results for unapproved drugs could be delayed until approval of the drug. The Department of Health and Human Services recently broadened these reporting requirements to also apply to unapproved drugs, regardless of whether FDA approval is or will be sought. The allowable delay period for submitting results for applicable clinical trials of unapproved drugs is one year after the primary completion date of the study, and potentially an additional two years beyond that after submission of a certification; in any event, not to exceed three years in total. Consequently, clinical trial information could be subject to posting even if a drug is not approved and does not make it to market.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more proposed indications. The testing and approval process requires substantial time, effort and financial resources. Unless the applicant qualifies for an exemption, the filing of an NDA typically must be accompanied by a substantial payment to the FDA, referred to as a "user fee," which currently exceeds $2 million. The FDA reviews the application and may deem it to be inadequate, and companies cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee, but the Agency historically has tended to follow such recommendations.

The FDA has various programs, including fast track designation, breakthrough therapy designation, priority review and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs and/or provide for approval on the basis of surrogate endpoints. Generally, drugs that may be eligible for one or more

of these programs are those intended to treat serious or life-threatening diseases or conditions, those with the potential to address unmet medical needs for those disease or conditions, and those that provide meaningful benefit over existing treatments. For example, a sponsor may be granted FDA designation of a drug candidate as a "breakthrough therapy" if the drug candidate is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a drug is designated as breakthrough therapy, FDA will take actions to help expedite the development and review of such drug. From time to time, we anticipate applying for such programs where we believe we meet the applicable FDA criteria. A company cannot be sure that any of its drugs will qualify for any of these programs, or even if a drug does qualify, that the review time will be reduced.

In addition to the existing programs described above, additional measures intended to expedite drug product development and review were also included in the 21st Century Cures Act ("Cures Act"). The Cures Act, which was enacted in December 2016, includes provisions intended to enhance and accelerate the FDA's processes for reviewing and approving new drugs and supplements to approved NDAs. These provisions include (1) requirements that FDA establish a program to evaluate the potential use of real world evidence to help to support the approval of a new indication for an approved drug and to help to support or satisfy post-approval study requirements, (2) requirements that FDA issue guidance for purposes of assisting sponsors in incorporating complex adaptive and other novel trial designs into proposed clinical protocols and applications for new drugs, and (3) authorizing FDA to rely upon qualified data summaries to support the approval of a supplemental application with respect to a qualified indication for an already approved drug.

Before approving an NDA, the FDA usually will inspect the facility or the facilities at which the drug is manufactured and will not approve the product unless the manufacturing and production and testing facilities are in compliance with cGMP regulations. If the NDA and the manufacturing facilities are deemed acceptable by the FDA, it may issue an approval letter, and, if not, the agency may issue a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for a specific indication(s). A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. Such a letter usually describes all the deficiencies that the FDA has identified in an NDA that must be satisfactorily addressed before it can be approved. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also require, as a condition of NDA approval, post-marketing testing and surveillance to monitor the drug's safety or efficacy or impose other conditions. Approval may also be contingent on a Risk Evaluation and Mitigation Strategy ("REMS") that may include both special labeling and controls, known as Elements to Assure Safe Use, on the distribution, prescribing, dispensing and use of a drug product. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-marketing studies or clinical trials. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the product reaches the market.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes or making certain additional labeling claims, are subject to further FDA review and approval. Before a company can market products for additional indications, it must obtain additional approvals from the FDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. A company cannot be sure that any additional approval for new indications for any investigational product candidate will be approved on a timely basis, or at all.

Post-Approval Requirements—Often times, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical

studies. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to, among other requirements: (1) report certain adverse reactions to the FDA within specific time frames, (2) comply with certain requirements concerning advertising and promotional labeling for their products, (3) continue to have quality control and manufacturing procedures conform to cGMP regulations after approval, (4) make periodic reports to FDA about the approved product, and (5) comply with requirements regarding distribution of the drug product. The FDA periodically inspects the sponsor's records related to safety reporting, distribution and/or manufacturing facilities; this latter effort includes assessment of ongoing compliance with cGMP regulations. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. We have used and intend to continue to use third-party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, including recall or withdrawal of the product from the market, labeling changes, imposition of REMS, or the requirement to conduct additional studies.

Hatch-Waxman Act-Under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, Congress created an abbreviated FDA review process for generic versions of pioneer (brand name) drug products under section 505(j) of the FDCA. Section 505(j) provides for approval of an abbreviated new drug application ("ANDA") that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved drug (commonly known as the reference drug). In considering whether to approve such a generic drug product, the FDA requires that an ANDA applicant demonstrate, among other things, that the proposed generic drug product's active ingredient is the same as that of the reference product, that the proposed generic is bioequivalent to the reference product, that any impurities in the proposed product do not affect the product's safety or effectiveness, and that its manufacturing processes and methods ensure the consistent potency and purity of its proposed product. In addition to the ANDA pathway, the Hatch-Waxman Act also established an abbreviated approval pathway under section 505(b)(2) of the FDCA for applications that contain full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2) permits approval of applications other than those for duplicate products and permits reliance for such approvals on literature or on FDA's finding of safety or effectiveness for an approved drug product.

The Hatch-Waxman Act provides five years of data exclusivity for new chemical entities ("NCE") referred to as NCE exclusivity, which generally (except as discussed below) prevents the FDA from accepting ANDAs and section 505(b)(2) applications containing the protected active ingredient or active moiety for five years after initial approval of the NCE. A drug is a NCE if the FDA has not previously approved an NDA for another drug that contains the same active moiety, which FDA defines to mean the molecule or ion (excluding certain specified appended portions) responsible for the physiological or pharmacological action of the drug substance. TYMLOS qualified as an NCE, thus received five years of NCE exclusivity following the FDA's approval in April 2017. Under FDA's "umbrella policy," NCE exclusivity protects all drug products that contain the qualifying NCE, so if abaloparatide-patch is approved prior to the expiration to the NCE exclusivity granted to TYMLOS, we would expect abaloparatide-patch to be protected by any remaining NCE exclusivity period.

The Hatch-Waxman Act also provides three years of exclusivity for applications (including supplements) containing the results of new clinical investigations (other than bioavailability studies) essential to the FDA's approval of new versions or conditions of use of previously approved drug products, such as new indications, delivery mechanisms, dosage forms, strengths, or other conditions of use. For example, if we are successful in performing a clinical trial of abaloparatide-patch that provides a new basis for approval (a different delivery mechanism) and that FDA considers essential to approval of the drug, it is possible that we may become eligible for a three-year period of market exclusivity for approval of an NDA for abaloparatide-patch. Any such three-

year exclusivity period would protect against the approval (but not the filing) of ANDAs and section 505(b)(2) applications referencing abaloparatide-patch for the protected transdermal route of administration. Such exclusivity period for abaloparatide-patch would generally not, however, prohibit the FDA from accepting or approving ANDAs or section 505(b)(2) applications referencing only abaloparatide-SC or section 505(b)(2) applications that reference abaloparatide-patch but that seek approval for a different route of administration or for a use other than for the indication that has been approved for abaloparatide-patch.

The Hatch-Waxman Act requires NDA applicants and NDA holders to submit certain information about patents related to their drugs for listing in the FDA's list of Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book). ANDA and section 505(b)(2) applicants generally must submit a certification or statement regarding each of the patents listed with the FDA for the reference product. A certification that a listed patent is invalid and/or will not be infringed by the marketing of the ANDA or section 505(b)(2) applicant's product is called a "Paragraph IV certification." If the sponsor of an ANDA or section 505(b)(2) application that references a drug with unexpired exclusivity provides a Paragraph IV certification for a patent for a reference product that is protected by NCE exclusivity, then the FDA may accept the ANDA or section 505(b)(2) application beginning four years after approval of the reference product's NDA (rather than five years). If an ANDA or section 505(b)(2) application containing a Paragraph IV certification is submitted to the FDA and accepted as a reviewable filing by the Agency, the ANDA or section 505(b)(2) applicant then must provide, within 20 days of FDA acceptance, notice to the NDA holder and patent owner stating that the application has been submitted and providing the factual and legal basis for the applicant's opinion that the patent is invalid and/or not infringed. The NDA holder or patent owner then may file suit against the ANDA or section 505(b)(2) applicant for patent infringement. If this is done within 45 days of receiving notice of the Paragraph IV certification, a 30-month stay of the FDA's ability to approve the ANDA or section 505(b)(2) application is triggered. The 30-month stay begins on the date of receipt of the Paragraph IV notice and, in the case where an ANDA or section 505(b)(2) application is submitted before a reference product's NCE exclusivity expires (i.e., four years after approval of the reference product), the 30-month period is extended to ensure that approval of the ANDA or section 505(b)(2) application cannot be granted for 7-$^1/_2$ years after initial approval of the reference product. Nevertheless, the FDA may approve the proposed product before the expiration of the 30-month stay (or 7-$^1/_2$ year period) if a court finds the patent invalid and/or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

European Union—Product Approval Process

In the European Union, medicinal products are authorized following a similar demanding process as that required in the United States and applications for marketing authorization must be submitted based on the ICH Common Technical Document format. In the European Economic Area ("EEA") (comprising 28 EU Member States plus Iceland, Liechtenstein and Norway), medicines can be authorized by using either the centralized authorization procedure or national authorization procedures, albeit through the decentralized or mutual recognition procedure to gain access to two or more EEA Member States.

Centralized procedure—Under the centralized procedure governed by Regulation (EC) 726/2004, a single marketing authorization application is submitted to the EMA for its scientific evaluation of the safety, quality and efficacy. The CHMP then carries out a scientific assessment of the application and issues an opinion on the approvability of the medicine. Following adoption of the CHMP's opinion, the European Commission, as the EU licensing authority, will adopt a legally binding decision on granting of a centralized marketing authorization which is valid across the EU and through the EEA Treaty, the Member States of the EEA. The centralized procedure is mandatory for human medicines derived from certain biotechnology processes, advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), medicines containing a new active substance falling within the mandatory centralized procedure such as those which are indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, or neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions, viral diseases, and orphan-designated medicines. The centralized procedure is optional for applicants seeking marketing authorizations for medicines which

contain a new active substance which is not authorized in the EEA. Alternatively, a medicine which is shown to constitute a significant therapeutic, scientific or technical innovation, or if its authorization via the centralized procedure would be in the interest of public health in the EEA would be considered as eligible for centralized assessment. In November 2015, we submitted an MAA for abaloparatide-SC to the EMA under the centralized procedure. The MAA was validated in December 2015 and is currently being reviewed by the EMA and its advisory committees such as the Committee for Medicinal Products for Human Use.

National authorization procedure—Pure national authorization procedure is applicable where the applicant intends to market the product only in one Member State. However, if an applicant intends to market the product in two or more Member States, there are two other possible regulatory procedures for products that fall outside the scope of the mandatory or the optional centralized procedure:

- *Decentralized procedure.* Where a medicinal product has not been authorized anywhere in the EEA and the product does not fall within the mandatory centralized procedure, an applicant may request a Member State to act as the Reference Member State to lead the assessment of the marketing authorization for it to be considered by the selected number of Member States which are concerned by the procedure. A positive decision adopted during the decentralized procedure will result in national marketing authorizations being granted by the Reference and Concerned Member States.
- *Mutual recognition procedure.* Where the medicinal product has been authorized in a EU Member State, the applicant can request the Member State to act as the Reference Member State for the national marketing authorization to be recognized progressively in the other Concerned Member States.

Under both decentralized and mutual recognition procedures, the Reference Member State leads the assessment for it to be recognized by the national authorities in Member States concerned by the procedure. A satisfactory conclusion of a procedure will result in granting of a national marketing authorization.

In November 2015, we submitted an MAA for abaloparatide-SC to the EMA, which was validated and is currently undergoing active regulatory assessment by the CHMP. In December 2017, the CHMP issued a third Day-180 List of Outstanding Issues. As part of its on-going risk-benefit assessment, the CHMP informed the Company that it intends to refer the marketing authorisation application to a scientific advisory group for additional advice. We expect that the CHMP may adopt an opinion regarding our MAA during the first half of 2018.

Good manufacturing practices—Like the FDA, the EMA, the competent authorities of the EU Member States and other regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacture of pharmaceutical and biologic products. Prior to the CHMP adopting an opinion with respect to approvability of an application for marketing authorization, the EMA, acting upon the advice of the CHMP, may decide to coordinate an inspection to be undertaken by the designated EU Supervising Authority of the proposed manufacturing site to verify the manufacturer's compliance with EU GMP principles and guidelines or to investigate a specific GMP-related matter that may arise from the assessment of the application. If there is a material change in manufacturing equipment, location, or process, affecting the quality of the product, additional regulatory review and approval may be required from the relevant competent regulatory authority. Once we or our partners commercialize products, we will be required to comply with GMP with regard to manufacture and control, and product-specific requirements according to the terms of the marketing authorization. Also, like the FDA, the EMA (as a coordinating body for centrally authorized medicinal products), the competent authorities of the EU Member States and other regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. If it is determined that the equipment, facilities, or processes used to manufacture our product do not comply with applicable regulations and conditions of product approval, regulatory agencies may seek civil, criminal or administrative sanctions, or enforcement actions and/or remedies against the manufacturer holding the requisite manufacturing authorization and us, including the suspension of our manufacturing operations or the withdrawal of our product from the market.

Data and market exclusivity—Similar to the United States, there is a process for approval of generic versions of innovator drug products in the European Union. Abridged applications for the authorization of generic versions of drugs authorized centrally by the European Commission can be submitted to the EMA through the centralized procedure referencing the innovator's non-clinical and clinical data to support generic approval provided always that the following conditions are met: the generic product has the same qualitative and quantitative composition in the active substances and the same pharmaceutical form as the reference innovator drug product and the generic product is shown to be bioequivalent to the reference product.

New medicinal products authorized according to the EU regulatory requirements will benefit from eight years of data protection within which the generic applicant cannot rely on the non-clinical and clinical data contained in the dossier of the reference product to support product approval, and two years of market protection within which the generic applicant is not permitted to place the generic product on the market even if it is approved. This period of data and market protection can be extended to a maximum of eleven years if during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which during the scientific assessment prior to their authorization are held to bring a significant benefit in comparison with existing therapies. We expect that if abaloparatide-SC is approved in the European Union, it will benefit from at least ten years of data and market protection. At this time, we do not believe that there are orphan or pediatric applications for abaloparatide that would be likely to result in respectively a grant of orphan market exclusivity or 6-month extension of supplementary protection certificate in the European Union.

Other International Markets—Drug approval process

In some international markets (e.g., China or Japan), although data generated in U.S. or EU trials may be submitted in support of a marketing authorization application, additional clinical trials conducted in the host territory, or studying people of the ethnicity of the host territory, may be required prior to the filing or approval of marketing applications within the country.

Pricing and Reimbursement

In the United States and internationally, sales of products that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability and level of coverage and reimbursement from third-party payors such as state and federal governments, pharmacy benefit managers and health insurance plans. Third-party payors have implemented cost-cutting and reimbursement initiatives and likely will continue to do so in the future. These include establishing formularies that limit and govern the drugs and biologics that will be offered, determining the evidence and documentation required to support medical need, setting the out-of-pocket obligations of member patients, and negotiating discounts, rebates and price concessions with manufacturers for such products. In addition, particularly in the United States and increasingly in other countries, we may be required to provide discounts, price concessions and pay rebates to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities. It is possible that future legislation in the United States and other jurisdictions could be enacted which could potentially impact the reimbursement rates for the products we are developing and may develop in the future, and also could further impact the levels of discounts, price concessions and rebates paid to federal and state government entities. Any legislation that impacts these areas could impact, in a significant way, our ability to generate revenues from sales of products that, if successfully developed, we bring to market.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities to provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Parts A and B, Part D coverage may vary based on the Part D plan sponsor. Part D prescription drug plan sponsors are not

required to pay for all covered Part D drugs, and each Part D prescription drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, although not necessarily all of the drugs within each category or class and must cover all or substantially all medications within six protected classes of drugs: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. We anticipate that a significant proportion of patients eligible for TYMLOS will be Medicare beneficiaries and we expect that TYMLOS will be covered under Medicare Part D, although we cannot assure you that Part D prescription drug plan sponsors will cover TYMLOS, or, if covered, at what tier or level.

Government payment for some of the costs of prescription drugs may increase demand for any of our products that are successfully developed and approved. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, although the MMA applies only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own payment rates. Accordingly, any reduction in payment under Medicare may result in a similar reduction in payments from non-governmental payers.

We expect that there will continue to be a number of federal and state proposals to implement governmental pricing controls and limit the growth of healthcare costs, including the cost of prescription drugs. Currently, Medicare is prohibited from negotiating directly with pharmaceutical companies for drugs. However, the U.S. Congress may in the future consider legislation that would lift the ban on federal negotiations.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research would be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes of Health, and periodic reports on the status of the research and related expenditures would be made to the U.S. Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payers, it is not clear whether research would have any effect on the sales of any of our products that is successfully developed and approved, if the product or the condition that it is intended to treat becomes the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits of a competitor's product could adversely affect the sales of any of our products that is successfully developed and approved. If third-party payers do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Patient Protection and Affordable Care Act (the "ACA") as amended by the Health Care and Education Affordability Reconciliation Act of 2010, or collectively the ACA, is expected to have a significant impact on the health care industry. The ACA expands coverage for the uninsured while at the same time containing overall healthcare costs. Among other things, the ACA expands and increases industry rebates for drugs covered under Medicaid programs and make changes to the coverage requirements under the Medicare Part D program. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. Any such legislative changes associated with healthcare reform, including the ACA, may have a significant impact on drug pricing, and could limit pricing flexibility or expand rebate liabilities of drug manufacturers.

On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and,

due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 (the "ATRA") was enacted, which among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers.

Several states enacted legislation in 2017 related to prescription drug pricing transparency. Savings projected under these proposals are targeted as a means to fund both health care expenditures and non-health care initiatives, or to manage federal and state budgets. The Bipartisan Budget Act, enacted on February 9, 2018, will require manufacturers of brand name drugs, biologics, and biosimilars to pay a 70 percent discount in the Medicare Part D Coverage Gap, up from the current 50 percent discount. This increase in Coverage Gap discounts will be effective beginning in 2019.

Decisions on pricing and reimbursement of medicinal products in the European Union are based upon national rules subject to the control of the Transparency Directive, (Council Directive 89/105/EEC) which aims to ensure the transparency of measures established by EU countries to control the pricing and reimbursement of medicinal products. It defines a series of procedural requirements designed to verify that national pricing and reimbursement decisions do not create obstacles to the pharmaceutical trade within the EU's Internal Market. The competent authorities of each of the 28 EU Member States have adopted individual national measures aimed at regulating the pricing and reimbursement of medicinal products in their territory. These measures often vary widely in nature, scope and application. However, a major element that they have in common is an increased move toward reduction in the reimbursement price of medicinal products, a reduction in the number and type of products selected for reimbursement, and an increased preference for generic products over innovative products. These efforts have mostly been executed through these countries' existing price-control methodologies, including price cuts, mandatory rebates, value-based pricing, and reference pricing (i.e., referencing prices in other countries and using those reference prices to set a price). It is increasingly common in many EU Member States for Marketing Authorization Holders to be required, in order to get support for reimbursement under national health schemes and, therefore, access to the market, to demonstrate the cost effectiveness or otherwise added value benefit of their products as compared to products (which are considered as standard of care) already subject to pricing and reimbursement in specific countries. In order for drugs to be evaluated positively under such criteria, pharmaceutical companies may need to re-examine, and consider altering, a number of traditional functions relating to the selection, study, and management of drugs, whether currently marketed, under development, or being evaluated as candidates for research and/or development.

Future legislation, including the current versions being considered at the federal and state level in the United States and at the national level in EU Member States, or regulatory actions implementing recent or future legislation may have a significant effect on our business. Our ability to successfully commercialize products depends in part on the extent to which coverage and reimbursement for the costs of our products and related treatments will be available in the United States and worldwide from government health administration authorities, private health insurers and other organizations. Substantial uncertainty exists as to the reimbursement status of newly approved healthcare products by third-party payors. In addition, negotiating prices with government authorities under current and proposed legislation can delay the commercialization of our product candidates.

Sales and Marketing

The FDA regulates all advertising and promotion activities for products under its jurisdiction both prior to and after approval. Generally, a company can make only those claims relating to safety and efficacy that are approved by the FDA following review and approval of an NDA. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, and often reflect a physician's belief that the off-label use is the best treatment for the patients. The FDA does not regulate the behavior of physicians in their choice of treatments, but FDA regulations and enforcement policies do impose stringent restrictions on

manufacturers' communications regarding off-label uses. In addition, the FDA also regulates communications about investigational drugs, including with respect to the pre-approval promotion of investigational drugs. Recent case law suggests that pharmaceutical companies may have a First Amendment right to provide truthful and non-misleading information about off-label uses of their products to physicians and others, but the scope of this right remains unclear. Accordingly, failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA.

We may also be subject to various federal and state laws pertaining to healthcare "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations and very few court decisions addressing industry practices, it is possible that our practices might be challenged under anti-kickback or similar laws. Moreover, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes, so that 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 permits the government to assert that a claim that includes 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 statutes.

False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment, to third-party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products, if approved, may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid) and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties also can be imposed upon executive officers and employees, including criminal sanctions against executive officers under the so-called "responsible corporate officer" doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing.

Given the significant penalties and fines that can be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government were to allege or convict us or our executive officers of violating these laws, our business could be harmed. In addition, private individuals have the ability to bring similar actions. The majority of states also have anti-kickback and false claims laws, which establish similar prohibitions and, in some cases, may apply to items or services reimbursed by any third-party payor, including commercial insurers. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA, among other things, imposed new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit reports to the government by the 90th day of each calendar year. Certain

states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our actions could be subject to the penalty provisions of the pertinent state authorities.

Similar rigid restrictions are imposed on the promotion and marketing of medicinal products in the EU and other countries. Laws (including those governing promotion, marketing and anti-kickback provisions), industry regulations and professional codes of conduct often are strictly enforced. Even in those countries where we are not directly responsible for the promotion and marketing of our products, inappropriate activity by our international distribution partners can have adverse implications for us.

Other Laws and Regulatory Processes

We are subject to a variety of financial disclosure and securities trading regulations as a public company in the United States, including laws relating to the oversight activities of the Securities and Exchange Commission ("SEC") and the regulations of the NASDAQ Global Market or any national securities exchange on which our capital stock may be traded. In addition, the Financial Accounting Standards Board ("FASB") the SEC and other bodies that have jurisdiction over the form and content of our accounts, our consolidated financial statements and other public disclosure are constantly discussing and interpreting proposals and existing pronouncements designed to ensure that companies best display relevant and transparent information relating to their respective businesses.

Our international operations are subject to compliance with the Foreign Corrupt Practices Act (the "FCPA") which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. We also may be implicated under the FCPA for activities by our partners, collaborators, clinical research organizations, vendors or other agents.

Our present and future business has been and will continue to be, subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances used in connection with our research work are or may be applicable to our activities. Certain agreements entered into by us involving exclusive license rights or acquisitions may be subject to national or supranational antitrust regulatory control, the effect of which cannot be predicted. The extent of government regulation, which might result from future legislation or administrative action, cannot accurately be predicted.

Employees

As of December 31, 2017, we employed 463 full-time employees and 98 part-time employees. Of the total 561 employees, 131 of our employees were engaged in research and development activities and 430 were engaged in support administration, including business development and finance. Of the 430 employees engaged in support administration, 301 are part of our commercial organization. We use and intend to continue using clinical research organizations ("CRO") and other third parties to perform our clinical studies and manufacturing.

Corporate Information

We were incorporated in the state of Delaware on February 4, 2008 under the name MPM Acquisition Corp. In May 2011, we entered into a reverse merger transaction, or the Merger, with our predecessor, Radius Health, Inc., a Delaware corporation formed on October 3, 2003 (the "Former Operating Company") pursuant to which the Former

Operating Company became a wholly-owned subsidiary of ours. Immediately following the Merger, the Former Operating Company was merged with and into us and we assumed the business of the Former Operating Company and changed our name to Radius Health, Inc.

Legal Proceedings

In November 2016, we received notice that in October 2016, Ipsen had initiated arbitration proceedings against us in the International Chamber of Commerce's International Court of Arbitration. Ipsen's Request for Arbitration alleged that we breached various provisions of the License Agreement concerning abaloparatide, including with regard to Ipsen's right to co-promote abaloparatide in France and a license from us with respect to Japan. Ipsen has sought declaratory relief, compliance with the License Agreement, damages, costs and fees as a result of the purported breaches and has alleged the monetary value of these claims is approximately €50 million (approximately $59.9 million).

In January 2017, we submitted an Answer denying Ipsen's claims and alleging counterclaims against Ipsen for breach of the License Agreement and other declaratory judgment. We asserted, among other things, that Ipsen's claimed rights to co-promote abaloparatide in France and to a license from us with respect to Japan have permanently expired, and that Ipsen has breached the License Agreement by, among other things, allowing certain patents to expire and by purporting to license to a third party certain manufacturing and other rights that we contend Ipsen exclusively licensed to us. We have sought dismissal of Ipsen's claims, as well as declaratory relief, compliance with the License Agreement, and other damages, costs and fees to be determined by the Arbitral Tribunal.

In February 2017, Ipsen submitted a Reply denying our counterclaims and alleging that we are precluded from asserting them. Following a preliminary hearing before the Arbitral Tribunal to determine certain jurisdictional and contractual defenses asserted by Ipsen in its Reply, on July 17, 2017, the Arbitral Tribunal issued a decision finding it has jurisdiction to decide our counterclaims and that our counterclaims are not contractually barred.

On July 31, 2017, Ipsen submitted its Statement of Claim to the Arbitral Tribunal and on September 14, 2017, Radius submitted its Statement of Defense and Counterclaims. Subsequently, on October 20, 2017, Ipsen submitted its Reply and Statement of Defense to Radius's Counterclaims and on November 10, 2017, Radius submitted its Rejoinder on Claims and Reply on Counterclaims. Ipsen submitted a Rejoinder on Counterclaims on November 24, 2017. A hearing on the merits was held on December 18 and 19, 2017, and additional submissions on cost and fee allocation were made on February 9, 2018. We expect a final decision by the Arbitral Tribunal in the first half of 2018. Until we receive a decision from the Arbitral Tribunal, we cannot predict or assess the likely outcome of these proceedings.

Investor Information

Financial and other information about us is available on our website at www.radiuspharm.com. We make available on our website, free of charge, copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. In addition, we have previously filed registration statements and other documents with the SEC. Any document we file may be inspected, without charge, at the SEC's public reference room at 100 F Street NE, Washington, DC 20549, or at the SEC's internet address at www.sec.gov. These website addresses are not intended to function as hyperlinks, and the information contained in our website and in the SEC's website is not intended to be a part of this filing. Information related to the operation of the SEC's public reference room may be obtained by calling the SEC at 800-SEC-0330.

ITEM 1A. RISK FACTORS.

Our business faces significant risks and uncertainties. Certain important factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in or incorporated by reference into this Annual Report on Form 10-K and our other public filings with the SEC.

Risks Related to Our Business

Risks Related to Our Financial Position and Need for Capital

We are not currently profitable and may never become profitable.

We had net losses of $254.2 million, $182.8 million, and $101.5 million for the years ended December 31, 2017, 2016, and 2015, respectively. As of December 31, 2017, we had an accumulated deficit of $882.3 million. Until we succeed in commercializing TYMLOS, we expect to incur substantial losses and may never achieve or maintain profitability. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially as we:

- continue to build our commercial infrastructure, including adding internal systems and hiring additional personnel;
- commercialize TYMLOS or any other product candidates, if approved;
- continue to undertake preclinical development and clinical trials for product candidates; and
- seek regulatory approvals for product candidates.

We also expect to experience negative cash flow as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. Accordingly, unless and until we generate additional revenues and become profitable, we will need to raise additional capital to continue to operate our business. Our failure to achieve or maintain profitability or to raise additional capital could negatively impact the value of our securities.

We only started generating product revenues in 2017 and unless and until we become profitable, we expect that we will need to raise additional capital, which may not be available on favorable terms, if at all, in order to continue operating our business.

We only started to generate product revenues in 2017. Our ability to become profitable depends upon our ability to generate sufficient revenue. Despite obtaining FDA approval for TYMLOS for the treatment of postmenopausal women with osteoporosis, we may not be able to generate sufficient revenue to attain profitability. Our ability to generate profits from sales of TYMLOS is subject to our ability to manufacture commercial quantities of TYMLOS with third parties at acceptable cost levels and maintain sales and marketing capabilities in the United States or identify and enter into one or more strategic collaborations to effectively market and sell TYMLOS outside of the United States. Even though TYMLOS has been approved by the FDA for marketing and commercial sale for the treatment of postmenopausal women with osteoporosis, it may not gain market acceptance or achieve commercial success. We expect to continue to incur significant expenses and net losses as we commercialize TYMLOS and continue development and commercialization efforts for our other product candidates. Therefore, for the foreseeable future, we will have to fund our operations and capital expenditures with our existing cash and cash equivalents and short and long-term marketable securities, or through strategic financing opportunities, that could include, but are not limited to partnering or other collaboration agreements, future offerings of our equity, royalty-based financing arrangements or the incurrence of debt.

Based upon our cash, cash equivalents and marketable securities balance as of December 31, 2017, we believe that, prior to the consideration of proceeds from partnering and/or collaboration activities, we have sufficient capital to fund our development plans, U.S. commercial and other operational activities for not less than twelve months from the date of this filing. We have based this estimate on assumptions that may prove to be wrong, and we could use up our available capital resources sooner than we currently expect. If we fail to obtain additional capital, we may be forced to reduce or forego sales and marketing efforts for TYMLOS or unable to complete our planned preclinical and clinical trials and obtain approval of product candidates from the FDA and foreign regulatory authorities. In addition, we could be forced to discontinue product development or forego attractive business opportunities or discontinue our operations entirely. Any additional sources of financing may not be available or may not be available on favorable terms and will likely involve the issuance of additional equity securities, which will have a dilutive effect on stockholders. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and our clinical studies and the expenses associated with our commercialization efforts for TYMLOS.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of collaborations, strategic alliances, licensing arrangements, other marketing and distribution arrangements, equity offerings, royalty-based financing arrangements and debt financings. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties or royalty-based financing arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or we may need to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our commercialization or product development efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We are a company with a limited operating history upon which to base an investment decision.

We are a company with a limited operating history and have not demonstrated an ability to perform the functions necessary for the successful commercialization of TYMLOS or any of our other product candidates. The successful commercialization of TYMLOS or any product candidates will require us to perform a variety of functions, including:

- conducting sales and marketing activities for products if and when approved;
- continuing to undertake preclinical development and clinical trials;
- participating in regulatory approval processes; and
- formulating and manufacturing products.

Our operations have been limited to organizing and staffing our company, acquiring, developing and securing our proprietary technology and undertaking preclinical and clinical trials of our product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing further in our securities.

Our financial results may fluctuate from quarter to quarter, which makes our results difficult to predict and could cause our results to fall short of expectations.

Our financial results may fluctuate as a result of a number of factors, many of which are outside of our control. For these reasons, comparing our financial results on a period-to-period basis may not be meaningful, and you should not rely on our past results as an indication of our future performance. Particularly over the near term as we continue to build our commercial capabilities and commercialize TYMLOS, our revenues may fluctuate from quarter to quarter and our future quarterly and annual expenses as a percentage of our revenues may be significantly different from those we have recorded in the past or which we expect for the future. Our financial results in some quarters may fall below expectations. Any of these events as well as the various risk factors listed in this "Risk Factors" section could adversely affect our financial results and cause our stock price to fall.

Our cash and cash equivalents could be adversely affected if the financial institutions in which we hold our cash and cash equivalents fail.

We regularly maintain cash balances at third-party financial institutions in excess of the Federal Deposit Insurance Corporation insurance limit. While we monitor daily the cash balances in the operating accounts and adjust the balances as appropriate, these balances could be impacted, and there could be a material adverse effect on our business, if one or more of the financial institutions with which we deposit fails or is subject to other adverse conditions in the financial or credit markets. To date, we have experienced no loss or lack of access to our cash or cash equivalents; however, we can provide no assurance that access to our cash and cash equivalents will not be impacted by adverse conditions in the financial and credit markets.

Our investments in marketable securities are subject to market, interest and credit risk that may reduce their value.

The value of our investments in marketable securities may be adversely affected by changes in interest rates, downgrades in the creditworthiness of any bonds we hold, turmoil in the credit markets and financial services industry and by other factors which may result in other than temporary declines in the value of our investments. Decreases in the market value of our marketable securities could have an adverse impact on our statements of financial position, results of operations and cash flow.

We are subject to foreign currency risk.

A significant portion of our clinical trial activities, in addition to our contract manufacturing processes in support of TYMLOS, are conducted outside of the United States and a large portion of the costs incurred with these activities are denominated in the local currency of the country in which the activity is being conducted. As such, these costs could be subject to fluctuations in foreign exchange rates. At present, we do not engage in hedging transactions to protect against uncertainty in future exchange rates between foreign currencies and the U.S. dollar. A decline in the value of the U.S. dollar against currencies in geographies in which we conduct clinical trials or contract manufacturing activities could have a negative impact on our research and development costs, our future inventory valuations, or our future cost of sales. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our business and our results of operations. For further discussion of our foreign currency risks, see "Item 3. Quantitative and Qualitative Disclosures About Market Risk".

An adverse determination in any current or future lawsuits or arbitration proceedings to which we are a party could have a material adverse effect on our business.

