Use these links to rapidly review the document
TABLE OF CONTENTS
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
PART IV

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

OR

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

For the transition period from to

Commission file 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)

617-551-4000
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	RDUS	The Nasdaq Global Market

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☐	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, 2019 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 21, 2020: 46,217,719

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2020 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, 2019
INDEX

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., including our market access coverage expectations, and our ability to successfully commercialize TYMLOS in the U.S.;*
- *the therapeutic benefits and effectiveness of TYMLOS and our investigational product candidates and the potential indications and market opportunities therefor;*
- *our ability to obtain U.S. and foreign regulatory approval for our product candidates, including supplemental regulatory approvals for TYMLOS, 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 expectations regarding the timing of our regulatory submissions;*
- *our expectations for our Phase 3 studies of elacestrant and abaloparatide transdermal patch (abaloparatide-patch) or our other clinical trials, including projected costs, study designs or the timing for initiation, recruitment, completion, or reporting top-line data;*
- *our plans with respect to collaborations and licenses related to the development, manufacture or sale of TYMLOS and our investigational product candidates, including our plans to explore all strategic options for our oncology programs, including elacestrant (RAD1901) and RAD140;*
- *our plans with respect to expanding our product portfolio;*
- *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, the uncertainties inherent in the early stages of commercializing any new pharmaceutical product or the initiation, execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from our clinical trials, ongoing discussions with and actions by regulatory authorities, 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 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 January 1, 2020, TYMLOS was available and covered for approximately 290 million U.S. insured lives, representing approximately 99% of U.S. Commercial and 79% of Medicare Part D insured lives. 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 March 2018, we initiated 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. We expect to report top-line data from the study in the second half of 2021. In July 2018, we initiated a bone histomorphometry study to evaluate the early effects of TYMLOS on tissue-based bone remodeling and structural indices in postmenopausal women. Study enrollment is now complete, and we expect to present data from this study in the second half of 2020. In October 2018, the FDA approved a labeling supplement for TYMLOS to reflect that after 24 months of open-label alendronate therapy, the vertebral fracture risk reduction achieved with TYMLOS therapy was maintained. In January 2019, the European Commission adopted a decision refusing approval of our European Marketing Authorization Application ("MAA") for abaloparatide-SC.

We are developing an abaloparatide transdermal patch ("abaloparatide-patch"), for potential use in the treatment of postmenopausal women with osteoporosis. In May 2019, we received a special protocol assessment agreement from the FDA for our Phase 3 study of abaloparatide-patch. We initiated our Phase 3 wearABLe study of abaloparatide-patch in August 2019 and expect to report top-line data from the study in the second half of 2021. The wearABLe study is a single, pivotal, randomized, open label, active-controlled, bone mineral density ("BMD") non-inferiority bridging study with a planned enrollment of approximately 470 patients with postmenopausal osteoporosis at high risk of fracture, which, if successful, will support an NDA submission. The primary endpoint of the study is percentage change in lumbar spine BMD at 12 months. Non-inferiority of abaloparatide-patch to abaloparatide-SC will be concluded if the lower bound of the 2-sided 95% confidence interval for the estimated treatment difference (abaloparatide-patch minus abaloparatide-SC) in the percentage change from baseline in lumbar spine BMD at 12 months is above -2.0%. In February 2018, we entered into a Scale-Up and Commercial Supply Agreement (the "Supply Agreement") with 3M Company and 3M Innovative Properties Company (collectively with 3M Company, "3M") pursuant to which 3M agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-patch. In partnership with 3M, we selected Patheon N.V., now known as Thermo Fisher Scientific ("Thermo Fisher"), to conduct the abaloparatide-patch coating process and packaging operations. We have successfully completed development activities associated with the scale up of manufacturing to supply our ongoing abaloparatide-patch Phase 3 wearABLe study. We have also made significant progress scaling up for potential commercial batches, if our Phase 3 trial is successful and abaloparatide-patch is approved. In October 2018, we committed to fund 3M's purchase of capital equipment totaling approximately $9.6 million in preparation for manufacturing Phase 3 and potential commercial supplies of abaloparatide-patch. Milestone payments for the equipment commenced in the fourth quarter of 2018 and are expected to be paid in full in the second quarter of 2021. In addition, there are cancellable purchase commitments in place to fund the facility build out and future purchases of capital equipment. The completion of the engineering equipment designs for critical equipment to produce the abaloparatide-patch at the commercial site is on target, and critical equipment has started to arrive and is being installed. In December 2019, we aligned with the FDA on requirements for an NDA filing.

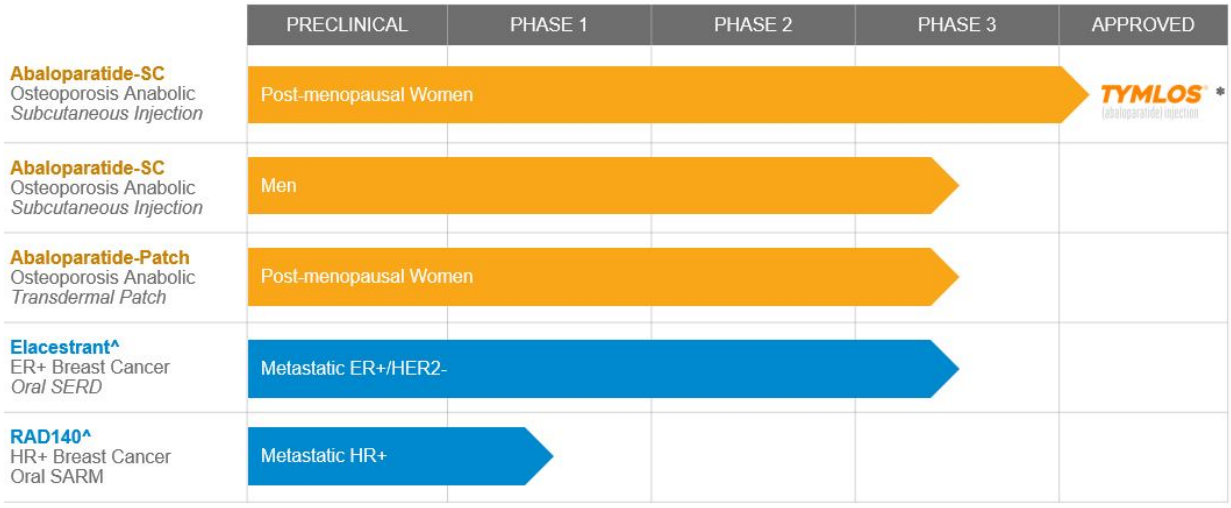
In connection with our strategic plans to focus on bone health and targeted endocrine diseases, we are exploring all strategic options for our oncology programs, including elacestrant (RAD1901) and RAD140. Our investigational product candidate, elacestrant (RAD1901), a selective estrogen receptor degrader ("SERD"), is being developed for potential use in the treatment of hormone receptor-positive breast cancer. We initiated our Phase 3 EMERALD study of elacestrant in late November 2018 and expect to complete enrollment in the third quarter of 2020. The Phase 3 study is a single, randomized, open label, active-controlled Phase 3 trial of elacestrant as a second or third-line monotherapy in approximately 460 patients with estrogen receptor-positive ("ER+") and human epidermal growth factor receptor 2-negative ("HER2-") advanced or

metastatic breast cancer who have received prior treatment with one or two endocrine therapies, including a cyclin-dependent kinase ("CDK") 4/6 inhibitor. Patients in the study will be randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent. The primary endpoint of the study will be progression-free survival ("PFS"), which we will analyze in the overall patient population and in patients with estrogen receptor 1 gene ("ESR1") mutations. Secondary endpoints will include evaluation of overall survival ("OS"), objective response rate ("ORR"), and duration of response ("DOR"). We believe that, depending on results, this single trial would support applications for marketing approvals for elacestrant as a second- and third-line monotherapy in the U.S., European Union ("EU"), and other markets. In November 2018, the FDA granted Fast Track designation for elacestrant for the population to be included in the Phase 3 study. We do not plan to initiate any further clinical development of elacestrant beyond the ongoing EMERALD study.

We developed 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 ER+/AR+/HER2- locally advanced or metastatic breast cancer. The clinical trial was designed to evaluate the safety and maximum tolerated dose ("MTD") of RAD140 in approximately 40 patients. Primary safety endpoints from the trial included the incidence 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 were evaluated. In December 2019, we presented the Phase 1A data based on a data cut-off of October 31, 2019. The data showed that a total of 22 patients with advanced/metastatic breast cancer had been treated at once daily oral doses ranging from 50mg to 150mg, and that the MTD was 100mg per day. The patients were heavily pre-treated, with a median of four prior lines of therapy for metastatic disease, including chemotherapy in all but two patients. As of February 11, 2020, one patient remained on treatment. Evidence of clinical activity was seen with a partial response in one of nine RECIST evaluable patients and pharmacodynamic data consistent with androgen receptor ("AR") modulatory activity was also seen. We do not plan to initiate any additional clinical studies of RAD140.

Our Marketed Product and Investigational Product Candidates

The success of our business is primarily dependent upon our ability to commercialize TYMLOS in the U.S. 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 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.



*Approved in the U.S.
^Given our refined focus on bone health and targeted endocrine diseases, we are evaluating all strategic options for our oncology assets.

Our Strategy

To achieve our goal of becoming a leading provider of innovative endocrine therapeutics, we plan to:

- **Gain anabolic osteoporosis market leadership and expand use of TYMLOS** . We commenced U.S. commercial sales of TYMLOS in May 2017 and we remain focused on growing our market share in anabolic appropriate patients. In October 2018, the FDA approved a labelling supplement for TYMLOS to reflect that after 24 months of open-label alendronate therapy, the vertebral fracture risk reduction achieved with TYMLOS therapy was maintained. TYMLOS exited 2019 with a 52% market share in new anabolic patient starts in December and a 42% total U.S. anabolic market share in December. We are conducting additional research towards potential additional indications for TYMLOS, including a clinical trial in men with osteoporosis that we initiated in March 2018, 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. We expect to report top-line data from the study in the second half of 2021. In July 2018, we also initiated a bone histomorphometry study to evaluate the early effects of TYMLOS on tissue-based bone remodeling and structural indices in postmenopausal women. Study enrollment is now complete, and we expect to present data from this study in the second half of 2020.

- **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 May 2019, we received a special protocol assessment agreement from the FDA for our Phase 3 (wearABLe) study of abaloparatide-patch, which means the FDA considers the study design to be adequate and well-controlled to support marketing approval provided the study endpoints are achieved. The wearABLe study is a single, pivotal, randomized, open label, active-controlled, BMD non-inferiority bridging study with a planned enrollment of approximately 470 patients with postmenopausal osteoporosis at high risk of fracture, which if successful, will support an NDA submission. The primary endpoint of the study is percentage change in lumbar spine BMD at 12 months. Non-inferiority of abaloparatide-patch to abaloparatide-SC will be concluded if the lower bound of the 2-sided 95% confidence interval for the estimated treatment difference (abaloparatide-patch minus abaloparatide-SC) in the percentage change from baseline in lumbar spine BMD at 12 months is above -2.0%.We initiated this pivotal study in August 2019 and expect to report top-line data in the second half of 2021. In February 2018, we entered into the Supply Agreement pursuant to which 3M agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-patch. In partnership with 3M, we selected Thermo Fisher Scientific (“Thermo Fisher”) to conduct the abaloparatide-patch coating process and packaging operations. We have successfully completed development activities associated with the scale up of manufacturing to supply our ongoing abaloparatide-patch Phase 3 wearABLe study. We have also made significant progress scaling up for potential commercial batches, if our Phase 3 trial is successful and abaloparatide-patch is approved.

- **Evaluate strategic options for oncology assets**. We are developing our investigational product candidate elacestrant as a potential treatment for hormone receptor-positive breast cancer. We initiated our Phase 3 EMERALD study of elacestrant in late November 2018 and expect to complete enrollment in the third quarter of 2020. The Phase 3 study is a single, randomized, open label, active-controlled Phase 3 trial of elacestrant as a second or third-line monotherapy in approximately 460 patients with ER+ and HER2- advanced or metastatic breast cancer who have received prior treatment with one or two endocrine therapies, including a CDK 4/6 inhibitor. Patients in the study will be randomized to receive either elacestrant or the investigator’s choice of an approved hormonal agent. The primary endpoint of the study will be PFS, which we will analyze in the overall patient population and in patients with ESR1 mutations. Secondary endpoints will include evaluation of OS, ORR, and DOR. We believe that, depending on results, this single trial would support applications for marketing approvals for elacestrant as a second- and third-line monotherapy in the U.S., EU, and other markets. In September 2017 we initiated a Phase 1 study of RAD140 in patients with locally advanced or metastatic breast cancer. In December 2019, we presented the Phase 1A data based on a data cut-off of October 31, 2019. The data showed that a total of 22 patients with advanced/metastatic breast cancer had been treated at once daily oral doses ranging from 50mg to 150mg, and that the MTD was 100mg per day. We plan to explore all strategic options for our oncology programs, including elacestrant (RAD1901) and RAD140.