We are currently involved in a pending arbitration proceeding. In November 2016, we received notice that in October 2016, Ipsen Pharma SAS, or Ipsen, had initiated arbitration proceedings against us in the International

Chamber of Commerce's International Court of Arbitration. Ipsen's Request for Arbitration alleges that we breached various provisions of the License Agreement concerning abaloparatide, including with regard to Ipsen's right to co-promote abaloparatide in France and a license from us with respect to Japan. Ipsen seeks declaratory relief, compliance with the License Agreement, damages, costs and fees as a result of the purported breaches, and alleges the monetary value of these claims is approximately €50 million (approximately $59.9 million). In January 2017, we submitted an Answer denying Ipsen's claims and alleging counterclaims against Ipsen for breach of the License Agreement and other declaratory judgment. We asserted, among other things, that Ipsen's claimed rights to co-promote abaloparatide in France and to a license from us with respect to Japan have permanently expired, and that Ipsen has breached the License Agreement by, among other things, allowing certain patents to expire and by purporting to license to a third-party certain manufacturing and other rights that we contend Ipsen exclusively licensed to us. In February 2017, Ipsen submitted a Reply denying our counterclaims and alleging that we are precluded from asserting them. Following a preliminary hearing before the Arbitral Tribunal to determine certain jurisdictional and contractual defenses asserted by Ipsen in its Reply, on July 17, 2017, the Arbitral Tribunal issued a decision finding it has jurisdiction to decide our counterclaims and that our counterclaims are not contractually barred. On July 31, 2017, Ipsen submitted its Statement of Claim to the Arbitral Tribunal and on September 14, 2017, Radius submitted its Statement of Defense and Counterclaims. Subsequently, on October 20, 2017, Ipsen submitted its Reply and Statement of Defense to Radius's Counterclaims and on November 10, 2017, Radius submitted its Rejoinder on Claims and Reply on Counterclaims. Ipsen submitted a Rejoinder on Counterclaims on November 24, 2017. A hearing on the merits was held on December 18 and 19, 2017, and additional submissions on cost and fee allocation is anticipated in early 2018. We expect a final decision by the Arbitral Tribunal in the first half of 2018. Until we receive a decision from the Arbitral Tribunal, we cannot predict or assess the likely outcome of these proceedings. We have sought dismissal of Ipsen's claims, as well as declaratory relief, compliance with the License Agreement, and other damages, costs and fees to be determined by the Arbitral Tribunal. However, if such defense is unsuccessful, and Ipsen prevails on any of its claims, such an adverse determination could have a material adverse effect on our business, operating results, financial condition and liquidity.

Additionally, we may be the target of claims asserting violations of securities fraud and derivative actions, or other litigation or arbitration proceedings in the future. Any future litigation or arbitration proceedings could result in substantial costs and divert management's attention and resources. These lawsuits or arbitration proceedings may result in large judgments or settlements against us, any of which could have a material adverse effect on its business, operating results, financial condition and liquidity.

We are also subject to a variety of other types of potential claims, proceedings, investigations and litigation which may be initiated by government agencies or third parties. These include compliance matters, product regulation or safety, taxes, employee benefit plans, employment discrimination, health and safety, environmental, antitrust, customs, import/export, government contract compliance, financial controls or reporting, intellectual property, allegations of misrepresentation, false claims or false statements, commercial claims, claims regarding promotion of our product candidates, or other similar matters. In addition, government investigations related to the use of products, but not the efficacy themselves, may cause reputational harm to us. Negative publicity-whether accurate or inaccurate-about the efficacy, safety or side effects of our product candidates or product categories, whether involving us or a competitor, could materially reduce market acceptance for our product candidates, cause consumers to seek alternatives to our product candidates, result in product withdrawals and cause our stock price to decline. Negative publicity could also result in an increased number of product liability claims, whether or not these claims have a basis in scientific fact. Any such claims, proceedings, investigations or litigation, regardless of the merits, might result in substantial costs, restrictions on product use or sales, or otherwise injure our business.

Risks Related to the Commercialization and Development of Our Product Candidates

We are heavily dependent on the commercial success of TYMLOS, which was approved by the FDA in April 2017; we may not be able to meet expectations with respect to TYMLOS sales or attain profitability and positive cash-flow from operations.

Our ability to successfully commercialize TYMLOS, our first approved product, is critical to the execution of our business strategy. TYMLOS may not achieve market acceptance in the United States, or in any international markets where it may subsequently be approved, among physicians, patients, and third-party payors, and may not be commercially successful. The degree of market acceptance and commercial success of TYMLOS will depend on a number of factors, including the following:

- the acceptance of TYMLOS by patients and the medical community and the availability, perceived advantages and relative cost, safety and efficacy of alternative and competing treatments;
- the cost-effectiveness of TYMLOS, availability and level of coverage and reimbursement by third-party payors, including state and federal governments, pharmacy benefit managers and health insurance plans, the willingness and ability of patients to pay for TYMLOS, and the commensurate discounts, price concessions or rebates required to secure coverage and reimbursement by third-party payors;
- the effectiveness of our marketing, sales, and distribution strategy and efforts and the degree to which the approved labeling supports promotional initiatives for commercial success;
- the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these areas;
- the ability of our third-party manufacturer(s) to manufacture commercial supplies of TYMLOS at acceptable costs, to remain in good standing with regulatory agencies, and to develop, validate and maintain commercially viable manufacturing processes that are, to the extent required, compliant with current good manufacturing practice regulations;
- our ability to remain compliant with laws and regulations that apply to us and our commercial activities;
- our ability to comply with changes in legislation or regulations in state or federal government programs that increase manufacturer financial obligations;
- our ability to obtain marketing approvals from foreign regulatory authorities, where and as applicable;
- FDA-mandated package inserts or labeling requirements;
- the actual market size for TYMLOS, which may be different than expected;
- the sufficiency of our drug supply to meet commercial and clinical demands which could be negatively impacted if our projections regarding the potential number of patients are inaccurate, we are subject to unanticipated regulatory requirements, our current drug supply is destroyed or negatively impacted at our manufacturing sites, storage sites or in transit, or any significant portion of our TYMLOS supply expires before we are able to sell it; and
- our ability to maintain, enforce and defend third-party challenges to our intellectual property rights in and to TYMLOS.

We may experience significant fluctuations in sales of TYMLOS from period to period and, ultimately, we may never generate sufficient revenues from TYMLOS to reach or maintain profitability or sustain our anticipated levels of operations. Any inability on our part to successfully commercialize TYMLOS in the United States and any international markets where it may subsequently be approved, or any significant delay, could have a material adverse impact on our ability to execute upon our business strategy.

Except for TYMLOS, our product candidates are at an early stage of development and may never receive regulatory approval.

Other than TYMLOS, which the FDA approved for use in the United States in April 2017, we have no drug products for sale and may never be able to develop additional approved and marketable drug products. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA in the United States and foreign regulatory authorities in other countries, which regulations differ from country to country. We are not permitted to market TYMLOS in any foreign countries unless and until we receive the requisite approval from regulatory authorities in those foreign countries. Obtaining approval of a product candidate is an extensive, lengthy, expensive and uncertain process, and may be delayed, limited or denied for many reasons, including:

- we may not be able to demonstrate that the product candidate is safe and effective to the satisfaction of the FDA or foreign regulatory authorities;
- the results of our clinical studies may not meet the level of statistical or clinical significance required for marketing approval;
- the FDA or foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical studies;
- any clinical research organizations, or CROs, that we have retained or may in the future retain, to conduct clinical studies may have taken or may take actions outside of our control that materially adversely impact our clinical studies;
- the FDA or foreign regulatory authorities may not accept data generated at our clinical study sites;
- the FDA or foreign regulatory authorities may not find the data from preclinical studies and clinical studies sufficient to demonstrate that the product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or foreign regulatory authorities may disagree with our interpretation of data from our preclinical studies and clinical studies or may require that we conduct additional studies;
- the FDA or foreign regulatory authorities may not agree with our proposed labeling and may require labeling that undermines or otherwise significantly impairs the commercial value of the product if it were to be approved with such labeling;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval;
- if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions; and
- the FDA or foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers.

In addition, the FDA or foreign regulatory authorities may change their approval policies or adopt new regulations.

We cannot assure you that we will receive the approvals necessary to commercialize any additional product candidates, including any product candidates we are currently developing or may acquire or develop in the future. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its indicated use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well

as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for proposed uses.

In 2007, we entered into a global pharmacovigilance agreement with Teijin Limited, or Teijin, a Japanese pharmaceutical company, that provides for the exchange of information related to serious and non-serious adverse reactions to abaloparatide by patients enrolled in clinical studies. The purpose of the agreement is to enable safety reporting to global health agencies. Teijin has initiated a Phase 3 clinical study of abaloparatide-SC in Japan for the treatment of postmenopausal osteoporosis. Should Teijin advise us in accordance with our agreement of a serious adverse event experienced by patients enrolled in their study, we would need to report the serious adverse event to the FDA and the European Medicines Agency, or EMA, which could adversely affect or delay our ability to maintain or obtain regulatory approvals in the United States or Europe.

In addition, the FDA or foreign regulatory authorities each has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during its regulatory review. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates for sale outside the United States.

We may never receive approval for, or commercialize, our products outside of the United States.

In order to market any products outside of the United States, we must comply with numerous and varying regulatory requirements of other countries for marketing authorization, including those regarding safety, efficacy and manufacturing. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others.

In November 2015, we submitted a marketing authorization application for abaloparatide-SC to the EMA through the centralized procedure. The MAA was validated and is currently undergoing active regulatory assessment by the Committee for Medicinal Products for Human Use, or CHMP, a scientific committee of the EMA. In December 2017, the CHMP issued a third Day-180 List of Outstanding Issues. As part of its on-going risk-benefit assessment, the CHMP informed the Company that it intends to refer the marketing authorisation application (MAA) to a scientific advisory group for additional advice. We expect that the CHMP may adopt an opinion regarding our MAA during the first half of 2018.

While we believe we have adequate data to demonstrate the safety and efficacy of abaloparatide-SC for the treatment of osteoporosis, the EMA and the CHMP may not be satisfied with our responses or may require additional information, which we may not be able to provide in a timely manner or at all. If we are unable to demonstrate the safety and efficacy of abaloparatide-SC to the satisfaction of the EMA and the CHMP, we may not receive marketing authorization for abaloparatide-SC in the EU, or if we need additional time to satisfy the EMA of abaloparatide-SC's safety and efficacy, the granting of a centralized marketing authorization in Europe could be delayed.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize TYMLOS, or any of our other product candidates.

Our product development programs and the commercialization of TYMLOS or any of our product candidates will require substantial cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements.

The terms of any collaborations or other arrangements that we may establish may not be favorable to us. If that were to occur, we may have to curtail the development of a particular product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our future collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. If a collaborator fails to provide sufficient effort and resources to a development program, we may not realize the full potential or intended benefit of the collaboration, and the development program may be delayed or curtailed.

Clinical trials are very expensive, time-consuming and difficult to design and implement.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. A substantial portion of our expected development costs will be denominated in euros and any adverse movement in the dollar/euro exchange rate will result in increased costs and could require us to raise additional capital to complete the development of our products. The clinical trial process is also time consuming. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed by several factors, including:

- changes in government regulation, administrative action or changes in FDA or foreign regulatory authority policy with respect to clinical trials that change the requirements for approval, including the size of any such trials;
- unforeseen safety issues;
- determination of dosing issues;
- lack of effectiveness during clinical trials;
- slower than expected rates of patient recruitment and enrollment;
- failure of sites to comply with requirements for conducting clinical trials;
- inability to monitor patients adequately during or after treatment; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we, the FDA, or other equivalent regulatory authorities and ethics committees with jurisdiction over our studies may suspend our clinical trials at any time if it appears that we are exposing participants to

unacceptable health risks or if the FDA or foreign regulatory authorities find deficiencies in our regulatory submissions or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for existing or future clinical trials. Any such unexpected expenses or delays in our clinical trials could increase our need for additional capital, which may not be available on favorable terms or at all.

Most of our investigational product candidates are in early stages of clinical trials.

Except for abaloparatide-SC and abaloparatide-patch, each of our other product candidates (i.e., elacestrant (RAD1901) and RAD140) are in the early stages of development and require extensive preclinical and clinical testing. We cannot predict with any certainty if or when we might submit an NDA or equivalent application to foreign regulatory authorities for regulatory approval for any of these other product candidates or whether any such NDA or equivalent application would be accepted for filing by the FDA or foreign regulatory authorities or approved if filed.

The results of clinical trials may not support our product candidate claims.

Even if our clinical trials are completed as planned, we cannot be certain that the results will support regulatory approval of our product candidates. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for proposed uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the submission of our NDAs to the FDA or equivalent application to foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials to date (other than the ACTIVE Phase 3 Clinical Trial for abaloparatide-SC) have involved small patient populations. Because of the small sample sizes, the results of these clinical trials may not be indicative of future results.

In addition, third parties could conduct clinical trials using the product candidates we license. We would have no control over how these trials are conducted and the results could potentially contradict the results we have obtained, or will obtain from the clinical trials we conduct.

We cannot be certain that a single Phase 2 trial of elacestrant will be sufficient to support the submission of an NDA or foreign marketing authorization application for this product candidate and in any event, we may be required to obtain additional clinical and non-clinical data before an NDA or foreign marketing authorization application for elacestrant may be submitted.

In general, the FDA and other foreign regulatory authorities require two pivotal trials to support approval of an NDA or foreign equivalent, but in certain circumstances, will approve an NDA based on only one pivotal trial. The FDA indicated that, depending on the study results, a single Phase 2 trial of elacestrant could be considered a pivotal study sufficient for us to request approval. As a result of these and other additional requirements, the FDA or other foreign authorities may require that we conduct additional trials beyond the currently contemplated single-arm Phase 2 trial before we can submit an NDA or foreign marketing authorization application for elacestrant even if such trial is successful.

If serious adverse or undesirable side effects are identified during the development or commercialization of our product candidates, we may need to abandon our development or commercialization of some of our product candidates or products.

Undesirable side effects caused by our product candidates could cause us, regulatory authorities, and/or ethics committees to interrupt, delay or halt clinical trials and could result in a more restrictive label or cause the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. It is impossible to

predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval, if ever. If our product candidates result in undesirable side effects or have characteristics that are unexpected, we may need to abandon their development. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if we or others later identify undesirable side effects caused by TYMLOS or any other product candidate that may receive marketing approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- regulatory authorities may require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS;
- regulatory authorities may require us to conduct additional post-market studies, including clinical studies, to assess the safety of the product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate and could significantly harm our business, results of operations and prospects.

Any product candidate for which we obtain marketing approval, including TYMLOS, is subject to restrictions or potential withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

TYMLOS and any other product candidate for which we obtain marketing approval, along with the manufacturing processes, distribution processes, post-approval clinical data, labeling, advertising and promotional activities for such product, are subject to continuing requirements of and review by the FDA and foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of drug products, including drug samples to physicians and recordkeeping. Marketing approval of TYMLOS and any other product candidate for which we obtain marketing approval is subject to limitations on the indicated uses for which it may be marketed or to the conditions of approval, and contain requirements for costly post-marketing testing and surveillance to monitor the safety and/or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and, if we market TYMLOS or any of our other products which may be approved for other than their approved indications, we may be subject to enforcement action for off-label marketing.

In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;

- restrictions on product distribution or use;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- voluntary or mandatory recall of products and related publicity requirements;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

In addition, the FDA's policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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.

The commercial success of TYMLOS and any other product candidates that we may develop and that may be approved will depend upon the degree of market acceptance by regulators, key opinion leaders, physicians, patients, third-party payors and others in the medical community.

Even if the FDA or foreign regulatory authorities approves one or more of our product candidates, physicians and patients may not accept and use them. Acceptance and use of any of our products will depend upon a number of factors including:

- perceptions by members of the healthcare community, including physicians and key opinion leaders, about the safety and effectiveness of our drug;
- the approved indicated uses for our product;
- cost-effectiveness of our product relative to competing products;
- availability and level of coverage and reimbursement by third-party payors, including state and federal governments, pharmacy benefit managers and health insurance plans, the willingness and ability of patients to pay for TYMLOS, and the commensurate discounts, price concessions or rebates required to secure coverage and reimbursement by third-party payors; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

If TYMLOS or any of our other product candidates are commercialized and unexpected adverse events are reported in connection with the use of any of those products, physician and patient acceptance of the product could deteriorate and the commercial success of such product could be adversely affected. We are required to report to the FDA or similar regulatory authorities in other countries events associated with our products relating to death or serious injury. Adverse events could result in additional regulatory controls, such as for the imposition of costly post-approval clinical studies, imposition of a REMS, or revisions to approved labeling which could limit the indications or patient population for a product, or could even lead to the withdrawal of a

product from the market. Because we expect sales of TYMLOS to generate substantially all of our product revenues for the foreseeable future, its failure to gain market acceptance or, once gained, a decrease in market acceptance would harm our business and would require us to seek additional financing.

Our ability to successfully commercialize products depends in part on the extent to which coverage and reimbursement for the costs of our products and related treatments will be available in the United States and worldwide from government health administration authorities, private health insurers and other organizations.

Our ability to successfully commercialize TYMLOS or any of our other product candidates if approved, alone or with collaborators, will depend in large part on the availability and level of coverage and reimbursement by third-party payors, including government and health administration authorities, pharmacy benefit managers, health insurance plans and other healthcare payors.

In the United States and internationally, sales of products that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability and level of coverage and reimbursement from third-party payors such as state and federal governments, pharmacy benefit managers and health insurance plans. Third-party payors have implemented cost cutting and reimbursement initiatives and likely will continue to do so in the future. These include establishing formularies that limit and govern the drugs and biologics that will be offered, determining the evidence and documentation required to support medical need, setting the out-of-pocket obligations of member patients, and negotiating discounts, rebates and price concessions with manufacturers for such products. In addition, particularly in the United States and increasingly in other countries, we may be required to provide discounts, price concessions and pay rebates to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities. It is possible that future legislation in the United States and other jurisdictions could be enacted which could potentially impact the coverage and reimbursement for the products we are developing and may develop in the future and also could further impact the levels of discounts, price concessions, and rebates paid to federal and state government entities. For example, in 2017 the Tax Cuts and Jobs Acts was signed into law, which, among other things, removed penalties for not complying with the individual mandate to carry health insurance. Any legislation that impacts these areas, including the ongoing consideration of the repeal and replacement of the ACA and other legislation focused on drug pricing, could impact, in a significant way, our ability to generate revenues from sales of products that we bring to market, including TYMLOS and any other product candidates that may receive marketing approval.

Decisions in the European Union on pricing and reimbursement of medicinal products are based upon national rules subject to the control of the Transparency Directive, which aims to ensure the transparency measures established by EU countries to control the pricing and reimbursement of medicinal products. The Transparency Directive defines a series of procedural requirements designed to verify that national pricing and reimbursement decisions do not create obstacles to the pharmaceutical trade within the EU's Internal Market. The competent authorities of each of the 28 EU Member States have adopted individual policies and rules regulating the pricing and reimbursement of medicinal products in their territory. These national measures controlling pricing and reimbursement often vary widely in nature, scope and application. However, a major element that they have in common is an increased move toward reduction in the reimbursement price of medicinal products, a reduction in the number and type of products selected for reimbursement, and an increased preference for generic products over innovative products. These efforts have mostly been executed through these countries' existing price-control methodologies, including price cuts, mandatory rebates, value-based pricing, and reference pricing (i.e., referencing prices in other countries and using those reference prices to set a price). It is increasingly common in many EU Member States for Marketing Authorization Holders to be required, in order to obtain support for reimbursement under national health systems and, therefore, practical access to the market to demonstrate the cost-effectiveness or added value benefit of their products as compared to products (which are considered as standard of care) already subject to pricing and reimbursement in specific countries. In order for drugs to be evaluated positively under such criteria, pharmaceutical companies may need to re-examine, and

consider altering, a number of traditional functions relating to the selection, study, and management of drugs, whether currently marketed, under development, or being evaluated as candidates for research and/or development.

Future legislation, including the current versions being considered at the federal and state level in the United States and at the national level in EU Member States, or regulatory actions implementing recent or future legislation may have a significant effect on our business. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for TYMLOS or our other product candidates, once approved, market acceptance of our products could be reduced. In addition, negotiating prices with government authorities under current and proposed legislation can delay the commercialization of our product candidates.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we narrowly focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for some of our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or foreign regulatory authorities. In addition, many of our competitors have ongoing clinical trials for product candidates that could be competitive with our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

Risks Related to Our Dependence on Third Parties

Our drug development programs depend upon third-party researchers, investigators and collaborators who are outside our control.

We depend upon independent researchers, investigators and collaborators, to conduct our preclinical studies and clinical trials under agreements with us. These third parties are not our employees and we cannot control the amount or timing of resources that they devote to our programs. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and requirements, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and our third-party researchers, investigators and collaborators are required to comply with good clinical practice, or GCP, requirements, which are regulations and guidelines enforced by the FDA, the Competent

Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or other comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications or require a more restrictive label for the product. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. In addition, these third parties may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard, the approval of our FDA or foreign regulatory authority applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist competitors at our expense, our competitive position would be harmed.

We currently rely on third parties to manufacture TYMLOS and to produce our other product candidates; our dependence on these parties, including any inability on our part to accurately anticipate product demand and timely secure manufacturing capacity to meet commercial or clinical product demand may impair the commercialization of TYMLOS and the research and development activities and potential commercialization of our other product candidates.

We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to internally formulate or manufacture TYMLOS or our other product candidates in the quantities needed to meet commercial demand for TYMLOS, or to internally conduct our research and development activities and clinical trials for our other product candidates. Therefore, we rely on, and expect to continue relying on for the foreseeable future, a limited number of third parties to manufacture and supply materials (including raw materials and subunits), drug substance, or API, and drug product, as well as to perform additional steps in the manufacturing process, such as filling, labeling, and storage of TYMLOS and our other product candidates. There are a limited number of third parties with facilities and capabilities suited for the manufacturing process of TYMLOS and our other product candidates, which creates a heightened risk that we may not be able to obtain materials and APIs in the quantity and purity that we require. In addition, the process for adding new manufacturing capacity can be lengthy and could cause delays in our development efforts. Any interruption of the development or operation of those facilities due to, among other reasons, events such as order delays for equipment or materials, equipment malfunction, quality control and quality assurance issues, regulatory delays and possible negative effects of such delays on supply chains and expected timelines for product availability, production yield issues, shortages of qualified personnel, discontinuation of a facility or business or failure or damage to a facility by natural disasters such as earthquake or fire, could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available TYMLOS, our other product candidates or materials.

We have entered into agreements with contract manufacturers to manufacture TYMLOS in the quantities needed to meet commercial demand and our other product candidates for use in research and development activities and clinical trials. These contract manufacturers are currently our only source for the production and formulation of TYMLOS and our other product candidates. If our contract manufacturers are unable to produce, in a timely manner, adequate supplies of TYMLOS on commercially reasonable terms necessary to provide adequate supply to meet demands that exceed our commercial assumptions or our other product candidates to meet our commercial demand and our other product candidates to meet the needs of our clinical studies, we would be required to seek new contract manufacturers that may require us to modify our finished product formulation and modify or terminate our clinical studies. Any modification of our finished product or modification or termination of our clinical studies could adversely affect the commercial potential of TYMLOS

or any other product candidate that may be approved and impair our ability to obtain necessary regulatory approvals, which would materially harm our business and impair our ability to raise capital.

In addition, the facilities and processes and controls used by our contract manufacturers to manufacture TYMLOS and our other product candidates must be approved by the EMA, and by the FDA pursuant to inspections that will be conducted following our regulatory approval submissions. We do not control the facilities or manufacturing process, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve our contract manufacturers for the manufacture of our product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market, with respect to TYMLOS, or for our other product candidates, if approved.

We depend on a number of single source contract manufacturers to supply key components of abaloparatide. For example, we depend on PPL, which has agreed to produce supplies of abaloparatide API to support the abaloparatide-SC and abaloparatide-patch clinical studies and the commercial supplies of TYMLOS. We also depend on Vetter and Ypsomed for the production of finished drug product clinical and commercial supplies of TYMLOS and we depend on 3M for the production of abaloparatide-patch. If our relationship with any of these contract manufacturers is terminated, or if they are unable to produce abaloparatide or related components in required quantities, on a timely basis or at all, and/or in compliance with the terms of our agreements, our business and financial condition would be materially harmed. Because the manufacturing process for abaloparatide-patch requires the use of 3M's proprietary technology, 3M is the sole source for supplies of abaloparatide-patch. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs or related components in the volume and of the quality required to meet our clinical needs and commercial needs.
- Our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other government regulations and corresponding foreign standards, and failure to comply with cGMP or corresponding foreign standards can result in compliance actions that may limit a manufacturer's production or prohibit a manufacturer from producing some or all products at a facility and/or importing it into the United States or a foreign country. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, any such improvement(s) could be subject to FDA review and prior approval, and we may not own, or may have to share, the intellectual property rights to the innovation.

Each of these risks could delay our clinical trials, the approval of our product candidates by the FDA or foreign regulatory authorities or the commercialization of TYMLOS or any of our other product candidates that may be approved or result in higher costs or deprive us of potential product revenues.

Risks Related to Marketing and Sale of Our Products

If we are unable to maintain our commercial capabilities on our own or through partnerships or collaborations, we may not be able to successfully commercialize TYMLOS or any future product candidates or generate product revenue.

We established a sales force to market and sell TYMLOS in the United States to specialists and also intend to pursue collaborative arrangements to market and sell abaloparatide-SC outside of the United States. Therefore, our future success depends, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborators' strategic interest in the products under development and such collaborators' ability to successfully market and sell any such products.

In addition, our ability to build and maintain effective commercial, medical affairs, marketing, sales, market access, managerial and other non-technical capabilities will depend on a number of factors, including our ability to:

- identify, recruit, hire, train, incentivize and retain a significant number of commercial and medical affairs personnel, including a specialty sales force with appropriate technical expertise;
- train our sales representatives, to deliver clear and compelling messages within the scope of the approved labeling and in accordance with other applicable FDA requirements regarding TYMLOS and to be credible and persuasive in educating physicians on the appropriate situations to consider prescribing it as set forth in the approved labeling;
- ensure our commercial customer-facing team, including sales, market access, and field logistics professionals, effectively build relationships with their respective customers;
- manage a geographically dispersed national commercial customer-facing organization; and
- manage our significant projected growth and the integration of new personnel.

Building and maintaining our commercial and medical affairs capabilities may be more expensive and time consuming than we anticipate, requiring us to divert resources from other intended purposes or preventing us from building these capabilities to the desired levels. Any failure or delay in building and maintaining these capabilities on our own or through partnerships or collaborations will adversely impact the successful commercialization of TYMLOS, or any future product candidate. If we establish a partnership or collaboration for purposes of commercializing abaloparatide-SC, or any future product candidate, the launch of that product candidate would need to be established in conjunction with our partner, which could result in a change in timing of the commercial launch.

In addition, given our existing resources and emerging experience in marketing, selling and distributing pharmaceutical products, our initial specialty sales force may be materially smaller than the actual number of sales representatives required to successfully commercialize TYMLOS. As such, we may be required to hire substantially more sales representatives to adequately support the commercialization of TYMLOS.

If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our product candidates is characterized by intense competition and rapid technological advances. TYMLOS and any of our product candidates that may receive FDA or foreign regulatory authority

approval will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If TYMLOS or any of our other potential products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

In April 2017, we received FDA approval of TYMLOS for the treatment of postmenopausal women with osteoporosis at high risk for fracture. TYMLOS competes in the U.S. against well-known treatment options, including teriparatide, marketed by Lilly in the U.S. as Forteo. TYMLOS may also face competition from generic or biosimilar versions of teriparatide. For example, in January 2017 a biosimilar version of teriparatide was approved in the European Union, although the product is not expected to be launched until the expiration or invalidation of applicable patents covering teriparatide. We are also aware of other companies pursuing development of biosimilar and/or generic versions of teriparatide in the U.S. and EU through various regulatory pathways. The availability of a generic or biosimilar teriparatide on the market would likely exert pricing and reimbursement pressure on the anabolic class in which abaloparatide-SC would compete. In addition, there are other organizations working to develop new therapies to treat osteoporosis. For example, UCB and Amgen are co-developing an anti-sclerostin anabolic monoclonal antibody for the treatment of osteoporosis. In order to compete successfully in this market, we will have to demonstrate to patients, physicians and third-party payors that the treatment of postmenopausal women with osteoporosis at high risk of fracture with TYMLOS is worthwhile and is a better alternative to existing or new therapies.

We face significant competition from many fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have compounds already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing, distributing, and selling drugs.

Developments by competitors may render our products or technologies obsolete or non-competitive.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our product TYMLOS, and product candidates abaloparatide-patch, elacestrant and RAD140, if approved, will compete against existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the United States and abroad. In addition, companies doing business in different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals, and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations, and therefore, we may not be able to hire or retain qualified personnel to run all facets of our business. These risks could render our products or technologies obsolete or non-competitive.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators.

Risks Related to Our Intellectual Property

If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are a party to a number of intellectual property license agreements with third parties and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that any future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, our licensors may have the right to terminate these agreements, in which event we might not be able to develop and market any product that is covered by these agreements. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms. The occurrence of such events could materially harm our business.

In November 2016, we received notice that in October 2016, Ipsen initiated arbitration proceedings against us in the International Chamber of Commerce's International Court of Arbitration. Ipsen's Request for Arbitration alleges that we breached various provisions of the License Agreement concerning abaloparatide, including with regard to Ipsen's right to co-promote abaloparatide in France and a license from us with respect to Japan. Ipsen seeks declaratory relief, compliance with the License Agreement, damages, costs and fees as a result of the purported breaches, and alleges the monetary value of these claims is approximately €50 million (approximately $59.9 million). We have sought dismissal of Ipsen's claims, as well as declaratory relief, compliance with the License Agreement, and other damages, costs and fees to be determined by the Arbitral Tribunal. A hearing on the merits was held on December 18 and 19, 2017, and additional submissions on cost and fee allocation is anticipated in early 2018. We expect a final decision by the Arbitral Tribunal in the first half of 2018. Until we receive a decision from the Arbitral Tribunal, we cannot predict or assess the likely outcome of these proceedings.

If our efforts to protect our intellectual property related to abaloparatide-SC, abaloparatide-patch, elacestrant and/or RAD140 fail to adequately protect these assets or if we are unable to secure all necessary intellectual property, we may lose the ability to license or successfully commercialize one or more of these candidates.

Our commercial success is significantly dependent on intellectual property related to our portfolio of product candidates. We are either the licensee or assignee of numerous issued and pending patent applications that cover various aspects of our assets, including abaloparatide-SC, abaloparatide-patch, elacestrant and RAD140.

Patents covering abaloparatide as a composition of matter have been issued in the United States (U.S. Patent No. 5,969,095) and several additional countries. Because the abaloparatide composition of matter patent was filed in 1996, it expired in 2016 in the United States, and additional countries where it had issued. Prior to its expiration, European Patent No. 0847278, which was included in the license from Ipsen and claimed the composition of matter of abaloparatide, lapsed due to Ipsen's failure to pay annuities. Prior to expiration, we pursued restoration of those patent rights in various countries. As a result of the lapse and expiration of patent rights, we believe that some of Ipsen's rights under our license agreement with Ipsen have terminated. We are currently involved in a pending arbitration proceeding with Ipsen regarding these Ipsen rights and related terms of our license agreement.

We and Ipsen are also co-assignees to U.S. Patent No. 7,803,770 that we believe provides exclusivity until October 3, 2027 and may be adjusted to March 26, 2028 in the United States (not including any Hatch-Waxman patent term extension) for the method of treating osteoporosis with the intended therapeutic dose for abaloparatide-SC. A closely-related patent (European Patent No. 2957278) has been issued in Europe. This patent also has an expiration date of October 3, 2027, absent any issued supplementary protection certificates, or SPCs.

We and Ipsen are also co-assignees to U.S. Patent No. 8,148,333 that we believe provides exclusivity until 2027 in the United States (not including any Hatch-Waxman patent term extension) for the intended therapeutic formulation for abaloparatide-SC.

We and 3M are co-assignees to several foreign and corresponding U.S. patent applications, which cover various aspects of abaloparatide for microneedle application. Any issued patents resulting from these applications will have statutory expiration dates ranging from 2032 to 2037, not taking into account extension under any applicable laws. However, pending patent applications in the United States and elsewhere may not issue since the interpretation of the legal requirements of patentability in view of claimed inventions are not always predictable. Additional intellectual property covering abaloparatide-patch technology exists in the form of proprietary information protected as trade secrets. These can be accidentally disclosed to, independently derived by or misappropriated by competitors, possibly reducing or eliminating the exclusivity advantages of this form of intellectual property, thereby allowing those competitors more rapid entry into the marketplace with a competitive product, which reduces our advantage with abaloparatide-patch. In addition, trade secrets may in some instances become publicly available through required disclosures in regulatory files. Alternatively, competitors may sometimes reverse engineer a product once it becomes available on the market. Even where a competitor does not use an identical technology for the delivery of abaloparatide, it is possible that they could achieve an equivalent or even superior result using another technology. Such occurrences could lead to either one or more alternative competitor products becoming available on the market and/or one or more generic competitor products on the market gaining market share and causing a corresponding decrease in market share and/or price for abaloparatide-patch even if it were to be successfully developed and approved by the FDA.

Patents covering elacestrant as a composition of matter, as well as the use of elacestrant for the treatment of estrogen-dependent breast cancer, have been issued in the United States, Canada, Australia, Japan and Europe, and are pending in India. The elacestrant composition of matter patents in the United States expire in 2023 and may be adjusted to 2026 (not including any Hatch-Waxman patent term extension). We exclusively licensed US 9,421,264 covering the treatment of ER+, SERM-resistant (such as tamoxifen and fulvestrant) breast cancer brain metastasis with elacestrant and related applications covering, more broadly, the use of elacestrant for the treatment of ER+ cancers, such as SERM-resitant ER+ breast cancer (statutory term expires October 10, 2034, not taking into account any extension under any applicable laws). Corresponding applications pending in Europe and Canada will have a statutory expiration date in 2035. Polymorphic forms of elacestrant are covered in a U.S. application and a PCT application (filed January 2018) having a projected statutory expiration date in 2038, not taking into account any extension under any applicable laws. Elacestrant combination therapies with a CDK4/6 inhibitor (e.g., palbociclib) or an mTOR inhibitor (e.g., everolimus) for treatment of cancers that are drug-resistant and/or expressing mutant ERα+ are covered by applications pending in the U.S., Australia, Brazil, Canada, China, Europe, Israel, Japan, South Korea, Mexico, New Zealand, Russia, and Singapore (statutory expiration date in 2036, not taking into account any extension under any applicable laws). We could encounter challenges or difficulties in maintaining and/or defending our intellectual property both in the United States and abroad.

Patent applications covering RAD140 and other selective androgen receptor modulator compounds have been granted in the United States, Europe, Canada, Mexico, Japan and Australia, and are pending in Brazil and India. The RAD140 composition of matter patents expire in 2029 in the United States (not including any Hatch-Waxman patent term extension) and additional countries if and when they issue. The PCT application covering RAD140 for the treatment of AR+ breast cancer has been filed and has a projected statutory expiration date in

2037, not taking into account extension under any applicable laws. This PCT application covers the use of RAD140 alone or in combination with a CDK4/6 inhibitor (e.g., palbociclib) or an mTOR inhibitor (e.g., everolimus).

Since patents are technical legal documents that are frequently subject to intense litigation pressure, there is risk that even if one or more patents related to our products does issue and is asserted that the patent(s) will be found invalid, unenforceable and/or not infringed when subject to said litigation. Finally, the intellectual property laws and practices can vary considerably from one country to another and also can change with time. As a result, we could encounter challenges or difficulties in building, maintaining and defending our intellectual property both in the United States and abroad.

We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to patents issued or licensed to us, including interference proceedings before the USPTO. Third parties also may assert infringement claims against us. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

If we are unable to obtain and maintain patent protection for our technology and products, or if our licensors are unable to obtain and maintain patent protection for the technology or products that we license from them, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if third parties who license patents to us fail to maintain these patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued that protect our technology or products or that effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Assuming the other requirements for patentability are met, in the United States, prior to March 16, 2013, the first to make the claimed invention was entitled to the patent, or a "first-to-invent" system, while outside the United States, the first to file a patent application is entitled to the patent, or a "first-to-file" system. With the implementation of the Leahy-Smith America Invents Act, the United States now has a first-to-file system for patent applications filed on or after March 16, 2013. We may become involved in opposition, interference or derivation proceedings challenging our patent rights or the patent rights of others. For example, we are aware of two oppositions to European Patent No. 2957278 filed with the European Patent Office. One opposition was filed

on February 16, 2018 by Teva Pharmaceutical Industries Ltd and the other opposition was filed on February 19, 2018 in the name of a patent law firm Isenbruck Bosl Horschler LLP. There may be additional oppositions we are not aware of, but filed before the opposition period expired on February 19, 2018. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. An adverse determination in any such proceeding could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Any challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are approved or commercialized. As a result, our owned and licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Payments, fees, submissions and various additional requirements must be met in order for pending patent applications to advance in prosecution and issued patents to be maintained. Rigorous compliance with these requirements is essential to procurement and maintenance of patents integral to our product portfolio.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will come due for payment periodically throughout the lifecycle of patent applications and issued patents. In order to help ensure that we comply with any required fee payment, documentary and/or procedural requirements as they might relate to any patents for which we are an assignee or co-assignee, we employ competent legal help and related professionals as needed to comply with those requirements. Our outside patent counsel uses CPA Global for patent annuity payments. We depend on Eisai to comply with any required fee payment, documentary and/or procedural requirements as they might relate to any patents we have licensed from them. Failure to meet a required fee payment, document production or procedural requirement can result in the abandonment of a pending patent application or the lapse of an issued patent. In some instances, the defect can be cured through late compliance but there are situations where the failure to meet the required event cannot be cured. Any failures could compromise the intellectual property protection around our preclinical or clinical candidates and possibly weaken or eliminate our ability to protect our eventual market share for that product.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to our patented technology and products, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to our trade secrets, such as our corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach the agreements and disclose our proprietary information, and we may not be able

to obtain adequate remedies for any breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by a competitor, our competitive position would be harmed.

If we infringe the rights of third parties, we could be prevented from selling products and could be forced to pay damages and defend against litigation.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing drug candidate;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings which may be costly whether we win or lose, which could result in a substantial diversion of our financial and management resources.

We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid and/or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated and/or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, our licensors may have rights to file and prosecute these types of claims, and we may be reliant on them to do so.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Some of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from

their normal responsibilities, delaying the development of our product candidates. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Litigation or other proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct any litigation or proceedings. Some of our competitors may be able to sustain the costs of any litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Risks Related to Legislation and Administrative Actions

Healthcare reform may have a material adverse effect on our industry and our results of operations.

From time to time, legislation is implemented to reign in rising healthcare expenditures. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or ACA, was enacted. ACA includes a number of provisions affecting the pharmaceutical industry, including annual, non-deductible fees on any entity that manufactures or imports some types of branded prescription drugs and biologics and increases in Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program. In addition, among other things, ACA also establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities and conduct comparative clinical effectiveness research. In addition, other legislative changes have been proposed and adopted since ACA was enacted, which also may impact our business. In August 2011, the Budget Control Act of 2011, or BCA, was enacted, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. These reductions include aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2025 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, or ATRA, was enacted, which among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers. The full impact on our business of these laws is uncertain. We cannot predict whether other legislative changes will be adopted, if any, or how such changes would affect the pharmaceutical industry generally or our business in particular.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates once approved or additional pricing pressures, and may adversely affect our operating results. Such legislation may also reduce our flexibility in setting prices for our product candidates, or in taking price increases.

We are subject to healthcare laws, regulation and enforcement, and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

We are subject to several healthcare regulations and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of various electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or

indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, 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 False Claims Act;

- federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation;
- the federal Physician Payment Sunshine Act, or the Sunshine Act, requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. Manufacturers are required to submit reports to the government by the 90th day of each calendar year; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require drug manufacturers to report and make public drug prices and/or price increases; and state laws governing 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.

Our operations and commercial activities in connection with TYMLOS any other product candidate that may be approved are and will be subject to comprehensive compliance obligations under state and federal fraud and abuse, false claims, physician payment transparency laws and government pricing regulations, as described above. If we are found to be in violation of these regulations, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

The potential U.K. exit from the European Union as a result of the June 2016 U.K. referendum could harm our business, financial condition or results of operations.

In June 2016, the U.K. affirmatively voted in a referendum advising for the exit of the U.K. from the European Union, commonly referred to as "Brexit". In March 2017, the U.K. government formally notified the European Council of its intention to leave the EU. The formal notification triggered a procedure set out in Article 50 of the Lisbon Treaty to begin the two-year negotiation process to conclude an agreement between the U.K. and the EU setting out the arrangements for the U.K.'s withdrawal, taking account of the framework for the U.K.'s future relationship with the EU. The agreement must be concluded on behalf of the EU by the European Council acting by a qualified majority, after obtaining the consent of the European Parliament. There is uncertainty about the terms of the final agreement and the framework for the future relationship between the U.K. and the EU. The U.K. government has prepared the European Union (Withdrawal) Bill which is currently being considered by the U.K. legislature in both Houses of the Parliament. The Bill seeks to repeal the European Communities Act 1972 (ECA) that confers power to incorporate EU law into the UK domestic legal order and provides for the supremacy of EU law. The U.K. Government recognizes that simply repealing the ECA would lead to a confused and incomplete legal system. The Bill will convert directly-applicable EU laws into UK law once the U.K. leaves the EU, and confer delegated power on the U.K. Government to make changes to the full body of EU-derived law Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which European Union laws to replace or replicate and could have a material impact on its economy and the future growth of its various industries. In particular, there is uncertainty about the U.K. will continue to be within the single market and customs union for goods and services to be moved freely within the EU.

The announcement of Brexit caused significant volatility in global stock markets and currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against foreign currencies in which we conduct business. The strengthening of the U.S. dollar relative to other currencies may adversely affect our operating results. The announcement of Brexit and the withdrawal of the U.K. from the European Union have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity. Any of these effects of Brexit, among others, could adversely affect our business, financial condition, operating results and cash flows.

Recent decisions from the European General Court on public access to clinical trial data held by the EMA could result in disclosure of our pre-clinical and clinical trial data to competitors, or other third parties, which could harm our business, financial condition or results of operations.

In the EU, Regulation 1049/2001/EC, commonly known as the EU Freedom of Information Regulation or Public Access Regulation (the "Transparency Regulation"), allows any EU citizens and any natural or legal persons residing or having their headquarters in an EU country to request access to the documents held by a EU institution on grounds relating to public interest. The Transparency Regulation applies to the EMA, which has implemented the provisions in its established policy. The EMA policy favors public access, subject to certain limited exceptions if disclosure undermines, among others, the protection of commercial interests. The EMA policy has been the subject of three recent rulings of the European General Court in the following cases: Pari Pharma GmbH v EMA (Case T-235/1); MSD Animal Health Innovation and Intervet International v EMA(Case T-729/15) and PTC Therapeutics International v EMA (Case T-718/15). These decisions responded to demands for greater transparency and disclosure of pre-clinical and clinical data and validated the EMA's transparency policy to provide greater public access to information held and documents drawn up by the EMA. These decisions clarified that misuse of the data by a competitor is not relevant to an assessment of confidentiality under the Transparency Regulation and the argument that data exclusivity or protection in countries outside the EU may be lost due to use of the disclosed documents does not make the data in question confidential.

The potential risk to our business under the Transparency Regulation is significant. For example, our marketing authorisation application for abaloparatide-SC in the EU is currently being reviewed centrally by the

EMA and its advisory committees. At present, according to the established EMA policy, the information contained in our marketing authorisation application, responses we provide to the questions raised by the EMA and its advisory committees as well as the assessment reports drawn up by the EMA and its advisory committees would not be disclosed. However, in light of the European General Court's recent Transparency Regulation decisions, such information could be susceptible to disclosure to third parties, including to our competitors, once a decision on the approvability of abaloparatide-SC is made and our marketing authorisation application is withdrawn from the centralized procedure. The potential disclosure of such information to third parties, including our competitors, and the potential loss of data exclusivity or protections in countries outside the EU could adversely affect our business, financial condition, operating results and cash flows.

Risks Related to Employee Matters and Managing Growth

We have recently increased the size of our organization, and will need to continue to increase the size of our organization. We may encounter difficulties with managing our growth, which could adversely affect our results of operations.

Although we have already added several capabilities, we may need to add additional qualified personnel and resources as we launch TYMLOS. Our current infrastructure may be inadequate to support our recent and expected growth. In particular, we may need to grow our internal sales, marketing, and distribution capabilities to successfully market TYMLOS and any other drug that we may successfully develop. Future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees, and may take time away from running other aspects of our business, including development and commercialization of our product candidates.

Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. In particular, as our commercialization plans and strategies develop, we will recruit and train a substantial number of sales and marketing personnel and expect to expand the size of our employee base for managerial, operational, financial and other resources. To that end, we must be able to:

- manage our development efforts effectively;
- integrate additional management, administrative and manufacturing personnel;
- build a marketing and sales organization; and
- maintain sufficient administrative, accounting and management information systems and controls.

We may not be able to accomplish these tasks or successfully manage our operations and, accordingly, may not achieve our research, development, and commercialization goals. Our failure to accomplish any of these goals could harm our financial results and prospects.

As we evolve from a company primarily involved in drug development into one that is also involved in the commercialization of pharmaceutical products, we may have difficulty managing our growth and expanding our operations successfully.

Our success will depend upon the expansion of our operations and the effective management of our growth, and if we are unable to manage this growth effectively, our business will be harmed. We have recently expanded, and will continue to expand, our development, regulatory, manufacturing, quality, distribution, sales and marketing capabilities. As part of this expansion, we expect we will need to manage additional relationships with various collaborators, suppliers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our operational, financial and management controls, reporting systems and procedures. For example, some jurisdictions, such as the District of Columbia, have imposed licensing requirements for sales representatives. In addition, the District of Columbia and the Commonwealth of Massachusetts, as well as the federal government by way of the Sunshine Act, have established reporting

requirements that would require public reporting of compensation and other "transfers of value" paid to health care professionals and teaching hospitals, as well as ownership and investment interests held by such professionals and their immediate family members. Because the reporting requirements vary in each jurisdiction, compliance will be complex and expensive and may create barriers to entering the commercialization phase. The need to build new systems as part of our growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Such requirements may also impact our opportunities to collaborate with physicians at academic research centers as new restrictions on academic-industry relationships are put in place. In the past, collaborations between academia and industry have led to important new innovations, but the new laws may have an effect on these activities. While we cannot predict whether any legislative or regulatory changes will have negative or positive effects, they could have a material adverse effect on our business, financial condition and potential profitability.

If we are unable to successfully maintain and further develop internal commercialization capabilities, sales of TYMLOS may be negatively impacted.

We have only recently started to commercialize our first drug product. We have built a commercial team and established the organizational infrastructure we believe necessary for a successful commercial launch of TYMLOS in the United States. We will need to commit significant time, financial and managerial resources to maintain and further develop our marketing and sales force to ensure they have the technical expertise required to address any challenges we may face with the commercialization of TYMLOS. Factors that may inhibit our efforts to maintain and develop our commercialization capabilities include:

- an inability to retain an adequate number of effective commercial personnel;
- our ability to train sales personnel, who may have limited experience with our company or TYMLOS, to deliver a consistent and compliant message regarding TYMLOS that will be compelling to physicians who may prescribe TYMLOS;
- an inability to equip sales personnel with effective materials, including medical and sales literature to help them educate physicians and our healthcare providers regarding TYMLOS and its proper administration;
- unforeseen costs and expenses associated with maintaining and further developing an independent sales and marketing organization.

If we are not successful in establishing and maintaining an effective commercial infrastructure, we will have difficulty generating product revenue, which would adversely affect our business and financial condition. If the cost of establishing and maintaining a sales and marketing organization exceeds the cost-effectiveness of doing so, we may not become profitable.

We may enter into or seek to enter into business combinations and acquisitions which may be difficult to integrate, disrupt our business, divert management attention or dilute stockholder value.

We may enter into business combinations and acquisitions. We have limited experience in making acquisitions, which are typically accompanied by a number of risks, including:

- the difficulty of integrating the operations and personnel of the acquired companies;
- the potential disruption of our ongoing business and distraction of management;
- the potential for unknown liabilities and expenses;
- the failure to achieve the expected benefits of the combination or acquisition;
- the maintenance of acceptable standards, controls, procedures and policies; and
- the impairment of relationships with employees as a result of any integration of new management and other personnel.

If we are not successful in completing acquisitions that we may pursue in the future, we would be required to reevaluate our business strategy and we may have incurred substantial expenses and devoted significant management time and resources in seeking to complete the acquisitions. In addition, we could use substantial portions of our available cash as all or a portion of the purchase price, or we could issue additional securities as consideration for these acquisitions, which could cause our stockholders to suffer significant dilution.

We rely on key executive officers and scientific and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace.

We are highly dependent on our chief executive officer and our principal scientific, regulatory and medical advisors. We do not have "key person" life insurance policies for any of our officers. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

We will need to hire additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success.

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex and interdependent information technology systems to support business processes as well as internal and external communications. Our computer systems are vulnerable to breakdown, malicious intrusion and computer viruses. Any failure to protect against breakdowns, malicious intrusions and computer viruses may result in the impairment of production and key business processes. In addition, our systems are potentially vulnerable to data security breaches, whether by employees or others, which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information of our employees, clinical trial patients, customers, and others. Such disruptions and breaches of security could expose us to liability and have a material adverse effect on the operating results and financial condition of our business.

Risks Relating to Our Securities

Our stock price may be volatile, and the value of an investment in our common stock may decline.

The trading price of our common stock may be subject to wide fluctuations in response to various factors, some of which are beyond our control, including:

- actions or delays by the FDA, EMA or other foreign regulatory authority in respect of any NDA, MAA or other application we may submit for any of our product candidates, including our MAA for abaloparatide-SC;
- results of clinical trials of our product candidates or those of our competitors;
- our operating performance and the operating performance of similar companies;
- the success of competitive products;
- the overall performance of the equity markets;

- the number of shares of our common stock publicly owned and available for trading;
- threatened or actual litigation;
- changes in laws or regulations relating to our products, including changes in the structure of healthcare payment systems;
- any major change in our board of directors or management;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- large volumes of sales or other transfers of our shares of common stock by existing stockholders;
- general political, economic and market conditions; and
- the other factors described in this "Risk Factors" section.

In addition, the stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of the companies whose shares trade in the stock market. Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company's securities. Such litigation, if instituted against us, could result in very substantial costs, divert our management's attention and resources and harm our business, operating results and financial condition.

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 gain.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company listed on the NASDAQ Global Market, or NASDAQ, we have incurred and will continue to incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the Securities and Exchange Commission, or the SEC, and NASDAQ have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and are making some activities more time-consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, and are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to maintain effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a publicly traded company or comply with the requirements of the SEC or Section 404. This could result in a restatement of our consolidated financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common shares, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain.

Our directors and executive officers, together with their affiliates, have substantial influence over us and could delay or prevent a change in corporate control.

Our directors and executive officers, together with their affiliates, beneficially own a substantial amount of shares of our common stock. These stockholders, acting together, have the ability to significantly influence the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, these stockholders, acting together, have the ability to significantly influence the management and affairs of our company. Accordingly, this concentration of ownership might harm the market price of our common stock by:

- delaying, deferring or preventing a change in corporate control;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

Pursuant to our equity incentive plans, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. We have reserved 9,860,000 shares of our common stock for issuance under our equity incentive plans as of December 31, 2017, which includes 2,584,000 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2017, and approximately 147,000 restricted stock units, each of which will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. In addition, as of December 31, 2017, warrants to purchase 605,415 shares of our common stock were outstanding. Pursuant to our employee stock purchase plan, eligible employees may participate in an employee stock purchase plan sponsored by us. The current plan allows for the issuance of 1,290,954 shares of common stock to eligible employees. As of December 31, 2017, there were 1,214,314 shares available for future sale to employees under this plan. Shares of our common stock issued upon exercise of these warrants may be sold in the public market, subject to prior registration or under an exemption from registration.

If securities or industry analysts cease to publish research or publish inaccurate or 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. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We may be required to pay severance benefits to our employees who are terminated in connection with a change in control, which could harm our financial condition or results.

Each of our executive officers is party to an employment agreement, and each of our other employees is party to an agreement or participates in a plan that provides change in control severance benefits including cash

payments for severance and other benefits and acceleration of vesting of stock options and other equity awards in the event of a termination of employment in connection with a change in control of us. The payment of these severance benefits could harm our financial condition and results. The accelerated vesting of options and equity awards could result in dilution to our existing stockholders and harm the market price of our common stock.

Anti-takeover provisions contained in our restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could impair a takeover attempt.

Our restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions. These provisions include:

- a staggered board of directors;
- authorizing the board to issue, without stockholder approval, preferred stock with rights senior to those of our common stock;
- authorizing the board to amend our bylaws and to fill board vacancies until the next annual meeting of the stockholders;
- prohibiting stockholder action by written consent;
- limiting the liability of, and providing indemnification to, our directors and officers;
- eliminating the ability of our stockholders to call special meetings; and
- requiring advance notification of stockholder nominations and proposals.

Section 203 of the Delaware General Corporation Law prohibits, subject to some exceptions, "business combinations" between a Delaware corporation and an "interested stockholder," which is generally defined as a stockholder who becomes a beneficial owner of 15% or more of a Delaware corporation's voting stock, for a three-year period following the date that the stockholder became an interested stockholder.

These and other provisions in our restated certificate of incorporation and our amended and restated bylaws under Delaware law could discourage potential takeover attempts, reduce the price that investors might be willing to pay in the future for shares of our common stock and result in the market price of our common stock being lower than it would be without these provisions.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2017, we had $751.7 million of federal and $669.3 million of state net operating loss carryforwards available to offset future taxable income. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have completed studies through December 31, 2015, to determine whether any ownership change has occurred since our formation and have determined that transactions have resulted in two ownership changes, as defined under Section 382. There could be additional ownership changes in the future that could further limit the amount of net operating loss and tax credit carryforwards that we can utilize.

Under the Tax Cuts and Jobs Act (the Tax Act), the amount of post 2017 net operating loss carryforwards that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the net operating loss carryforward deduction itself. The Tax Act generally eliminates the ability to carry back any net operating loss to prior taxable years, while allowing post 2017 unused net operating loss carryforwards to be carried forward indefinitely. There is a risk that due to changes under the Tax Act, regulatory changes or other unforeseen reasons, our existing net operating loss carryforwards could expire or otherwise be unavailable to offset future income tax liabilities.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Details of each of our principal properties as of December 31, 2017, are provided below:

Location	Function	Size (approximate square feet)	Property Interest
Waltham, MA, USA	Corporate Headquarters	27,208	Leased
Parsippany, NJ, USA	Office space	10,528	Leased
Cambridge, MA, USA	Laboratory and office space	4,607	Subleased
Wayne, PA, USA	Office space	28,805	Subleased

ITEM 3. LEGAL PROCEEDINGS.

In November 2016, we received notice that in October 2016, Ipsen had initiated arbitration proceedings against us in the International Chamber of Commerce's International Court of Arbitration. Ipsen's Request for Arbitration alleged that we breached various provisions of the License Agreement concerning abaloparatide, including with regard to Ipsen's right to co-promote abaloparatide in France and a license from us with respect to Japan. Ipsen is seeking declaratory relief, compliance with the License Agreement, damages, costs and fees as a result of the purported breaches and has alleged the monetary value of these claims is approximately €50 million (approximately $59.9 million).

In January 2017, we submitted an Answer denying Ipsen's claims and alleging counterclaims against Ipsen for breach of the License Agreement and other declaratory judgment. We asserted, among other things, that Ipsen's claimed rights to co-promote abaloparatide in France and to a license from us with respect to Japan have permanently expired, and that Ipsen has breached the License Agreement by, among other things, allowing certain patents to expire and by purporting to license to a third party certain manufacturing and other rights that we contend Ipsen exclusively licensed to us. We are seeking dismissal of Ipsen's claims, as well as declaratory relief, compliance with the License Agreement, and other damages, costs and fees to be determined by the Arbitral Tribunal.

In February 2017, Ipsen submitted a Reply denying our counterclaims and alleging that we are precluded from asserting them. Following a preliminary hearing before the Arbitral Tribunal to determine certain jurisdictional and contractual defenses asserted by Ipsen in its Reply, on July 17, 2017, the Arbitral Tribunal issued a decision finding it has jurisdiction to decide our counterclaims and that our counterclaims are not contractually barred.

On July 31, 2017, Ipsen submitted its Statement of Claim to the Arbitral Tribunal and on September 14, 2017 Radius submitted its Statement of Defense and Counterclaims. Subsequently, on October 20, 2017, Ipsen submitted its Reply and Statement of Defense to Radius's Counterclaims and on November 10, 2017, Radius submitted its Rejoinder on Claims and Reply on Counterclaims. Ipsen submitted a Rejoinder on Counterclaims on November 24, 2017. A hearing on the merits was held on December 18 and 19, 2017, and additional submissions on cost and fee allocation were made on February 9, 2018. We expect a final decision by the Arbitral Tribunal in the first half of 2018. Until we receive a decision from the Arbitral Tribunal, we cannot predict or assess the likely outcome of these proceedings.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

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

The information required to be disclosed by Item 201(d) of Regulation S-K, "Securities Authorized for Issuance Under Equity Compensation Plans," is incorporated herein by reference. Refer to Item 12 of Part III of this Annual Report on Form 10-K for additional information.

Market Information

Our common stock has been traded on The NASDAQ Global Market under the symbol "RDUS" since the initial public offering of our common stock on June 6, 2014. Prior to that time there was no public market for our common stock. The following table presents reported quarterly high and low per share sale prices of our common stock on The NASDAQ Global Market for the periods presented.

2017	High	Low
Quarter Ended March 31, 2017	$48.06	$35.63
Quarter Ended June 30, 2017	47.12	32.88
Quarter Ended September 30, 2017	48.35	32.99
Quarter Ended December 31, 2017	40.00	26.35

2016	High	Low
Quarter Ended March 31, 2016	$62.61	$24.75
Quarter Ended June 30, 2016	40.91	29.27
Quarter Ended September 30, 2016	59.88	36.45
Quarter Ended December 31, 2016	55.97	24.75

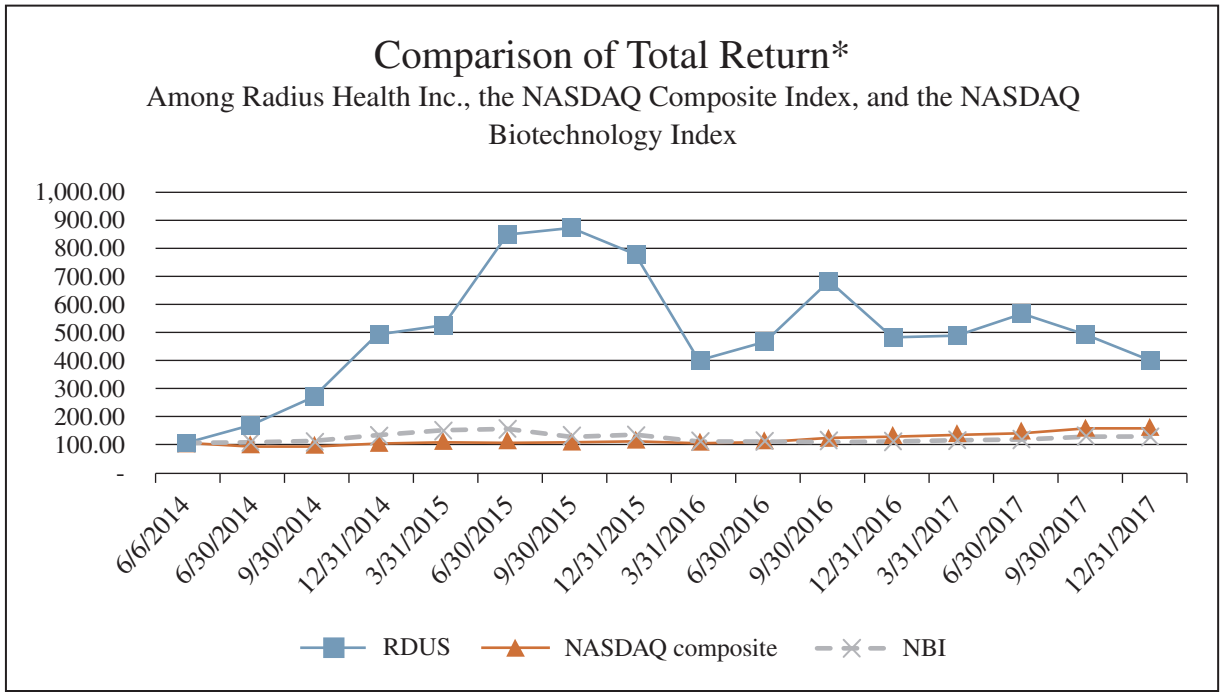
On February 26, 2018, the closing price of our common stock was $40.22 per share as reported on The NASDAQ Global Market.

Stock Performance Graph

This performance graph is furnished and shall not be deemed "filed" with the SEC or subject to Section 18 of the Exchange Act, nor shall it be deemed incorporated by reference in any filings under the Securities Act of 1933, as amended.

The graph set forth below compares the cumulative total stockholder return on our common stock between June 6, 2014 (the date of the initial public offering of our common stock) and December 31, 2017, with the cumulative total return of (a) the Nasdaq Biotechnology Index and (b) the Nasdaq Composite Index, over the same period. This graph assumes the investment of $100 on June 6, 2014 in our common stock, the Nasdaq Biotechnology Index and the Nasdaq Composite Index and assumes the reinvestment of dividends, if any. The graph assumes our closing sales price on June 6, 2014 of $8.01 per share as the initial value of our common stock and not the initial offering price to the public of $8.00 per share.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock. Information used in the graph was obtained from the Nasdaq Stock Market LLC, a financial data provider and a source believed to be reliable. The Nasdaq Stock Market LLC is not responsible for any errors or omissions in such information.



* $100 invested on June 6, 2014 in stock or index

Holders

As of February 26, 2018, there were 20 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have not paid any cash dividends on our common stock since inception and do not anticipate paying cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

We did not make any sales of unregistered securities during the fourth quarter ended December 31, 2017.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

There were no such repurchases of shares of common stock made during the fourth quarter of the fiscal year ended December 31, 2017.

ITEM 6. SELECTED FINANCIAL DATA.

You should read the following selected financial data together with our consolidated financial statements and the related notes contained in Item 8 of Part II of this Annual Report on Form 10-K. We have derived the statements of operations data for each of the three years ended December 31, 2017, 2016 and 2015 and the balance sheet data as of December 31, 2017 and 2016 from the audited consolidated financial statements contained in Item 8 of Part II of this Form 10-K. The selected balance sheet data as of December 31, 2015, 2014 and 2013 and the statement of operations data for the years ended December 31, 2014 and 2013 has been derived from the audited financial statements for such years not included in this Form 10-K.

The financial information set forth below for the year ended December 31, 2017, 2016, 2015, 2014, and 2013 has been recast to reflect the adoption of Accounting Standards Update No. 2011-05, *Presentation of Comprehensive Income*.

The historical financial information set forth below may not be indicative of our future performance and should be read together with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our historical consolidated financial statements and notes to those statements included in Item 7 of Part II and Item 8 of Part II, respectively, of this Annual Report on Form 10-K.

	Year Ended December 31,				
Statement of Operations and Comprehensive Loss Data	**2017**	**2016**	**2015**	**2014**	**2013**
	(in thousands)				
REVENUES:					
Product revenue, net	$ 12,112	$ —	$ —	$ —	$ —
License revenue	10,000	—	—	—	—
Operating expenses:					
Cost of sales—product	932	—	—	—	—
Cost of sales—intangible amortization	400	—	—	—	—
Research and development	83,076	107,406	68,280	45,719	60,536
General and administrative	186,677	77,542	30,797	13,674	6,829
Loss from operations	(248,973)	(184,948)	(99,077)	(59,393)	(67,365)
Other (expense) income:					
Other (expense) income, net	(192)	(293)	(1,607)	(713)	9,085
Interest (expense) income, net	(5,072)	2,437	(842)	(2,373)	(2,410)
Net loss	(254,237)	(182,804)	(101,526)	(62,479)	(60,690)
Other comprehensive loss, net of tax:					
Unrealized gain (loss) from available-for-sale securities	(385)	66	26	(21)	—
Comprehensive loss	$ (254,622)	$ (182,738)	$ (101,500)	$ (62,500)	$ (60,690)
Net loss attributable to common stockholders	$ (254,237)	$ (182,804)	$ (101,526)	$ (71,479)	$ (78,161)
Net loss per share applicable to common stockholders—basic and diluted	$ (5.80)	$ (4.24)	$ (2.56)	$ (4.04)	$ (203.91)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	43,804,660	43,067,952	39,643,099	17,699,487	383,310

Balance Sheet Data	As of December 31,				
	2017	2016	2015	2014	2013
	(in thousands)				
Cash and cash equivalents	$118,564	$258,567	$159,678	$ 28,518	$ 12,303
Marketable securities	134,714	73,880	313,661	76,758	—
Working capital	216,079	302,084	459,128	86,774	(22,675)
Total assets	461,658	340,282	482,465	108,417	12,758
Long-term liabilities	166,195	379	—	24,394	1,945
Total liabilities	219,622	33,104	21,180	44,953	37,257
Total convertible preferred stock and redeemable convertible preferred stock	—	—	—	—	252,802
Total liabilities, convertible preferred stock, redeemable convertible preferred stock and stockholders' equity	461,658	340,282	482,465	108,417	12,758

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

You should read the following discussions in conjunction with our consolidated financial statements and related notes included in this report. This discussion includes forward-looking statements that involve risk and uncertainties. As a result of many factors, such as those set forth under "Risk Factors," actual results may differ materially from those anticipated in these forward-looking statements.

Executive Overview

We are a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics in the areas of osteoporosis and oncology. In April 2017, our first commercial product, TYMLOS (abaloparatide) injection, was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In May 2017, we commenced U.S. commercial sales of TYMLOS and as of February 2018, TYMLOS was available and covered for approximately 259 million U.S. insured lives, representing approximately 86% of U.S. insured lives. In May 2017, we announced positive top-line results from our completed 24-month ACTIVExtend clinical trial for TYMLOS, which met all of its primary and secondary endpoints. In July 2017, we entered into a license and development agreement with Teijin Limited ("Teijin") for abaloparatide for subcutaneous injection ("abaloparatide-SC") in Japan. Under this agreement, we received an upfront payment and are entitled to receive milestone payments upon the achievement of certain regulatory and sales milestones, and a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term. In addition, we have an option to negotiate for a co-promotion agreement with Teijin for abaloparatide-SC in Japan. Our European Marketing Authorisation Application ("MAA") for abaloparatide-SC is under review by the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") and we expect an opinion from the CHMP regarding the MAA during the first half of 2018. We submitted a labeling supplement to the FDA in connection with the results from our ACTIVExtend trial in December 2017. In the first quarter of 2018, we expect to initiate a clinical trial in men with osteoporosis which, if successful, will form the basis of a supplemental NDA seeking to expand the use of TYMLOS to treat men with osteoporosis at high risk for fracture. In the first half of 2018, we plan to initiate a bone histomorphometry study, which would enroll approximately 25 postmenopausal women with osteoporosis to evaluate the early effects of TYMLOS on tissue-based bone remodeling and structural indices.