- **Continue to expand our product portfolio**. We plan to leverage our drug development expertise to discover and develop additional investigational product candidates focused on bone health and targeted endocrine diseases. For example, we may consider opportunistically expanding our product portfolio within these areas through in-licensing, acquisitions or partnerships.

Our Opportunity in 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 $23.5 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 2019, total sales of branded osteoporosis drugs approximated $8.1 billion worldwide, of which $5.3 billion was attributable to injectable therapies. Osteoporosis drugs currently available in the United States include anti-resorptive agents, anabolic agents and a sclerostin inhibitor agent that has both anabolic and anti-resorptive characteristics. 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) sold by Eli Lilly and Company ("Lilly"), Prolia® (denosumab) marketed by Amgen Inc. ("Amgen"), and Evenity® (romosozumab-aqqg) marketed by Amgen and UCB are three alternatives to bisphosphonates that are approved for the treatment of osteoporosis. Prolia and Evenity have also been associated with infrequent but serious adverse events, such as osteonecrosis of the jaw and atypical fractures. In 2019, Forteo/Forsteo, Prolia, and Evenity reported total worldwide sales of approximately $4.3 billion, $2.5 billion in the U.S. and $1.8 billion outside of the U.S.

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.

Abaloparatide

In April 2017, the FDA approved TYMLOS (abaloparatide-SC) 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 January 1, 2020, TYMLOS was available and covered for approximately 290 million U.S. insured lives, representing approximately 99% of U.S. Commercial and 79% of Medicare Part D insured lives. In October 2018, the FDA approved a labelling supplement for TYMLOS to reflect that after 24 months of open-label alendronate therapy, the vertebral fracture risk reduction achieved with

TYMLOS therapy was maintained. We are commercializing TYMLOS in the United States through our commercial organization and have built an external distribution network comprised of specialty distributors and specialty pharmacies. Under our distribution model, both the specialty distributors and specialty pharmacies take physical delivery of TYMLOS and pharmacies dispense TYMLOS directly to patients.

We hold worldwide commercialization rights to abaloparatide-SC, except for 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. In January 2019, the European Commission adopted a decision refusing approval of our MAA for abaloparatide-SC.

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 and royalty payments as discussed above. Teijin is conducting a Phase 3 clinical trial of abaloparatide in Japan for the treatment of postmenopausal osteoporosis.

In March 2018, we initiated 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 is 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 includes specialized high-resolution imaging to examine the effect of abaloparatide on bone structure, such as the hip, in a subset of the study participants. We expect to report top-line data from the study in the second half of 2021.

In June 2018, the FDA approved a labeling supplement for TYMLOS to revise the needle length in the Instructions for Use from 8 mm to 5 mm. We believe health care providers, specialty pharmacies, and patients may prefer a shorter needle size for injectable products like TYMLOS.

In July 2018, we initiated a bone histomorphometry study to evaluate the early effects of TYMLOS on tissue-based bone remodeling and structural indices in postmenopausal women. Study enrollment is now complete, and we expect to present data from this study in the second half of 2020.

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 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, which were designed to improve the ease of use and patient experience. In the second half of 2018, we completed further evaluation confirming that a five minute application of the current abaloparatide-patch to the thigh resulted in a pharmacokinetic exposure highly similar (AUC >90%) to abaloparatide-SC.

In May 2019, we received a special protocol assessment agreement from the FDA for our Phase 3 (wearABLe) study of abaloparatide-patch, which means the FDA considers the study design to be adequate and well-controlled to support marketing approval provided the study endpoints are achieved. We initiated our Phase 3 wearABLe study of abaloparatide-patch in August 2019 and expect to report top-line data from the study in the second half of 2021. The wearABLe study is a single, pivotal, randomized, open label, active-controlled, BMD non-inferiority bridging study with a planned enrollment of approximately 470 patients with postmenopausal osteoporosis at high risk of fracture, which if successful, will support an NDA submission. The primary endpoint of the study is percentage change in lumbar spine BMD at 12 months. Non-inferiority of abaloparatide-patch to abaloparatide-SC will be concluded if the lower bound of the 2-sided 95% confidence interval for the estimated treatment difference (abaloparatide-patch minus abaloparatide-SC) in the percentage change from baseline in lumbar spine BMD at 12 months is above -2.0%. We are implementing a revised enrollment plan for the wearABLe study that includes additional measures and resources intended to improve site recruitment efforts, as well as the addition of clinical trial sites outside the U.S.

In July 2019, we obtained preliminary results from a patient assessment study which evaluated self-administration of abaloparatide-patch over 29 days in 22 post-menopausal women with low bone density. Study patients were observed at a study site on the first, 15th and 29th day of the study. Top-line results showed that study patients were able to follow the instructions for use ("IFU") and applied the patches accurately on 99.7% of all applications. The safety data from this study showed that most of the study patients had mild, transient redness at the application site. The mean subject acceptability score on a 5-point scale was 4.5, 4.6 and 4.5 on day 1, 15 and 29, respectively. The laboratory data from this study included an exploratory assessment of PINP, a biomarker that indicates bone formation. At baseline the median PINP level in this study was 50.5 ng/ml, increasing to a median value of 100.1 ng/ml at day 29, while, by comparison, the median PINP values observed with abaloparatide-SC in our registrational ACTIVE study were 50.6 ng/ml at baseline and 100.5 ng/ml at one month.

In February 2018, we entered into the Supply Agreement pursuant to which 3M agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-patch. In partnership with 3M, we selected Thermo Fisher to conduct the abaloparatide-patch coating process and packaging operations. In December 2019, 3M announced that it entered into an agreement to sell its drug delivery business, which manufactures clinical supplies of abaloparatide-patch, to an affiliate of Altaris Capital Partners, LLC ("Altaris"). The transaction with Altaris, which is subject to closing conditions and regulatory approvals, is expected to close in the first half of 2020. In connection with the transaction, we anticipate that the Supply Agreement will transfer to Altaris following the completion of certain transition arrangements between 3M and Altaris.

In October 2018, we committed to fund 3M's purchase of capital equipment totaling approximately $9.6 million in preparation for manufacturing Phase 3 and commercial supplies of abaloparatide-patch. Milestone payments for the equipment commenced in the fourth quarter of 2018 and are expected to be paid in full in the second quarter of 2021. In addition, there are cancellable purchase commitments in place to fund the facility build out and future purchases of capital equipment.

We have successfully completed development activities associated with the scale up of manufacturing to supply our ongoing abaloparatide-patch Phase 3 wearABLe study. The completion of the engineering equipment designs for critical equipment to produce abaloparatide-patch at the commercial site is on target, and critical equipment has started to arrive and is being installed. In December 2019, we aligned with the FDA on requirements for an NDA filing.

Our Oncology Portfolio and Strategic Plan For Oncology Assets

Given our refined focus on bone health and targeted endocrine diseases, we are evaluating all strategic options for our oncology assets. 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 is a SERD that we are studying 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 patients 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.

Phase 3 - EMERALD Study

We initiated our Phase 3 EMERALD study of elacestrant in late November 2018 and expect to complete enrollment in the third quarter of 2020. The Phase 3 study is a single, randomized, open label, active-controlled Phase 3 trial of elacestrant as a second- or third-line monotherapy in approximately 460 patients with ER+ and HER2- advanced or metastatic breast cancer who have received prior treatment with one or two endocrine therapies, including a CDK 4/6 inhibitor. Patients in the study will be randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent. The primary endpoint of the study will be PFS, which we will analyze in the overall patient population and in patients with ESR1 mutations. Secondary endpoints will include evaluation of OS, ORR, and DOR. We believe that, depending on results, this single trial would support applications for marketing approvals for elacestrant as a second- and third-line monotherapy in the U.S., EU and other markets. In November 2018, the FDA granted Fast Track designation for elacestrant consistent with the population to be included in the Phase 3 study. We do not plan to initiate any further clinical trials of elacestrant beyond our ongoing EMERALD study.

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 were heavily pretreated ER-positive, HER2-negative advanced breast cancer patients who had 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 to support the elacestrant clinical development program anticipated at that time. We discontinued recruitment in the Part D cohort as the data was no longer required to support the final design of our Phase 3 study.

In December 2017, we reported 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 Parts A through C of this study. As of the study interim 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 PFS 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.

We initiated Part D of the Phase 1 dose-escalation and expansion study to evaluate the safety and preliminary efficacy of elacestrant at a 400 mg tablet dose in a population with different eligibility requirements from Parts A, B, and C of this study. In Part D, patients were required to have at least two prior lines of endocrine therapy for advanced/metastatic breast cancer, including fulvestrant, and prior treatment with a CDK 4/6 inhibitor. Ten patients of an originally planned thirty-six were enrolled in Part D. A review of the data as of October 24, 2019 showed that overall the patients in Part D were more heavily pretreated and more likely to have visceral metastases than patients in Parts A through C of this study. In addition, out of the nine patients with measurable disease, four had a best response of stable disease, two of them for greater than 24 weeks. Combined data, as of October 24, 2019, from all four study Parts (A through D) at 400 mg showed that the overall elacestrant single agent ORR was 19.4% and the median PFS was 4.5 months.

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 included the use of FES-PET imaging to assess estrogen receptor occupancy in tumor lesions following elacestrant treatment.

In December 2017, we reported data from the Phase 1 FES-PET study showing 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 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. In December 2018, we announced additional preclinical data that showed that elacestrant demonstrated marked tumor growth inhibition as a single agent in models harboring ESR1 point mutations, models insensitive to fulvestrant, and models insensitive to CDK 4/6 inhibitors such as palbociclib, ribociclib, or abemaciclib.

Collaborations

After a comprehensive partnership evaluation for elacestrant and consistent with our plan to focus on bone health and targeted endocrine diseases, we are now exploring all strategic options for elacestrant.

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 trial. In February 2020, we terminated this collaboration.

RAD140

RAD140 is our 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 September 2017, we initiated a Phase 1 study of RAD140 in patients with ER+/AR+/HER2- locally advanced or metastatic breast cancer. The clinical trial was designed to evaluate the safety and MTD of RAD140 in approximately 40 patients. Primary safety endpoints from the trial included the incidence 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 were also evaluated. In December 2019, we presented the Phase 1A data based on a data cut-off of October 31, 2019. The data showed that a total of 22 patients with advanced/metastatic breast cancer had been treated at once daily oral doses ranging from 50mg to 150mg, and that the MTD was 100mg per day. The patients were heavily pre-treated, with a median of four prior lines of therapy for metastatic disease, including chemotherapy in all but two patients. As of February 11, 2020, one patient remained on treatment. Evidence of clinical activity was seen with a partial response in one of nine RECIST evaluable patients and pharmacodynamic data consistent with AR modulatory activity was also seen. We do not plan to initiate any additional clinical studies of 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 CDK 4/6 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 December 2018, we presented a preclinical poster further demonstrating anti-tumor activity of RAD140 in breast cancer models resistant to standard-of-care endocrine treatments.

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. In partnership with 3M, we selected Thermo Fisher to conduct the abaloparatide-patch coating process and packaging operations. In December 2019, 3M announced that it entered into an agreement to sell its drug delivery business, which manufactures clinical supplies of abaloparatide-patch, to an affiliate of Altaris. The transaction with Altaris, which is subject to closing conditions and regulatory approvals, is expected to close in the first half of 2020.

Elacestrant API and drug product are manufactured for us on a contract basis by Patheon, Inc., now known as Thermo Fisher. We are in the process of transferring the elacestrant API manufacturing process to Asymchem, Inc., which we expect to complete by the end of 2020.