We are developing an abaloparatide transdermal patch, or abaloparatide-patch, for potential use in the treatment of postmenopausal women with osteoporosis. In January 2018, we met with the FDA and gained alignment with the agency on a single, pivotal BMD non-inferiority bridging study to support an NDA submission. The FDA agreed that, depending on the study results, a randomized, open label, active-controlled, non-inferiority Phase 3 study of up to 500 patients with postmenopausal osteoporosis at high risk of fracture would be sufficient to gain approval for abaloparatide-patch. The FDA confirmed that the primary endpoint will be change in lumbar spine BMD at 12 months and that the non-inferiority margin must preserve 75% of the active control (abaloparatide-SC) based on the lower bound of the 95% confidence interval. We expect to initiate this pivotal study in mid-2019 and to complete it in 2020. In February 2018, we entered into a scale-up and commercial supply agreement with 3M Company pursuant to which 3M has agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-patch.

We are also developing our investigational product candidate, elacestrant (RAD1901), a selective estrogen receptor degrader ("SERD"), for potential use in the treatment of hormone-receptor positive breast cancer. We have completed enrollment in our ongoing dose escalation Part A, and dose expansion Part B and C, and in the ^{18}F fluoroestradiol positron emission tomography ("FES-PET") imaging Phase 1 studies of elacestrant in advanced metastatic breast cancer. In October 2017, the FDA granted Fast Track designation for our elacestrant breast cancer program. Based on feedback from the EMA and the FDA, we now intend to conduct a single,

randomized, controlled Phase 2 trial of elacestrant as a third-line monotherapy in approximately 300 patients with ER+/HER2- advanced/metastatic breast cancer. Patients in the study would be randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent and the primary endpoint of the study will be progression-free survival (PFS). The study would also include a planned interim PFS analysis. We believe that, depending on results, this single trial would support applications for global marketing approvals for elacestrant as a third-line monotherapy. In addition, depending on results of the interim analysis, the Company could seek accelerated approval for elacestrant in the United States. We will provide further study details when the Phase 2 study is started, which we expect will be in the second half of 2018.

We are developing our internally discovered investigational product candidate, RAD140, a non-steroidal selective androgen receptor modulator ("SARM") for potential use in the treatment of hormone-receptor positive breast cancer. In September 2017, we initiated a Phase 1 study of RAD140 in patients with locally advanced or metastatic breast cancer. We expect to provide an update on our RAD140 development program by the end of 2018.

Abaloparatide

In April 2017, the FDA approved TYMLOS for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. We are developing two formulations of abaloparatide: abaloparatide-SC and abaloparatide-patch.

Abaloparatide-SC

TYMLOS was approved in the United States in April 2017 for the treatment of postmenopausal women with osteoporosis at high risk for fracture. The first commercial sales of TYMLOS in the United States occurred in May 2017 and as of February 2018, TYMLOS was available and covered for approximately 259 million U.S. insured lives, representing approximately 86% of U.S. insured lives. We are commercializing TYMLOS in the United States through our commercial organization. We have built a distribution network for TYMLOS in the United States, comprised of well-established distributors and specialty pharmacies. Under our distribution model, both the distributors and specialty pharmacies take physical delivery of TYMLOS and the specialty pharmacies dispense TYMLOS directly to patients. We hold worldwide commercialization rights to abaloparatide-SC, except for Japan, where we have an option to negotiate a co-promotion agreement with Teijin for abaloparatide-SC. The combined 25-month fracture data from our Phase 3 clinical trial program for TYMLOS formed the basis of our regulatory submissions in the United States and Europe. In November 2015, we submitted a marketing authorisation application ("MAA") for abaloparatide-SC to the EMA, which was validated and is currently undergoing active regulatory assessment by the CHMP. In December 2017, the CHMP issued a third Day-180 List of Outstanding Issues. As part of its on-going risk-benefit assessment, the CHMP informed the Company that it intends to refer the MAA to a scientific advisory group for additional advice. We expect that the CHMP may adopt an opinion regarding our MAA during the first half of 2018. We intend to enter a collaboration for the commercialization of abaloparatide-SC outside of the United States and Japan.

In May 2017, we announced positive top-line results from the completed 24-month ACTIVExtend clinical trial of TYMLOS, which met all of its primary and secondary endpoints. In ACTIVExtend, patients who had completed 18 months of TYMLOS (abaloparatide) injections or placebo in the ACTIVE Phase 3 trial were transitioned to receive 24 additional months of open-label alendronate. For the subset of ACTIVE trial patients (n=1139) that enrolled in the ACTIVExtend trial, the previous TYMLOS-treated patients had a significant 84% relative risk reduction ($p<0.0001$) in the incidence of new vertebral fractures compared with patients who received placebo followed by alendronate. They also demonstrated a 39% risk reduction in nonvertebral fractures ($p=0.038$), a 34% risk reduction clinical fractures ($p=0.045$) and a 50% risk reduction in major osteoporotic fractures ($p=0.011$) compared with patients who received placebo followed by alendronate. At the 43-month timepoint, for all patients (n=1645) that enrolled in the ACTIVE trial, TYMLOS-treated patients had a statistically significant risk reduction

in new vertebral fractures ($p<0.0001$), nonvertebral fractures ($p=0.038$), clinical fractures ($p=0.045$), and major osteoporotic fractures ($p<0.001$), compared with patients who received placebo followed by alendronate. While not a pre-specified endpoint, there was also a statistically significant risk reduction in hip fractures ($p=0.027$) at the 43-month time point in the TYMLOS-treated patients, compared with patients who received placebo followed by alendronate. The adverse events reported during the alendronate treatment period were similar between the previous TYMLOS-treated patients and the previous placebo group. The incidences of cardiovascular adverse events including serious adverse events were similar between groups. There have been no cases of osteonecrosis of the jaw or atypical femoral fracture in the entire TYMLOS development program. The results from the completed ACTIVExtend trial were presented at a major scientific meeting in September 2017 and we submitted a labeling supplement in connection with this data to the FDA in December 2017.

In July 2017, we entered into a license and development agreement with Teijin for abaloparatide-SC in Japan. Pursuant to the agreement, we received an upfront payment and may receive additional milestone payments upon the achievement of certain regulatory and sales milestones, and a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term. In addition, we have an option to negotiate for a co-promotion agreement with Teijin for abaloparatide-SC in Japan.

In late 2017, we gained agreement with the FDA on the design of a clinical trial in men with osteoporosis which, if successful, will form the basis of a supplemental NDA seeking to expand the use of TYMLOS to treat men with osteoporosis at high risk for fracture. The study will be a randomized, double-blind, placebo-controlled trial that will enroll approximately 225 men with osteoporosis. The primary endpoint is change in lumbar spine BMD at 12 months compared with placebo. In previous clinical trials, TYMLOS has demonstrated increases in BMD in postmenopausal women. The study will include specialized high-resolution imaging of bone structure in a subset of the study participants. We expect to initiate the trial in the first quarter of 2018.

In the first half of 2018, we plan to initiate a bone histomorphometry study, which would enroll approximately 25 postmenopausal women with osteoporosis to evaluate the early effects of TYMLOS on tissue-based bone remodeling and structural indices.

Abaloparatide-patch

We are also developing abaloparatide-patch, based on 3M's patented Microstructured Transdermal System technology, for potential use as a short wear-time transdermal patch. We hold worldwide commercialization rights to the abaloparatide-patch technology and we are developing abaloparatide-patch toward future global regulatory submissions to build upon the potential success of TYMLOS. Our development strategy for abaloparatide patch is to bridge to the established efficacy and safety of our approved abaloparatide-SC formulation.

We commenced a human replicative clinical evaluation of the optimized abaloparatide-patch in December 2015, with the goal of achieving comparability to abaloparatide-SC. In September 2016, we presented results from this evaluation of the first and second abaloparatide-patch prototypes, demonstrating that formulation technology can modify the pharmacokinetic profile of abaloparatide, including Tmax, half-life ("T1/2"), and area under the curve ("AUC"). In March 2018, we announced that through further optimization we had achieved comparability to the abaloparatide-SC profile with a third prototype (the "current abaloparatide-patch"). The current abaloparatide-patch optimized the drug-device combination through process improvements, a finalized formulation, selection of a dose (300 μg), and the introduction of a new clinical applicator. Together these changes, which were designed to improve the ease of use and patient experience, resulted in an increased half-life and AUC (915 pg.hr/ml for the current abaloparatide-patch, compared to 242 pg.hr/ml for the first patch prototype, 645 pg.hr/ml for the second patch prototype, and 936 pg.hr/ml for abaloparatide-SC).

In January 2018, we met with the FDA to align on a regulatory and development path for registration of abaloparatide-patch. We gained alignment with the agency on a single, pivotal BMD non-inferiority bridging

study to support an NDA submission. The FDA agreed that, depending on the study results, a randomized, open label, active-controlled, non-inferiority Phase 3 study of up to 500 patients with postmenopausal osteoporosis at high risk of fracture would be sufficient to gain approval for abaloparatide-patch. The FDA confirmed that the primary endpoint will be change in lumbar spine BMD at 12 months and that the non-inferiority margin must preserve 75% of the active control (abaloparatide-SC) based on the lower bound of the 95% confidence interval. We expect to initiate this pivotal study in mid-2019 and to complete it in 2020. On February 27, 2018, we entered into a scale-up and commercial supply agreement with 3M Company pursuant to which 3M has agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-patch.

Elacestrant (RAD1901)

Elacestrant is a SERD that we are evaluating for potential use as a once daily oral treatment for hormone-receptor positive breast cancer. We hold worldwide commercialization rights to elacestrant. Elacestrant is currently being investigated in women with advanced ER-positive and HER2-negative breast cancer, the most common subtype of the disease. Studies completed to date indicate that the compound has the potential for use as a single agent or in combination with other therapies for the treatment of breast cancer. To date, no dose limiting toxicities have been reported in the elacestrant program.

We have completed enrollment in our 18-F fluoroestradiol positron emission tomography ("FES-PET") imaging study and dose-escalation Part A and expansion study parts B and C Phase 1 breast cancer trials. In June 2017, we discussed the data from these ongoing Phase 1 studies with the FDA to gain alignment on defining the next steps for our elacestrant breast cancer program, including the design of a Phase 2 trial. In this meeting, the FDA agreed that a single-arm monotherapy Phase 2 study of up to 200 patients, could be appropriate with the primary endpoint being ORR, coupled with DOR. Depending on the study results, which must demonstrate an improvement over then available therapies, this study could be considered a pivotal study for accelerated approval as long as a confirmatory study is ongoing at the time of our NDA submission. In October 2017, the FDA granted Fast Track designation for our elacestrant breast cancer program.

In February 2018 we received scientific advice from the European Medicines Agency ("EMA") regarding a potential single-arm monotherapy Phase 2 trial of elacestrant in patients with ER+, HER2- advanced or metastatic breast cancer. In addition, we had a further meeting in February 2018 with the FDA regarding the registrational pathway for elacestrant at which we confirmed FDA's guidance for a single-arm study and gained alignment with the agency on an alternative potential comparator study design for our monotherapy program. Based on feedback from the EMA and the FDA, we now intend to conduct a single, randomized, controlled Phase 2 trial of elacestrant as a third-line monotherapy in approximately 300 patients with ER+/HER2- advanced/metastatic breast cancer. Patients in the study would be randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent and the primary endpoint of the study will be progression-free survival (PFS). The study would also include a planned interim PFS analysis. We believe that, depending on results, this single trial would support applications for global marketing approvals for elacestrant as a third-line monotherapy. In addition, depending on results of the interim analysis, the Company could seek accelerated approval for elacestrant in the United States. We will provide further study details when the Phase 2 study is started, which we expect will be in the second half of 2018.

Phase 1—Dose-Escalation and Expansion Study

In December 2014, we commenced a Phase 1, multicenter, open-label, multiple-part, dose-escalation study of elacestrant in postmenopausal women with ER-positive and HER2-negative advanced breast cancer in the United States to determine the recommended dose for a Phase 2 clinical trial and to make a preliminary evaluation of the potential anti-tumor effect of elacestrant. Part A of this Phase 1 study was designed to evaluate escalating doses of elacestrant. The Part B expansion cohort was initiated at 400-mg daily dosing in March 2016 to allow for an evaluation of additional safety, tolerability and preliminary efficacy. The patients enrolled in this study are heavily pretreated ER-positive, HER2-negative advanced breast cancer patients who have received a

median of 3 prior lines of therapy including fulvestrant and CDK4/6 inhibitors, and about 50% of the patients had ESR1 mutations. We have completed enrollment in the ongoing dose-escalation Part A and expansion study parts B and C. In December 2017, we opened a Part D cohort in this study to provide additional data on a more homogeneous and genetically defined patient population to support our overall elacestrant clinical development program and anticipated regulatory submissions.

In December 2016 and June 2017, we reported positive results from this ongoing Phase 1 dose-escalation and expansion study. As of the study cut-off date of April 28, 2017, the elacestrant single agent ORR, was 23% with five confirmed partial responses in heavily pre-treated patients with advanced ER-positive breast cancer and in the 400-mg patient group of 26 patients with mature data, the median progression free survival was 4.5 months. These results showed that elacestrant was well-tolerated with the most commonly reported adverse events being low grade nausea and dyspepsia. In December 2017, we reported updated data from this ongoing Phase 1 dose-escalation and expansion study, which included mature data from 40 patients treated at the 400 mg dose in this study. As of the study cut-off date of October 30, 2017, the elacestrant single agent ORR was 27.3% with six confirmed partial responses out of 22 patients with RECIST measurable disease. The median progression free survival was 5.4 months and clinical benefit rate at 24 weeks was 47.4%. These results showed that elacestrant was well-tolerated with the most commonly reported adverse events being low grade nausea, dyspepsia and vomiting.

Phase 1—FES-PET Study

In December 2015, we commenced a Phase 1 18-F fluoroestradiol positron emission tomography, or FES-PET, study in patients with metastatic breast cancer in the European Union, which includes the use of FES-PET imaging to assess estrogen receptor occupancy in tumor lesions following elacestrant treatment.

In December 2016, we reported positive results from the Phase 1 FES-PET study. The first three enrolled patients dosed at the 400-mg cohort had a tumor FES-PET signal intensity reduction ranging from 79% to 91% at day 14 compared to baseline. This study enrolled five additional patients in the 400-mg daily oral cohort, followed by eight patients in the 200-mg daily oral cohort. In December 2017, we reported updated data from the Phase 1 FES-PET study that elacestrant demonstrated robust reduction in tumor ER availability in patients with advanced ER+ breast cancer who progressed on prior endocrine therapy. Seven out of eight patients dosed at the 400-mg cohort, and four out of seven patients dosed at the 200-mg cohort, had a tumor FES-PET signal intensity reduction equal to, or greater than, 75% at day 14 compared to baseline. The reduction in FES uptake supports flexibility for both 200-mg and 400-mg elacestrant dose selection for further clinical development in combination studies with various targeted agents and was similar in patients harboring mutant or wild-type ESR-1. The most commonly reported adverse events reported were grade 1 and 2 nausea and dyspepsia.

Potential for use in Combination Therapy

In July 2015, we announced that early but promising preclinical data showed that our investigational drug elacestrant, in combination with Pfizer's palbociclib, a cyclin-dependent kinase, or CDK 4/6 inhibitor, or Novartis' everolimus, an mTOR inhibitor, was effective in shrinking tumors. In preclinical patient-derived xenograft breast cancer models with either wild type or mutant ESR1, treatment with elacestrant resulted in marked tumor growth inhibition, and the combination of elacestrant with either agent, palbociclib or everolimus, showed anti-tumor activity that was significantly greater than either agent alone. We believe that this pre-clinical data suggests that elacestrant has the potential to overcome endocrine resistance, is well-tolerated, and has a profile that is well suited for use in combination therapy.

In December 2017, we announced additional preclinical data that continues to demonstrate elacestrant anti-tumor activity, as a single agent and in combination, in multiple models. In these preclinical models, elacestrant demonstrated marked tumor growth inhibition, as a single agent in models treated with multiple rounds of fulvestrant and in combination with CDK 4/6 inhibitors such as palbociclib and abemaciclib and with a phosphoinositide 3-kinase inhibitor, alpelisib.

Collaborations

In July 2016, we entered into a pre-clinical collaboration with Takeda Pharmaceutical Company Limited to evaluate the combination of elacestrant with Takeda's investigational drug TAK-228, an oral mTORC 1/2 inhibitor in Phase 2b development for the treatment of breast, endometrial and renal cancer, with the goal of potentially exploring such combination in a clinical study. We and Takeda have each agreed to contribute resources and supply compound material necessary for studies to be conducted under the collaboration and will share third party out-of-pocket research and development expenses. Activities under this collaboration are ongoing. Upon completion, both parties will agree upon the appropriate communication of the results.

In January 2016, we entered into a worldwide clinical collaboration with Novartis Pharmaceuticals to evaluate the safety and efficacy of combining elacestrant with Novartis' investigational agent LEE011 (ribociclib), a CDK 4/6 inhibitor, and BYL719 (alpelisib), an investigational phosphoinositide 3-kinase inhibitor. In January 2018, we terminated this collaboration following the completion of pre-clinical studies. We are evaluating additional opportunities to collaborate with companies to evaluate the safety and efficacy of combining elacestrant with other agents for the treatment of breast cancer. We believe that such combinations may be suitable in earlier lines of treatment for patients with advanced disease.

Vasomotor Symptoms

In December 2017, following a strategic review, we announced that we decided to discontinue further evaluation of elacestrant for vasomotor symptoms to focus instead on the continued clinical development of the compound as a potential treatment option in breast cancer.

RAD140

RAD140 is an internally discovered SARM. The androgen receptor, or AR, is highly expressed in many ER-positive, ER-negative, and triple-negative receptor breast cancers. Due to its receptor and tissue selectivity, potent activity, oral bioavailability, and long half-life, we believe RAD140 could have clinical potential in the treatment of breast cancer. We hold worldwide commercialization rights to RAD140.

In July 2016, we reported that RAD140 in preclinical xenograft models of breast cancer demonstrated potent tumor growth inhibition when administered alone or in combinations with CDK4/6 inhibitors. It is estimated that 77% of breast cancers show expression of the androgen receptor. Our data suggest that RAD140 activity at the androgen receptor leads to activation of AR signaling pathways including an AR-specific tumor suppressor and suppression of ER signaling. In April 2017, we presented these RAD140 preclinical results at a major scientific congress.

In September 2017, we initiated a Phase 1 study of RAD140 in patients with locally advanced or metastatic breast cancer. The clinical trial is designed to evaluate the safety and maximum tolerated dose of RAD140 in approximately 40 patients. Primary safety outcomes from the trial include rate of dose-limiting toxicities, adverse events related to treatment, and tolerability as measured by dose interruptions or adjustments. In addition, pharmacokinetics, pharmacodynamics and tumor response will also be evaluated. We expect to provide an update on our RAD140 development program by the end of 2018.

Financial Overview

Product Revenue

Product revenue is derived from sales of our product, TYMLOS™, in the United States.

Research and Development Expenses

Research and development expenses consist primarily of clinical testing costs, including payments made to contract research organizations, or CROs, salaries and related personnel costs, fees paid to consultants and

outside service providers for regulatory and quality assurance support, licensing of drug compounds and other expenses relating to the manufacture, development, testing, and enhancement of our investigational product candidates. We expense our research and development costs as they are incurred.

None of the research and development expenses, in relation to our investigational product candidates, are currently borne by third parties. Our lead investigational product candidate is abaloparatide and it currently represents the largest portion of our research and development expenses for our investigational product candidates. We began tracking program expenses for abaloparatide-SC in 2005, and program expenses from inception to December 31, 2017 were approximately $214.6 million. We began tracking program expenses for abaloparatide-patch in 2007, and program expenses from inception to December 31, 2017 were approximately $42.1 million. We began tracking program expenses for elacestrant in 2006, and program expenses from inception to December 31, 2017 were approximately $68.0 million. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to December 31, 2017 were approximately $11.0 million. These expenses relate primarily to external costs associated with manufacturing, preclinical studies, and clinical trial costs.

Costs related to facilities, depreciation, stock-based compensation and research and development support services are not directly charged to programs as they benefit multiple research programs that share resources.

The following table sets forth our research and development expenses related to abaloparatide-SC, abaloparatide-patch, elacestrant and RAD140 for the years ended December 31, 2017, 2016 and 2015 (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Program-specific costs—external:			
Abaloparatide-SC	$ 1,686	$ 17,016	$19,870
Abaloparatide-patch	2,991	5,394	2,585
Elacestrant	12,486	27,751	9,926
RAD140	2,135	3,181	495
Total program-specific costs—external	$19,298	$ 53,342	$32,876
Shared-services costs—external:			
R&D support costs	12,206	11,863	14,718
Other operating costs	2,871	3,518	868
Total shared-services costs—external:	$15,077	$ 15,381	$15,586
Shared-services costs—internal:			
Personnel-related costs	30,995	24,905	11,212
Share-based compensation	14,698	11,190	7,866
Occupancy costs	2,158	2,217	615
Depreciation	850	371	125
Total shared-services costs—internal:	$48,701	$ 38,683	$19,818
Total R&D costs	$83,076	$107,406	$68,280

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related expenses for pre-launch and post-launch commercial operations, executive, finance and other administrative personnel, professional fees, business insurance, rent, general legal activities, including the cost of maintaining our intellectual property portfolio, and other corporate expenses.

Our financial results also include stock-based compensation expense related to the issuance of stock option grants, restricted stock units, and performance unit grants to employees, directors, and consultants. The stock-based compensation expense is included in the respective categories of expense in the statement of operations (i.e., research and development or general and administrative expenses). We expect to record additional non-cash compensation expense in the future, which may be significant.

Interest Income and Other Income

Interest income reflects interest earned on our cash, cash equivalents and marketable securities.

Interest Expense

Interest expense consists of interest expense related to the aggregate $305.0 million principal amount of Convertible Notes the Company issued in a registered underwritten public offering on August 14, 2017 ("Convertible Notes"). A portion of the interest expense on the Convertible Notes is non-cash expense relating to accretion of the debt discount and amortization of issuance costs.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which we have prepared in accordance with the rules and regulations of the Securities and Exchange Commission ("SEC") and generally accepted accounting principles in the United States ("U.S. GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. Estimates include useful lives with respect to revenue recognition, inventory obsolescence, long-lived assets and intangible assets, accounting for stock-based compensation, contingencies, tax valuation reserves, fair value measures, and accrued expenses. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

Accrued Clinical Expenses

When preparing our consolidated financial statements, we are required to estimate our accrued clinical expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. Payments under some of the contracts we have with parties depend on factors such as

successful enrollment of certain numbers of patients, site initiation and the completion of clinical trial milestones. Examples of estimated accrued clinical expenses include:

- fees paid to investigative sites and laboratories in connection with clinical studies;
- fees paid to CROs in connection with clinical studies, if CROs are used; and
- fees paid to contract manufacturers in connection with the production of clinical study materials.

When accruing clinical expenses, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from our service providers. However, we may be required to estimate the cost of these services based only on information available to us. If we underestimate or overestimate the cost associated with a trial or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued clinical expenses have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in our accruals.

Research and Development Expenses

We account for research and development costs by expensing such costs to operations as incurred. Research and development costs primarily consist of personnel costs, outsourced research activities, pre-commercial manufacturing activities, laboratory supplies and consulting fees.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed. If expectations change such that we do not expect we will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payments would be charged to expense.

Stock-based Compensation

Options

We measure stock-based compensation cost at the accounting measurement date based on the fair value of the option and recognize the expense on a straight-line basis over the requisite service period of the option, which is typically the vesting period.

We estimate the fair value of each option using the Black-Scholes option pricing model that takes into account the fair value of our common stock, the exercise price, the expected life of the option, the expected volatility of our common stock, expected dividends on our common stock, and the risk-free interest rate over the expected life of the option. Due to the limited trading history of our common stock since our June 2014 initial public offering, we use the simplified method described in the SEC's Staff Accounting Bulletin No. 107, *Share-Based Payment,* to determine the expected life of the option grants. The estimate of expected volatility is based on a review of the historical volatility of similar publicly held companies in the biotechnology field over a period commensurate with the option's expected term. We have never declared or paid any cash dividends on our common stock and we do not expect to do so in the foreseeable future. Accordingly, we use an expected dividend yield of zero. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant valuation for a period commensurate with the option's expected term. These assumptions are highly subjective and changes in them could significantly impact the value of the option and hence the related compensation expense.

Stock-based compensation expense recognized for options granted to consultants is also based upon the fair value of the options issued, as determined by the Black-Scholes option pricing model. However, the unvested portion of such option grants is re-measured at each reporting period, until such time as the option is fully vested.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). This revised standard affects the accounting for forfeitures, cash flow presentation and income taxes. Specifically, this standard provides an accounting policy election to account for forfeitures as they occur, requires all excess tax benefits and deficiencies on share-based payment awards to be recognized as income tax expense or benefit in the statement of operations, requires the tax effects of exercised or vested awards should be treated as discrete items in the reporting period in which they occur, and requires that excess tax benefits to be classified with other income tax cash flows as an operating activity. The standard permits early adoption in any annual or interim period and will be applied by means of a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption.

Historically, the Company recognized stock-based compensation net of estimated forfeitures over the vesting period of the respective grant. Effective January 1, 2017, the Company adopted ASU 2016-09 and changed its accounting policy to recognize forfeitures as they occur. The new forfeiture policy election was adopted using a modified retrospective approach with a cumulative effect adjustment of approximately $0.5 million to retained earnings as of January 1, 2017. In addition, the Company recognized $6.1 million of accumulated excess tax benefits as deferred tax assets that under the previous guidance could not be recognized until the benefits were realized through a reduction in cash taxes paid. This part of the guidance was applied using a modified retrospective method with a cumulative-effect adjustment to the accumulated deficit for the excess tax benefits not previously recognized. However, given the full valuation allowance placed on the additional $6.1 million of deferred tax assets, the recognition upon adoption had no impact to our accumulated deficit as of January 1, 2017. The adoption of ASU 2016-09 effective January 1, 2017 had no other material impacts on the Company's results of operations, financial position or cash flows.

Performance Units

We measure stock-based compensation cost at the accounting measurement date based on the fair value of the performance unit grant and recognize the expense over the derived service period of the performance units.

We estimate the fair value of each grant using a Monte Carlo simulation analysis that takes into account the forecasted price of our common stock, historical volatility of our common stock, risk-free rate as of the valuation date, price of our common stock as of the grant date and the trigger for the performance condition to be met.

The derived service period for each grant is calculated using a Monte Carlo simulation analysis.

Fair Value Measurements

Fair value is determined based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal market for the asset or liability in an orderly transaction between market participants. Authoritative guidance specifies a hierarchy of valuation techniques based upon whether the inputs to those valuation techniques reflect assumptions other market participants would use based upon market data obtained from independent sources (observable inputs) or reflect the Company's own assumptions of market participant valuation (unobservable inputs). The fair value hierarchy consists of three levels:

Level 1—Quoted prices in active markets that are unadjusted and accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2—Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The authoritative guidance requires the use of observable market data if such data is available without undue cost and effort. When available, the Company uses unadjusted quoted market prices to measure fair value and classify such items within Level 1. If quoted market prices are not available, fair value is based upon internally developed models that use, where possible, current market-based or independently-sourced market parameters, such as interest and currency rates and comparable transactions. Items valued using internally generated models are classified according to the lowest level input or value driver that is significant to the valuation. Thus, items may be classified in Level 3 even though there may be inputs that are readily observable. If quoted market prices are not available, the valuation model used generally depends on the specific asset or liability being valued.

Some assets and liabilities are required to be recorded at fair value on a recurring basis, while other assets and liabilities are recorded at fair value on a nonrecurring basis. The Company records the fair value of long-lived assets and other intangible assets on a nonrecurring basis. The carrying amounts of current financial instruments, which include accounts receivable, accounts payable and accrued expenses, approximate their fair values due to the short-term nature of these instruments. The fair value of notes payable is determined based upon data from readily available pricing sources which utilize market observable inputs and other characteristics for similar types of instruments.

The Company reviews the carrying value of long-lived assets and other intangible assets on an annual basis or whenever events or changes in circumstances indicate the fair value of the asset is below its carrying amount. Fair value is determined using various valuation techniques, including discounted cash flows, market-related multiples, and recently reported transactions for similar assets in the market place.

As of December 31, 2017 and 2016, we held financial assets that were measured using Level 1 and Level 2 inputs. Assets measured using Level 1 inputs include money market funds, which are valued using quoted market prices with no valuation adjustments applied. Assets measured using Level 2 inputs include marketable securities that consist primarily of domestic corporate debt securities (direct issuance bonds, corporate bonds, etc.) and are valued using third-party pricing resources, which generally use interest rates and yield curves observable at commonly quoted intervals of similar assets as observable inputs for pricing.

As of December 31, 2017 and 2016, we held no Level 3 assets or liabilities.

Revenue Recognition

On April 28, 2017, the FDA approved TYMLOS in the U.S. Subsequent to receiving FDA approval, the Company entered into a limited number of arrangements with wholesalers in the U.S. (collectively, its "Customers") to distribute TYMLOS. These arrangements are the Company's initial contracts with customers and, as a result, the Company adopted Accounting Standards Codification ("ASC") Topic 606—*Revenue from Contracts with Customers* ("Topic 606"). There is no transition to Topic 606 because the Company has no historical revenue. 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 Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled in exchange for those goods or services.

To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract under Topic 606, including when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised

within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

The Company sells TYMLOS to a limited number of wholesalers in the U.S (collectively, its "Customers"). These Customers subsequently resell the Company's products to specialty pharmacy providers, as well as other retail pharmacies and certain medical centers or hospitals. In addition to distribution agreements with Customers, the Company enters into arrangements with health care providers and payors that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products.

The Company recognizes revenue on product sales when the Customer obtains control of the Company's product, which occurs at a point in time (upon delivery). Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

If taxes should be collected from Customers relating to product sales and remitted to governmental authorities, they will be excluded from revenue. The Company expenses incremental costs of obtaining a contract when incurred, if the expected amortization period of the asset that the Company would have recognized is one year or less. However, no such costs were incurred during the twelve months ended December 31, 2017.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, third-party payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its Customers, payors, and other indirect customers relating to the Company's sale of its products. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable (if the amount is payable to the Customer) or a current liability (if the amount is payable to a party other than a Customer). These estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in Topic 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplated application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of December 31, 2017 and, therefore, the transaction price was not reduced further during the twelve months ended December 31, 2017. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances

The Company generally provides Customers with discounts which include incentive fees that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product

revenue is recognized. In addition, the Company compensates (through trade discounts and allowances) its Customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of products to the Customer and, therefore, these payments have been recorded as a reduction of revenue within the statement of operations and comprehensive loss through December 31, 2017, as well as a reduction to trade receivables, net on the consolidated balance sheets.

Product Returns

Consistent with industry practice, the Company generally offers Customers a limited right of return for product that has been purchased from the Company based on the product's expiration date, which lapses upon shipment to a patient. The Company estimates the amount of its product sales that may be returned by its Customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as reductions to trade receivables, net on the consolidated balance sheets. The Company currently estimates product return liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company has received an immaterial amount of returns to date and believes that returns of product in future periods will be minimal.

Provider Chargebacks and Discounts

Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and trade receivables, net. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and the Company generally issues credits for such amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, and chargebacks that Customers have claimed, but for which the Company has not yet issued a credit.

Government Rebates

The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Payor Rebates

The Company contracts with certain third-party payors, primarily health insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Other Incentives

Other incentives which the Company offers include voluntary patient assistance programs, such as the Company's co-pay assistance program, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as a component of accrued expenses and other current liabilities on the consolidated balance sheets.

Product Revenue Reserves and Allowances

Chargebacks, discounts, fees, and returns are recorded as reductions of trade receivables, net on the consolidated balance sheets. Government and other rebates are recoded as a component of accrued expenses and other current liabilities on the consolidated balance sheets.

Collaboration Revenues

The Company enters into out-licensing agreements which are within the scope of Topic 606, under which it licenses certain rights to its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; development, regulatory, and commercial milestone payments; payments for manufacturing supply services the Company provides through its contract manufacturers; and royalties on net sales of licensed products. Each of these payments may result in license, collaboration, or other revenue, except revenue from royalties on net sales of licensed products, which would be classified as royalty revenue.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success.

Licenses of Intellectual Property

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company will evaluate the measure of progress 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 milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the customer, 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 on a relative stand-alone selling price basis, for which the Company recognizes revenue as, or when, the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration, other revenue, and earnings in the period of adjustment.

Manufacturing Supply Services

Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply, at the customer's discretion, are generally considered as options. The Company assesses if these options provide a material right to the licensee and, if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the licensee exercises these options, any additional payments are recorded in license, collaboration, or other revenue when the customer obtains control of the goods, which is upon delivery.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from its out-licensing arrangement.

Inventory

The Company values its inventories at the lower of cost or estimated net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded within cost of product revenues. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded as a cost of product sales in the consolidated statements of operations and comprehensive loss.

The Company capitalizes inventory costs associated with the Company's products after regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Inventory acquired prior to receipt of marketing approval of a product candidate is expensed as research and development expense as incurred. Inventory that can be used in either the production of clinical or commercial product is expensed as research and development expense when selected for use in a clinical manufacturing campaign.

Shipping and handling costs for product shipments are recorded as incurred in cost of product revenues along with costs associated with manufacturing the product, and any inventory write-downs.

Inventory acquired prior to receipt of the marketing approval for TYMLOS, totaling approximately $1.6 million, was expensed as research and development expense as incurred. The Company began to capitalize the costs associated with the production of TYMLOS upon receipt of FDA approval on April 28, 2017.

Results of Operations

The following discussion summarizes the key factors our management team believes are necessary for an understanding of our consolidated financial statements.

Years Ended December 31, 2017 and December 31, 2016

	Years Ended December 31,		Change	
	2017	2016	$	%
	(in thousands)			
Revenues:				
Product revenue, net	$ 12,112	$ —	$ 12,112	— %
License revenue	10,000	—	10,000	— %
Operating expenses:				
Cost of sales—product	932	—	932	— %
Cost of sales—intangible amortization	400	—	400	— %
Research and development	83,076	107,406	(24,330)	(23)%
General and administrative	186,677	77,542	109,135	141%
Loss from operations	(248,973)	(184,948)	(64,025)	35%
Other (expense) income:				
Other (expense), net	(192)	(293)	101	(34)%
Interest income (expense), net	(5,072)	2,437	(7,509)	(308)%
Net loss	$(254,237)	$(182,804)	(71,433)	39%

Product revenue—We began commercial sales of TYMLOS within the United States in May 2017, following receipt of FDA marketing approval on April 28, 2017. For the year ended December 31, 2017 we recorded approximately $12.1 million of net product revenue. For further discussion regarding our revenue recognition policy, see Note 2, “Summary of Significant Accounting Policies”, in the Notes to the Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Cost of sales—Cost of sales of $0.9 million for the year ended December 31, 2017 consisted of costs associated with the manufacturing of TYMLOS, royalties owed to our licensor for such sales, and amortization of milestone payments to our licensor. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of TYMLOS units recognized as revenue during the twelve months ended December 31, 2017, or $0.2 million, were expensed prior to the April 2017 FDA approval and, therefore, are not included in cost of sales during this period. We expect cost of sales to increase in relation to product revenues as we deplete these inventories.

Research and development expenses—For the year ended December 31, 2017, research and development expense was $83.1 million, as compared to $107.4 million for the year ended December 31, 2016, a decrease of $24.3 million, or 23%. This decrease was primarily a result of a decrease of $15.3 million in program spending

for the elacestrant investigational drug product, a decrease of $15.3 million in program spending related to TYMLOS, and a decrease of $2.4 million of program spending for the abaloparatide-patch investigational drug product. These decreases were partially offset by an increase in compensation related costs due to growth in headcount from 107 research and development employees as of December 31, 2016 to 131 research and development employees as of December 31, 2017.

Selling, general and administrative expenses—For the year ended December 31, 2017, selling, general, and administrative expense was $186.7 million, as compared to $77.5 million for the year ended December 31, 2016, an increase of $109.1 million, or 141%. This increase was primarily due to increased professional support costs of approximately $37.3 million, including $18.4 million of promotional costs and $14.2 million of professional fees related to the commercial launch of TYMLOS. This increase in spend was also driven by a $60.5 million increase in compensation expense, including an increase of $5.4 million of non-cash stock-based compensation expense, due to growth in headcount from 130 general and administrative employees as of December 31, 2016 to 430 selling, general, and administrative employees as of December 31, 2017.

Other (expense), net—For the year ended December 31, 2017, other expense, net of other income, was $0.2 million, as compared to $0.3 million during the year ended December 31, 2016. Other expense, net of other income, for the year ended December 31, 2017 consisted primarily of other taxes and foreign currency revaluation losses. The $0.3 million of other expense, net of income, for the year ended December 31, 2016 was primarily due to other taxes.

Interest income (expense), net—For the year ended December 31, 2017, net interest expense was $5.1 million, as compared to net interest income of $2.4 million during the year ended December 31, 2016, a total change of $7.5 million, or 308%. This change was a result of the issuance of the convertible notes during the year ended December 31, 2017, which resulted in the Company incurring interest expense charges to partially offset the interest income earned on investments. During the prior year, no debt was outstanding and the company was earning interest on investments.

Years Ended December 31, 2016 and December 31, 2015

	Years Ended December 31,		Change	
	2016	2015	$	%
	(in thousands)			
Research and development	$ 107,406	$ 68,280	$ 39,126	57%
General and administrative	77,542	30,797	46,745	152%
Loss from operations	(184,948)	(99,077)	(85,871)	87%
Other (expense) income:				
Other (expense) income, net	(293)	(35)	(258)	737%
Loss on retirement of note payable	—	(1,572)	1,572	(100)%
Interest (expense) income, net	2,437	(842)	3,279	(389)%
Net loss	$(182,804)	$(101,526)	(81,278)	80%

Research and development expenses—For the year ended December 31, 2016, research and development expense was $107.4 million compared to $68.3 million for the year ended December 31, 2015, an increase of $39.1 million, or 57%. This increase was primarily a result of increased compensation expense, including an increase of $3.3 million of non-cash stock-based compensation expense, due to growth in headcount from 48 research and development employees as of December 31, 2015, to 107 research and development employees

as of December 31, 2016. This increase in spend was also driven by higher contract service costs associated with the development of our investigational product candidate elacestrant as a result of the increased clinical and manufacturing activities in 2016, as compared to 2015. These amounts were partially offset by a decrease in the total professional contract service costs associated with the development of abaloparatide-SC as more patients completed study protocol activities associated with the 24-month ACTIVExtend clinical trial in 2016, as compared to 2015.

General and administrative expenses—For the year ended December 31, 2016, general and administrative expense was $77.5 million compared to $30.8 million for the year ended December 31, 2015, an increase of $46.7 million, or 152%. This increase was primarily due to increased professional support costs of approximately $19.4 million, including costs associated with preparing for the potential commercialization of abaloparatide-SC (subject to a favorable regulatory review), as compared to 2015. This increase in spend was also driven by increased compensation expense, including an increase of $8.0 million of non-cash stock-based compensation expense, due to growth in headcount from 27 general and administrative employees as of December 31, 2015, to 130 general and administrative employees as of December 31, 2016. We expect our general and administrative costs to continue to increase as we build out our commercial organization.

Other (expense) income, net—For the year ended December 31, 2016, other expense, net of other income, was $0.3 million, as compared to $35.0 thousand during the year ended December 31, 2015. Other expense, net of other income, for the year ended December 31, 2016 consisted primarily of other taxes and foreign currency revaluation losses. The $35.0 thousand of other expense, net of income, for the year ended December 31, 2015 was primarily due to other taxes.

Loss on retirement of note payable—For the year ended December 31, 2015, loss on retirement of note payable was approximately $1.6 million. This loss was a result of the prepayment of our 2014 Credit Facility in May 2015. We had no outstanding debt during the year ended December 31, 2016.

Interest (expense) income—For the year ended December 31, 2016, interest income was $2.4 million, as compared to $0.8 million during the year ended December 31, 2015, a total change of $3.3 million, or 389%. This change was a result of the elimination of interest expense during the year ended December 31, 2016, as compared to the same period ended 2015, due to the prepayment of all outstanding long-term debt on August 4, 2015, combined with a $1.4 million increase in interest income earned on cash, cash equivalents, and marketable securities during the year ended December 31, 2016, as compared to the same period ended 2015.

Liquidity and Capital Resources

From inception to December 31, 2017, we have incurred an accumulated deficit of $882.3 million, primarily as a result of expenses incurred through a combination of research and development activities related to our various investigational product candidates and expenses supporting those activities. Our total cash, cash equivalents and marketable securities balance as of December 31, 2017 was $430.3 million. We have financed our operations since inception primarily through the public offerings of our common stock, private sale of preferred stock, borrowing under credit facilities and the receipt of $5.0 million in fees associated with an option agreement.

Based upon our cash, cash equivalents and marketable securities balance, we believe that, prior to the consideration of revenue from the potential future sales of any of our investigational products that may receive regulatory approval or proceeds from partnering and/or collaboration activities, we have sufficient capital to fund our development plans, U.S. commercial scale-up and other operational activities, for not less than twelve months from the date of this filing. We expect to finance the future development costs of our clinical product portfolio with our existing cash, cash equivalents and marketable securities, or through strategic financing opportunities, that could include, but are not limited to, partnering or other collaboration agreements, future offerings of equity, royalty-based financing arrangements, or the incurrence of debt. However, there is no

guarantee that any of these strategic financing opportunities will be available to us on favorable terms, and some could be dilutive to existing stockholders. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development and commercialization activities, the results of our clinical trials, and the review and potential approval of our products by the FDA and foreign regulatory authorities. The successful development of our investigational product candidates is subject to numerous risks and uncertainties associated with developing drugs, which could have a significant impact on the cost and timing associated with the development of our product candidates. If we fail to obtain additional future capital, we may be unable to complete our planned preclinical and clinical trials and obtain approval of any investigational product candidates from the FDA and foreign regulatory authorities.

The following table sets forth the major sources and uses of cash for each of the periods set forth below (in thousands):

	Years ended December 31,		
	2017	2016	2015
Net cash (used in) provided by:			
Operating activities	$(206,685)	$(139,804)	$ (87,103)
Investing activities	(248,986)	236,120	(239,822)
Financing activities	315,668	2,573	458,085
Net increase in cash and cash equivalents	$(140,003)	$ 98,889	$ 131,160

Cash Flows from Operating Activities

Net cash used in operating activities during the year ended December 31, 2017 was $206.7 million, which was primarily the result of a net loss of $254.2 million, partially offset by net changes in working capital of $6.0 million and $41.5 million of net non-cash adjustments to reconcile net loss to net cash used in operations. The $254.2 million net loss was primarily due to costs related to the commercial launch of TYMLOS such as increased compensation costs, professional support costs, and consulting fees. The $41.5 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of $35.0 million, amortization of debt discount and issuance costs of $4.8 million, and depreciation and amortization of $2.0 million, offset by amortization of premiums (discounts) on marketable securities of $0.3 million.

Net cash used in operating activities during the year ended December 31, 2016 was $139.8 million, which was primarily the result of a net loss of $182.8 million, partially offset by net changes in working capital of $15.6 million and $27.4 million of net non-cash adjustments to reconcile net loss to net cash used in operations. The $182.8 million net loss was primarily due to elacestrant and RAD140 program development expenses along with compensation costs, professional support costs, and consulting fees incurred in preparation for the potential commercial launch of abaloparatide-SC. The $27.4 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of $26.1 million, and amortization of premiums (discounts) on marketable securities of $0.8 million.

Net cash used in operating activities during the year ended December 31, 2015 was $87.1 million, which was primarily the result of a net loss of $101.5 million and net changes in working capital of $4.0 million, partially offset by $18.4 million of net non-cash adjustments to reconcile net loss to net cash used in operations. The $101.5 million net loss was primarily due abaloparatide-SC and pipeline program development expenses, along with employee compensation and consulting costs incurred to support future regulatory submissions, and preparation for the potential commercial launch of abaloparatide-SC. The $18.4 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of $14.7 million,

loss on retirement of note payable of $1.6 million and amortization of premiums (discounts) on marketable securities of $1.7 million.

Cash Flows from Investing Activities

Net cash used in investing activities for the year ended December 31, 2017 was $249.0 million, as compared to net cash provided by investing activities of $236.1 million for the year ended December 31, 2016.

The net cash used in investing activities during the year ended December 31, 2017 was primarily a result of $191.4 million of net proceeds received from the sale or maturity of marketable securities, offset by $429.3 million in purchases of marketable securities, an $8.7 million milestone payment, and $2.3 million of purchases of property and equipment. The net cash provided by investing activities during the year ended December 31, 2016 was primarily a result of $260.5 million in purchases of marketable securities and $2.9 million of purchases of property and equipment, offset by $499.6 million of net proceeds received from the sale or maturity of marketable securities.

Our investing cash flows will be impacted by the timing of purchases and sales of marketable securities. All of our marketable securities have contractual maturities of less than one year. Due to the short-term nature of our marketable securities, we would not expect our operational results or cash flows to be significantly affected by a change in market interest rates due to the short-term duration of our investments.

Cash Flows from Financing Activities

Net cash provided by financing activities for the year ended December 31, 2017 was $315.7 million, as compared to $2.6 million of net cash provided by financing activities for the year ended December 31, 2016.

Net cash provided by financing activities during the year ended December 31, 2017 consisted of $305.0 million of proceeds received from the issuance of the Convertible Notes, $17.5 million of proceeds as the result of stock option exercises, and $2.6 million of proceeds received from the issuance of stock in connection to the stock purchase plan. These proceeds received were offset by $9.4 million of cash payments for debt issuance costs

Net cash provided by financing activities during the year ended December 31, 2016 consisted of $2.6 million of proceeds received from the exercise of stock options.

Sales of Common Stock

On July 28, 2015, we completed a public offering of 4,054,054 shares of our common stock at a price of $74.00 per share, for aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately $281.5 million. Also, on July 28, 2015, the underwriters purchased an additional 608,108 shares by exercising an option to purchase additional shares that was granted to them in connection with the offering. As a result of the public offering and subsequent exercise of the underwriters' option, we received aggregate proceeds, net of underwriting discounts, commissions and estimated offering costs of approximately $323.8 million.

On January 28, 2015, we completed a public offering of 4,000,000 shares of our common stock at a price of $36.75 per share, for aggregate estimated proceeds, net of underwriting discounts, commissions and offering costs, of approximately $137.8 million. On January 28, 2015, the underwriters purchased an additional 600,000 shares in the aggregate by exercising an option to purchase additional shares that was granted to them in connection with the offering. As a result of the public offering and subsequent exercise of the underwriters' option, we received aggregate proceeds, net of underwriting discounts, commissions and offering costs of approximately $158.4 million.

On October 7, 2014, we completed a public offering whereby we sold 2,750,000 shares of common stock at a price of $18.25 per share, for aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately $46.9 million. On October 7, 2014, the underwriters purchased an additional 378,524 shares in the aggregate by exercising a portion of the over-allotment option granted to them in connection with the offering. As a result of the public offering and subsequent exercise of the over-allotment option, we received aggregate proceeds, net of underwriting discounts, commissions and offering costs of approximately $53.4 million.

On June 11, 2014, we completed our initial public offering whereby we sold 6,500,000 shares of our common stock at a price of $8.00 per share. The shares began trading on the NASDAQ Global Market on June 6, 2014. In connection with the completion of the offering, all outstanding shares of our convertible preferred stock converted into 19,465,132 shares of common stock, and 2,862,654 shares of common stock were issued in satisfaction of accumulated dividends accrued on the preferred stock. In addition, all outstanding warrants to purchase shares of series A-1 convertible preferred stock and warrants to purchase shares of series B-2 convertible preferred stock were converted into the right to purchase 149,452 shares of common stock and our warrant liability was reclassified to equity. On June 18, 2014 and June 25, 2014, the underwriters purchased an additional 512,744 shares in the aggregate by exercising a portion of the over-allotment option granted to them in connection with the initial public offering. As a result of the closing of the initial public offering and subsequent exercise of the over-allotment option, we received aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately $50.4 million.

Sales of Preferred Stock

We had no sales of preferred stock during the year ended December 31, 2017 and 2016. Through December 31, 2017, we had received aggregate net cash proceeds of $238.2 million from the sale of shares of our preferred stock as follows:

Issue	Year	No. Shares	Net Proceeds (in thousands)
Series B redeemable convertible preferred stock (1)	2003, 2004, 2005	1,599,997	$ 23,775
Series C redeemable convertible preferred stock (1)	2006, 2007, 2008	10,146,629	82,096
Series A-1 convertible preferred stock (1)	2011	9,223,041	61,591
Series A-5 convertible preferred stock (1)	2011	64,430	525
Series B convertible preferred stock	2013	701,235	42,870
Series B-2 convertible preferred stock	2014	448,060	27,368
Total		22,183,392	$238,225

(1) Share amounts stated in pre-Merger shares, which converted into the rights to one-tenth of one share pursuant to the Merger.

On February 14, 2014, we entered into a Series B-2 Convertible Preferred Stock and Warrant Purchase Agreement, or Purchase Agreement, pursuant to which we were able to raise up to approximately $40.2 million through the issuance of (1) up to 655,000 series B-2 Shares convertible preferred stock, or Series B-2, par value $.0001 per share, and (2) warrants to acquire up to 718,201 shares of our common stock, at an exercise price of $14.004 per share. On February 14, 2014, February 19, 2014, February 24, 2014, March 14, 2014 and March 28, 2014, we consummated closings under the Series B-2 Purchase Agreement, whereby, in exchange for aggregate proceeds to us of approximately $27.5 million, we issued an aggregate of 448,060 Series B-2 Shares and warrants to purchase up to a total of 491,293 shares of our common stock. The warrants issuable pursuant to the Purchase Agreement are exercisable for a period of five years from issuance.

Upon completion of our initial public offering, all shares of preferred stock were converted into shares of our common stock.

Debt Borrowings

In May 2014, we entered into our 2014 Credit Facility with Solar and Oxford Finance, pursuant to which Solar and Oxford agreed to make available to us $30.0 million in the aggregate subject to certain conditions to funding. An initial term loan was made in May 2014 in an aggregate principal amount equal to $21.0 million, or the Initial Term Loan.

The Initial Term Loan bore interest per annum at 9.85% plus one-month LIBOR (customarily defined). All principal and accrued interest on the initial term loan had been due on June 1, 2018.

In July 2014, we entered into a first amendment to the 2014 Credit Facility, or the First Amendment. Pursuant to the terms of the First Amendment, a second term loan of $4.0 million was drawn in July 2014.

In August 2015, the Company prepaid all amounts owed under the 2014 Credit Facility and the First Amendment. After consideration of relevant fees required under the 2014 Credit Facility and the First Amendment, the total payment amounted to $26.5 million.

Convertible Notes Payable

On August 14, 2017, in a registered underwritten public offering, the Company issued $300.0 million aggregate principal amount of the Convertible Notes. In addition, on September 12, 2017, the Company issued an additional $5.0 million principal amount of Convertible Notes pursuant to the exercise of an over-allotment option granted to the underwriters in the offering. In accordance with accounting guidance for debt with conversion and other options, the Company separately accounted for the Liability and Equity Components of the Convertible Notes by allocating the proceeds between the Liability Component and the Equity Component, due to the Company's ability to settle the Convertible Notes in cash, common stock or a combination of cash and common stock, at its option. In connection with the issuance of the Convertible Notes, the Company incurred approximately $9.4 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs to the Liability and Equity Components based on the allocation of the proceeds. Of the total $9.4 million of debt issuance costs, $4.3 million was allocated to the Equity Component and recorded as a reduction to additional paid-in capital and $5.1 million was allocated to the liability component and is now recorded as a reduction of the Convertible Notes in the Company's consolidated balance sheet. The portion allocated to the liability component is amortized to interest expense using the effective interest method over seven years.

The Convertible Notes are senior unsecured obligations of the Company and bear interest at a rate of 3.00% per annum, payable semi-annually in arrears on March 1 and September 1, beginning on March 1, 2018. Upon conversion, the Convertible Notes will be convertible into cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election. Prior to December 31, 2017, the Convertible Notes were not convertible except in connection with a make whole fundamental change, as defined in the respective indentures. The Convertible Notes will be subject to redemption at our option, on or after September 1, 2021, in whole or in part, if the conditions described below are satisfied. The Convertible Notes will mature on September 1, 2024, unless earlier converted, redeemed or repurchased in accordance with their terms. Subject to satisfaction of certain conditions and during the periods described below, the Convertible Notes may be converted at an initial conversion rate of 20.4891 shares of common stock per $1,000 principal amount of the Convertible Notes (equivalent to an initial conversion price of approximately $48.81 per share of common stock and 6,249,176 shares).

Holders of the Convertible Notes may convert all or any portion of their notes, in multiples of $1,000 principal amount, at their option at any time prior to the close of business on the business day immediately preceding June 1, 2024 only under the following circumstances:

(1) during any calendar quarter commencing after the calendar quarter ending on December 31, 2017 (and only during such calendar quarter), if the last reported sale price of the Company's common stock for at least 20 trading days (whether consecutive or not) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

(2) during the five-business day period after any five-consecutive trading day period (the "measurement period") in which the "trading price" per $1,000 principal amount of the Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day;

(3) if the Company calls the Convertible Notes for redemption, until the close of business on the business day immediately preceding the redemption date; or

(4) upon the occurrence of specified corporate events.

Prior to September 1, 2021, the Company may not redeem the Convertible Notes. On or after September 1, 2021, the Company may redeem for cash all or part of the Convertible Notes if the last reported sale price of the Company's common stock equals or exceeds 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30-consecutive trading day period ending within five trading days prior to the date on which the Company provides notice of the redemption. The redemption price will be the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. In addition, calling any Convertible Note for redemption will constitute a make-whole fundamental change with respect to that Convertible Note, in which case the conversion rate applicable to the conversion of that Convertible Note, if it is converted in connection with the redemption, will be increased in certain circumstances.

Future Financing Needs

We expect to finance the future development costs of our clinical product portfolio with our existing cash and cash equivalents and marketable securities, or through strategic financing opportunities that could include, but are not limited to, collaboration agreements, future offerings of our equity, royalty-based financing arrangements, or the incurrence of debt or convertible debt. We anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data of each investigational product candidate, progress on securing third-party collaborators, as well as ongoing assessments of such investigational product candidate's commercial potential and our ability to fund this product development.

The successful development of our investigational product candidates is subject to numerous risks and uncertainties associated with developing drugs, including, but not limited to, the variables listed below. A change in the outcome of any of these variables with respect to the development of any of our investigational product candidates could mean a significant change in the cost and timing associated with the development of that investigational product candidate.

Our first and only commercial product, TYMLOS, was approved in the U.S. in April 2017. Our ability to successfully commercialize TYMLOS is critical to the execution of our business strategy. in November 2015, we submitted an MAA for abaloparatide-SC to the EMA, which was validated and is currently undergoing active regulatory assessment by the CHMP. In December 2017, the CHMP issued a third Day-180 List of Outstanding Issues. As part of its on-going risk-benefit assessment, the CHMP informed the Company that it intends to refer the MAA to a scientific advisory group for additional advice. We expect that the CHMP may adopt an opinion

regarding our MAA during the first half of 2018. The rest of our investigational product candidates are currently in clinical development.

Obtaining approval of an investigational product candidate is an extensive, lengthy, expensive, and uncertain process, and any approval may be delayed, limited or denied for many reasons, including:

- we may not be able to demonstrate that abaloparatide is safe and effective as a treatment for reduction of fracture risk in postmenopausal women with osteoporosis to the satisfaction of the EMA or other foreign regulatory authorities;
- the results of our clinical studies may not meet the level of statistical or clinical significance required for marketing approval;
- the FDA or other foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical studies;
- the CRO or other study personnel that we retain to conduct clinical studies may take actions outside of our control that materially adversely impact our clinical studies;
- the FDA or other foreign regulatory authorities may not find the data from preclinical studies and clinical studies sufficient to demonstrate that the investigational product candidate's clinical and other potential benefits outweigh its safety risks;
- the FDA or other foreign regulatory authorities may disagree with our interpretation of data from our preclinical studies and clinical studies or may require that we conduct additional studies;
- the FDA or other foreign regulatory authorities may not agree with our proposed labeling and may require labeling that undermines or otherwise significantly impairs the commercial value of the product if it were to be approved with such labeling;
- the FDA or other foreign regulatory authorities may not accept data generated at our clinical study sites;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval;
- if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions; or
- the FDA or other foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers.

In addition, the FDA or other foreign regulatory authorities may change their approval policies or adopt new regulations. Additional important risks related to the potential approval of our investigational product candidates are discussed in Item 1A of this Annual Report on Form 10-K under the caption "Risk Factors."

Contractual Obligations and Commitments

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent liabilities for which we cannot reasonably predict future payment. We enter into contracts in the normal course of business for marketing and promotion, commercial related activities, preclinical and clinical research studies, research supplies, and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations and commitments. In addition, we have certain obligations to make future

payments to third parties that become due and payable on the achievement of certain development, regulatory and commercial milestones, such as the start of a clinical trial, filing of an NDA, approval by the FDA, or product launch. The disclosed balances and table below exclude the potential payments we may be required to make under our agreements because the timing of payments and actual amounts paid under those agreements may be different depending on the timing of receipt of goods or services or changes to agreed-upon terms or amounts for some obligations, and those agreements are cancelable upon written notice by us and therefore, not long-term liabilities. Additionally, the expected timing of payment of the obligations presented below is estimated based on current information.

Manufacturing Agreements—In June 2016, the Company entered into a Supply Agreement with Ypsomed AG, pursuant to which Ypsomed agreed to supply commercial and clinical supplies of a disposable pen injection device customized for subcutaneous injection of abaloparatide. The Company has agreed to purchase a minimum number of devices at prices per device that decrease with an increase in quantity supplied. In addition, the Company has agreed to make milestone payments for Ypsomed's capital developments in connection with the initiation of the commercial supply of the device and to pay a one-time capacity fee. All costs and payments under the agreement are delineated in Swiss Francs. The agreement has an initial term of three years from the earlier of the date of delivery of the first commercial batch of devices after regulatory approval and June 1, 2017, after which, it automatically renews for two-year terms until terminated. The Company will purchase the device subject to minimum annual quantity requirements over the initial three-year term of the agreement. The Company is required to purchase a minimum number of batches for CHF 2.4 million ($2.5 million) through the year ended December 31, 2022.

In June 2016, the Company entered into a Commercial Supply Agreement with Vetter Pharma International GmbH, pursuant to which Vetter has agreed to formulate the finished abaloparatide-SC drug product containing the active pharmaceutical ingredient of abaloparatide, to fill cartridges with the drug product, to assemble the pen delivery device, and to package the pen for commercial distribution. The Company has agreed to purchase the cartridges and pens in specified batch sizes at a price per unit. For labeling and packaging services, the Company has agreed to pay a per unit price dependent upon the number of pens loaded with cartridges that are labeled and packaged. These prices are subject to an annual price adjustment. The agreement has an initial term of five years, which began on January 1, 2016, after which, it automatically renews for two-year terms unless either party notifies the other party two years before the end of the then-current term that it does not intend to renew.

In July 2016, the Company entered into a Manufacturing Services Agreement with Polypeptide Laboratories Holding AB, as successor-in-interest to Lonza Group Ltd., pursuant to which PPL has agreed to manufacture the commercial and clinical supplies of the API for abaloparatide. The Company has agreed to purchase the API in batches at a price per gram in euros, subject to an annual increase by PPL. The Company is also required to purchase a minimum number of batches annually, equal to €2.9 million ($3.4 million) per year and $17.2 million in total through the year ended December 31, 2022. The agreement has an initial term of a six years, after which, it automatically renews for three-year terms unless either party provides notice of non-renewal 24 months before the end of the then-current term.

Operating Lease Agreements—Our contractual obligations result from property leases for office space. However, more information regarding significant contracts and our obligations to make future payments to third parties that become due and payable upon achievement of certain development, regulatory and commercial milestones can be found below under "Research and Development Agreements" and "License Agreement Obligations".

The following table summarizes our contractual lease obligations at December 31, 2017:

	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
			(in thousands)		
Operating lease obligations	$12,062	$2,682	$4,470	$2,067	$2,843

In June 2016, the Massachusetts Life Sciences Center awarded us approximately $0.5 million of tax incentives under its Life Science Tax Incentive Program, which allows us a cash refund equivalent to $0.5 million of state research and development tax credits. We received this payment in the first quarter of 2017. In exchange for these incentives, we hired an incremental 35 employees in Massachusetts and to maintain the additional headcount through at least December 31, 2020. Failure to do so could have resulted in us being required to repay some or all of these incentives. This contingent obligation has not been included in the above table as we cannot estimate if, or when, it will become payable.

Research and Development Agreements

Abaloparatide-SC Phase 3 Clinical Trial—We entered into agreements with Nordic Bioscience Clinical Development VII A/S, or Nordic, to conduct our Phase 3 clinical trial of abaloparatide-SC, or the Phase 3 Clinical Trial. In February 2013, we contracted with Nordic for it to perform an extension study to evaluate six months of standard-of-care osteoporosis management following the completion of the Phase 3 Clinical Trial (the "Extension Study"), and, upon completion of this initial six months, an additional period of 18 months of standard-of-care osteoporosis management (the "Second Extension").

In April 2015, we contracted with Nordic to perform additional services, including additional monitoring of patients enrolled in the Second Extension. Payments in cash to be made to Nordic for these additional services are denominated in euro and total up to approximately €4.1 million (approximately $4.3 million).

Payments in cash to be made to Nordic for the services related to the Extension Study and the Second Extension are denominated in both euros and U.S. dollars and total up to €11.9 million (approximately $12.5 million) and $1.1 million, respectively. As of December 31, 2016, the last patient last visit in the Second Extension had occurred and all obligations due to Nordic in relation to the Extension Study have been paid.

License Agreement Obligations

TYMLOS (Abaloparatide)

In September 2005, we entered into a license agreement with Ipsen Pharma SAS, as amended, under which we exclusively licensed certain Ipsen compound technology and related patents covering abaloparatide to research, develop, manufacture and commercialize certain compounds and related products in all countries, except Japan (where the Company has an option to negotiate a co-promotion agreement for abaloparatide-SC)) and France (where our commercialization rights were subject to certain co-marketing and co-promotion rights exercisable by Ipsen, provided that certain conditions included in the License Agreement were met). We believe that Ipsen's co-marketing and co-promotion rights in France have permanently expired. Ipsen also granted us an exclusive right and license under the Ipsen compound technology and related patents to make and have made compounds or product in Japan. Ipsen further granted us an exclusive right and license under certain Ipsen formulation technology and related patents solely for purposes of enabling us to develop, manufacture and commercialize compounds and products covered by the compound technology license in all countries, except Japan and France (as discussed above).

In consideration for these rights, the Company made nonrefundable, non-creditable payments in the aggregate of $13.0 million to Ipsen, including payment in recognition of certain milestones having been achieved through December 31, 2017. The License Agreement provides for further payments upon the achievement of certain future regulatory and commercial milestones. Total additional milestone payments that could be payable under the agreement are €24.0 million (approximately $28.7 million). In connection with the FDA's approval of TYMLOS in April 2017, the Company paid Ipsen a milestone of €8.0 million (approximately $8.7 million) under the License Agreement, which the Company recorded as an intangible asset within the consolidated balance sheet and will amortize over the remaining patent life or the estimated useful life of the underlying product. The agreement provides that the Company would pay to Ipsen a fixed five percent royalty based on net sales of the

product by the Company or its sublicensees on a country-by-country basis until the later of the last to expire of the licensed patents or for a period of 10 years after the first commercial sale in such country. The royalty expense was immaterial for the year ended December 31, 2017. The date of the last to expire of the abaloparatide patents licensed from or co-owned with Ipsen, barring any extension thereof, is expected to be March 26, 2028.

Prior to executing the license agreement for abaloparatide with us, Ipsen licensed the Japanese rights for abaloparatide to Teijin Limited, a Japanese pharmaceutical company. Teijin has initiated a Phase 3 clinical study of abaloparatide in Japan for the treatment of postmenopausal osteoporosis.

We are currently in arbitration proceedings with Ipsen in connection with the License Agreement. See "Legal Proceedings" for more information.

Elacestrant (RAD1901)

In June 2006, the Company entered into a license agreement with Eisai Co. Ltd. Under the Eisai Agreement, Eisai granted to the Company an exclusive right and license to research, develop, manufacture and commercialize elacestrant and related products from Eisai in all countries, except Japan. In consideration for the rights to elacestrant, the Company paid Eisai an initial license fee of $0.5 million, which was expensed during 2006. In March 2015, the Company entered into an amendment to the Eisai Agreement in which Eisai granted to the Company the exclusive right and license to research, develop, manufacture and commercialize elacestrant in Japan. In consideration for the rights to elacestrant in Japan, the Company paid Eisai a license fee of $0.4 million upon execution of the Eisai Amendment, which was recognized as research and development expense in 2015. The Eisai Amendment, as amended, also provides for additional payments of up to $22.3 million, payable upon the achievement of certain clinical and regulatory milestones.

Under the Eisai Agreement, as amended, should a product covered by the licensed technology be commercialized, the Company will be obligated to pay to Eisai royalties in a variable mid-single digit range based on net sales of the product on a country-by-country basis. The royalty rate will be reduced, on a country-by-country basis, at such time as the last remaining valid claim in the licensed patents expires, lapses or is invalidated and the product is not covered by data protection clauses. In addition, the royalty rate will be reduced, on a country-by-country basis, if, in addition to the conditions specified in the previous sentence, sales of lawful generic versions of such product account for more than a specified minimum percentage of the total sales of all products that contain the licensed compound during a calendar quarter. The latest licensed patent is expected to expire, barring any extension thereof, on August 18, 2026.

The Eisai Agreement, as amended, also grants the Company the right to grant sublicenses with prior written approval from Eisai. If the Company sublicenses the licensed technology to a third party, the Company will be obligated to pay Eisai, in addition to the milestones referenced above, a fixed low double digit percentage of certain fees received from such sublicensee and royalties in the low single digit range based on net sales of the sublicensee. The license agreement expires on a country-by-country basis on the later of (1) the date the last remaining valid claim in the licensed patents expires, lapses or is invalidated in that country, the product is not covered by data protection clauses, and the sales of lawful generic versions of the product account for more than a specified percentage of the total sales of all pharmaceutical products containing the licensed compound in that country; or (2) a period of 10 years after the first commercial sale of the licensed products in such country, unless it is sooner terminated.