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, 2019, we owned or co-owned 13 issued U.S. patents, as well as 48 pending U.S. patent applications, 5 pending Patent Cooperation Treaty ("PCT") applications, 103 pending foreign patent applications in the European Patent Office and 14 other jurisdictions, and 90 granted foreign patents. As of December 31, 2019, 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 and TYMLOS® for use in the treatment of bone diseases. In addition, we own the federal trademark registrations for TYMLOS in Canada, the European Union and Mexico; Radius in Mexico and Europe; and 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), Australia, Canada, China, Hong Kong, South Korea, New Zealand, Russia, Singapore, Mexico, and Taiwan. These patents 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 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 therapeutic formulation for abaloparatide-SC is covered by Patent No. 8,148,333 until October 3, 2027 in the United States (not including any patent term extension under the Hatch-Waxman Act) and Patent No. 8,748,382 (not including any patent

term extension under the Hatch-Waxman Act). Related patents granted in Australia, China, Israel, Japan, South Korea, Mexico, New Zealand, Russia, Singapore, and Ukraine, and additional patent applications pending in Brazil, Canada, Hong Kong, India, and South Korea, will have a patent expiration date of 2027, not taking into account extension under any applicable laws. 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) 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, India and Europe 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, now issued as U.S. Patent Nos. 10,420,734 and 10,071,066 (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 U.S. Patent No. 10,385,008 (statutory term expires January 5, 2038, not taking into account any patent term extensions) and a companion PCT application US2018/012714 has a projected expiration date in 2038 in Australia, Canada, China, Europe, Israel, Japan, South Korea and Mexico, 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 ER+ 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, India and Mexico and an additional patent application is pending in Brazil. 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 in Australia, Brazil, Canada, Europe, Israel, Japan, South Korea, Mexico, New Zealand, Russia and Singapore (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 marketed and 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 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

Osteoporosis drugs currently available in the United States include anti-resorptive agents, anabolic agents, and an agent that has both anabolic and anti-resorptive characteristics. 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 targeting the PTH receptor approved in the United States for the treatment of osteoporosis. We are aware of companies pursuing development in the United States of biosimilar and/or generic versions of teriparatide through various regulatory pathways, including Pfenex, Inc., which received FDA approval in October 2019 and is under regulatory review for the submission of a therapeutic equivalence designation (commonly referred to as "A" rated); Teva Pharmaceutical Industries, Ltd., under regulatory review; and APOTEX, under regulatory review. We believe other companies may be in earlier stages of development of a generic version of teriparatide. Romosozumab, an anti-sclerostin monoclonal antibody for the treatment of osteoporosis, marketed by Amgen and UCB under the name Evenity, received marketing approval in Japan in January 2019, the United States in April 2019, and the European Union in December 2019. In addition, we may also face competition from companies that seek to market generic versions of TYMLOS through an abbreviated new drug ("ANDA") application.

Other organizations are also working to develop new therapies to treat osteoporosis. For example, we are aware that Corium is developing a transdermal formulation of parathyroid hormone ("PTH") (1-34) that is in Phase 2 clinical development and which, if approved, would compete with abaloparatide-patch, if approved.

Elacestrant (RAD1901)

Elacestrant is being investigated for the treatment of hormone receptor positive breast cancer. If approved, elacestrant 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 hormone receptor-positive breast cancer, including Genentech, AstraZeneca, G1 Therapeutics, InventisBio, H3 Biomedicine, Novartis, and Sanofi, which are each developing oral SERD's that are in various phases of 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 have been select competitive molecules in development across a range of indications, including 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

In February 2018, the Company entered into a Scale-Up And Commercial Supply Agreement (the "Supply Agreement") with 3M Company and 3M Innovative Properties Company (collectively with 3M Company, "3M"), pursuant to which 3M 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 the Company according to agreed-upon specifications in sufficient quantities to meet the Company's projected supply requirements. 3M will manufacture commercial supplies of Product at unit prices that decrease with an increase in the quantity the Company orders. The Company 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. The Company is responsible for providing, at its expense, supplies of abaloparatide drug substance to be used in manufacturing Product. During the term of the Supply Agreement, 3M and the Company 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, February 27, 2018, 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. The Company may terminate the Supply Agreement upon the occurrence of certain events, including for certain clinical, technical, or commercial reasons impacting Product, if it is unable to obtain U.S. regulatory approval for Product within a certain time period, or if it ceases 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 the Company is unable to obtain U.S. regulatory approval for Product within a certain time period, or if the Company fails 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 the Company or a mutually agreeable third party and continue supplying Product and Applicator for a period of time pursuant to the Company's projected supply requirements.

In partnership with 3M, the Company selected Thermo Fisher to conduct the abaloparatide-patch coating process and packaging operations. In October 2018, the Company committed to fund 3M's purchase of capital equipment totaling approximately $9.6 million in preparation for manufacturing Phase 3 and potential commercial supplies of Product. Milestone payments for the equipment commenced in the fourth quarter of 2018 and are expected to be paid in full in the second quarter of 2021. In addition, there are cancellable purchase commitments in place to fund the facility build out and future purchases of capital equipment. The Company has paid 3M approximately $14.4 million, in the aggregate, through December 31, 2019 with respect to performance under the Supply Agreement.

In June 2009, the Company 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 on an exclusive basis. The initial term of the Development Agreement remained in effect until June 2019, after which it automatically renews for successive 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. The Company pays 3M for services delivered pursuant to the agreement on a fee-for-service or a fee-for-deliverable basis as specified in the agreement. The Company has paid 3M approximately $28.9 million, in the aggregate, through December 31, 2019 with respect to services and deliverables delivered pursuant to the Development Agreement.

Ipsen Pharma

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 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, to date, the Company has 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, 2019. 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 on the date paid) 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 also provides that the Company will 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 $8.7 million, $5.0 million and $0.6 million for the twelve months ended December 31, 2019, 2018 and 2017, respectively, and is included within cost of sales within the consolidated statement of operations and comprehensive loss. 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 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.

Pursuant to a June 2018 final decision in arbitration proceedings with Ipsen in connection with the License Agreement, the Company paid Ipsen $10.0 million (and pre-award interest of $0.8 million) and is obligated to pay Ipsen (i) $5.0 million if abaloparatide receives marketing approval in Japan, and (ii) a fixed mid single-digit royalty based on net sales of abaloparatide in Japan. The Company recorded the $10.8 million payment to other operating expenses in its consolidated statement of operations and comprehensive loss in the second quarter of 2018. The $5.0 million payment upon abaloparatide receiving marketing approval in Japan will be accrued in the period in which the approval is determined to be probable. Royalties based on net sales of abaloparatide in Japan will be accrued during the period that revenue for such sales, which is subject to a royalty arrangement, is recognized and will be presented as cost of sales within the Company's consolidated statement of operations and comprehensive loss.

The arbitration decision does not impact the Company's rights under the License Agreement or its license agreement with Teijin for abaloparatide-SC in Japan, under which the Company previously received a $10.0 million upfront payment and is entitled to 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.

Eisai

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 (RAD1901) 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 an initial license fee of $0.4 million upon execution of the Eisai Amendment, which was recognized as research and development expense in 2015. The Eisai Agreement, as amended, also provides for additional payments of up to $22.3 million, payable upon the achievement of certain clinical and regulatory milestones. To date, the Company has paid Eisai approximately $1.0 million in connection with the achievement of certain 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 Eisai 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 Eisai 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 Eisai 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 Eisai Agreement upon an uncured material breach by the other party or upon the bankruptcy or insolvency of the other party. Eisai may terminate the Eisai 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 Eisai 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

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

In consideration for these rights, the Company incurred non-refundable, non-creditable obligations to pay Duke, totaling $1.3 million in the aggregate, which were expensed as research and development costs during 2017. The Duke Agreement provides for further payments upon the achievement of certain future regulatory and commercial milestones totaling up to $3.8 million. To date, the Company has paid Duke approximately $0.5 million in connection with the achievement of certain milestones. The agreement provides that the Company would pay Duke a fixed low single-digit royalty based on net sales of a licensed product, on a country-by-country basis, beginning in August 2029 and ending upon expiration of the last patent rights to expire in a country. The latest licensed patent is expected to expire, barring any extension thereon, on October 10, 2034.

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 of a pre-specified amount. The Duke Agreement may be terminated by Duke upon a material uncured breach of the Duke Agreement. The Company may terminate the Duke 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, (v) a right to request that 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, and (vi) a right to request that the Company 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, 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.

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.

Supply and Manufacturing Agreements

In June 2016, we entered into a Supply Agreement with Ypsomed AG ("Ypsomed"), pursuant to which Ypsomed agreed to supply commercial and clinical supplies of a disposable pen injection device customized for subcutaneous injection of abaloparatide, the API for TYMLOS. We agreed to purchase a minimum number of devices at prices per device that decrease with an increase in quantity supplied. In addition, we made milestone payments for Ypsomed's capital developments in connection with the initiation of the commercial supply of the device and paid 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 which began on June 1, 2017, after which, it automatically renews for two-year terms unless either party terminates the agreement upon 18 months' notice prior to the end of the then-current term. 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. 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, we entered into a Commercial Supply Agreement with Vetter Pharma International GmbH ("Vetter"), pursuant to which Vetter has agreed to formulate the finished abaloparatide-SC drug product, 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, 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. Vetter may terminate the 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 with Polypeptide Laboratories Holding AB ("PPL"), 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 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 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 products and product candidates are extensively regulated by governmental authorities in the United States and other countries. In the United States, the U.S. Food and Drug Administration ("FDA" or the "Agency") 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 new drug applications ("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—Absent certain exceptions, 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 for which progress reports must be submitted annually to the FDA;
- approval by an independent institutional review board ("IRB") or Ethics Committee at each clinical trial site before each trial may be initiated;
- adequate and well-controlled human clinical trials, conducted in accordance with applicable IND regulations, Good Clinical Practices ("GCP"), and other clinical trial related regulations, to establish the safety and efficacy of the drug for each proposed indication to FDA's satisfaction;
- submission to the FDA of an NDA and payment of user fees for FDA review of the NDA (unless a fee waiver applies);
- 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) and/or of us as a clinical trial sponsor to assess compliance with 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 current Good Manufacturing Practices ("cGMPs") regulations;

- agreement with FDA on the final labeling for the product and the design and implementation of any required Risk Evaluation and Mitigation Strategy ("REMS"); and

- FDA review and approval of the NDA, including satisfactory completion of an FDA advisory committee review, if applicable, 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, including GLP regulations. 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, and places the clinical trial(s) on a clinical hold. 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 certain 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, among other things, the objectives of the study, inclusion and exclusion criteria, 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 or be combined. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an 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, among other things, informed consent and privacy of individually identifiable information.

Phase 1 trials usually involve 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 studies usually involve 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 or standard of care. For example, 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 product 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. For example, delays in subject enrollment or interruptions in clinical trial supplies or investigational product may significantly extend a trial past its anticipated end date. Furthermore, we, the FDA, or an IRB (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.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after receiving initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In

certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or, in certain circumstances, post-approval.

In addition, clinical trial sponsors are required to register and report results from certain applicable clinical trials for publication on www.clinicaltrials.gov. These reporting requirements also apply to unapproved drugs, regardless of whether FDA approval is or will be sought. Generally, results for applicable clinical trials must be submitted no later than one year after the primary completion date of the study. However, if the study is for an unapproved drug or a new use for an already-approved drug, a certification may be submitted before this deadline delaying the reporting timeframe to 30 days after the occurrence of certain specified events (*e.g.*, FDA approval of the initial or supplemental NDA) or 2 years after the date of submission of the certification, whichever occurs first. Consequently, clinical trial information could be subject to posting even if a drug is not approved and does not make it to market. On December 30, 2019, NIH issued a Request for Information to solicit input to guide infrastructure enhancements for ClinicalTrials.gov as part of a multi-year modernization initiative. While we do not expect these enhancements will result in substantive changes to our registration and reporting obligations, we cannot yet determine what effects, if any, such modifications will have on our ability to comply with such requirements.

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 the development, and FDA's review of drugs (*e.g.*, approving an NDA on the basis of surrogate endpoints subject to post-approval trials). 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/or those that provide a 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. Moreover, if a sponsor submits an NDA for a product intended to treat certain rare pediatric or tropical diseases or for use as a medical countermeasure for a material threat, and that meets other eligibility criteria, upon approval such sponsor may be granted a priority review voucher that can be used for a subsequent NDA. 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, among other things, (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, (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, (4) requirements that FDA issue guidance regarding the collection of patient experience data and their use in drug development, and (5) requirements that FDA establish a process for the qualification of drug development tools.

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 is currently almost $3 million. Moreover, an NDA must contain data that are adequate to assess the safety and efficacy, and to support dosing and administration, of the product for the proposed indication(s) in all relevant pediatric subpopulations unless the FDA grants a deferral, or full or partial waiver, for the submission of such pediatric data. After an NDA is accepted for filing, the FDA substantively 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.

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 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, among other things, ongoing regulatory requirements are not met, certain defects exist in the NDA, or safety or efficacy problems occur after the product reaches the market. FDA may order the withdrawal of the product or seek the manufacturer's agreement to such withdrawal.

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 an approval from the FDA for each indication. 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 product will be approved on a timely basis, or at all. In addition, FDA may require certain labeling changes based on its receipt of new safety or efficacy information, such as additional warnings and information on reduced effectiveness.

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 adverse events 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.

On December 20, 2019, the Further Consolidated Appropriations Act, 2020 (FCAA 2020) became law. Section 610, entitled "Actions for Delays of Generic Drugs and Biological Products", provides generic drug (ANDA and 505(b)(2)) and biosimilar developers with a private right of action to obtain sufficient quantities of reference product from the brand manufacturer, or a generic or biosimilar manufacturer, necessary for approval of the developers' generic or biosimilar product. If a generic drug or biosimilar developer is successful in its suit, the defendant manufacturer would be required to provide sufficient quantities of product on commercially-reasonable, market-based terms and may be required to pay the developer's reasonable attorney's fees and costs as well as financial compensation under certain circumstances. The purpose of section 610 is to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar products. We cannot determine what effect section 610 of the FCAA 2020 may have on manufacturers that may develop generic or other competing versions of our products.

European Union—Product Approval Process

In the European Union ("EU"), medicinal products are subject to a variety of EU and EU Member States regulations governing clinical trials, commercial sales, and distribution. Pharmaceutical companies are required to obtain marketing authorization in the EU before they can market their medicinal products. The conduct of clinical trials in the EU is governed by, among others, Directive 2001/20/EC and the EU Good Clinical Practice rules. These impose legal and regulatory obligations that are similar to those provided in applicable U.S. laws. The conduct of clinical trials in the EU must be approved by the competent authorities of each of the EU Member States in which the clinical trials take place following the submission of a related clinical trial application. In addition, an application for a positive opinion must be submitted to the competent Ethics Committee in these EU Member States and a related positive opinion must be obtained prior to initiation of the conduct of the clinical trial. The objective of Directive 2001/20/EC was to harmonize the EU clinical trials regulatory framework. The actual authorization procedure and its duration vary, however, between the EU Member States. This is due to the fact that the transposition of the Directive into the national laws of the EU Member States is not always uniform. To address this issue, the EU legislator adopted Regulation (EU) No 536/2014 (the "Clinical Trials Regulation") in 2014. The new EU Clinical Trials Regulation, which will replace the EU Clinical Trials Directive, introduces a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU, including a new coordinated procedure for authorization of clinical trials that is reminiscent of the mutual recognition procedure for marketing authorization of medicinal products, and increased obligations on sponsors to publish clinical trial results. The Clinical Trials Regulation is not expected to start to apply before early 2022.

In the EU, 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. The applicable legislation in the EU also requires applicants to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan ("PIP") approved by the Pediatric Committee of the European Medicines Agency ("EMA") or to obtain a waiver or deferral from the conduct of these studies by this Committee. In the European Economic Area ("EEA") (comprising 27 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. The marketing authorization process is essentially the same in both types of procedures and its maximum duration is 210 days, excluding clock-stops.

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 Agreement, 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. Accelerated evaluation may be sought by an applicant and granted by the CHMP in exceptional cases in relation to medicinal products that are expected to be of a "major public health interest" provided that three cumulative criteria are fulfilled. These relate to the seriousness of the disease; the absence or insufficiency of an appropriate alternative therapeutic approach; and the anticipated high therapeutic benefit of the medicinal product. CHMP delivers its opinion within 150 days in the framework of accelerated procedures.

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. Concerned Member States may refuse to approve the assessment made by the Reference Member State only on the basis of a potential serious risk to public health. In these circumstances, the

disputed elements are be referred to the Heads of Medicines Agencies ("CMDh") for review. This review, which may also be escalated to the CHMP in case of disagreement in CMDh would result in a decision by the European Commission. This decision is binding on all EU Member States.

- *Mutual recognition procedure.* Where the medicinal product has been authorized in an 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.

Marketing authorizations granted in the EU are initially valid for five years and can be subsequently renewed and remain valid for an unlimited period unless the national competent authorities of the EU Member State or the European Commission decides on justified grounds to proceed with one additional five-year renewal period. The renewal of a marketing authorization is subject to a re-evaluation of the risk-benefit balance of the product by the national competent authorities of the EU Member State or the EMA.

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, which in turn could potentially result in the suspension or withdrawal of the related marketing authorization for the medicinal product.

Data and market exclusivity—Similar to the United States, there is a process for approval of generic versions of innovator drug products in the EU. 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.

Medicinal products authorized in the EU on the basis of a full marketing authorization application (as opposed to an application for marketing authorization that relies on data available in the marketing authorization dossier for another, previously approved, medicinal product) and not falling within the scope of the so-called "global marketing authorization" 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.

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. A significant proportion of patients eligible for TYMLOS are Medicare beneficiaries and as of January 1, 2020, TYMLOS was covered for 79% of the covered lives under Medicare Part D.

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. Congress could also enact legislation increasing mandatory discounts in Part D. For example, the Bipartisan Budget Act of 2018 required manufacturers of brand name drugs, biologics, and biosimilars to pay a 70 percent discount in the Medicare Part D Coverage Gap, up from a 50 percent discount beginning in 2019. 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. For instance, currently, Medicare is prohibited from negotiating directly with pharmaceutical companies for drugs. However, the U.S. Congress is considering legislation that would lift the ban on federal negotiations or otherwise restrict price increases by, for example, instituting inflationary rebates for price increases that exceed a certain rate. For more information regarding additional risk factors concerning pricing and reimbursement, please see the discussion in ITEM 1A, RISK FACTORS, under the heading entitled “Risks Related to Legislation and Administrative Actions”.

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, has had a significant impact on the health care industry. The ACA

expanded coverage for the uninsured and underinsured, requiring coverage for prescription drugs under qualified health plans, while at the same time containing overall healthcare costs. Additionally, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made 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, including removal of the individual mandate. Any such legislative changes associated with healthcare reform, including the ACA, may have a significant impact on drug pricing and reimbursement, and could limit pricing flexibility or expand rebate liabilities of drug manufacturers. Additionally, an ongoing lawsuit or future lawsuits challenging the ACA could have a material adverse effect on the availability of prescription drug coverage, which could in turn affect pricing and reimbursement for our products.

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 related to prescription drug pricing transparency, including California, Oregon, Vermont, and Nevada. Our revenue and future profitability could be negatively affected by the passage of these laws or similar federal or state legislation.

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 27 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.

Many EU Member States review periodically their decisions concerning the pricing and reimbursement of medicinal products. The outcome of this review cannot be predicted and it could have an adverse effect on the pricing and reimbursement of our medicinal products in the EU Member States. Potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing systems, parallel distribution and parallel trade. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced countries. Reductions in the pricing of our medicinal products in one EU Member State could affect the price in other EU Member States and, thus, have a negative impact on our financial results.

Health Technology Assessment ("HTA") of medicinal products in the EU is an essential element of the pricing and reimbursement decision-making process in a number of EU Member States. This includes most of the big markets in the EU, such as France, Germany and Sweden. HTA is currently mainly governed by the national laws of the EU Member States. The HTA authorities of the EU Member States assess the public health impact, therapeutic benefit and the economic and societal impact of use of a given medicinal product in the national healthcare system of the individual country. The outcome of HTA has a direct impact on the pricing and reimbursement status granted to the medicinal product. The extent of this impact varies between the EU Member States. Moreover, a negative HTA by a leading and recognized HTA body concerning a medicinal product could undermine the prospects to obtain reimbursement for such product not only in the EU Member State in which the negative assessment was issued, but also in other EU Member States.

In 2011, Directive 2011/24/EU was adopted at the EU level. This Directive establishes a voluntary network of national authorities or bodies responsible for HTA in the individual EU Member States. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, on January 31, 2018, the European Commission adopted a proposal for a regulation on HTA. This legislative proposal is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The European Commission has stated that the role of the draft HTA regulation is not to influence pricing and reimbursement decisions in the individual EU Member States. However, this consequence cannot be excluded.

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 claims relating to uses 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 FDA guidance allows for the presentation of truthful and non-misleading information that is not in the drug's labeling but is considered consistent with the label as well as the communication of certain information regarding unapproved products or uses to payors. Failure to comply with applicable FDA requirements may make a product misbranded and, therefore, subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, lawsuits or other actions by competitors, 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, on October 17, 2019, the Office of the Inspector General of the Department of Health and Human Services issued a Proposed Rule: Revisions to Safe Harbors under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements to, among other things, add new safe harbors for certain value-based arrangements. Although the value-based proposals would not include pharmaceutical manufacturers among the entities that could permissibly enter into such contracting arrangements, the general trend toward outcomes and value-based contracts in the healthcare industry may continue. It is possible that payors, among other customers, could push manufacturers for novel contracting approaches, including those that would incorporate value-based principles, and these efforts could affect our business. It is unclear at this time whether this proposed rule will be adopted or, if adopted, what effect, if any, it would have on the cost and ability to comply with the federal Anti-Kickback Statute or on our business.

Recent healthcare reform legislation has also 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 product and product candidates, 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 trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The ACA, among other things, imposes 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. These reporting requirements will be expanded in 2022 to apply to certain allied healthcare providers, such as physician assistants, nurse practitioners, and clinical nurse specialists. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year and "knowing failures" may separately result in civil monetary penalties up to an aggregate of $1 million per year, 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 and other healthcare providers. 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.

The advertising of medicinal products in the EU and the United Kingdom ("UK") is subject to strict regulation set out in the EU, EU Member States' and UK national laws, including, among others, the laws governing the promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. Promotional materials for medicinal products must comply with the Summary of Product Characteristics ("SmPC") as approved by the competent authorities. The SmPC is the document that provides information to physicians concerning the safe and effective use of the medicinal product and forms an intrinsic and integral part of the related marketing authorization. Promotional materials that do not comply with the SmPC are considered to constitute off-label promotion which is prohibited. The direct-to-consumer advertising of prescription-only medicinal products is also prohibited in the EU and the UK.

Interactions between pharmaceutical companies and physicians in the EU and the UK are subject to strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct in the individual EU Member States and the UK, including the anti-corruption laws. These rules prohibit the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products.

In the UK, the Bribery Act 2010 applies to any company incorporated in or "carrying on business" in the UK, irrespective of where in the world the alleged bribery activity occurs and could have implications for company's interactions with physicians in and outside the UK.

In addition, transfers of value to physicians in certain EU Member States and the UK must be publicly disclosed. Agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual EU Member States and the UK.

Prohibited promotion of medicinal products in the EU and the UK, prohibited interactions with healthcare professionals or failures to publicly disclose transfers of value to healthcare professionals in the EU and the UK could lead to restriction of the promotional activities conducted by a company and the imposition of administrative penalties, fines and imprisonment.

Similar rigid restrictions are imposed on the promotion and marketing of medicinal products in 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, 2019, we employed 383 full-time employees and 45 contractors. Of the total 428 employees and contractors, 125 were engaged in research and development activities and 303 were engaged in support administration, including business development and finance. Of the 303 employees and contractors engaged in support administration, 214 are part of our commercial organization. We use and intend to continue using clinical research organizations 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

From time to time, we are party to litigation arising in the ordinary course of our business. As of February 1, 2020, we were not party to any significant litigation.

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 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.

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 are not currently profitable and may never become profitable. We had net losses of $133.0 million, $221.3 million, and $254.2 million for the years ended December 31, 2019, 2018, and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of $1.2 billion. Even if we succeed in commercializing TYMLOS, we may 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 maintain and build our commercial infrastructure, including adding internal systems and hiring additional personnel that may be required for our existing or any future product candidates, including product candidates that we acquire from other companies;
- continue to commercialize TYMLOS or any 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 operations 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 our commercialization of TYMLOS, we may not be able to generate sufficient revenue to attain or maintain 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 potentially 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 sufficiently gain or maintain market acceptance, leadership or 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 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, 2019 and funds available to us through our credit facilities, 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 at least 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 may be unable to complete our planned preclinical and clinical trials and obtain approval of our 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 and to the extent permitted under our existing January 2020 senior and secured Credit and Security Agreements with MidCap Financial Trust ("MidCap"), 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. For example, our financing agreements with MidCap contain affirmative and negative covenants customarily applicable to senior secured credit facilities, including covenants that, among other things, will limit or restrict our ability, subject to negotiated exceptions, to incur additional indebtedness and additional liens on our assets, engage in mergers or acquisitions or dispose of assets, pay dividends or make other distributions, voluntarily prepay other indebtedness, enter into transactions with affiliated persons, make investments, and change the nature of our businesses. 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. We have and may in the future engage in collaborations, sponsored research agreements, and other arrangements with academic researchers and institutions that have received and may receive funding from U.S. government agencies. As a result of these arrangements, the U.S. government or certain third parties may have rights in certain inventions developed during the course of the performance of such collaborations and agreements as required by law or by such agreements. 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 only commercialized TYMLOS in the U.S. since 2017. The successful commercialization of TYMLOS or any of our product candidates, if approved, 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.

Until our commercial launch of TYMLOS in the U.S. in 2017, 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 maintain and refine 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 7A. Quantitative and Qualitative Disclosures About Market Risk”.

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

We or our partners or suppliers may be the target of claims asserting violations of securities fraud and derivative actions, or other litigation or arbitration proceedings, including with respect to intellectual property rights. Any litigation or arbitration proceedings could result in substantial costs and divert management’s attention and resources. These lawsuits or arbitration proceedings may result in injunctive relief, large judgments or settlements against us, or our partners or suppliers, any of which could have a material adverse effect on our 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 we launched in 2017; we may not be able to meet expectations with respect to TYMLOS sales or attain or maintain profitability and positive cash-flow from operations.

Our ability to successfully commercialize TYMLOS, our first and currently only approved product, is critical to the execution of our business strategy. TYMLOS may not achieve or maintain market acceptance or leadership 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 or remain 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.

Our current and future product candidates 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 not perform sufficiently and may have taken or may take actions, or may have failed to take or may fail to 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 trial 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 or guidance.