Duke (RAD1901)

In December 2017, the Company entered into a License Agreement with Duke University ("Duke") (collectively "Duke License Agreement") pursuant to which Radius acquired the exclusive worldwide license to certain Duke patents associated with elacestrant (RAD1901) related to the use of elacestrant in the treatment of breast cancer as a monotherapy and in a combination therapy (collectively "Duke Patents").

In consideration for these rights, the Company incurred non-refundable, non-creditable obligations to pay Duke, totaling $1.3 million, which were expensed as research and development during 2017. The Duke License Agreement provides for further payments upon the achievement of certain future regulatory and commercial milestones totaling up to $3.8 million. The agreement provides that the Company would pay Duke a fixed low single-digit royalty based on net sales, on a country-by-country basis, beginning in August 2029 and ending upon expiration of the last patent rights to expire.

If the Company sublicenses the Duke Patents to a third party, the agreement provides that the Company will pay Duke a percentage of certain payments received by it from such sublicensee(s). The applicable percentage is in the high single-digit range on certain payments received in excess a pre-specified amount. The License Agreement may be terminated by Duke upon a material uncured breach of the License Agreement. The Company may terminate the License Agreement upon 60 days written notice.

Teijin Limited

In July 2017, the Company entered into a license and development agreement with Teijin (the "Teijin Agreement") for abaloparatide-SC in Japan.

Pursuant to the Teijin Agreement, the Company granted Teijin: (i) an exclusive payment-bearing license under certain of the Company's intellectual property to develop and commercialize abaloparatide-SC in Japan, (ii) a non-exclusive payment-bearing license under certain of the Company's intellectual property to manufacture abaloparatide-SC for commercial supply in Japan, (iii) a right of reference to certain of the Company's regulatory data related to abaloparatide-SC for purposes of developing, manufacturing and commercializing abaloparatide-SC in Japan, (iv) a manufacture transfer package, upon Teijin's request, consisting of information and the Company's know-how that is necessary for the manufacture of active pharmaceutical ingredient and abaloparatide-SC, and (v) right, at Teijin's request, to have the Company manufacture (or arrange for a third party to manufacture) and supply (or arrange for a third party to supply) the active pharmaceutical ingredient for the clinical supply of abaloparatide-SC in sufficient quantities to enable Teijin to conduct its clinical trials in Japan. In consideration for these rights, the Company received an upfront payment of $10.0 million, and may receive further payments upon the achievement of certain regulatory and sales milestones, as well as a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term, as defined below. In addition, the Company has an option to negotiate a co-promotion agreement with Teijin for abaloparatide-SC in Japan upon commercialization.

The Company assessed this arrangement in accordance with Topic 606 and concluded that the contract counterparty, Teijin, is a customer. The Company identified the following material promises under the contract: the commercialization and manufacturing licenses under certain intellectual property rights relating to abaloparatide-SC in Japan, as well as the right of reference to certain regulatory information. In addition, the Company identified the following customer option that would create an obligation for the Company if exercised by Teijin—the transfer of manufacturing know-how. The customer option for the transfer of manufacturing know-how represents a material right. Finally, the Company also identified the following customer option that would create a manufacturing obligation for the Company if exercised by Teijin—the supply of abaloparatide-SC for Teijin's clinical trial needs. The customer option for clinical supply of abaloparatide-SC does not represent a material right. Based on these assessments, the Company identified the (i) commercialization and manufacturing licenses, as well as the right of reference to certain regulatory information, and (ii) transfer of manufacturing know-how as the only performance obligations at the inception of the arrangement, which were both deemed to be distinct.

Upon execution of the Teijin Agreement, the transaction price included only the $10.0 million up-front payment owed to the Company. As referenced above, the Company may receive further payments upon the achievement of certain regulatory and sales milestones, totaling up to $40.0 million, as well as a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term. The future

regulatory milestone, which represents variable consideration that was evaluated under the most likely amount method, has not been included in the transaction price, because the amount was fully constrained as of December 31, 2017. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestone is outside the control of the Company. Separately, any consideration related to sales-based milestones as well as royalties on net sales upon commercialization by Teijin, will be recognized when the related sales occur as they were determined to relate predominantly to the licenses granted to Teijin and, therefore, have also been excluded from the transaction price in accordance with the sales-based royalty exception. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

Net Operating Loss Carryforwards

As of December 31, 2017, we had federal and state net operating loss carryforwards of approximately $751.7 million and $669.3 million, respectively, the use of which may be limited, as described below. If not utilized, the net operating loss carryforwards will expire at various dates through 2036.

Under Section 382 of the Internal Revenue Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards that could be used annually in the future to offset taxable income. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards before they expire. The private placements and other transactions that have occurred since our inception, may have triggered an ownership change pursuant to Section 382, which could limit the amount of net operating loss carryforwards that could be utilized annually in the future to offset taxable income, if any. Any such limitation, whether as the result of prior private placements, sales of common stock by our existing stockholders or additional sales of common stock by us, could have a material adverse effect on our results of operations in future years. We have completed studies through December 31, 2015, to determine whether any ownership change has occurred since our formation and have determined that transactions have resulted in two ownership changes, as defined under Section 382. There could be additional ownership changes in the future that could further limit the amount of net operating loss and tax credit carryforwards that we can utilize.

In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal or state income tax benefit in our statement of operations.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements or any relationships with unconsolidated entities of financial partnerships, such as entities often referred to as structured finance or special purpose entities.

Accounting Standards Updates

For a discussion of recent accounting standards updates, see Note 2 to our consolidated financial statements included in this Annual Report.

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

We are exposed to market risk related to changes in the dollar/euro exchange rate because a portion of our development costs are denominated in euros. We do not hedge our foreign currency exchange rate risk. However, an immediate 10 percent adverse change in the dollar/euro exchange rate would not have a material effect on financial results.

We are exposed to market risk related to changes in interest rates. As of December 31, 2017, we had cash, cash equivalents and short-term marketable securities of $430.3 million, consisting of cash, money market funds, domestic corporate debt securities, domestic corporate commercial paper, and asset-backed securities. This exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We generally have the ability to hold our investments until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We carry our investments based on publicly available information. As of December 31, 2017, we do not have any hard to value investment securities or securities for which a market is not readily available or active.

We are not subject to significant credit risk as this risk does not have the potential to materially impact the value of assets and liabilities.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

FINANCIAL STATEMENTS

Radius Health, Inc.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors of Radius Health, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Radius Health, Inc. (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated March 1, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

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

Boston, Massachusetts
March 1, 2018

Radius Health, Inc.

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 118,564	$ 258,567
Restricted cash	55	47
Marketable securities	134,714	73,880
Accounts receivable, net	4,441	—
Inventory	4,366	—
Prepaid expenses	5,175	1,486
Other current assets	2,191	829
Total current assets	269,506	334,809
Investments	176,978	—
Property and equipment, net	6,195	4,922
Intangible assets	8,180	—
Other assets	799	551
Total assets	$ 461,658	$ 340,282
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,915	$ 6,128
Accrued expenses and other current liabilities	49,512	26,597
Total current liabilities	53,427	32,725
Other non-current liabilities	189	379
Notes payable	166,006	—
Total liabilities	$ 219,622	$ 33,104
Commitments and contingencies		
Stockholders' equity:		
Common stock, $.0001 par value; 200,000,000 shares authorized, 44,616,586 shares and 43,141,134 shares issued and outstanding at December 31, 2017 and 2016, respectively	4	4
Additional paid-in-capital	1,124,630	935,671
Accumulated other comprehensive income (loss)	(314)	71
Accumulated deficit	(882,284)	(628,568)
Total stockholders' equity	242,036	307,178
Total liabilities and stockholders' equity	$ 461,658	$ 340,282

See accompanying notes to consolidated financial statements.

Radius Health, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

	December 31,		
	2017	2016	2015
REVENUES:			
Product revenue, net	$ 12,112	$ —	$ —
License revenue	10,000	—	—
OPERATING EXPENSES:			
Cost of sales—product	932	—	—
Cost of sales—intangible amortization	400	—	—
Research and development	83,076	107,406	68,280
Selling, general and administrative	186,677	77,542	30,797
Loss from operations	(248,973)	(184,948)	(99,077)
OTHER (EXPENSE) INCOME:			
Other (expense), net	(192)	(293)	(35)
Loss on retirement of note payable	—	—	(1,572)
Interest income	3,226	2,437	1,043
Interest expense	(8,298)	—	(1,885)
NET LOSS	$ (254,237)	$ (182,804)	$ (101,526)
OTHER COMPREHENSIVE LOSS, NET OF TAX:			
Unrealized gain (loss) from available-for-sale securities	(385)	66	26
COMPREHENSIVE LOSS	$ (254,622)	$ (182,738)	$ (101,500)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS—BASIC AND DILUTED (Note 13)	$ (254,237)	$ (182,804)	$ (101,526)
LOSS PER SHARE:			
Basic and diluted	$ (5.80)	$ (4.24)	$ (2.56)
WEIGHTED AVERAGE SHARES:			
Basic and diluted	43,804,660	43,067,952	39,643,099

See accompanying notes to consolidated financial statements.

Radius Health, Inc.

Consolidated Statements of Stockholders' Equity

(In thousands, except share and per share amounts)

	Stockholders' Equity					
	Common Stock		Additional Paid-In Capital Amount	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Amount	Amount	Amount	Amount
Balance at December 31, 2014	32,924,535	$3	$ 407,720	$ (21)	$(344,238)	$ 63,464
Net loss					(101,526)	(101,526)
Unrealized loss from available-for-sale securities				26		26
Exercise of warrants	529,862					—
Exercise of options	267,684		2,337			2,337
Share-based compensation expense			14,734			14,734
Issuance of common stock, net	9,262,162	1	482,249			482,250
December 31, 2015	42,984,243	$4	$ 907,040	$ 5	$(445,764)	$ 461,285
Net loss					(182,804)	(182,804)
Unrealized gain from available-for-sale securities				66		66
Exercise of warrants	19,172					—
Exercise of options	137,719		2,573			2,573
Share-based compensation expense			26,058			26,058
December 31, 2016	43,141,134	$4	$ 935,671	$ 71	$(628,568)	$ 307,178
ASU 2016-09 adoption			(521)		521	—
Net loss					(254,237)	(254,237)
Unrealized gain from available-for-sale securities				(385)		(385)
Vesting of restricted shares	14,052					—
Exercise of options	1,385,120		17,477			17,477
Share-based compensation expense related to share-based awards for employee stock purchase plan			1,164			1,164
Issuance of common stock upon purchase by employee stock purchase plan	76,280		2,550			2,550
Equity component of 2024 Notes			138,707			138,707
Equity component of deferred financing costs for 2024 Notes			(4,257)			(4,257)
Share-based compensation expense			33,839			33,839
Balance at December 31, 2017	44,616,586	$4	$1,124,630	$(314)	$(882,284)	$ 242,036

See accompanying notes to consolidated financial statements.

Radius Health, Inc.

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2017	2016	2015
CASH FLOWS USED IN OPERATING ACTIVITIES:			
Net loss	$(254,237)	$(182,804)	$(101,526)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,951	586	176
Amortization of premium (accretion of discount) marketable securities, net	(264)	791	1,714
Stock-based compensation expense	35,003	26,058	14,734
Amortization of debt discount and issuance costs	4,816	—	183
Loss on retirement of note payable	—	—	1,572
Changes in operating assets and liabilities:			
Inventory	(4,366)	—	—
Trade receivables, net	(4,441)	—	—
Prepaid expenses	(3,689)	(342)	(1,157)
Other current assets	(1,362)	4,949	(3,757)
Other long-term assets	(256)	(291)	(108)
Accounts payable	(2,213)	(100)	3,936
Accrued expenses and other current liabilities	22,563	11,349	(2,870)
Other non-current liabilities	(190)	—	—
Net cash used in operating activities	(206,685)	(139,804)	(87,103)
CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES:			
Purchases of property and equipment	(2,341)	(2,936)	(1,231)
Payment of milestone related to intangible asset	(8,712)	—	—
Purchases of marketable securities	(429,296)	(260,547)	(579,088)
Sales and maturities of marketable securities	191,363	499,603	340,497
Net cash (used in) provided by investing activities	(248,986)	236,120	(239,822)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:			
Proceeds from exercise of stock options	17,478	2,573	2,337
Proceeds from issuance of convertible notes	305,000	—	—
Proceeds from issuance of common stock, net	—	—	482,250
Deferred financing costs	(9,360)	—	—
Payments on note payable	—	—	(25,000)
Fee for early prepayment of note payable	—	—	(1,502)
Proceeds from employee stock purchase plan	2,550	—	—
Net cash provided by financing activities	315,668	2,573	458,085
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(140,003)	98,889	131,160
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	258,567	159,678	28,518
CASH AND CASH EQUIVALENTS AT END OF YEAR	$ 118,564	$ 258,567	$ 159,678
SUPPLEMENTAL DISCLOSURES:			
Cash paid for interest	$ —	$ —	$ 1,490
Property and equipment purchases in accrued expense	$ 352	$ 675	$ —

See accompanying notes to consolidated financial statements.

Radius Health, Inc.

Notes to Consolidated Financial Statements

1. Nature of Business

Radius Health, Inc. ("Radius" or the "Company") is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics in the areas of osteoporosis and oncology. In April 2017, our first commercial product, TYMLOS (abaloparatide) injection, was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. The Company's European Marketing Authorisation Application ("MAA") for abaloparatide-SC is under review by the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") and the Company expects an opinion from the CHMP regarding the MAA during the first half of 2018. The Company is developing an abaloparatide transdermal patch, or abaloparatide-patch, for potential use in the treatment of postmenopausal women with osteoporosis. The Company is also developing our investigational product candidate, elacestrant ("RAD1901"), a selective estrogen receptor degrader ("SERD"), for potential use in the treatment of hormone-receptor positive breast cancer. The Company developing our internally discovered investigational product candidate, RAD140, a non-steroidal selective androgen receptor modulator ("SARM") for potential use in the treatment of hormone-receptor positive breast cancer.

The Company is subject to the risks associated with emerging companies with a limited operating history, including dependence on key individuals, a developing business model, the necessity of securing regulatory approvals to market its investigational product candidates, market acceptance of the Company's investigational product candidates following receipt of regulatory approval, competition for its investigational product candidates following receipt of regulatory approval, and the continued ability to obtain adequate financing to fund the Company's future operations. The Company has incurred losses and expects to continue to incur additional losses for the foreseeable future. As of December 31, 2017, the Company had an accumulated deficit of $882.3 million, and total cash, cash equivalents, marketable securities, and investments of $430.3 million.

Based upon its cash, cash equivalents, marketable securities, and investments balance as of December 31, 2017, the Company believes that, prior to the consideration of revenue from the potential future sales of any of its investigational products that may receive regulatory approval or proceeds from partnering and/or collaboration activities, it has sufficient capital to fund its development plans, U.S. commercial scale-up and other operational activities, for not less than twelve months from the date of this filing. The Company expects to finance the future development costs of its clinical product portfolio with its existing cash and cash equivalents, marketable securities, and investments, or through strategic financing opportunities that could include, but are not limited to collaboration agreements, future offerings of its equity, or the incurrence of debt. However, there is no guarantee that any of these strategic or financing opportunities will be executed or executed on favorable terms, and some could be dilutive to existing stockholders. If the Company fails to obtain additional future capital, it may be unable to complete its planned preclinical studies and clinical trials and obtain approval of certain investigational product candidates from the FDA or foreign regulatory authorities.

2. Summary of Significant Accounting Policies

Basis of Presentation—The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All material intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates—The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires the Company's management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and

accompanying notes. Actual results could differ from those estimates. The Company considers events or transactions that occur after the balance sheet date but before the consolidated financial statements are issued as additional evidence for certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated up to the date of issuance of these consolidated financial statements.

Cash Equivalents—The Company considers all highly liquid investment instruments with an original maturity when purchased of three months or less to be cash equivalents. Money market funds represents a majority of the cash equivalents balance at December 31, 2017 and 2016.

Accounts Receivable—Accounts receivable primarily relates to amounts due from customers. Accounts receivable are typically due within 31 days. The Company analyzes accounts that are past due for collectability. Given the nature and historical collectability of the Company's accounts receivable, an allowance for doubtful accounts is not deemed necessary at December 31, 2017.

Marketable Securities—All investment instruments with an original maturity date, when purchased, in excess of three months have been classified as current marketable securities. The Company classifies securities that are available to fund current operations as current assets. These marketable securities are classified as available-for-sale and are carried at fair value. Unrealized gains and losses, if any, are included within other comprehensive (loss) income within stockholders' equity. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Realized gains and losses on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. The Company periodically reviews the portfolio of securities to determine whether an other-than-temporary impairment has occurred. No such losses have occurred to date. There were no realized gains or losses on the sale of securities for the years ended December 31, 2017 and 2016.

Fair Value Measurements—Fair value is determined based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal market for the asset or liability in an orderly transaction between market participants. Authoritative guidance specifies a hierarchy of valuation techniques based upon whether the inputs to those valuation techniques reflect assumptions other market participants would use based upon market data obtained from independent sources (observable inputs) or reflect the Company's own assumptions of market participant valuation (unobservable inputs). The fair value hierarchy consists of three levels:

Level 1—Quoted prices in active markets that are unadjusted and accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2—Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The authoritative guidance requires the use of observable market data if such data is available without undue cost and effort. When available, the Company uses unadjusted quoted market prices to measure fair value and classify such items within Level 1. If quoted market prices are not available, fair value is based upon internally developed models that use, where possible, current market-based or independently-sourced market parameters, such as interest and currency rates and comparable transactions. Items valued using internally generated models are classified according to the lowest level input or value driver that is significant to the valuation. Thus, items may be classified in Level 3 even though there may be inputs that are readily observable. If quoted market prices are not available, the valuation model used generally depends on the specific asset or liability being valued.

Some assets and liabilities are required to be recorded at fair value on a recurring basis, while other assets and liabilities are recorded at fair value on a nonrecurring basis. The Company records the fair value of long-lived assets and other intangible assets on a nonrecurring basis. The carrying amounts of current financial instruments, which include accounts receivable, accounts payable and accrued expenses, approximate their fair values due to the short-term nature of these instruments. The fair value of notes payable is determined based upon data from readily available pricing sources which utilize market observable inputs and other characteristics for similar types of instruments.

The Company reviews the carrying value of long-lived assets and other intangible assets on an annual basis or whenever events or changes in circumstances indicate the fair value of the asset is below its carrying amount. Fair value is determined using various valuation techniques, including discounted cash flows, market-related multiples, and recently reported transactions for similar assets in the market place.

Concentrations of Credit Risk and Off-Balance-Sheet Risk—Financial instruments that potentially subject the Company to credit risk primarily consist of cash and cash equivalents and available-for-sale marketable securities. The Company mitigates its risk with respect to cash and cash equivalents and marketable securities by maintaining its deposits and investments at high-quality financial institutions. The Company invests any excess cash in money market funds and other securities, and the management of these investments is not discretionary on the part of the financial institution. The Company has no significant off-balance-sheet risks such as foreign exchange contracts, option contracts, or other hedging arrangements.

The Company is also subject to credit risk from its accounts receivable related to its product sales. As part of its credit management policy, the Company performs ongoing credit evaluations of its customers, and the Company has not required collateral from any customer.

Property and Equipment—Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets.

Research and Development Costs—The Company accounts for research and development costs by expensing such costs to operations as incurred. Research and development costs primarily consist of clinical testing costs, including payments made to contract research organizations, personnel costs, outsourced research activities, laboratory supplies, and license fees.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

Licensing Agreements—Costs associated with licensing early-stage technologies are expensed as incurred and are included in research and development expenses.

Impairment of Long-Lived Assets—The Company evaluates long-lived assets for potential impairment when there is evidence that events or changes in circumstances have occurred that indicate that the carrying amount of a long-lived asset may not be recovered. Recoverability of these assets is assessed based on the undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends, and product development cycles. Impairment in the carrying value of each asset is assessed when the undiscounted expected future cash flows derived from the asset are less than its carrying value.

An impairment loss would be recognized in an amount equal to the excess of the carrying amount over the undiscounted expected future cash flows. No impairment charges have been recognized since the Company's inception.

Segment Information—Operating segments are defined as components of an enterprise engaged in business activities for which discrete financial information is available and regularly reviewed by the chief decision maker in determining how to allocate resources and in assessing performance. The Company views its operations and manages its business as one operating segment and operates in one geographic area.

Income Taxes—The Company recognizes deferred tax assets and liabilities for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis, as well as operating loss and tax credit carryforwards. The Company measures deferred tax assets and liabilities using enacted tax rates expected to apply to taxable income in the years in which those temporary differences and carryforwards are expected to be recovered or settled. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization. The effect on deferred tax assets and liabilities as a result of a change in tax rates is recognized as income in the period that includes the enactment date.

The Company uses judgment to determine the recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Any material interest and penalties related to unrecognized tax benefits are recognized in income tax expense.

Due to uncertainty surrounding the realization of the favorable tax attributes in future tax returns the Company has recorded a full valuation allowance against otherwise realizable net deferred tax assets as of December 31, 2017 and 2016.

Stock-Based Compensation-Options—The Company measures stock-based compensation cost at the accounting measurement date based on the fair value of the option and recognizes the expense related to awards to employees on a straight-line basis over the requisite service period of the option, which is typically the vesting period.

The Company estimates the fair value of each option using the Black-Scholes option pricing model that considers the fair value of its common stock, the exercise price, the expected life of the option, the expected volatility of its common stock, expected dividends on its common stock, and the risk-free interest rate over the expected life of the option. Due to the limited trading history of the Company's common stock since its initial public offering in June 2014, the Company uses the simplified method described in the SEC's Staff Accounting Bulletin No. 107, *Share-Based Payment,* to determine the expected life of the option grants. The estimate of expected volatility is based on a review of the historical volatility of similar publicly held companies in the biotechnology field over a period commensurate with the option's expected term. The Company has never declared or paid any cash dividends on its common stock and does not expect to do so in the foreseeable future. Accordingly, it uses an expected dividend yield of zero. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant valuation for a period commensurate with the option's expected term. These assumptions are highly subjective and changes in them could significantly impact the value of the option and hence the related compensation expense.

Stock-based compensation expense recognized for options granted to consultants is also based upon the fair value of the options issued, as determined by the Black-Scholes option pricing model. However, the unvested portion of such option grants is re-measured at each reporting period, until such time as the option is fully vested.

Stock-Based Compensation-Performance Units—The Company measures stock-based compensation cost at the accounting measurement date based on the fair value of the performance unit grant and recognizes the expense over the derived service period of the performance units.

The Company estimates the fair value of each grant using a Monte Carlo simulation analysis that takes into account the forecasted price of its common stock, historical volatility of its common stock, risk-free rate as of valuation date, price of its common stock as of the grant date and the trigger for the performance condition to be met.

The derived service period for each grant is calculated using a Monte Carlo simulation analysis.

Revenue Recognition—In April 2017, the FDA approved TYMLOS. Subsequent to receiving FDA approval, the Company entered into a limited number of arrangements with wholesalers in the U.S. (collectively, its "Customers") to distribute TYMLOS. Additionally, in July 2017, the Company entered into a License and Development Agreement (the "Teijin Agreement") with Teijin Limited ("Teijin") for abaloparatide-SC in Japan. These arrangements are the Company's initial contracts with customers and, as such, were evaluated and accounted for in compliance with Accounting Standards Codification ("ASC") Topic 606—*Revenue from Contracts with Customers* ("Topic 606"), which was adopted during the quarter ended June 30, 2017. In connection therewith, there was no transition to Topic 606 because the Company has no historical revenue. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled in exchange for those goods or services.

To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract under Topic 606, including when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. For a complete discussion of accounting for product revenue, see *Product Revenue, Net* (below).

Product Revenue, Net—The Company sells TYMLOS to a limited number of wholesalers in the U.S (collectively, its "Customers"). These Customers subsequently resell the Company's products to specialty pharmacy providers, as well as other retail pharmacies and certain medical centers or hospitals. In addition to distribution agreements with Customers, the Company enters into arrangements with health care providers and payors that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products.

The Company recognizes revenue on product sales when the Customer obtains control of the Company's product, which occurs at a point in time (upon delivery). Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

If taxes should be collected from Customers relating to product sales and remitted to governmental authorities, they will be excluded from revenue. The Company expenses incremental costs of obtaining a contract when incurred, if the expected amortization period of the asset that the Company would have recognized is one year or less. However, no such costs were incurred during the twelve months ended December 31, 2017.

Reserves for Variable Consideration—Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, provider chargebacks and discounts, government rebates, third-party payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between the Company and its Customers, payors, and other indirect customers relating to the Company's sale of its products. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable (if the amount is payable to the Customer) or a current liability (if the amount is payable to a party other than a Customer). These estimates take into consideration a range of possible

outcomes which are probability-weighted in accordance with the expected value method in Topic 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplated application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period, for the estimates detailed below, as of December 31, 2017 and, therefore, the transaction price was not reduced further during the twelve months ended December 31, 2017. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances—The Company generally provides Customers with discounts which include incentive fees that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company compensates (through trade discounts and allowances) its Customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of products to the Customer and, therefore, these payments have been recorded as a reduction of revenue within the statement of operations and comprehensive loss through December 31, 2017, as well as a reduction to trade receivables, net on the consolidated balance sheets.

Product Returns—Consistent with industry practice, the Company generally offers Customers a limited right of return for product that has been purchased from the Company based on the product's expiration date, which lapses upon shipment to a patient. The Company estimates the amount of its product sales that may be returned by its Customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as reductions to trade receivables, net on the consolidated balance sheets. The Company currently estimates product return liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company has received an immaterial amount of returns to date and believes that returns of product in future periods will be minimal.

The Company's limited right of return policy allows for eligible returns of TYMLOS in the following circumstances:

- Shipment errors that were the result of an error by the Company;
- Quantity delivered that is greater than the quantity ordered;
- Product distributed by the Company that is damaged in transit prior to receipt by the customer;
- Expired product, previously purchased directly from the Company, that is returned during the period beginning six months prior to the product's expiration date and ending twelve months after the product's expiration date;
- Product subject to a recall; and
- Product that the Company, at its sole discretion, has specified to be returned.

Provider Chargebacks and Discounts—Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from the Company.

Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and trade receivables, net. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and the Company generally issues credits for such amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, and chargebacks that Customers have claimed, but for which the Company has not yet issued a credit.

Government Rebates—The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Payor Rebates—The Company contracts with certain third-party payors, primarily health insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Other Incentives—Other incentives which the Company offers include voluntary patient assistance programs, such as the Company's co-pay assistance program, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as a component of accrued expenses and other current liabilities on the consolidated balance sheets.

Product Revenue Reserves and Allowances—Chargebacks, discounts, fees, and returns are recorded as reductions of trade receivables, net on the consolidated balance sheets. Government and other rebates are recoded as a component of accrued expenses and other current liabilities on the consolidated balance sheets.

Collaboration Revenues—The Company enters into out-licensing agreements which are within the scope of Topic 606, under which it licenses certain rights to its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; development, regulatory, and commercial milestone payments; payments for manufacturing supply services the Company provides through its contract manufacturers; and royalties on net sales of licensed products. Each of these payments may result in license, collaboration, or other revenue, except revenue from royalties on net sales of licensed products, which would be classified as royalty revenue.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and

(v) recognition of revenue when (or as) the Company satisfies each performance obligation. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success.

Licenses of Intellectual Property—If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company will evaluate the measure of progress 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 milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company or the customer, 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 on a relative stand-alone selling price basis, for which the Company recognizes revenue as, or when, the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, collaboration, other revenue, and earnings in the period of adjustment.

Manufacturing Supply Services—Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply, at the customer's discretion, are generally considered as options. The Company assesses if these options provide a material right to the licensee and, if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the licensee exercises these options, any additional payments are recorded in license, collaboration, or other revenue when the customer obtains control of the goods, which is upon delivery.

Royalties—For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from its out-licensing arrangement.

Inventory—The Company values its inventories at the lower of cost or estimated net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and it writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded within cost of product revenues. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required which would be recorded as a cost of product sales in the consolidated statements of operations and comprehensive loss.

The Company capitalizes inventory costs associated with the Company's products after regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. Inventory acquired prior to receipt of marketing approval of a product candidate is expensed as research and development expense as incurred. Inventory that can be used in either the production of clinical or commercial product is expensed as research and development expense when selected for use in a clinical manufacturing campaign.

Shipping and handling costs for product shipments are recorded as incurred in cost of product revenues along with costs associated with manufacturing the product and any inventory write-downs.

Intangible Assets—The Company maintains definite-lived intangible assets related to certain capitalized milestones. These assets are amortized over their remaining useful lives, which are estimated based on the shorter of the remaining patent life or the estimated useful life of the underlying product. Intangible assets are amortized using the economic consumption method if anticipated future revenues can be reasonably estimated. The straight-line method is used when future revenues cannot be reasonably estimated.

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of the Company's drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales for the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value.

Convertible Note Payable—In accordance with accounting guidance for debt with conversion and other options, the Company separately accounted for the liability and equity components of the Company's 3% Convertible Senior Notes due by 2024 (the "Convertible Notes") by allocating the proceeds between the liability component and the embedded conversion option (the "Equity Component") due to the Company's ability to settle the Convertible Notes in cash, common stock or a combination of cash and common stock, at its option. The carrying amount of the liability components was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected the Company's non-convertible debt borrowing rate for similar debt. The Equity Component of the Convertible Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the Convertible Notes and the fair value of the liability of the Convertible Notes on their respective dates of issuance. The excess of the principal amount of the liability component over its carrying amount (the "Debt Discount") is amortized to interest expense using the effective interest method over seven years. The Equity Component is not remeasured as long as it continues to meet the conditions for equity classification. In connection with issuance of the Convertible Notes, the Company also incurred certain offering costs directly attributable to the offering. Such costs are deferred and amortized over the term of the debt to interest expense using the effective interest method. A portion of the deferred financing costs incurred in connection with the Convertible Notes was deemed to relate to the Equity Component and was allocated to additional paid-in capital.

Net Loss Per Common Share—Net loss per common share is calculated using an earnings allocation formula that determines net loss per share for the holders of the Company's common shares and participating securities. Prior to the initial public offering, all of the Company's series of preferred stock contained participation rights in any dividend paid by the Company and were deemed to be participating securities. Net income available to common shareholders and participating preferred shares was allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. The participating securities do not include a contractual obligation to share in losses of the Company and are not included in the calculation of net loss per share in the periods that have a net loss.

Diluted net income per share is computed using the more dilutive of (a) the two-class method, or (b) the if-converted method. The weighted-average number of common shares outstanding gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, and, prior to the Company's initial public offering, potential issuance of stock upon the issuance of the Company's series A-6 convertible preferred stock ("Series A-6") as settlement of the liability to Nordic Bioscience ("Nordic"). Common equivalent shares are excluded from the computation of diluted net income per share if their effect is anti-dilutive.

Comprehensive Income (Loss)—Comprehensive income (loss) refers to revenues, expenses, gains and losses that are excluded from net income (loss), as these amounts are recorded directly as an adjustment to stockholders' equity, net of tax. The Company's other comprehensive (loss) income is comprised of unrealized gains (losses) on its available-for-sale marketable securities.

Accounting Standards Updates—Recently Adopted

In April 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2015-05, Intangibles—*Goodwill and Other Internal-Use Software* (Subtopic 350-40): Customer's Accounting for Fees Paid in a Cloud Computing Arrangement). ASU 2015-05 provides guidance to Subtopic 350-40 to help entities evaluate the accounting for fees paid by a customer in a cloud computing arrangement. The amendments under ASU 2015-15 are effective for annual fiscal period ending after December 15, 2016 and interim periods thereafter, with early adoption permitted. The adoption of ASU 2015-05 on a prospective basis did not have a material impact on the Company's results of operations, financial position or cash flows.

In July 2015, the FASB issued ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory* ("ASU 2015-11"). ASU 2015-11 applies only to inventory for which cost is determined by methods other than last in, first-out and the retail inventory method, which includes inventory that is measured using first-in, first-out or average cost. Inventory within the scope of this standard is required to be measured at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. ASU 2015-11 was effective for us beginning in the second quarter of 2017. The adoption of this standard did not have a material impact on our consolidated financial statements and related disclosures.

In November 2015, the FASB issued ASU 2015-17, *Balance Sheet Classification of Deferred Taxes* (Topic 740). Under the new guidance, companies are required to classify all deferred tax assets and liabilities as noncurrent on the balance sheet instead of separating deferred taxes into current and noncurrent amounts. In addition, companies will no longer allocate valuation allowances between current and noncurrent deferred tax assets because those allowances will also be classified as noncurrent. This guidance is effective for financial statements issued for annual periods beginning after December 15, 2016. The Company adopted this standard in the first quarter of 2017 and it did not have a material impact on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). This revised standard affects the accounting for forfeitures, cash flow presentation and income taxes. Specifically, this standard provides an accounting policy election to account for forfeitures as they occur, requires all excess tax benefits and deficiencies on share-based payment awards to be recognized as income tax expense or benefit in the statement of operations, requires the tax effects of exercised or vested awards be treated as discrete items in the reporting period in which they occur, and requires that excess tax benefits to be classified with other income tax cash flows as an operating activity. The standard permits early adoption in any annual or interim period and will be applied by means of a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption.

Historically, the Company recognized stock-based compensation net of estimated forfeitures over the vesting period of the respective grant. Effective January 1, 2017, the Company adopted ASU 2016-09 and changed its accounting policy to recognize forfeitures as they occur. The new forfeiture policy election was

adopted using a modified retrospective approach with a cumulative effect adjustment of approximately $0.5 million to retained earnings as of January 1, 2017. In addition, the Company recognized $6.1 million of accumulated excess tax benefits as deferred tax assets that under the previous guidance could not be recognized until the benefits were realized through a reduction in cash taxes paid. This part of the guidance was applied using a modified retrospective method by means of a cumulative-effect adjustment to the accumulated deficit for the excess tax benefits as of the beginning of the fiscal year in which the guidance is adopted. However, given the full valuation allowance placed on the additional $6.1 million of deferred tax assets, the recognition upon adoption had no impact to our accumulated deficit as of January 1, 2017. The adoption of ASU 2016-09 effective January 1, 2017 had no other material impacts on the Company's results of operations, financial position, or its cash flows.