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.

We have 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. The purpose of the agreement is to enable safety reporting to global health agencies. Teijin is conducting a Phase 3 clinical trial 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, which could adversely affect or delay our ability to maintain or obtain regulatory approval in the United States.

In addition, the FDA or foreign regulatory authorities each have 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 or guidance 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 in these Risk Factors 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. For example, in March 2018, the CHMP adopted a negative opinion on our MAA for abaloparatide-SC. In July 2018, following a re-examination procedure, the CHMP maintained its negative opinion and on January 7, 2019, the European Commission adopted a decision refusing approval of the MAA on the basis of the negative opinion of the Committee. As a result, we did not receive marketing authorization for abaloparatide-SC in the European Union.

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 product candidates.

The commercialization of TYMLOS and the development and potential commercialization of 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. For example, we plan to explore all strategic options for our oncology programs. We will face significant competition in seeking appropriate collaborators and/or partners. Moreover, licensing arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement such arrangements should we so choose 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 or if we are not successful in entering into collaborations or other arrangements, 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 or other arrangement that we enter into may not be successful. The success of our collaboration or other arrangements will depend heavily on the efforts and activities of our future collaborators and/or partners. Collaborators and/or partners generally have significant discretion in determining the efforts and resources that they will apply to these collaborations or other arrangements. If a collaborator or partner fails to provide sufficient effort and resources to a development program, we may not realize the full potential or intended benefit of the collaboration or arrangement, 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 product candidates. 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 or guidance 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;
- unforeseen issues with drug supply, including batch failures and other supply chain issues;
- lack of effectiveness during clinical trials;
- actions, or failures to act, by clinical research organizations or other organizations contracted to perform services for a clinical trial(s);
- slower than expected rates of patient recruitment and enrollment in the overall population or other prespecified populations;
- higher than expected screen failure rates;
- 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.

We have decided to explore all strategic options for our oncology assets; however there can be no assurance that we will be successful in entering into or consummating a transaction or that any such transaction will yield additional value for stockholders.

During 2019, we announced that we are exploring all strategic options for our oncology assets given our refined focus on bone health and targeted endocrine diseases. There can be no assurances that any such evaluation and consideration will result in a sale, spin-off, license, or any other transaction being entered into or consummated. The process may be time-consuming, distracting to management and disruptive to our business operations, and if we are unable to effectively manage the process, our business, financial condition, and results of operations could be adversely affected. In addition, identifying and evaluating potential strategic options may result in the incurrence of additional expenses.

Any strategic decision will involve risks and uncertainties, and we cannot guarantee that any potential transaction or other strategic option, if identified, evaluated and consummated, will provide greater value to our stockholders than that reflected in our current stock price. Any potential transaction would be dependent upon a number of factors that may be beyond our control,

including, among other factors, market conditions, industry trends and the interest of third parties in our oncology assets, including RAD140 which is in the early stages of clinical development.

Any uncertainties related to consummating any transaction for our oncology assets may result in the loss of potential business opportunities and may make it more difficult for us to attract and retain qualified personnel and business partners.

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 applications to foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials to date have generally 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 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, additional clinical and non-clinical data may need to be obtained 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 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 additional trials beyond the currently contemplated single, randomized, controlled Phase 3 trial be conducted before an NDA or foreign marketing authorization application for elacestrant may be submitted 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 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 or 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 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 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 product candidates 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 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 approve 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 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 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 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 or 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 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 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 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 or trial sites 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 comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our or our contract manufacturers' 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 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 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 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 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 product candidates. There are a limited number of third parties with facilities and capabilities suited for the manufacturing process of TYMLOS and our product candidates, which creates a heightened risk that we may not be able to

obtain materials, APIs and drug products 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 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 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 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 product candidates to meet the needs of our clinical studies or future commercial demand, if approved, 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 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 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 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, 3M for the production of abaloparatide-patch and Thermo Fisher for the production of elacestrant API and drug product. If our relationship with any of these contract manufacturers is terminated, or if they are unable to produce abaloparatide or related components or elacestrant 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.

In addition, in connection with Thermo Fisher’s decision to cease commercial operations at its site that produces elacestrant API, we are in the process of transferring the elacestrant API manufacturing process to Asymchem, Inc.’s facility located in China and will depend exclusively on this facility for elacestrant API manufacturing by year-end. This transfer also exposes us to a number of risks specific to conducting business in China, including U.S. legislation, regulation, tariffs and other import or export restrictions and other trade barriers that could be adverse to our doing business with a Chinese supplier, and more recently, as a result of the coronavirus outbreak, which has resulted in a number of public health safety measures, including extended shutdowns of businesses in the region. In addition, as a result of such transfer, our current manufacturers may prioritize other customers or otherwise be unable to meet our demand. If such transfer is unsuccessful or takes a longer period of time than expected, it could result in interruptions in supply and would likely impact our financial condition and results of operations.

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.
- Our third-party manufacturers may be subject to litigation or arbitration with respect to the manufacturing and supply of our products, including claims of intellectual property infringement by third parties.

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 product candidates that may be approved or result in higher costs or deprive us of potential product revenues.

The recent coronavirus outbreak in China could materially and adversely affect our business.

In December 2019, a novel strain of coronavirus was reported to have surfaced in Wuhan, China. We are currently in the process of transferring the elacestrant API manufacturing process to Asymchem, Inc.'s facility located in China. The outbreak of the coronavirus and other adverse public health developments could materially and adversely affect our business, financial condition and results of operations. These could include disruptions from the temporary closure of Asymchem's Chinese manufacturing facility to which we are transferring elacestrant API production, restrictions on the export or shipment of our products, significant cutback of ocean container delivery from China and restrictions on our employees' and other service providers' ability to travel. For example, on January 27, 2020, the Shanghai city government issued a notice that most employers, including the offices of Asymchem, may not reopen until mid-February, extending the spring festival holiday. The extent to which the coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others.

Risks Related to Marketing and Sale of Our Products

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

We established a sales force to market and sell TYMLOS in the United States to specialists and intend to pursue collaborative arrangements to market and sell abaloparatide-SC outside of the United States. In addition, we are exploring all strategic options for our oncology programs, including elacestrant (RAD1901) and RAD140. Therefore, our future success depends, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborators' or partners' strategic interest in the products under development and such collaborators' or partners' ability to successfully develop, 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, or any of our product candidates that may be approved, and to be credible and persuasive in educating physicians on the appropriate situations to consider prescribing 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 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 of our product candidates. If we establish a partnership or collaboration for purposes of commercializing TYMLOS or any of our current or future product candidates, 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 any of our product candidates. As such, we may be required to hire substantially more sales representatives to adequately support the commercialization of our product candidates.

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 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, Pfenex, Inc., received FDA approval for a biosimilar version of teriparatide in October 2019 and is under regulatory review for the submission of a therapeutic equivalence designation (commonly referred to as “A” rated) and generic versions of teriparatide from Teva Pharmaceutical Industries, Ltd. and APOTEX are both under regulatory review in the U.S. The availability of a generic or biosimilar teriparatide on the market would likely exert pricing and reimbursement pressure on the anabolic class in which TYMLOS competes. In addition, UCB and Amgen are marketing romosozumab, an anti-sclerostin monoclonal antibody for the treatment of osteoporosis, under the name Evenity, which received marketing approval in Japan in January 2019, in the United States in April 2019, and in the European Union in December 2019. 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 may also face competition from companies that seek to market generic versions of TYMLOS through an ANDA application.

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 our product candidates, 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.

If our efforts to protect our intellectual property related to TYMLOS/abaloparatide-SC, abaloparatide-patch, and/or our other current or future product candidates 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 products or product candidates.

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

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 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 therapeutic dose for abaloparatide-SC. We and Ipsen are also co-assignees to U.S. Patent Nos. 8,148,333 and 8,748,382 for the therapeutic formulation for abaloparatide-SC that we believe provides exclusivity until October 3, 2027 in the United States (not including any Hatch-Waxman patent term extension).

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, India and Europe. 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 now issued in the United States as US 10,071,066 and 10,420,734 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, 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) now issued in the United States as US 10,385,008 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 ERa+ 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 or inter partes reviews 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.

Our trademarks are considered to be material to our business. These trademarks are covered by registrations or pending applications for registration in the U.S. Patent and Trademark Office and in other countries. Trademark protection continues in some countries for as long as the mark is used and, in other countries, for as long as it is registered. Registrations generally are for fixed, but renewable, terms. We cannot assure you that the trademark protection that we have pursued or will pursue in the future will afford us significant commercial protection.

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. 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.

Of particular concern for a company like ours, having one marketed product, is that third parties may seek to market generic versions of TYMLOS by filing an Abbreviated New Drug Application, or ANDA, with the FDA in which they claim that patents protecting TYMLOS owned or licensed by us and listed with the FDA in what is called "the Orange Book" are invalid, unenforceable and/or not infringed, a so-called Paragraph IV filing. April 28, 2021 is the first opportunity under United States patent law for a generic company to make a Paragraph IV filing. If such a filing is made, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid, not infringed and/or unenforceable, which would have a material adverse impact on our business and results of operations. During the period in which such litigation is pending, the uncertainty of its outcome may cause investors to disfavor our stock, and our stock price could decline. Even if we are successful in prosecuting such claims, litigation could result in substantial costs and be a distraction to management.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours for a meaningful amount of time, or at all.

The primary composition of matter patent covering TYMLOS in the United States and several additional countries has expired. We own or have licensed rights to a limited number of patents directed toward methods of treating osteoporosis with the therapeutic dose for TYMLOS and for the therapeutic formulation of TYMLOS. We cannot be sure that patents will be granted with respect to any of our pending patent applications for TYMLOS, our other drug candidates, or our research technologies or with respect to any patent applications filed by us in the future; nor can we be sure that any of our existing

patents or any patents that may be granted to us in the future will be commercially useful in protecting TYMLOS, our other drug candidates or our other technology.

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 third parties 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 address 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.

The Tax Cuts and Jobs Act of 2017 (“TCJA”) repealed the requirement that individuals maintain health insurance coverage or face a penalty (known as the individual mandate). In December 2018, U.S. District Court for the Northern District of Texas held in Texas v. Azar that the TCJA, which zeroed out the tax penalties associated with the Affordable Care Act’s individual mandate, rendered the mandate unconstitutional. The court further concluded that since the individual mandate is “essential” to the ACA, it could not be severed from the rest of the ACA, and the entire ACA was therefore unconstitutional. The decision was appealed to the U.S. Court of Appeals for the Fifth Circuit. On December 18, 2019, the Fifth Circuit issued an opinion holding that, while the individual mandate was no longer constitutional, the case must be remanded to the District Court to further evaluate whether the mandate can be severed from the PPACA or the entire PPACA must be stricken down. On January 3, 2020, petitions for certiorari were filed with motions to expedite requesting that the U.S. Supreme Court review the Fifth Circuit’s decision and ultimately decide the constitutionality of the PPACA. The U.S. Supreme Court has not yet decided whether to grant the petitions.

The current litigation regarding the ACA, coupled with potential future legislation, threatens the stability of the insurance marketplace and may have consequences for the coverage and accessibility of prescription drugs.

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. Currently Congress and state legislatures are considering a number of bills designed to address drug prices.

Moreover, the Trump Administration continues to scrutinize drug prices and is seeking ways to lower prices. For example, the Trump Administration’s “Blueprint” on drug prices describes a number of mechanisms for lowering manufacturer list prices

and reducing patient out-of-pocket costs. Although the Blueprint contains a number of policy objectives, we cannot know the form that any new requirements will take or the effect that they may have on our business. On December 23, 2019, the Trump Administration, through the FDA, released a proposed rule and draft guidance that set forth two pathways for the legal importation of certain drugs in an effort to control drug costs. Since these pathways are not yet effective and are subject to revision pending receipt of public comments, we cannot determine what effect these pathways may have on our business and financials.

The full impact on our business of these laws, or future laws and regulations is uncertain. We cannot predict whether other legislative or administrative 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 or any 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 United Kingdom's exit from the European Union may have a negative effect on global economic conditions, financial markets and our business.

In June 2016, the UK held a referendum in which voters approved an exit from the EU, commonly referred to as "Brexit," 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. This withdrawal has created political and economic uncertainty, particularly in the UK and the EU. While the UK's withdrawal from the EU was completed on January 31, 2020, there remains considerable uncertainty about the terms of the UK's trade agreements and other relationships with the EU following the transition period which ends December 31, 2020. During the transition period, which could be extended to December 31, 2022 by the agreement of the UK and all EU Member States, the UK will continue to follow all of the EU's rules and will maintain its current trading relationship with the EU. We expect that uncertainty over the terms of the trade and other agreements between the UK and EU will continue to cause political and economic uncertainty, which could harm our business and financial results. The withdrawal could, among other outcomes, disrupt the free movement of goods, personal data, services and people between the UK and the EU, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe. Until the terms of the free trade and other agreements that the UK will eventually enter into with the EU are known, it is not possible to determine the impact that the UK's departure from the EU and/or any related matters may have on us; however, any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, business opportunities, results of operations, financial condition and cash flows. Likewise, similar actions taken by European and other countries in which we operate could have a similar or even more profound impact.

For example, Brexit could result in the UK significantly altering its regulations affecting the clearance or approval of our product candidates and the transfer of personal data between the EU and the UK as the UK determines which EU laws to replace or replicate. Any new regulations could add time and expense to the conduct of our business, the transfer of personal data between the EU and the UK, as well as the process by which our products receive regulatory approval in the UK, the EU and elsewhere. In addition, the announcement of Brexit and the withdrawal of the UK from the EU 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 and restrict the ability of key market participants to operate in certain financial markets. Any of these effects of Brexit, among others, could adversely affect our business, our results of operations, liquidity and financial condition.

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 a number of recent rulings of the EU 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); PTC Therapeutics International v EMA (Case T-718/15); Intercept Pharma and Intercept Pharmaceuticals v EMA (Case T-377/18); and Amicus Therapeutics UK and Amicus Therapeutics v EMA (Case T-33/17). 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 there is no presumption of confidentiality of documents held by the EMA, that the potential risk of 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. In two of these cases, the rulings of the General Court were appealed to the Court of

Justice of the European Union (Cases C-178/18 P - MSD Animal Health Innovation and Intervet International v EMA and C-175/18 P - PTC Therapeutics International v EMA). The Court of Justice upheld the rulings of the General Court and dismissed the appeals.

The potential risk to our business under the Transparency Regulation is significant. For example, our marketing authorisation application for abaloparatide-SC in the EU was reviewed centrally by the EMA and its advisory committees, which application was rejected in January 2019. According to the established EMA policy, the information contained in our marketing authorisation application, responses we provided 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 were not disclosed during the course of the EMA's review. However, now that the EMA has completed its review of our marketing application, such information may now be susceptible to disclosure to third parties, including to our competitors, in light of the recent rulings of the General Court and the Court of Justice in relation to the Transparency Regulation. 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.

The EMA has also implemented a policy for the proactive publication of clinical data submitted by pharmaceutical companies to support their applications for marketing authorization. The implementation of this policy is currently suspended due to Brexit and the relocation of the EMA to the Netherlands. While, due to this suspension, the clinical data contained in our application for marketing authorization for abaloparatide-SC in the EU was not published, such proactive publication by the EMA cannot be excluded should the implementation of the EMA policy for the proactive publication of clinical data be resumed by the EMA.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including most recently from December 22, 2018 to January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act 2010, or Bribery Act, and other anti-corruption laws that apply in countries where we do business and may do business in the future. The FCPA, Bribery Act and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials. Our clinical trials are conducted around the world, and our payments to hospitals may lead to FCPA enforcement actions.

Though we currently do not have any partners that commercialize our products in other countries, we may in the future operate in jurisdictions that pose a high risk of potential FCPA or Bribery Act violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA, Bribery Act or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory

requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the UK and the United States, and authorities in the EU Member States, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the FCPA, the Bribery Act or other legal requirements, including Trade Control laws. If we are not in compliance with the FCPA, Bribery Act and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Any investigation of any potential violations of the FCPA, the Bribery Act, other anti-corruption laws or Trade Control laws by U.S., U.K. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

We may fail to comply with evolving European Union and other privacy laws, which could adversely affect our business, results of operations and financial condition.

We currently conduct clinical trials in the European Economic Area, or EEA. As a result, we are subject to additional privacy laws. The General Data Protection Regulation, (EU) 2016/679, or GDPR, became effective on May 25, 2018, and deals with the processing of personal data and on the free movement of such data. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information on our behalf, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the limited enforcement of the GDPR to date, we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of member states of the EU have implemented national laws which may partially deviate from the GDPR and impose different and more restrictive obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EU. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows member state nations to enact laws that impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty.

In addition, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States, in compliance with EU data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under EU privacy laws will be sufficient. If we are investigated by an EU Member State data protection authority, we may face fines and other penalties. Any such investigation or charges by EU Member State data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations.

For more information concerning the implications of Brexit for our activities in compliance with the EU data protection laws, please refer to the Risk Factor entitled *"The United Kingdom's exit from the European Union may have a negative effect on global economic conditions, financial markets and our business"*.

Risks Related to Employee Matters and Managing Growth

We may need 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 continue our commercialization of 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 built a commercial team and established the organizational infrastructure we believe necessary for successful commercialization 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, including as part of our strategic plans to focus on bone health on targeted endocrine diseases. 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;
- 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 plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants and pursuant to our employee stock purchase plan, eligible employees may also participate in an employee stock purchase plan sponsored by us. All such awards will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations, which will result in dilution to our existing shareholders.

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, which 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, 2019, we had $974.3 million of federal and $681.8 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, 2019, are provided below:

Location	Function	Size (approximate square feet)	Property Interest
Waltham, MA, USA	Corporate Headquarters	26,553	Leased
Parsippany, NJ, USA	Office space	10,528	Leased
Wayne, PA, USA	Office space	2,404	Leased
Wayne, PA, USA	Office space	26,401	Subleased
Cambridge, MA, USA	Laboratory and office space	5,500	Subleased

ITEM 3. LEGAL PROCEEDINGS.

From time to time, we are party to litigation arising in the ordinary course of our business. As of February 1, 2020, we were not party to any significant litigation.

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.

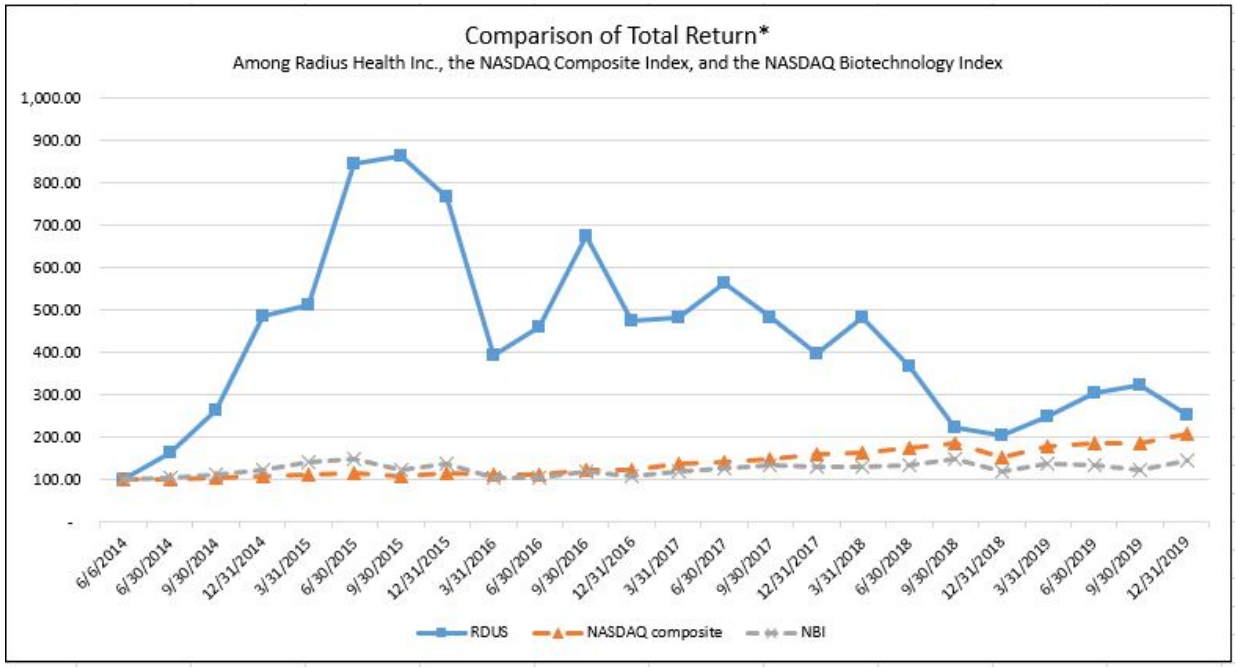
On February 21, 2020, the closing price of our common stock was $19.36 per share as reported on The Nasdaq Global Market.

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, 2019, 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 21, 2020, there were 19 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 year ended December 31, 2019.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

There were no such repurchases of shares of common stock made during the fiscal year ended December 31, 2019.

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, 2019, 2018 and 2017 and the balance sheet data as of December 31, 2019 and 2018 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, 2017, 2016 and 2015 and the statement of operations data for the years ended December 31, 2016 and 2015 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, 2019, 2018, 2017, 2016, and 2015 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.

Statement of Operations and Comprehensive Loss Data	**Year Ended December 31,**				
	2019	**2018**	**2017**	**2016**	**2015**
	(in thousands)				
REVENUES:					
Product revenue, net	$ 173,317	$ 99,239	$ 12,112	$ —	$ —
License revenue	—	—	10,000	—	—
Operating expenses:					
Cost of sales - product	15,287	7,627	932	—	—
Cost of sales - intangible amortization	798	799	400	—	—
Research and development	116,757	99,911	83,076	107,406	68,280
Selling, general and administrative	152,704	184,164	186,677	77,542	30,797
Other operating expense	—	10,801	—	—	—
Loss from operations	(112,229)	(204,063)	(248,973)	(184,948)	(99,077)
Other (expense) income:					
Other (expense) income, net	242	59	(192)	(293)	(1,607)
Interest (expense) income, net	(21,006)	(17,333)	(5,072)	2,437	(842)
Net loss	(132,993)	(221,337)	(254,237)	(182,804)	(101,526)
Other comprehensive loss, net of tax:					
Unrealized gain (loss) from available-for-sale securities	758	(441)	(385)	66	26
Comprehensive loss	$ (132,235)	$ (221,778)	$ (254,622)	$ (182,738)	$ (101,500)
Net loss attributable to common stockholders	$ (132,993)	$ (221,337)	$ (254,237)	$ (182,804)	$ (101,526)
Net loss per share applicable to common stockholders—basic and diluted	$ (2.89)	$ (4.88)	$ (5.80)	$ (4.24)	$ (2.56)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	46,026,217	45,356,263	43,804,660	43,067,952	39,643,099

Balance Sheet Data	As of December 31,				
	2019	2018	2017	2016	2015
	(in thousands)				
Cash and cash equivalents	$ 69,886	$ 59,321	$ 118,564	$ 258,567	$ 159,678
Marketable securities	91,015	177,140	311,692	73,880	313,661
Working capital	141,799	228,604	216,079	302,084	459,128
Total assets	219,151	286,962	461,658	340,282	482,465
Long-term liabilities	200,172	179,901	166,195	379	—
Total liabilities	261,430	226,330	219,622	33,104	21,180
Total liabilities, and stockholders' equity	219,151	286,962	461,658	340,282	482,465

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 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 January 1, 2020, TYMLOS was available and covered for approximately 290 million U.S. insured lives, representing approximately 99% of U.S. Commercial and 79% of Medicare Part D insured lives. 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 March 2018, we initiated 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. We expect to report top-line data from the study in the second half of 2021. In July 2018, we initiated a bone histomorphometry study to evaluate the early effects of TYMLOS on tissue-based bone remodeling and structural indices in postmenopausal women. Study enrollment is now complete, and we expect to present data from this study in the second half of 2020. In October 2018, the FDA approved a labeling supplement for TYMLOS to reflect that after 24 months of open-label alendronate therapy, the vertebral fracture risk reduction achieved with TYMLOS therapy was maintained.

We are developing an abaloparatide transdermal patch ("abaloparatide-patch"), for potential use in the treatment of postmenopausal women with osteoporosis. In May 2019, we received a special protocol assessment agreement from the FDA for our Phase 3 study of abaloparatide-patch. We initiated our Phase 3 wearABLe study of abaloparatide-patch in August 2019 and expect to report top-line data from the study in the second half of 2021. The wearABLe study is a single, pivotal, randomized, open label, active-controlled, bone mineral density ("BMD") non-inferiority bridging study with a planned enrollment of approximately 470 patients with postmenopausal osteoporosis at high risk of fracture, which, if successful, will support an NDA submission. The primary endpoint of the study is percentage change in lumbar spine BMD at 12 months. Non-inferiority of abaloparatide-patch to abaloparatide-SC will be concluded if the lower bound of the 2-sided 95% confidence interval for the estimated treatment difference (abaloparatide-patch minus abaloparatide-SC) in the percentage change from baseline in lumbar spine BMD at 12 months is above -2.0%. In February 2018, we entered into a Scale-Up and Commercial Supply Agreement (the "Supply Agreement") with 3M Company and 3M Innovative Properties Company (collectively with 3M Company, "3M") pursuant to which 3M agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-patch. In partnership with 3M, we selected Patheon N.V., now known as Thermo Fisher Scientific, ("Thermo Fisher") to conduct the abaloparatide-patch coating process and packaging operations. We have successfully completed development activities associated with the scale up of manufacturing to supply our ongoing abaloparatide-patch Phase 3 wearABLe study. We have also made significant progress scaling up for potential commercial batches, if our Phase 3 trial is successful and abaloparatide-patch is approved. In October 2018, we committed to fund 3M's purchase of capital equipment totaling approximately $9.6 million in preparation for manufacturing Phase 3 and potential commercial supplies of abaloparatide-patch. Milestone payments for the equipment commenced in the fourth quarter of 2018 and are expected to be paid in full in the second quarter of 2021. In addition, there are cancellable purchase commitments in place to fund the facility build out and future purchases of capital equipment. The completion of the engineering equipment designs for critical equipment to produce the abaloparatide-patch at the commercial site is on target, and critical equipment has started to arrive and is being installed. In December 2019, we aligned with the FDA on requirements for an NDA filing.