Accounting Standards Updates—Recently Issued

In February 2016, the FASB issued ASU 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 supersedes the lease guidance under FASB Accounting Standards Codification ("ASC") Topic 840, Leases, resulting in the creation of FASB ASC Topic 842, Leases. ASU 2016-02 requires a lessee to recognize in the statement of financial position a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term for both finance and operating leases. ASU 2016-02 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. Early adoption is permitted. The Company is currently assessing the potential impact of adopting ASU 2016-02 on its financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Statements* ("ASU 2016-13"). ASU 2016-13 affects entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. ASU 2016-13 affects loans, debt securities, trade receivables, net investments in leases, off-balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have contractual right to receive cash. ASU 2016-13 requires that a financial asset (or a group of financial assets) measured at amortized cost basis be presented at the net amount expected to be collected using an allowance for credit losses valuation account. ASU 2016-13 requires that credit losses relating to available-for-sale debt securities should be limited by the amount which the fair value is below amortized cost. ASU 2016-13 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019. Early adoption is permitted as of the fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The Company is currently assessing the potential impact of adopting ASU 2016-13 on its financial statements and related disclosures.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"). ASU 2016-15 addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. ASU 2016-15 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Early adoption is permitted. The Company does not expect the adoption of ASU 2016-05 to have a material impact on its results of operations, financial position or cash flows.

In November 2016, the FASB issued ASU 2016-18, *Restricted Cash* ("ASU 2016-18"). The amendments in ASU 2016-18 require an entity to reconcile and explain the period-over-period change in total cash, cash equivalents and restricted cash within its statements of cash flows. ASU 2016-18 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. A reporting entity must apply the amendments in ASU 2016-18 using a full retrospective approach. The Company is currently evaluating the impact the adoption of the ASU will have on its consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation* (Topic 718) ("ASU 2017-09") Scope of Modification Accounting. ASU 2017-09 provides clarification on when modification accounting should be used for changes to the terms or conditions of a share-based payment award. The amendments in ASU 2017-09 are effective for all entities for annual periods, and interim periods within those

annual periods, beginning after December 15, 2017, with early adoption permitted, applied prospectively to an award modified on or after the adoption date. This ASU does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The Company is currently assessing the impact that adopting this new accounting standard will have on its consolidated financial statements.

3. Marketable Securities

Available-for-sale marketable securities and cash and cash equivalents consist of the following (in thousands):

	December 31, 2017			
	Amortized Cost Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 73,302	$—	$ —	$ 73,302
Money market	325	—	—	325
Domestic corporate commercial paper	44,937	—	—	44,937
Total	$118,564	$—	$ —	$118,564
Marketable securities:				
Domestic corporate debt securities	$207,320	$ 1	$ (235)	$207,086
Domestic corporate commercial paper	29,844	—	(7)	29,837
Agency bonds	74,842	—	(73)	74,769
Total	$312,006	$ 1	$ (315)	$311,692

	December 31, 2016			
	Amortized Cost Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 77,443	$ —	$ —	$ 77,443
Money market funds	173,631	—	—	173,631
Domestic corporate commercial paper	5,487	—	—	5,487
Domestic corporate debt securities	2,006	—	—	2,006
Total	$258,567	$ —	$ —	$258,567
Marketable securities:				
Domestic corporate debt securities	$ 19,317	$ —	$ (2)	$ 19,315
Domestic corporate commercial paper	31,852	78	—	31,930
Asset-backed securities	22,639	—	(4)	22,635
Total	$ 73,808	$ 78	$ (6)	$ 73,880

There were no debt securities that had been in an unrealized loss position for more than 12 months as of December 31, 2017 or December 31, 2016. There were 38 debt securities in an unrealized loss position for less than 12 months at December 31, 2017 and there were 13 debt securities that had been in an unrealized loss position for less than 12 months at December 31, 2016. The aggregate unrealized loss on these securities as of December 31, 2017 and 2016 was approximately $315 thousand and $6 thousand, respectively, and the fair value was $299.2 million and $35.7 million, respectively. The Company considered the decline in market value for these securities to be primarily attributable to current economic conditions. As it was not more likely than not that the Company would be required to sell these securities before the recovery of their amortized cost basis, which may be maturity, the Company did not consider these investments to be other-than-temporarily impaired as of December 31, 2017 and 2016.

As of December 31, 2017, marketable securities consisted of investments that mature within one year, with the exception of certain corporate debt securities and agency bonds, which have maturities within 2 years and an aggregate fair value of $177.0 million.

4. Fair Value Measurements

The following table summarizes the financial instruments measured at fair value on a recurring basis in the accompanying consolidated balance sheets as of December 31, 2017 and December 31, 2016 (in thousands):

	As of December 31, 2017			
	Level 1	Level 2	Level 3	Total
Assets				
Cash and cash equivalents:				
Cash	$73,302	$ —	$—	$ 73,302
Money market funds (1)	325	—	—	325
Domestic corporate commercial paper (2)	—	44,937	—	44,937
Total	$73,627	$ 44,937	$—	$118,564
Marketable Securities				
Domestic corporate debt securities (2)	$ —	$207,086	$—	$207,086
Domestic corporate commercial paper (2)	—	29,837	—	29,837
Asset-backed securities (2)	—	74,769	—	74,769
Total	$ —	$311,692	$—	$311,692

	As of December 31, 2016			
	Level 1	Level 2	Level 3	Total
Assets				
Cash and cash equivalents:				
Cash	$ 77,443	$ —	$—	$ 77,443
Money market funds (1)	173,631	—	—	173,631
Domestic corporate commercial paper (2)	—	5,487	—	5,487
Domestic corporate debt securities (2)	—	2,006	—	2,006
Total	$251,074	$ 7,493	$—	$258,567
Marketable securities:				
Domestic corporate debt securities (2)	$ —	$19,315	$—	$ 19,315
Domestic corporate commercial paper (2)	—	31,930	—	31,930
Asset-backed securities (2)	—	22,635	—	22,635
Total	$ —	$73,880	$—	$ 73,880

(1) Fair value is based upon quoted market prices.

(2) Fair value is based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant assumptions are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Inputs are obtained from various sources, including market participants, dealers and brokers.

Transfers between levels are made to reflect changes in observability of inputs and market activity. Transfers into or out of any level are generally reported at the value as of the beginning of the quarter in which the transfers occur for any such assets still held at the end of the quarter. During the years ended December 31, 2017 and 2016, there were no transfers between Level 1 and Level 2.

5. Inventory

Inventory consists of the following at December 31, 2017 (in thousands):

	December 31, 2017	December 31, 2016
Raw materials	$3,852	$—
Work in process	313	—
Finished goods	201	—
Total inventories	$4,366	$—

Inventory acquired prior to receipt of the marketing approval for TYMLOS, totaling approximately $1.6 million, was expensed as research and development expense as incurred. The Company began to capitalize the costs associated with the production of TYMLOS upon receipt of FDA approval on April 28, 2017.

Finished goods manufactured by the Company have a 30-month shelf life from date of manufacture.

6. Property and Equipment

Property and equipment consists of the following (in thousands):

	Estimated Useful Life (In Years)	December 31, 2017	December 31, 2016
Furniture and fixtures, lab and office equipment	5	$ 1,145	$ 901
Computer equipment and software	3	3,602	1,412
Manufacturing equipment	10	1,617	1,209
Leasehold improvements	Shorter of useful life or remaining lease term	1,847	1,253
Construction in progress	—	326	1,078
		8,537	5,853
Less: accumulated depreciation		(2,342)	(931)
Property and equipment, net		$ 6,195	$ 4,922

The Company performed a qualitative impairment analysis to determine if any of the assets displayed indicators of impairment that would trigger the need for further analysis. As a result of the qualitative assessment, the Company concluded that there were no indicators of impairment for any property and equipment assets as of December 31, 2017. Depreciation expense related to property and equipment was approximately $1.4 million and $0.6 million for the years ended December 31, 2017 and 2016, respectively.

7. Intangible Assets

The following table presents intangible assets as of December 31, 2017 (in thousands):

	December 31, 2017	Estimated useful life (years)
Acquired and in-licensed rights	$8,712	11
Less: accumulated amortization	(532)	
Total intangible asset, net	$8,180	

The increase in acquired and in-licensed rights as of December 31, 2017 was due to the milestone of €8.0 million (approximately $8.7 million) paid to Ipsen, which was triggered by the FDA approval of TYMLOS on April 28, 2017.

The Company recorded approximately $0.5 million in amortization expense related to intangible assets, using the straight-line methodology which is considered the best estimate of economic benefit, during the twelve months ended December 31, 2017. Estimated future amortization expense for intangible assets as of December 31, 2017 is approximately $0.8 million per year thereafter.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses consist of the following (in thousands):

	December 31,	
	2017	2016
Commercial costs	$14,300	$ —
Research costs	8,406	9,632
Payroll and employee benefits	16,934	9,338
Interest	3,482	—
Professional fees	6,295	7,532
Other current liabilities	95	95
Total accrued expenses and other current liabilities	$49,512	$26,597

9. Notes Payable

In May 2014, the Company entered into a loan and security agreement (the "2014 Credit Facility"), with Solar Capital Ltd. ("Solar"), as collateral agent and a lender, and Oxford, as a lender (the "Lenders"), pursuant to which Solar and Oxford agreed to make available to the Company $30.0 million in the aggregate subject to certain conditions to funding. An initial term loan was made in May 2014 in an aggregate principal amount equal to $21.0 million (the "Initial Term Loan"). The Company used approximately $9.3 million of the Initial Term Loan to repay all amounts owed under a previous loan and security agreement with other financial institutions.

In July 2014, the Company entered into a first amendment to the 2014 Credit Facility (the "First Amendment"). The terms of the First Amendment, among other things, provided the Company with, subject to certain customary funding conditions, additional term loans in an aggregate principal amount of $4.0 million upon the closing of the First Amendment. The Company borrowed the additional $4.0 million in July 2014.

The Company had been required to make interest-only payments through December 1, 2015, and beginning on January 1, 2016, it would have been required to make payments of principal and accrued interest in equal monthly installments over a term of 30 months. The Initial Term Loan bore interest per annum at 9.85% plus one-month LIBOR (customarily defined). All principal and accrued interest on the Initial Term Loan had been due on June 1, 2018.

On August 4, 2015, the Company prepaid all amounts owed under the 2014 Credit Facility and the First Amendment. After consideration of relevant fees required under the 2014 Credit Facility and the First Amendment, the total payment amounted to $26.5 million, which resulted in a loss on retirement of $1.6 million during the third quarter of 2015.

Convertible Notes Payable

On August 14, 2017, in a registered underwritten public offering, the Company issued $300.0 million aggregate principal amount of the Convertible Notes. In addition, on September 12, 2017, the Company issued an additional $5.0 million principal amount of Convertible Notes pursuant to the exercise of an over-allotment option granted to the underwriters in the offering. In accordance with accounting guidance for debt with conversion and other options, the Company separately accounted for the Liability and Equity Components of the Convertible Notes by allocating the proceeds between the Liability Component and the Equity Component, due to the Company's ability to settle the Convertible Notes in cash, common stock or a combination of cash and common stock, at its option. In connection with the issuance of the Convertible Notes, the Company incurred

approximately $9.4 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs to the Liability and Equity Components based on the allocation of the proceeds. Of the total $9.4 million of debt issuance costs, $4.3 million was allocated to the Equity Component and recorded as a reduction to additional paid-in capital and $5.1 million was allocated to the liability component and is now recorded as a reduction of the Convertible Notes in the Company's consolidated balance sheet. The portion allocated to the liability component is amortized to interest expense using the effective interest method over seven years.

The Convertible Notes are senior unsecured obligations of the Company and bear interest at a rate of 3.00% per annum, payable semi-annually in arrears on March 1 and September 1, beginning on March 1, 2018. Upon conversion, the Convertible Notes will be convertible into cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election. Prior to December 31, 2017, the Convertible Notes were not convertible except in connection with a make whole fundamental change, as defined in the respective indentures. The Convertible Notes will be subject to redemption at our option, on or after September 1, 2021, in whole or in part, if the conditions described below are satisfied. The Convertible Notes will mature on September 1, 2024, unless earlier converted, redeemed or repurchased in accordance with their terms. Subject to satisfaction of certain conditions and during the periods described below, the Convertible Notes may be converted at an initial conversion rate of 20.4891 shares of common stock per $1,000 principal amount of the Convertible Notes (equivalent to an initial conversion price of approximately $48.81 per share of common stock and 6,249,176 shares).

Holders of the Convertible Notes may convert all or any portion of their notes, in multiples of $1,000 principal amount, at their option at any time prior to the close of business on the business day immediately preceding June 1, 2024 only under the following circumstances:

(1) during any calendar quarter commencing after the calendar quarter ending on December 31, 2017 (and only during such calendar quarter), if the last reported sale price of the Company's common stock for at least 20 trading days (whether consecutive or not) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

(2) during the five-business day period after any five-consecutive trading day period (the "measurement period") in which the "trading price" per $1,000 principal amount of the Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day;

(3) if the Company calls the Convertible Notes for redemption, until the close of business on the business day immediately preceding the redemption date; or

(4) upon the occurrence of specified corporate events.

Prior to September 1, 2021, the Company may not redeem the Convertible Notes. On or after September 1, 2021, the Company may redeem for cash all or part of the Convertible Notes if the last reported sale price of the Company's common stock equals or exceeds 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30-consecutive trading day period ending within 5 trading days prior to the date on which the Company provides notice of the redemption. The redemption price will be the principal amount of the Convertible Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. In addition, calling any Convertible Note for redemption will constitute a make-whole fundamental change with respect to that Convertible Note, in which case the conversion rate applicable to the conversion of that Convertible Note, if it is converted in connection with the redemption, will be increased in certain circumstances.

In accordance with accounting guidance for debt with conversion and other options, the Company separately accounted for the liability and equity components of the Convertible Notes by allocating the proceeds between

the liability component and the embedded conversion option (the "Equity Component") due to the Company's ability to settle the Convertible Notes in cash, common stock or a combination of cash and common stock, at its option. The carrying amount of the Liability Component of $166.3 million was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected the Company's non-convertible debt borrowing rate for similar debt. The Equity Component of the Convertible Notes of $138.7 million was recognized as a debt discount and represents the difference between the proceeds from the issuance of the Convertible Notes of $305.0 million and the fair value of the liability of the Convertible Notes of approximately $305.0 million on their respective dates of issuance. The excess of the principal amount of the liability component over its carrying amount (the "Debt Discount") is amortized to interest expense using the effective interest method over seven years. The Equity Component is not remeasured as long as it continues to meet the conditions for equity classification. In connection with issuance of the Convertible Notes, the Company also incurred certain offering costs directly attributable to the offering. Such costs are deferred and amortized over the term of the debt to interest expense using the effective interest method. A portion of the deferred financing costs incurred in connection with the Convertible Notes was deemed to relate to the Equity Component and was allocated to additional paid-in capital.

The outstanding balances of the Convertible Notes as of December 31, 2017 consisted of the following (in thousands):

	2024 Convertible Notes
Liability component:	
Principal	$ 305,000
Less: debt discount and issuance costs, net	(138,994)
Net carrying amount	$ 166,006
Equity component:	$ 134,450

The Company determined the expected life of the Convertible Notes was equal to its seven-year term. The effective interest rate on the Liability Components of the Convertible Notes for the period from the date of issuance through December 31, 2017 was 13.04%. As of December 31, 2017, the "if-converted value" did not exceed the remaining principal amount of the Convertible Notes. The fair values of the 3% Convertible Senior Notes due September 1, 2024 are based on data from readily available pricing sources which utilize market observable inputs and other characteristics for similar types of instruments, and, therefore, these convertible senior notes are classified within Level 2 in the fair value hierarchy. The fair value of the Convertible Notes, which differs from their carrying value, is influenced by interest rates, the Company's stock price and stock price volatility. The estimated fair value of the Convertible Notes as of December 31, 2017 was approximately $308.5 million.

The following table sets forth total interest expense recognized related to the Convertible Notes during the twelve months ended December 31, 2017 (in thousands):

	Twelve Months Ended December 31, 2017
	2017
Contractual interest expense	$3,482
Amortization of debt discount	4,641
Amortization of debt issuance	175
Total interest expense	$8,298

Future minimum payments on our long-term debt as of December 31, 2017 were as follows (in thousands):

Years ended December 31,	Future Minimum Payments
2018	$ 9,582
2019	9,150
2020	9,150
2021	9,150
2022 and thereafter	332,450
Total minimum payments	$ 369,482
Less: interest	(64,482)
Less: unamortized discount	(138,994)
Less: current portion	—
Long Term Debt	$ 166,006

10. Stockholders' Equity and Convertible Preferred Stock

Common Stock

On January 28, 2015, the Company completed an additional public offering of 4,000,000 shares of its common stock at a price of $36.75 per share, for aggregate estimated proceeds, net of underwriting discounts, commissions and offering costs, of approximately $137.8 million. Also, on January 28, 2015, the underwriters purchased an additional 600,000 shares in the aggregate by exercising an option to purchase additional shares that was granted to them in connection with the offering. As a result of the public offering and subsequent exercise of the underwriters' option, the Company received aggregate proceeds, net of underwriting discounts, commissions and offering costs of approximately $158.4 million.

On July 28, 2015, the Company completed an additional public offering of 4,054,054 shares of its common stock at a price of $74.00 per share, for aggregate proceeds, net of underwriting discounts, commissions and offering costs, of approximately $281.5 million. Also, on July 28, 2015, the underwriters purchased an additional 608,108 shares by exercising an option to purchase additional shares that was granted to them in connection with the offering. As a result of the public offering and subsequent exercise of the underwriters' option, the Company received aggregate proceeds, net of underwriting discounts, commissions and estimated offering costs of approximately $323.8 million.

Warrants

At December 31, 2017 and 2016, the company had outstanding warrants to purchase 605,415 and 630,444 shares of the Company's common stock, respectively, at prices ranging from $14.00 to $16.97 per share. The warrants became exercisable at various dates between 2011 and 2014 and expire at various dates through 2019.

11. Employee Stock Benefit Plans

Summary of Stock-based Compensation Plans

The Company has the following stock-based compensation plans as of December 31, 2017, under which equity awards have been granted to employees, directors and consultants:

- 2003 Long-Term Incentive Plan; and
- 2011 Equity Incentive Plan.

The Company's 2011 Equity Incentive Plan replaced the Company's 2003 Long-Term Incentive Plan when the Company's board of directors approved the new plan on November 7, 2011. As of December 31, 2017, an aggregate of approximately 9,860,000 shares have been authorized for issuance under the Company's stock-based compensation plans, with approximately 5,648,000 options outstanding. The number of common shares available for granting of future awards under these plans was approximately 2,688,000 at December 31, 2017.

2003 Long-Term Incentive Plan—The Company's 2003 Long-Term Incentive Plan (the "2003 Plan") provides for the granting of incentive stock options and nonqualified options to key employees, directors and consultants of the Company. The exercise price of the incentive stock options, as determined by the Company's board of directors, must be at least 100% (110% in the case of incentive stock options granted to a stockholder owning in excess of 10% of the Company's common stock) of the common stock fair value as of the date of the grant. The provisions of the 2003 Plan limit the exercise of incentive stock options, but in no case may the exercise period extend beyond ten years from the date of grant (five years in the case of incentive stock options granted to a stockholder owning in excess of 10% of the Company's common stock). Stock options generally vest over a four-year period. Certain options contain explicit performance conditions. The Company authorized approximately 884,000 shares of common stock for issuance under the 2003 Plan.

2011 Equity Incentive Plan—The Company's 2011 Equity Incentive Plan (the "2011 Plan") provides for the granting of incentive stock options and nonqualified options to key employees, directors and consultants of the Company. The exercise price of the incentive stock options, as determined by the Company's board of directors, must be at least 100% (110% in the case of incentive stock options granted to a stockholder owning in excess of 10% of the Company's common stock) of the common stock fair value as of the date of the grant. The provisions of the 2011 Plan limit the exercise of incentive stock options, but in no case may the exercise period extend beyond ten years from the date of grant (five years in the case of incentive stock options granted to a stockholder owning in excess of 10% of the Company's common stock). Stock options generally vest over a four-year period, subject to continued employment with, or services to, the Company. During 2015, the Company also issued stock options to certain members of its board of directors which vested immediately. Certain options contain explicit performance conditions. The Company has authorized approximately 8,976,000 shares of common stock for issuance under the 2011 Plan. In addition, the shares remaining available for issuance under the 2003 Plan were assumed as shares authorized under the 2011 Plan.

The Company granted inducement stock option awards to purchase the Company's common stock to certain new non-executive employees on March 7, 2016, March 28, 2016, and May 8, 2016. Inducement stock option awards to purchase the Company's common stock were also granted to new executive officers of the Company on May 15, 2017, July 17, 2017, and November 27, 2017. The total inducement stock options issued were 341,450 with exercise prices ranging between $30.25 to $33.49 per option in 2016 and 490,000 with exercise prices ranging between $27.80 to $42.97 per option in 2017. Each inducement option award vests 25% on the first anniversary of the employee's hire date, with the remaining 75% to vest in monthly installments over the three years thereafter and has a 10-year term. These inducement stock options were granted pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules for equity grants to induce the new employees to enter into employment with the Company.

2016 Employee Stock Purchase Plan

Eligible employees may participate in the Company's 2016 Employee Stock Purchase Plan with purchases occurring semiannually on February 28 and August 31. Under this plan, participants may purchase common stock of the Company at the end of a predetermined six-month offering period at 85% of the lower of the fair market value at the beginning or end of the offering period. Shares are purchased through payroll deductions of up to 25% of each participating employee's annual compensation over the course of the six-month offering period, subject to certain limitations. The current plan allows for the issuance of 1,290,594 shares of common stock to eligible employees. At December 31, 2017, there were 1,214,314 shares available for future sale to employees under this plan. As of December 31, 2017, the Company recorded a liability of $1.3 million related to employee withholdings under this plan.

Options—The Company uses the Black-Scholes option-pricing model to estimate the grant date fair value of its employee stock options. The weighted-average grant-date fair value per share of options granted during 2017, 2016, and 2015 was $22.74, $19.79, and $30.52 respectively. The weighted-average assumptions used in the Black-Scholes option-pricing model were as follows:

	Years Ended December 31,		
	2017	2016	2015
Expected term (years)	6.02	5.95	6.08
Volatility	57%	55%	55%
Expected dividend yield	0%	0%	0%
Risk-free interest rates	2.01%	1.91%	1.72%

A summary of stock option activity for the year ended December 31, 2017 is as follows (in thousands, except for per share and weighted-average contractual life amounts):

	Shares	Weighted-Average Exercise Price (in dollars per share)	Weighted-Average Contractual Life (In Years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2016	6,374	$31.60		
Granted	2,094	42.82		
Exercised	(1,385)	12.62		
Canceled	(1,340)	41.22		
Expired	(95)	57.56		
Options outstanding at December 31, 2017	5,648	$37.71	7.03	$23,150
Options exercisable at December 31, 2017	2,934	$33.23	5.44	$21,365

The aggregate intrinsic value of options exercised (i.e., the difference between the market price at exercise and the price paid by employees to exercise the option) during the years ended December 31, 2017 and 2016 was $33.1 million and $3.7 million, respectively.

As of December 31, 2017, there was approximately $51.1 million of total unrecognized compensation expense related to unvested option-based compensation arrangements, which is expected to be recognized over a weighted-average period of approximately 3 years.

Restricted Stock Units—In April 2016, the Company awarded 58,500 restricted stock units ("RSUs") to employees at an average grant date fair value of $33.03 per RSU. In the year ended December 31, 2017, the Company awarded 137,000 restricted stock units ("RSUs") to employees at an average grant date fair value of $38.62 per RSU. Each RSU entitles the holder to receive one share of the Company's common stock if and when the RSU vests. The RSUs vest in 4 substantially equal installments on each of the first 4 anniversaries of the vesting commencement date, subject to the employee's continued employment with, or services to, the Company on such vesting date. Compensation expense is recognized on a straight-line basis.

A summary of RSU activity during the year ended December 31, 2017 is as follows (in thousands, except for per share amounts):

	RSUs	Weighted-Average Grant Date Fair Value (in dollars per share)
RSUs Outstanding at December 31, 2016	57	$33.03
Granted	137	38.62
Vested	(14)	33.03
Forfeited	(33)	40.04
RSUs Outstanding at December 31, 2017	147	$36.69

As of December 31, 2017, there was approximately $4.5 million of total unrecognized compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 3 years.

The following table summarizes stock-based compensation expense by financial statement line (in thousands):

	Years Ended December 31,		
	2017	2016	2015
Research and development	$14,699	$11,190	$ 7,864
General and administrative	20,304	14,868	6,870
Share-based compensation expense included in operating expenses	$35,003	$26,058	$14,734

Performance Units—In September 2015, the Company awarded 25,000 performance units ("PUs") to an employee. Each PU which is earned entitles the holder to receive one share of the Company's common stock if and when the PU vests. The PUs can be earned in the three years subsequent to the grant date if the Company's average closing stock price over 45 consecutive trading days that begin and end during such three-year period reaches certain thresholds that were set at the time of issuance. The vesting of any earned units is subject to the employee's continued employment one year from the last day of the measurement period for which the PUs are earned. Compensation expense is recognized over the derived service period, calculated using a Monte Carlo simulation analysis.

There were no PU's granted during the years ended December 31, 2017 and 2016. The weighted-average grant-date fair value per unit of PUs granted during the year ended December 31, 2015 was $49.59, which was calculated using a Monte Carlo simulation analysis performed by an independent valuation firm. This valuation methodology utilizes several key assumptions including the forecasted stock price, stock price volatility, risk-free rate as of valuation date, stock price as of grant date, and the trigger for the performance condition to be met.

A summary of PSU activity during the year ended December 31, 2017 is as follows (in thousands, except for per share amounts):

	PSUs	Weighted-Average Grant Date Fair Value (in dollars per share)
PSUs Outstanding at December 31, 2016	25	$49.59
Granted	—	—
Vested	—	—
Forfeited	(25)	49.59
PSUs Outstanding at December 31, 2017	—	$ —

As of December 31, 2017, there was no unrecognized compensation expense related to unvested PUs to be recognized in future periods.

12. Product Revenue Reserves and Allowances

To date, the Company's only source of product revenue has been from the U.S. sales of TYMLOS, which it began shipping to Customers in May 2017. The following table summarizes activity in each of the product revenue allowance and reserve categories for the twelve months ended December 31, 2017 (in thousands):

	Chargebacks, Discounts, and Fees	Government and Other Rebates	Returns	Total
Beginning balance at December 31, 2016	$ —	$ —	$—	$ —
Provision related to sales in the current year, net of credits and payments	1,986	1,231	421	3,638
Ending balance at December 31, 2017	$1,986	$1,231	$421	$3,638

Chargebacks, discounts, fees, and returns are recorded as reductions of trade receivables, net on the consolidated balance sheets. Government and other rebates are recoded as a component of accrued expenses and other current liabilities on the consolidated balance sheets. Credits and payments for the twelve months ended December 31, 2017 are not significant.

13. Net Loss Per Share

Basic and diluted net loss per share is calculated as follows (in thousands, except share and per share amounts):

	Year Ended December 31,		
	2017	2016	2015
Numerator:			
Net loss	$ (254,237)	$ (182,804)	$ (101,526)
Loss attributable to common stockholders—basic	(254,237)	(182,804)	(101,526)
Effect of dilutive convertible preferred stock	—	—	—
Loss attributable to common stockholders—diluted	$ (254,237)	$ (182,804)	$ (101,526)
Denominator:			
Weighted-average number of common shares used in loss per share—basic and diluted	43,804,660	43,067,952	39,643,099
Loss per share—basic and diluted	$ (5.80)	$ (4.24)	$ (2.56)

The following potentially dilutive securities, prior to the use of the treasury stock method, have been excluded from the computation of diluted weighted-average shares outstanding, as they would be anti-dilutive. For the years ended December 31, 2017, 2016, and 2015 all of the Company's classes of convertible preferred stock, options to purchase common stock, warrants and performance units outstanding were assumed to be anti-dilutive as earnings attributable to common stockholders was in a loss position.

	Year Ended December 31		
	2017	2016	2015
Convertible preferred stock	—	—	—
Options to purchase common stock	5,647,895	6,373,542	4,408,369
Warrants	605,415	605,415	631,587
Restricted Stock Units	146,451	56,250	—

14. License Agreements

Ipsen

In September 2005, the Company entered into a license agreement (the "License Agreement"), as amended, with an affiliate of Ipsen Pharma SAS ("Ipsen") under which the Company exclusively licensed certain Ipsen compound technology and related patents covering abaloparatide to research, develop, manufacture, and commercialize certain compounds and related products in all countries, except Japan (where the Company has an option to negotiate a co-promotion agreement for abaloparatide-SC) and France (where the Company's commercialization rights were subject to certain co-marketing and co-promotion rights exercisable by Ipsen, provided that certain conditions included in the License Agreement were met). The Company believes that Ipsen's co-marketing and co-promotion rights in France have permanently expired. Ipsen also granted the Company an exclusive right and license under the Ipsen compound technology and related patents to make, and have made, compounds or products in Japan. Ipsen further granted the Company an exclusive right and license under certain Ipsen formulation technology and related patents solely for purposes of enabling the Company to develop, manufacture, and commercialize compounds and products covered by the compound technology license in all countries, except Japan and France (as discussed above).

In consideration for these rights, the Company made nonrefundable, non-creditable payments in aggregate of $13.0 million to Ipsen, including payment in recognition of certain milestones having been achieved through December 31, 2017. The License Agreement provides for further payments upon the achievement of certain future regulatory and commercial milestones. Total additional milestone payments that could be payable under the agreement is €24.0 million (approximately $28.7 million). In connection with the FDA's approval of TYMLOS in April 2017, the Company paid Ipsen a milestone of €8.0 million (approximately $8.7 million) under the License Agreement, which the Company recorded as an intangible asset within the consolidated balance sheet and will amortize over the remaining patent life or the estimated useful life of the underlying product. The agreement provides that the Company would pay to Ipsen a fixed five percent royalty based on net sales of the product by the Company or its sublicensees on a country-by-country basis until the later of the last to expire of the licensed patents or for a period of 10 years after the first commercial sale in such country. The royalty expense was $0.6 million for the year ended December 31, 2017. The date of the last to expire of the abaloparatide patents licensed from or co-owned with Ipsen, barring any extension thereof, is expected to be March 26, 2028.

If the Company sublicenses abaloparatide to a third party, then the agreement provides that the Company would pay Ipsen a percentage of certain payments received from such sublicensee (in lieu of milestone payments not achieved at the time of such sublicense). The applicable percentage is in the low double digit range. In addition, if the Company or its sublicensees commercialize a product that includes a compound discovered by it based on or derived from confidential Ipsen know-how, then the agreement provides that the Company would pay to Ipsen a fixed low single digit royalty on net sales of such product on a country-by-country basis until the later of the last to expire of licensed patents that cover such product or for a period of 10 years after the first commercial sale of such product in such country.

The License Agreement expires on a country-by-country basis on the later of (1) the date the last remaining valid claim in the licensed patents expires in that country, or (2) a period of 10 years after the first commercial sale of the licensed products in such country, unless it is sooner terminated in accordance with its terms.

The Company is currently in arbitration proceedings with Ipsen in connection with the License Agreement. See "Legal Proceedings" for more information.

Eisai Co. Ltd.

In June 2006, the Company entered into a license agreement (the "Eisai Agreement"), with Eisai Co. Ltd., ("Eisai"). Under the Eisai Agreement, Eisai granted to the Company an exclusive right and license to research, develop, manufacture and commercialize elacestrant and related products from Eisai in all countries, except Japan. In consideration for the rights to elacestrant, the Company paid Eisai an initial license fee of $0.5 million, which was expensed during 2006. In March 2015, the Company entered into an amendment to the Eisai Agreement (the "Eisai Amendment") in which Eisai granted to the Company the exclusive right and license to research, develop, manufacture and commercialize elacestrant in Japan. In consideration for the rights to elacestrant in Japan, the Company paid Eisai a license fee of $0.4 million upon execution of the Eisai Amendment, which was recognized as research and development expense in 2015. The Eisai Amendment, as amended, also provides for additional payments of up to $22.3 million, payable upon the achievement of certain clinical and regulatory milestones.

Under the Eisai Agreement, as amended, should a product covered by the licensed technology be commercialized, the Company will be obligated to pay to Eisai royalties in a variable mid-single digit range based on net sales of the product on a country-by-country basis. The royalty rate will be reduced, on a country-by-country basis, at such time as the last remaining valid claim in the licensed patents expires, lapses or is invalidated and the product is not covered by data protection clauses. In addition, the royalty rate will be reduced, on a country-by-country basis, if, in addition to the conditions specified in the previous sentence, sales of lawful generic versions of such product account for more than a specified minimum percentage of the total sales of all

products that contain the licensed compound during a calendar quarter. The latest licensed patent is expected to expire, barring any extension thereof, on August 18, 2026.

The Eisai Agreement, as amended, also grants the Company the right to grant sublicenses with prior written approval from Eisai. If the Company sublicenses the licensed technology to a third party, the Company will be obligated to pay Eisai, in addition to the milestones referenced above, a fixed low double digit percentage of certain fees received from such sublicensee and royalties in the low single digit range based on net sales of the sublicensee. The license agreement expires on a country-by-country basis on the later of (1) the date the last remaining valid claim in the licensed patents expires, lapses or is invalidated in that country, the product is not covered by data protection clauses, and the sales of lawful generic versions of the product account for more than a specified percentage of the total sales of all pharmaceutical products containing the licensed compound in that country; or (2) a period of 10 years after the first commercial sale of the licensed products in such country, unless it is sooner terminated.

Duke

In December 2017, the Company entered into a License Agreement with Duke University ("Duke") (collectively "Duke License Agreement") pursuant to which Radius acquired the exclusive worldwide license to certain Duke patents associated with elacestrant (RAD1901) related to the use of elacestrant in the treatment of breast cancer as a monotherapy and in a combination therapy (collectively "Duke Patents").

In consideration for these rights, the Company incurred non-refundable, non-creditable obligations to pay Duke, totaling $1.3 million, which were expensed as research and development during 2017. The Duke License Agreement provides for further payments upon the achievement of certain future regulatory and commercial milestones totaling up to $3.8 million. The agreement provides that the Company would pay Duke a fixed low single-digit royalty based on net sales, on a country-by-country basis, beginning in August 2029 and ending upon expiration of the last patent rights to expire.

If the Company sublicenses the Duke Patents to a third party, the agreement provides that the Company will pay Duke a percentage of certain payments received by it from such sublicensee(s). The applicable percentage is in the high single-digit range on certain payments received in excess a pre-specified amount. The License Agreement may be terminated by Duke upon a material uncured breach of the License Agreement. The Company may terminate the License Agreement upon 60 days written notice.

Teijin Limited

In July 2017, the Company entered into a License and Development Agreement (the "Teijin Agreement") with Teijin Limited ("Teijin") for abaloparatide-SC in Japan.

Pursuant to the Teijin Agreement, the Company granted Teijin: (i) an exclusive payment-bearing license under certain of the Company's intellectual property to develop and commercialize abaloparatide-SC in Japan, (ii) a non-exclusive payment-bearing license under certain of the Company's intellectual property to manufacture abaloparatide-SC for commercial supply in Japan, (iii) a right of reference to certain of the Company's regulatory data related to abaloparatide-SC for purposes of developing, manufacturing and commercializing abaloparatide-SC in Japan, (iv) a manufacture transfer package, upon Teijin's request, consisting of information and the Company's know-how that is necessary for the manufacture of active pharmaceutical ingredient and abaloparatide-SC, and (v) right, at Teijin's request, to have the Company manufacture (or arrange for a third party to manufacture) and supply (or arrange for a third party to supply) the active pharmaceutical ingredient for the clinical supply of abaloparatide-SC in sufficient quantities to enable Teijin to conduct its clinical trials in Japan. In consideration for these rights, the Company received an upfront payment of $10.0 million, and may receive further payments upon the achievement of certain regulatory and sales milestones, as well as a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan

during the royalty term, as defined below. In addition, the Company has an option to negotiate a co-promotion agreement with Teijin for abaloparatide-SC in Japan upon commercialization.

Pursuant to the Teijin Agreement, the parties may further collaborate on new indications for abaloparatide-SC, and the Company also maintains full global rights to its development program for abaloparatide-patch, which is not part of the Teijin Agreement.

Unless earlier terminated, the Teijin Agreement expires on the later of the (i) date on which the use, sale or importation of abaloparatide-SC is no longer covered by a valid claim under the Company's patent rights licensed to Teijin in Japan, (ii) expiration of marketing or data exclusivity for abaloparatide-SC in Japan, or (iii) 10th anniversary of the first commercial sale of abaloparatide-SC in Japan.

The Company assessed this arrangement in accordance with Topic 606 and concluded that the contract counterparty, Teijin, is a customer. The Company identified the following material promises under the contract: the commercialization and manufacturing licenses under certain intellectual property rights relating to abaloparatide-SC in Japan, as well as the right of reference to certain regulatory information. In addition, the Company identified the following customer option that would create an obligation for the Company if exercised by Teijin—the transfer of manufacturing know-how. The customer option for the transfer of manufacturing know-how represents a material right. Finally, the Company also identified the following customer option that would create a manufacturing obligation for the Company if exercised by Teijin—the supply of abaloparatide-SC for Teijin's clinical trial needs. The customer option for clinical supply of abaloparatide-SC does not represent a material right. Based on these assessments, the Company identified the (i) commercialization and manufacturing licenses, as well as the right of reference to certain regulatory information, and (ii) transfer of manufacturing know-how as the only performance obligations at the inception of the arrangement, which were both deemed to be distinct.

The Company further determined that the up-front payment of $10.0 million constituted the entirety of the consideration to be included in the transaction price, which was allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. For the commercialization and manufacturing licenses, including the right of reference to certain regulatory information, the stand-alone selling price was calculated using the expected cost approach by leveraging the direct costs incurred by the Company in its recently completed ACTIVExtend Phase 3 clinical trial for abaloparatide-SC, plus an estimated inflation rate. The stand-alone selling price of the transfer of manufacturing know-how was computed using a cost-plus margin approach reflecting the level of effort required, which can be reasonably estimated to be incurred over the performance period, multiplied by a fully-burdened internal labor rate plus an expected margin. Based on the estimates of the stand-alone selling prices for each of the performance obligations, as referenced above, the Company determined that substantially all of the $10.0 million transaction price should be allocated to the performance obligation for the commercialization and manufacturing licenses, including the right of reference to certain regulatory information. The consideration allocated to the performance obligation for the transfer of manufacturing know-how was immaterial. The Company believes that a change in the assumptions used to determine its best estimate of the selling price for the commercialization and manufacturing licenses, including the right of reference to certain regulatory information, would not have a significant effect on the allocation of the underlying consideration to the performance obligations.

Upon execution of the Teijin Agreement, the transaction price included only the $10.0 million up-front payment owed to the Company. As referenced above, the Company may receive further payments upon the achievement of certain regulatory and sales milestones, totaling up to $40.0 million, as well as a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term. The future regulatory milestone, which represents variable consideration that was evaluated under the most likely amount method, has not been included in the transaction price, because the amount was fully constrained as of December 31, 2017. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestone is outside the control of the Company. Separately, any consideration

related to sales-based milestones as well as royalties on net sales upon commercialization by Teijin, will be recognized when the related sales occur as they were determined to relate predominantly to the licenses granted to Teijin and, therefore, have also been excluded from the transaction price in accordance with the sales-based royalty exception. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur.

During the year ended December 31, 2017, the Company recognized $10.0 million of license revenue, as it had satisfied its promises under the performance obligation for the commercialization and manufacturing licenses, including the right of reference to certain regulatory information, by transferring them at a point in time during the year.

15. Research Agreements

Abaloparatide-SC Phase 3 Clinical Trial

The Company contracted with Nordic Bioscience Clinical Development VII A/S ("Nordic") to conduct the Company's Phase 3 clinical trial of abaloparatide-SC (the "Phase 3 Clinical Trial"). The Company also contracted with Nordic for Nordic to perform an extension study to evaluate six months of standard-of-care osteoporosis management following the completion of the Phase 3 Clinical Trial (the "Extension Study"), and, upon completion of this initial six months, an additional period of 18 months of standard-of-care osteoporosis management (the "Second Extension").

In April 2015, the Company contracted with Nordic to perform additional services, including additional monitoring of patients enrolled in the Second Extension. Payments in cash to be made to Nordic for these additional services are denominated in euros and total up to approximately €4.1 million (approximately $4.3 million).

Payments in cash to be made to Nordic for the services related to the Extension Study and Second Extension are denominated in both euros and U.S. dollars and total up to €11.9 million (approximately $12.5 million) and $1.1 million, respectively. As of December 31, 2017, the last patient's final visit in the Second Extension had occurred and all obligations due to Nordic in relation to the Extension Study have been paid.

16. Income Taxes

For the year ended December 31, 2017, 2016, and 2015 no income tax expense was recorded due to the Company's net operating losses (NOLs) and full valuation allowance.

A reconciliation of income taxes computed using the U.S. federal statutory rate to that reflected in operations follows (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Income tax benefit using U.S. federal statutory rate	$(86,426)	$(62,141)	$(34,391)
State income taxes, net of federal benefit	(22,148)	(5,236)	(4,434)
Stock-based compensation	(5,909)	1,585	752
Research and development tax credits	(2,468)	(2,794)	(1,469)
Effect of federal tax law change	82,767	—	—
Other adjustments—ASU 2016-09 adoption	6,135	—	—
Change in the valuation allowance	(19,198)	48,096	39,291
Convertible note	47,016	—	—
Permanent items	543	53	26
Other	(312)	1,371	225
Expiring NOLs and credits—382 Limitation	—	19,066	—
Income tax expense	$ —	$ —	$ —

The Company is subject to Massachusetts net worth taxes, not based on income, which is largely offset by allowable tax credits and recorded as a component of operating expenses.

The principal components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2017	2016
Deferred tax assets:		
NOL carryforwards	$ 207,620	$ 193,436
Capitalized research and development	1,411	1,970
Research and development credits	5,313	4,525
Depreciation	37	—
Accrued expenses	3,846	3,109
Stock-based compensation	15,040	14,903
UNICAP	234	—
Allowance for bad debt	346	—
Other	91	55
Gross non-current deferred tax assets	233,938	217,825
Valuation allowance	(233,938)	(217,825)
Net non-current deferred tax assets	$ —	$ —
Deferred tax liabilities:		
Depreciation	$ —	$ (173)
Convertible debt	(35,311)	—
Gross non-current deferred tax liabilities	(35,311)	(173)
Valuation allowance	35,311	173
Net non-current deferred tax liabilities	$ —	$ —

FASB ASC 740—Income Taxes requires that a valuation allowance be established to reduce a deferred tax asset to its realizable value when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence needs to be considered, including the utilization of past tax credits and length of carry-back and carry-forward periods, reversal of temporary differences, tax planning strategies, our current and past performance, the market environment in which we operate, and the evaluation of tax planning strategies to generate future taxable income.

The Company has recorded a valuation allowance against its deferred tax assets in each of the years ended December 31, 2017, 2016, and 2015, because the Company's management believes that it is more likely than not that these assets will not be realized. The increase in the valuation allowance in 2017 primarily relates to the net loss incurred by the Company.

As of December 31, 2017, the Company had federal and state net operating loss ("NOL") carryforwards of approximately $751.7 million and $669.3 million, respectively, which may be used to offset future taxable income.

As of December 31, 2017, the Company also had federal and state tax credits of $4.4 million and $1.2 million, respectively, to offset future tax liabilities. The federal general business and state research and

development tax credits will expire at various dates through 2037. During 2017, a formal study was conducted to document the qualified research activities of the Company for the years ended December 31, 2014 through December 31, 2016. The study resulted in $0.2 million of additional tax credit carryforward which has been fully offset by a valuation allowance.

The Company adopted ASU 2016-09, Compensation—Stock Compensation (Topic 718): Improvement to Employee Share-Based Payment Accounting. Upon adoption of this standard on January 1, 2017, the Company has recognized their previously unrecognized excess tax benefits, which resulted in a cumulative-effect increase of $6.1 million to their deferred tax assets along with an increase to the corresponding valuation allowance against these deferred tax assets. At December 31, 2016, $16.1 million of the federal and state NOL carryforwards relate to excess stock-based compensation tax benefits.

The Company applies the accounting guidance in ASC 740 related to accounting for uncertainty in income taxes. The Company's reserves related to taxes are based on a determination of whether, and how much of, a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. As of December 31, 2017, the unrecognized tax benefit was $1.3 million which, if recognized, will not affect the annual effective tax rate as these unrecognized tax benefits would increase deferred tax assets which would be subject to a full valuation allowance. A reconciliation of the beginning and ending amount of unrecognized tax benefit is as follows (in thousands):

	Uncertain Tax Position
Balance at December 31, 2016	$ (78)
Decreases related to prior year tax positions	(2,042)
Increases related to prior year tax positions	2,120
Decreases related to current year tax positions	—
Increases related to current year tax positions	1,263
Ending uncertain tax benefits	$ 1,263

In 2016, we completed an evaluation of our tax attributes through December 31, 2015 as outlined under Section 382 of the Internal Revenue Code, which resulted in a reduction of our NOL and credit carryforwards. We have adjusted our NOL and credit carryforwards, and the related valuation allowance, according to the results of this evaluation.

The Company and its subsidiaries file income tax returns in the United States, as well as various state and foreign jurisdictions. Generally, the tax years 2014 through 2016 remain open to examination by the major taxing jurisdictions to which the Company is subject. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, or state or foreign tax authorities, to the extent utilized in a future period.

No interest or penalties have been recorded for the years ended December 31, 2017, 2016, or 2015. The Company does not expect any significant change in its uncertain tax positions in the next 12 months.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Reform Act. The Company has recognized the provisional tax impacts related to the revaluation of the deferred tax assets and liabilities and included these amounts in its consolidated financial

statements for the year ended December 31, 2017. The ultimate impact may differ from these provisional amounts due to, among other things, additional analysis, changes in interpretations and assumptions the Company has made, additional regulatory guidance that may be issued, and actions the Company may take as a result of the Tax Reform Act. The accounting is expected to be complete when the 2017 U.S. corporate income tax return is filed in 2018. Among other changes, the Act reduces to the federal tax rate down to 21%. In regard to the change in the federal tax rate as it relates to the Company's deferred tax assets and liabilities, we have decreased our related deferred tax assets by $82.8 million along with the corresponding valuation allowance against these deferred tax assets.

17. Commitments and Contingencies

Litigation—The Company may be subject to legal proceedings and claims which arise in the ordinary course of its business. In the Company's opinion, the ultimate resolution of these matters is not expected to have a material effect on its consolidated financial statements. The Company records a liability in its consolidated financial statements for these matters when a loss is known or considered probable and the amount can be reasonably estimated. The Company reviews these estimates each accounting period as additional information is known and adjusts the loss provision when appropriate. If a matter is both probable to result in a liability and the amounts of loss can be reasonably estimated, the Company estimates and discloses the possible loss or range of loss to the extent necessary to make the consolidated financial statements not misleading. If the loss is not probable or cannot be reasonably estimated, a liability is not recorded in its consolidated financial statements.

In November 2016, we received notice that in October 2016, Ipsen had initiated arbitration proceedings against us in the International Chamber of Commerce's International Court of Arbitration. Ipsen's Request for Arbitration alleged that we breached various provisions of the License Agreement concerning abaloparatide, including with regard to Ipsen's right to co-promote abaloparatide in France and a license from us with respect to Japan. Ipsen is seeking declaratory relief, compliance with the License Agreement, damages, costs and fees as a result of the purported breaches and has alleged the monetary value of these claims is approximately €50 million (approximately $59.9 million).

In January 2017, we submitted an Answer denying Ipsen's claims and alleging counterclaims against Ipsen for breach of the License Agreement and other declaratory judgment. We asserted, among other things, that Ipsen's claimed rights to co-promote abaloparatide in France and to a license from us with respect to Japan have permanently expired, and that Ipsen has breached the License Agreement by, among other things, allowing certain patents to expire and by purporting to license to a third party certain manufacturing and other rights that we contend Ipsen exclusively licensed to us. We are seeking dismissal of Ipsen's claims, as well as declaratory relief, compliance with the License Agreement, and other damages, costs and fees to be determined by the Arbitral Tribunal.

In February 2017, Ipsen submitted a Reply denying our counterclaims and alleging that we are precluded from asserting them. Following a preliminary hearing before the Arbitral Tribunal to determine certain jurisdictional and contractual defenses asserted by Ipsen in its Reply, on July 17, 2017, the Arbitral Tribunal issued a decision finding it has jurisdiction to decide our counterclaims and that our counterclaims are not contractually barred.

On July 31, 2017, Ipsen submitted its Statement of Claim to the Arbitral Tribunal and on September 14, 2017 Radius submitted its Statement of Defense and Counterclaims. Subsequently, on October 20, 2017, Ipsen submitted its Reply and Statement of Defense to Radius's Counterclaims and on November 10, 2017, Radius submitted its Rejoinder on Claims and Reply on Counterclaims. Ipsen submitted a Rejoinder on Counterclaims on November 24, 2017. A hearing on the merits was held on December 18 and 19, 2017, and additional submissions on cost and fee allocation were made on February 9, 2018. We expect a final decision by the Arbitral Tribunal in the first half of 2018. Until we receive a decision from the Arbitral Tribunal, we cannot predict or assess the likely outcome of these proceedings.

Commitments—The Company leases certain office space in Massachusetts, New Jersey and Pennsylvania under non-cancellable operating leases that expire over various terms through the end of 2020.

The Company is obligated to make monthly rent payments pursuant to these non-cancellable agreements as set forth below (in thousands):

Years ended December 31,	Future Lease Commitments
2018	$ 2,682
2019	2,307
2020	2,163
2021	1,029
2022	1,038
Thereafter	2,843
Total minimum lease payments	$12,062

Rent expense for the years ended December 31, 2017, 2016, and 2015 was $3.4 million, $2.8 million and $0.6 million, respectively.

Manufacturing Agreements—In June 2016, the Company entered into a Supply Agreement with Ypsomed AG, pursuant to which Ypsomed agreed to supply commercial and clinical supplies of a disposable pen injection device customized for subcutaneous injection of abaloparatide. The Company has agreed to purchase a minimum number of devices at prices per device that decrease with an increase in quantity supplied. In addition, the Company has agreed to make milestone payments for Ypsomed's capital developments in connection with the initiation of the commercial supply of the device and to pay a one-time capacity fee. All costs and payments under the agreement are delineated in Swiss Francs. The agreement has an initial term of three years from the earlier of the date of delivery of the first commercial batch of devices after regulatory approval and June 1, 2017, after which, it automatically renews for two-year terms until terminated. The Company will purchase the device subject to minimum annual quantity requirements over the initial three-year term of the agreement. The Company is required to purchase a minimum number of batches for CHF 2.4 million ($2.5 million) through the year ended December 31, 2022.

In June 2016, the Company entered into a Commercial Supply Agreement with Vetter Pharma International GmbH, pursuant to which Vetter has agreed to formulate the finished abaloparatide-SC drug product containing the active pharmaceutical ingredient of abaloparatide, to fill cartridges with the drug product, to assemble the pen delivery device, and to package the pen for commercial distribution. The Company has agreed to purchase the cartridges and pens in specified batch sizes at a price per unit. For labeling and packaging services, the Company has agreed to pay a per unit price dependent upon the number of pens loaded with cartridges that are labeled and packaged. These prices are subject to an annual price adjustment. The agreement has an initial term of five years, which began on January 1, 2016, after which, it automatically renews for two-year terms unless either party notifies the other party two years before the end of the then-current term that it does not intend to renew.

In July 2016, the Company entered into a Manufacturing Services Agreement with Polypeptide Laboratories Holding AB, as successor-in-interest to Lonza Group Ltd., pursuant to which PPL has agreed to manufacture the commercial and clinical supplies of the API for abaloparatide. The Company has agreed to purchase the API in batches at a price per gram in euros, subject to an annual increase by PPL. The Company is also required to purchase a minimum number of batches annually, equal to €2.9 million ($3.4 million) per year and $17.2 million in total through the year ended December 31, 2022. The agreement has an initial term of a six years, after which,

it automatically renews for three-year terms unless either party provides notice of non-renewal 24 months before the end of the then-current term.

18. Subsequent Events

In February 2018, the Company entered into a Scale-Up and Commercial Supply Agreement with 3M (the "3M Supply Agreement"). Pursuant to the 3M Supply Agreement, 3M has agreed to exclusively manufacture Phase 3 and global commercial supplies of an abaloparatide-coated patch product and associated applicator device for Radius. The 3M Supply Agreement has an initial term ending five years after the first commercial sale of the product.

Under the 3M Supply Agreement, Radius will pay 3M a mid-to-low single digit royalty on worldwide net sales of the product. Radius is also responsible for providing supplies of abaloparatide to be used in the manufacturing of the patch product and will reimburse 3M for certain capital expenditures incurred to establish commercial supply of the product, which include scale-up and regulatory costs.

19. Selected Quarterly Financial Data (Unaudited)

Selected quarterly financial data for the years ended December 31, 2017 and 2016 is as follows (in thousands, except for share and per share data):

	Three Months Ended			
	March 31,	June 30,	September 30,	December 31,
2017:				
Net revenue	$ —	$ 980	$ 13,469	$ 7,663
Gross profit	—	875	13,016	6,889
Net loss	(56,939)	(68,438)	(57,843)	(71,017)
Net loss applicable to common stock	(56,939)	(68,438)	(57,843)	(71,017)
Net loss per share—basic and diluted	(1.32)	(1.58)	(1.31)	(1.59)
Weighted-average common shares outstanding—basic and diluted	43,185,952	43,410,053	43,999,451	44,602,254
2016:				
Net loss	$ (40,463)	$ (43,435)	$ (46,186)	$ (52,720)
Net loss applicable to common stock	(40,463)	(43,435)	(46,186)	(52,720)
Net loss per share—basic and diluted	(0.94)	(1.01)	(1.07)	(1.22)
Weighted-average common shares outstanding—basic and diluted	43,012,924	43,042,883	43,092,921	43,122,210

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

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures and internal control over financial reporting, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures and internal control over financial reporting must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2017.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2017, based on the criteria set forth in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on that assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2017.

The effectiveness of our internal control over financial reporting as of December 31, 2017 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report which is contained in Item 9A of this Annual Report on Form 10-K.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting during the quarter ended December 31, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors of Radius Health, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Radius Health, Inc.'s internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Radius Health, Inc. (the "Company") maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the 2017 financial statements of the Company and our report dated March 1, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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 (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 (3) 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/ Ernst & Young LLP

Boston, Massachusetts
March 1, 2018

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required with respect to this item will be set forth in our definitive Proxy Statement to be delivered to our stockholders in connection with our Annual Meeting of Stockholders, which currently is expected to be held on June 6, 2018. Such information is incorporated herein by reference.

Our Board of Directors adopted a Code of Conduct and Ethics applicable to the Board of Directors, our Chief Executive Officer, Chief Financial Officer, other officers of Radius and all other employees of Radius. The Code of Conduct and Ethics is available on our website, http://radiuspharm.com.

We intend to disclose on our website any amendments to, or waivers from, our Code of Conduct and Ethics that are required to be disclosed pursuant to SEC rules.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. The code of business conduct and ethics is available on our website at http://radiuspharm.com. Any amendments to the code, or any waivers from its requirements, will be disclosed on our website. Information contained on or accessible through our website is not incorporated by reference into this report, and you should not consider information contained on or accessible through our website to be part of this report.

The remainder of the response to this item will be set forth in our definitive Proxy Statement for our 2018 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

The information required to be disclosed by this item will be set forth in our definitive Proxy Statement for our 2018 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required to be disclosed by this item will be set forth in our definitive Proxy Statement for our 2018 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required to be disclosed by this item will be set forth in our definitive Proxy Statement for our 2018 Annual Meeting of Stockholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required to be disclosed by this item will be set forth in our definitive Proxy Statement for our 2018 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

• Financial Statements

The following consolidated financial statements and supplementary data are included in Part II of Item 8 filed of this Annual Report on Form 10-K:

• Financial Statement Schedules

All financial statement schedules have been omitted because they are not applicable or are not required, or because the information required to be set forth therein is included in the consolidated financial statements or notes thereto.

• Exhibits

The Exhibit Index follows Item 16 and is incorporated herein by reference.

ITEM 16. FORM 10-K SUMMARY.

Not applicable.

EXHIBIT INDEX

Unless otherwise indicated, all references to previously filed Exhibits refer to the Company's filings with the Securities and Exchange Commission, or SEC, under File No. 001-35726.

Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
3.1	Restated Certificate of Incorporation	8-K		3.1	6/13/2014	
3.2	Amended and Restated By-Laws					*
4.1	Fifth Amended and Restated Stockholders' Agreement, dated April 24, 2014, between the Company and the stockholders party thereto	S-1/A	333-194150	4.2	4/25/2014	
4.2	Base Indenture, dated as of August 14, 2017, between the Company and Wilmington Trust, National Association	8-K		4.1	8/14/2017	
4.3	First Supplemental Indenture, dated as of August 14, 2017, between the Company and Wilmington Trust, National Association	8-K		4.2	8/14/2017	
4.4	Form of 3.00% Convertible Senior Note due 2024 (included in Exhibit 4.2)	8-K		4.3	8/14/2017	
	Management Contracts and Compensatory Plans					
10.1	Radius Health, Inc. 2003 Long-Term Incentive Plan (as amended)	10-K		10.20	3/10/2015	
10.1(a)	Radius Health, Inc. 2003 Long-Term Incentive Plan Form of Stock Option Agreement	8-K	000-53173	10.32	5/23/2011	
10.2	Radius Health, Inc. 2011 Equity Incentive Plan (as amended and restated)	8-K		10.1	5/27/2016	
10.2(a)	Form of Radius Health, Inc. 2011 Equity Incentive Plan Stock Option Agreement for Incentive Stock Options	10-K		10.2(a)	2/24/2017	
10.2(b)	Form of Radius Health, Inc. 2011 Equity Incentive Plan Stock Option Agreement for Non-Incentive Stock Options	10-K		10.2(b)	2/24/2017	
10.2(c)	Form of Radius Health, Inc. 2011 Equity Incentive Plan Restricted Stock Unit Grant Notice and Restricted Stock Unit Agreement, attached as Exhibit A thereto	10-K		10.2(c)	2/24/2017	
10.3	Radius Health, Inc. 2016 Employee Stock Purchase Plan	8-K		10.2	5/27/2016	
10.4	Radius Health, Inc. Amended and Restated Non-Employee Director Compensation Program					*

Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
10.5	Employment Letter Agreement, dated November 14, 2003, between the Company, as successor to Nuvios, Inc., and Gary Hattersley	8-K	000-53173	10.49	5/23/2011	
10.5(a)	Executive Severance Agreement, dated July 1, 2015, between the Company and Gary Hattersley	8-K		10.2	7/10/2015	
10.6	Employment Letter Agreement, dated November 15, 2006, between the Company, as successor to Radius Health, Inc., and B. Nicholas Harvey	8-K	000-53173	10.51	5/23/2011	
10.6(a)	Executive Severance Agreement, dated July 1, 2015, between the Company and B. Nicholas Harvey	8-K		10.1	7/10/2015	
10.6(b)	Separation Agreement and General Release of Claims, dated May 15, 2017, between the Company and B. Nicholas Harvey.	8-K		10.3	5/15/2017	
10.6(c)	Consulting Agreement, dated May 17, 2017, between the Company and B. Nicholas Harvey	8-K		10.4	5/15/2017	
10.7	Executive Employment Agreement, dated December 12, 2013, between the Company and Robert Ward	8-K		10.1	12/17/2013	
10.7(a)	First Amendment, dated July 1, 2015, to Executive Employment Agreement, dated December 12, 2013, between the Company and Robert Ward	10-Q		10.1	5/2/2017	
10.7(b)	Agreement and General Release, dated July 16, 2017, between the Company and Robert Ward	8-K		10.3	7/17/2017	
10.8	Employment Letter Agreement, dated January 3, 2014, between the Company and Greg Williams	S-1/A	333-194150	10.141	4/3/2014	
10.8(a)	Executive Severance Agreement, dated July 1, 2015, between the Company and Greg Williams	8-K		10.4	7/10/2015	
10.9	Employment Letter Agreement, dated December 28, 2014, between the Company and Brent Hatzis-Schoch	10-K		10.9	2/24/2017	
10.10	Employment Letter Agreement, dated July 3, 2015, between the Company and Lorraine Fitzpatrick, M.D.	10-K		10.11	2/24/2017	

Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
10.11	Employment Letter Agreement, dated August 31, 2015, between the Company and David Snow	10-K		10.12	2/24/2017	
10.12	Form of Executive Severance Agreement between the Company and Jose Carmona, David Snow, Lorraine Fitzpatrick, and Brent Hatzis-Schoch	10-K		10.13	2/24/2017	
10.12(a)	Form of Executive Severance Agreement between the Company and Joseph Kelly					*
10.13	Employment Letter Agreement, dated May 9, 2017, between the Company and Jose Carmona	8-K		10.1	5/15/2017	
10.13(a)	Employment Inducement Stock Option Agreement, dated May 15, 2017, between the Company and Jose Carmona	8-K		10.2	5/15/2017	
10.14	Employment Agreement, dated June 23, 2017, between the Company and Jesper Høiland	8-K		10.1	7/17/2017	
10.14(a)	First Amendment to Employment Agreement between the Company and Jesper Høiland	8-K		10.1	11/16/2017	
10.14(b)	Employment Inducement Stock Option Agreement, dated July 17, 2017, between the Company and Jesper Høiland	8-K		10.2	7/17/2017	
10.15	Employment Letter Agreement, dated November 10, 2017, between the Company and Joseph Kelly					*
10.15(a)	Employment Inducement Stock Option Agreement, dated November 27, 2017, between the Company and Joseph Kelly					*
10.16	Form of Indemnification Agreement between the Company and its directors	10-K		10.30	3/10/2015	
	Other Agreements					
10.17	Form of Warrant to Purchase Shares of Common Stock in connection with the Series B Convertible Preferred Stock and Warrant Purchase Agreement, issued by the Company to certain investors and attached schedule with details	8-K		10.2	4/25/2013	

Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
10.18	Form of Warrant to Purchase Shares of Common Stock in connection with the Series B-2 Convertible Preferred Stock and Warrant Purchase Agreement, issued by the Company to certain investors and attached schedule with details	8-K		10.2	2/21/2014	
10.19	Form of Warrant to Purchase Shares of Series A-1 Convertible Preferred Stock issued by the Company to GE Capital Equity Investments	10-K		10.5	3/10/2015	
10.20^	License Agreement, dated September 27, 2005, between the Company, as successor to Nuvios, Inc., and Ipsen Pharma SAS (f/k/a SCRAS S.A.S.) on behalf of itself and its affiliates, as amended on September 12, 2007 and May 11, 2011	10-K		10.15	3/10/2015	
10.21^	Development and Clinical Supplies Agreement, dated June 19, 2009, between the Company, as successor to Radius Health, Inc., 3M Co. and 3M Innovative Properties Co., as amended on December 31, 2009, September 16, 2010, September 29, 2010, March 2, 2011 and November 30, 2012	10-K		10.18	3/10/2015	
10.22^	License Agreement, dated June 29, 2006, between the Company and Eisai Co., Ltd.	8-K/A	000-53173	10.25	10/24/2011	
10.22(a)	License Agreement Amendment No. 1, dated March 9, 2015, between the Company and Eisai Co., Ltd.	10-Q		10.3	5/6/2015	
10.23^	License and Development Agreement, dated July 13, 2017, between the Company and Teijin Limited	10-Q		10.1	11/2/2017	
10.24^	Supply Agreement, dated June 23, 2016, between the Company and Ypsomed AG	10-Q		10.1	8/4/2016	
10.25^	Commercial Supply Agreement, dated June 28, 2016, between the Company and Vetter Pharma International GmbH	10-Q		10.2	8/4/2016	
10.26^	Manufacturing Services Agreement, dated July 13, 2016, between the Company and Polypeptide Laboratories Holding (PPL) AB, as successor to Lonza Sales Ltd	10-Q		10.1	11/3/2016	
10.27	Indenture of Lease, dated May 14, 2014, between the Company and BP Bay Colony LLC	8-K		10.1	5/20/2014	

Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
10.27(a)	First Amendment, dated September 9, 2015, to Lease, dated May 14, 2014, between the Company and BP Bay Colony LLC	10-Q		10.6	11/5/2015	
10.28	Lease, dated June 28, 2017, between the Company and KBSIII Crosspoint at Valley Forge Trust	10-Q		10.1	8/4/2017	
10.29	Sublease, dated March 11, 2016, between the Company and Rovi Corporation	10-Q		10.2	8/4/2017	
10.29(a)	First Amendment to Sublease, dated July 7, 2017, between the Company and Rovi Corporation	10-Q		10.3	8/4/2017	
10.29(b)	Amended and Restated First Amendment to Sublease, dated August 1, 2017, between the Company and Rovi Corporation	10-Q		10.4	11/2/2017	
21.1	Subsidiaries of the Company					*
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm					*
31.1	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer					*
31.2	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer					*
32.1	Section 1350 Certification of Chief Executive Officer					**
32.2	Section 1350 Certification of Chief Financial Officer					**
101.INS	XBRL Instance Document					*
101.SCH	XBRL Taxonomy Extension Schema Document					*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					*

^ Confidential treatment has been granted with respect to redacted portions of this exhibit. Redacted portions of this exhibit have been filed separately with the SEC.

* Filed herewith.

** Furnished herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this annual report to be signed on its behalf by the undersigned, thereunto duly authorized.

RADIUS HEALTH, INC.

By: /s/ JESPER HOILAND
Jesper Hoiland
President and Chief Executive Officer

Date: March 1, 2018

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ JESPER HOILAND Jesper Hoiland	Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2018
/s/ JOSE CARMONA Jose Carmona	Chief Financial Officer (Principal Accounting and Financial Officer)	March 1, 2018
/s/ WILLARD H. DERE Willard H. Dere	Director	March 1, 2018
/s/ CATHERINE FRIEDMAN Catherine Friedman	Director	March 1, 2018
/s/ JEAN-PIERRE GARNIER Jean-Pierre Garnier	Director	March 1, 2018
/s/ KURT C. GRAVES Kurt C. Graves	Director	March 1, 2018
/s/ OWEN HUGHES Owen Hughes	Director	March 1, 2018
/s/ ANTHONY ROSENBERG Anthony Rosenberg	Director	March 1, 2018
/s/ DEBASISH ROYCHOWDHURY Debasish Roychowdhury	Director	March 1, 2018