In connection with our strategic plan to focus on bone health and targeted endocrine diseases, we are exploring all strategic options for our oncology programs, including elacestrant (RAD1901) and RAD140. Our investigational product candidate, elacestrant (RAD1901), a selective estrogen receptor degrader ("SERD"), is being developed for potential use in the treatment of hormone receptor-positive breast cancer. We initiated our Phase 3 EMERALD study of elacestrant in late November 2018 and expect to complete enrollment in the third quarter of 2020. The Phase 3 study is a single, randomized, open label, active-controlled Phase 3 trial of elacestrant as a second or third-line monotherapy in approximately 460 patients with estrogen receptor-positive ("ER+") and human epidermal growth factor receptor 2-negative ("HER2-") advanced or

metastatic breast cancer who have received prior treatment with one or two endocrine therapies, including a cyclin-dependent kinase ("CDK") 4/6 inhibitor. Patients in the study will be randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent. The primary endpoint of the study will be progression-free survival ("PFS"), which we will analyze in the overall patient population and in patients with estrogen receptor 1 gene ("ESR1") mutations. Secondary endpoints will include evaluation of overall survival ("OS"), objective response rate ("ORR"), and duration of response ("DOR"). We believe that, depending on results, this single trial would support applications for marketing approvals for elacestrant as a second- and third-line monotherapy in the U.S., European Union ("EU"), and other markets. In November 2018, the FDA granted Fast Track designation for elacestrant for the population to be included in the Phase 3 study. We previously completed enrollment in our ongoing dose escalation Part A, and dose expansion Parts B and C, and in the 18F fluoroestradiol positron emission tomography ("FES-PET") imaging Phase 1 studies of elacestrant in advanced metastatic breast cancer. Enrollment in Part D of the Phase 1 dose-escalation and expansion study was discontinued as the data was no longer required to support the final design of our Phase 3 study. We do not plan to initiate any further clinical development of elacestrant beyond the ongoing EMERALD study.

We developed 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 ER+/AR+/HER2- locally advanced or metastatic breast cancer. The clinical trial was designed to evaluate the safety and maximum tolerated dose ("MTD") of RAD140 in approximately 40 patients. Primary safety endpoints from the trial included the incidence 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 were evaluated. In December 2019, we presented the Phase 1A data based on a data cut-off of October 31, 2019. The data showed that a total of 22 patients with advanced/metastatic breast cancer had been treated at once daily oral doses ranging from 50mg to 150mg, and that the MTD was 100mg per day. The patients were heavily pre-treated, with a median of four prior lines of therapy for metastatic disease, including chemotherapy in all but two patients. As of February 11, 2020, one patient remained on treatment. Evidence of clinical activity was seen with a partial response in one of nine RECIST evaluable patients and pharmacodynamic data consistent with androgen receptor ("AR") modulatory activity was also seen. We do not plan to initiate any additional clinical studies of RAD140.

Abaloparatide

In April 2017, the FDA approved TYMLOS (abaloparatide-SC) 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 January 1, 2020, TYMLOS was available and covered for approximately 290 million U.S. insured lives, representing approximately 99% of U.S. Commercial and 79% of Medicare Part D insured lives. In October 2018, the FDA approved a labelling supplement for TYMLOS to reflect that after 24 months of open-label alendronate therapy, the vertebral fracture risk reduction achieved with TYMLOS therapy was maintained. We are commercializing TYMLOS in the United States through our commercial organization and have built an external distribution network comprised of specialty distributors and specialty pharmacies. Under our distribution model, both the specialty distributors and specialty pharmacies take physical delivery of TYMLOS and pharmacies dispense TYMLOS directly to patients.

We hold worldwide commercialization rights to abaloparatide-SC, except for Japan, where we are entitled to receive milestones and royalties based on the development and commercialization of abaloparatide-SC in Japan under our license and development agreement with Teijin. In January 2019, the European Commission adopted a decision refusing approval of our MAA for abaloparatide-SC.

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 February 2020, we elected not to exercise our option to negotiate for a co-promotion agreement with Teijin for abaloparatide-SC in Japan. Teijin is conducting a Phase 3 clinical trial of abaloparatide in Japan for the treatment of postmenopausal osteoporosis.

In March 2018, we initiated 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. We expect to

report top-line data from the study in the second half of 2021. The study is 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 includes specialized high-resolution imaging to examine the effect of abaloparatide on bone structure, such as the hip, in a subset of the study participants.

In June 2018, the FDA approved a labeling supplement for TYMLOS to revise the needle length in the Instructions for Use from 8 mm to 5 mm. We believe health care providers, specialty pharmacies, and patients may prefer a shorter needle size for injectable products like TYMLOS.

In July 2018, we initiated a bone histomorphometry study to evaluate the early effects of TYMLOS on tissue-based bone remodeling and structural indices in postmenopausal women. Study enrollment is now complete and we expect to report data from this study in the second half of 2020.

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 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, which were designed to improve the ease of use and patient experience. In the second half of 2018, we completed further evaluation confirming that a five minute application of the current abaloparatide-patch to the thigh resulted in a pharmacokinetic exposure highly similar (AUC >90%) to abaloparatide-SC.

In May 2019, we received a special protocol assessment agreement from the FDA for our Phase 3 (wearABLe) study of abaloparatide-patch, which means the FDA considers the study design to be adequate and well-controlled to support marketing approval provided the study endpoints are achieved. We initiated our Phase 3 wearABLe study of abaloparatide-patch in August 2019 and expect to report top-line data from the study in the second half of 2021. The wearABLe study is a single, pivotal, randomized, open label, active-controlled, BMD non-inferiority bridging study with a planned enrollment of approximately 470 patients with postmenopausal osteoporosis at high risk of fracture, which if successful, will support an NDA submission. The primary endpoint of the study is percentage change in lumbar spine BMD at 12 months. Non-inferiority of abaloparatide-patch to abaloparatide-SC will be concluded if the lower bound of the 2-sided 95% confidence interval for the estimated treatment difference (abaloparatide-patch minus abaloparatide-SC) in the percentage change from baseline in lumbar spine BMD at 12 months is above -2.0%. We are implementing a revised enrollment plan for the wearABLe study that includes additional measures and resources intended to improve site recruitment efforts, as well as the addition of clinical trial sites outside the U.S.

In July 2019, we obtained reported results from a patient assessment study which evaluated self-administration of abaloparatide-patch over 29 days in 22 post-menopausal women with low bone density. Study patients were observed at a study site on the first, 15th and 29th day of the study. Top-line results showed that study patients were able to follow the instructions for use ("IFU") and applied the patches accurately on 99.7% of all applications. The safety data from this study showed that most of the study patients had mild, transient redness at the application site. The mean subject acceptability score on a 5-point scale was 4.5, 4.6 and 4.5 on day 1, 15 and 29, respectively. The laboratory data from this study included an exploratory assessment of PINP, a biomarker that indicates bone formation. At baseline the median PINP level in this study was 50.5 ng/ml, increasing to a median value of 100.1 ng/ml at day 29, while, by comparison, the median PINP values observed with abaloparatide-SC in the ACTIVE study were 50.6 ng/ml at baseline and 100.5 ng/ml at one month.

In February 2018, we entered into the Supply Agreement pursuant to which 3M agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-patch. In partnership with 3M, we selected Thermo Fisher to conduct the abaloparatide-patch coating process and packaging operations. In December 2019, 3M announced that it entered into an agreement to sell its drug delivery business, which manufactures clinical trial supplies of abaloparatide-patch, to an affiliate of Altaris Capital Partners, LLC ("Altaris"). The transaction with Altaris, which is subject to closing conditions and regulatory

approvals, is expected to close in the first half of 2020. In connection with the transaction, we anticipate that the Scale-Up and Commercial Supply Agreement with 3M will transfer to Altaris following the completion of certain transition arrangements between 3M and Altaris.

In October 2018, we committed to fund 3M's purchase of capital equipment totaling approximately $9.6 million in preparation for manufacturing Phase 3 and commercial supplies of abaloparatide-patch, if approved. Milestone payments for the equipment commenced in the fourth quarter of 2018 and are expected to be paid in full in the second quarter of 2021. In addition, there are cancelable purchase commitments in place to fund the facility build out and future purchases of capital equipment.

We have successfully completed development activities associated with the scale up of manufacturing to supply our ongoing abaloparatide-patch Phase 3 wearABLe study. The completion of the engineering equipment designs for critical equipment to produce abaloparatide-patch at the commercial site is on target, and critical equipment has started to arrive and is being installed. In December 2019, we aligned with the FDA on requirements for an NDA filing.

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 patients 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.

Phase 3 - EMERALD Study

We initiated our Phase 3 EMERALD study of elacestrant in late November 2018 and expect to complete enrollment in the third quarter of 2020. The Phase 3 study is a single, randomized, open label, active-controlled Phase 3 trial of elacestrant as a second- or third-line monotherapy in approximately 460 patients with ER+ and HER2- advanced or metastatic breast cancer who have received prior treatment with one or two endocrine therapies, including a CDK 4/6 inhibitor. Patients in the study will be randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent. The primary endpoint of the study will be PFS, which we will analyze in the overall patient population and in patients with ESR1 mutations. Secondary endpoints will include evaluation of OS, ORR, and DOR. We believe that, depending on results, this single trial would support applications for marketing approvals for elacestrant as a second- and third-line monotherapy in the U.S., EU and other markets. In November 2018, the FDA granted Fast Track designation for elacestrant consistent with the population to be included in the Phase 3 study. We do not plan to initiate any further clinical trials of elacestrant beyond our ongoing EMERALD study.

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 were heavily pretreated ER-positive, HER2-negative advanced breast cancer patients who had 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 to support the elacestrant clinical development program anticipated at that time. We discontinued recruitment in the Part D cohort as the data was no longer required to support the final design of our Phase 3 study.

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 Parts A through C of this study. As of the study interim 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 PFS 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.

We initiated Part D of the Phase 1 dose-escalation and expansion study to evaluate the safety and preliminary efficacy of elacestrant at a 400 mg tablet dose in a population with different eligibility requirements from Parts A, B, and C of this study. In Part D, patients were required to have at least two prior lines of endocrine therapy for advanced/metastatic breast cancer, including fulvestrant, and prior treatment with a CDK 4/6 inhibitor. Ten patients of an originally planned thirty-six were enrolled in Part D. A review of the data as of October 24, 2019 showed that overall the patients in Part D were more heavily

pretreated and more likely to have visceral metastases than patients in Parts A through C of this study. In addition, out of the nine patients with measurable disease, four had a best response of stable disease, two of them for greater than 24 weeks. Combined data, as of October 24, 2019, from all four study Parts (A through D) at 400 mg showed that the overall elacestrant single agent ORR was 19.4% and the median PFS was 4.5 months.

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 included the use of FES-PET imaging to assess estrogen receptor occupancy in tumor lesions following elacestrant treatment.

In December 2017, we reported data from the Phase 1 FES-PET study showing 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 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. In December 2018, we announced additional preclinical data that showed that elacestrant demonstrated marked tumor growth inhibition as a single agent in models harboring ESR1 point mutations, models insensitive to fulvestrant, and models insensitive to CDK 4/6 inhibitors such as palbociclib, ribociclib, or abemaciclib.

Collaborations

After a comprehensive partnership evaluation for elacestrant and consistent with our plan to focus on bone health and targeted endocrine diseases, we are now exploring all strategic options for elacestrant.

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 trial. In February 2020, we terminated this collaboration.

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 September 2017, we initiated a Phase 1 study of RAD140 in patients with ER+/AR+/HER2- locally advanced or metastatic breast cancer. The clinical trial was designed to evaluate the safety and MTD of RAD140 in approximately 40 patients. Primary safety endpoints from the trial included the incidence 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 were also evaluated. In December 2019, we presented the Phase 1A data based on a data cut-off of October 31, 2019. The data showed that a total of 22 patients with advanced/metastatic breast cancer had been treated at once daily oral doses ranging from 50mg to 150mg, and that the MTD was 100mg per day. The patients were heavily pre-treated, with a median of four prior lines of therapy for metastatic disease, including chemotherapy in all but two patients. As of February 11, 2020, one patient remained on treatment. Evidence of clinical activity was seen with a partial response in one of nine RECIST

evaluable patients and pharmacodynamic data consistent with AR modulatory activity was also seen. We do not plan to initiate any additional clinical studies of 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 CDK 4/6 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 December 2018, we presented a preclinical poster further demonstrating anti-tumor activity of RAD140 in breast cancer models resistant to standard-of-care endocrine treatments.

Financial Overview

Product Revenue

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

Cost of Product Revenue

Cost of product revenue consists primarily of costs associated with the manufacturing of TYMLOS, royalties owed to our licensor for such sales, and certain period costs.

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. Abaloparatide represents the largest portion of our research and development expenses for our investigational product candidates since our inception. We began tracking program expenses for abaloparatide-SC in 2005, and program expenses from inception to December 31, 2019 were approximately $230.4 million. We began tracking program expenses for abaloparatide-patch in 2007, and program expenses from inception to December 31, 2019 were approximately $78.4 million. We began tracking program expenses for elacestrant in 2006, and program expenses from inception to December 31, 2019 were approximately $112.7 million. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to December 31, 2019 were approximately $17.2 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, 2019, 2018 and 2017 (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Program-specific costs - external:			
Abaloparatide-SC	$ 8,234	$ 7,591	$ 1,686
Abaloparatide-patch	26,185	10,112	2,991
Elacestrant	27,267	17,433	12,486
RAD140	2,126	4,055	2,135
Total program-specific costs - external	$ 63,812	$ 39,191	$ 19,298
Shared-services costs - external:			
R&D support costs	13,217	11,554	12,206
Other operating costs	2,152	2,468	2,871
Total shared-services costs - external:	$ 15,369	$ 14,022	$ 15,077
Shared-services costs - internal:			
Personnel-related costs	26,114	32,094	30,995
Share-based compensation	8,769	11,657	14,698
Occupancy costs	1,853	1,914	2,158
Depreciation	840	1,033	850
Total shared-services costs - internal:	$ 37,576	$ 46,698	$ 48,701
Total R&D costs	$ 116,757	$ 99,911	$ 83,076

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 results also include stock-based compensation expense as a result of the issuance of stock option, restricted stock unit, and performance unit grants to our employees, directors and consultants. The stock-based compensation expense is included in the respective categories of expense in our condensed consolidated statements of operations and comprehensive loss (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.

Other Operating Expenses

Other operating expenses reflect a payment we made to Ipsen in November 2018, pursuant to a final decision in arbitration proceedings with Ipsen.

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 trial 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.

Revenue recognition

On April 28, 2017, the FDA approved TYMLOS in the U.S. After receiving FDA approval, we entered into a limited number of arrangements with wholesalers in the U.S. (collectively, our “Customers”) to distribute TYMLOS. These arrangements are our initial contracts with customers and, as a result, we adopted Accounting Standards Codification (“ASC”) Topic 606 - Revenue from Contracts with Customers (“Topic 606”). There is no transition to Topic 606 because we had 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. We only apply the five-step model to arrangements that meet the definition of a contract under Topic 606, including when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to our customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

We sell TYMLOS to our Customers. These Customers subsequently resell our products to specialty pharmacy providers, as well as other retail pharmacies and certain medical centers or hospitals. In addition to distribution agreements with Customers, we enter into arrangements with specialty pharmacies, health care providers and payors that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of our products.

We recognize revenue on product sales when the Customer obtains control of our 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. Payment from Customers is typically due within 31 calendar days of the invoice date.

If taxes should be collected from Customers relating to product sales and remitted to governmental authorities, they will be excluded from revenue. We expense incremental costs of obtaining a contract when incurred, if the expected amortization period of the asset that we would have recognized is one year or less. However, no such costs were incurred during the twelve months ended December 31, 2019.

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, payor rebates, and other incentives, such as voluntary patient assistance, and other allowances that are offered within contracts between us and our Customers, payors, and other indirect customers relating to the sale of our 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 our 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. Our 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, 2019 and, therefore, the transaction price was not reduced further during the twelve months ended December 31, 2019. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances

We generally provide Customers with discounts which include incentive fees that are explicitly stated in our contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, we compensate (through trade discounts and allowances) our Customers for sales order management, data, and distribution services. However, we have determined such services received to date are not distinct from the sale of our 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, 2019, as well as a reduction to trade receivables, net on the consolidated balance sheets.

Product Returns

Consistent with industry practice, we generally offer Customers a limited right of return for product that has been purchased from us based on the product's expiration date, which lapses upon shipment to a patient. We estimate the amount of product sales that may be returned by our Customers and record 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. We currently estimate product return liabilities using available industry data and our own sales information, including our visibility into the inventory remaining in the distribution channel. We have received an immaterial amount of returns to date and believe that returns of product in future periods will be minimal.

Our limited right of return policy allows for eligible returns of TYMLOS from Customers in the following circumstances:

- Shipment errors that were the result of an error by us;
- Quantity delivered that is greater than the quantity ordered;
- Product distributed by us that is damaged in transit prior to receipt by the customer;
- Expired product, previously purchased directly from us, 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 we, at our sole discretion, have specified to be returned.

In addition, our limited right of return policy allows for eligible returns of TYMLOS from indirect purchasers in the following circumstances:

- Expired product 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 we, at our sole discretion, have 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 us. Customers charge us 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 we generally issue credits for such amounts within a few weeks of the Customer's notification to us of the resale. Reserves for chargebacks consist of credits that we expect to issue for units that remain in the distribution channel inventories at each reporting period-end that we expect will be sold to qualified healthcare providers, and chargebacks that Customers have claimed, but for which we have not yet issued a credit.

Government Rebates

We are 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, we also estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program. Our liability for these rebates consist 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

We contract with certain private payor organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of our products. We estimate these rebates and record 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 we offer include voluntary patient assistance programs, such as our 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 we expect 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 condensed consolidated balance sheets.

Licenses of Intellectual Property

We enter into out-licensing agreements within the scope of Topic 606, under which we license certain rights to our product candidates to third parties. Such agreements may include the transfer of intellectual property rights in the form of licenses, transfer of technological know-how, delivery of drug substances, research and development services, and participation on certain committees with the counterparty. Payments made by the customers may include one or more of the following: non-refundable, up-front license fees; payments upon the exercise of customer options; development, regulatory, and commercial milestone payments; payments for manufacturing supply services we provide through our contract manufacturers; and royalties on net sales of licensed products if they are successfully approved and commercialized. 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 we fulfill our obligations under each of our out-licensing agreements, we perform 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) we satisfy each performance obligation. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and determines those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from the transaction price allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. We evaluate all other promised goods or services in the agreement to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services to create a bundle of promised goods or services that is distinct. Optional future services where any additional consideration paid to us reflects their standalone selling prices do not provide the customer with a material right and, therefore, are not considered performance obligations. If optional future services are priced in a manner which provides the customer with a significant or incremental discount, they are material rights, and are accounted for as performance obligations.

We utilize judgment to determine the transaction price. In connection therewith, we evaluate contingent milestones at contract inception to estimate the amount which is not probable of a material reversal to include in the transaction price using the most likely amount method. Milestone payments that are not within our control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received and, therefore, the variable consideration is constrained. At the end of each reporting period, we re-evaluate the probability of achieving development milestone payments which may not be subject to a material reversal and, if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license and other revenue, as well as earnings, in the period of adjustment.

The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied.

We then determine whether the performance obligations or combined performance obligations are 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, upfront fees. We evaluate the measure of progress, as applicable, each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded within deferred revenue. Contract liabilities within deferred revenue are recognized as revenue after control of the goods or services is transferred to the customer and all revenue recognition criteria have been met.

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

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. We assess if these options provide a material right to the licensee and, if so, they are accounted for as separate performance obligations. If we are 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.

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, 2019 and December 31, 2018

	Years Ended December 31,		Change	
	2019	2018	$	%
	(in thousands)			
Revenues:				
Product revenue, net	$ 173,317	$ 99,239	$ 74,078	75 %
License revenue	—	—	—	— %
Operating expenses:				
Cost of sales - product	15,287	7,627	7,660	100 %
Cost of sales - intangible amortization	798	799	(1)	— %
Research and development	116,757	99,911	16,846	17 %
Selling, general and administrative	152,704	184,164	(31,460)	(17)%
Other operating expense	—	10,801	(10,801)	(100)%
Loss from operations	(112,229)	(204,063)	91,834	(45)%
Other (expense) income:				
Other income / (expense), net	242	59	183	310 %
Interest income / (expense), net	(21,006)	(17,333)	(3,673)	21 %
Net loss	$ (132,993)	$ (221,337)	$ 88,344	(40)%

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, 2019 we recorded approximately $173.3 million of net product revenue compared to $99.2 million for the year end December 31, 2018. The increase in product revenue was primarily driven by an increase in sales volume as a result of greater market penetration.

Cost of sales—For the year ended December 31, 2019, cost of sales was $16.1 million compared to $8.4 million for the year end December 31, 2018. The increase in cost of sales was primarily driven by the increase in product revenue.

Research and development expenses—For the year ended December 31, 2019, research and development expense was $116.8 million, as compared to $99.9 million for the year ended December 31, 2018, an increase of $16.8 million, or 17%. This increase was primarily a result of an increase of $16.1 million in program spending for the abaloparatide-patch program, a $9.8 million increase in program spending for elacestrant research, a $1.7 million increase in professional services, and $0.6 million increase in program spending for the abaloparatide-SC program. These increases were partially offset by a $1.9 million decrease in program spending for RAD-140 program, a $0.3 million decrease in R&D support costs as well as an $9.2 million decrease in compensation related costs.

Selling, general and administrative expenses—For the year ended December 31, 2019, selling, general, and administrative expense was $152.7 million, as compared to $184.2 million for the year ended December 31, 2018, a decrease of $31.5 million, or 17%. This decrease was primarily due to a $10.0 million decrease in professional fees related to commercial operations and general and administrative activities, a $17.9 million decrease in compensation and travel entertainment costs and a $3.6 million decrease in other costs.

Other operating expenses—For the year ended December 31, 2019, other operating expenses were approximately $0.0 million compared to $10.8 million for the year ended December 31, 2018, a decrease of $10.8 million. This decrease was the result of a $10.8 million payment made to Ipsen pursuant to a final decision in arbitration proceedings with Ipsen during the second quarter of 2018.

Other Income, net— For the year ended December 31, 2019, other expense, net of other income, was $0.2 million, as compared to $0.1 million during the year ended December 31, 2018. Other expense, net of other income, of $0.2 million for the year ended December 31, 2019 consisted primarily of other foreign currency revaluation gains of other taxes. The $0.1 million of other expense, net of income, for the year ended December 31, 2018 consisted primarily of other foreign currency revaluation losses.

Interest income (expense), net—For the year ended December 31, 2019, net interest expense was $21.0 million, as compared to net interest expense of $17.3 million during the year ended December 31, 2018, a total change of $3.7 million, or 21%. This change was primarily the result of the increasing interest expense incurred over the term of the convertible notes that was partially offset by the interest income earned on investments.

Years Ended December 31, 2018 and December 31, 2017

	Years Ended December 31,		Change	
	2018	2017	$	%
	(in thousands)			
Revenues:				
Product revenue, net	$ 99,239	$ 12,112	87,127	719 %
License revenue	—	10,000	(10,000)	(100)%
Operating expenses:				
Cost of sales - product	7,627	932	6,695	718 %
Cost of sales - intangible amortization	799	400	399	100 %
Research and development	99,911	83,076	16,835	20 %
Selling, General and administrative	184,164	186,677	(2,513)	(1)%
Other operating expense	10,801	—	10,801	100 %
Loss from operations	(204,063)	(248,973)	44,910	(18)%
Other (expense) income:				
Other (expense) income, net	59	(192)	251	(131)%
Interest (expense) income, net	(17,333)	(5,072)	(12,261)	242 %
Net loss	$ (221,337)	$ (254,237)	32,900	(13)%

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, 2018 we recorded approximately $99.2 million of net product revenue compared to $12.1 million for the year end December 31, 2017. The increase in product revenue was primarily driven by an increase in sales volume as a result of greater market penetration. 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 $8.4 million for the year ended December 31, 2018 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 compared to $1.3 million for the year end December 31, 2017. The increase in cost of sales was driven by the increase in product revenue. In addition, 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, 2018, or $0.5 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, 2018, research and development expense was $99.9 million compared to $83.1 million for the year ended December 31, 2017, an increase of $16.8 million, or 20%. This increase was primarily a result of an increase of $7.1 million in program spending for the abaloparatide-patch program, a $5.9 million increase in program spending for continuing research into TYMLOS, a $4.9 million increase in program spending for elacestrant research, and a $1.9 million increase in program spending for RAD140 research. These increases were partially offset by a $1.3 million decrease in R&D support costs as well as a $1.7 million decrease in compensation related costs primarily due to the decrease in stock compensation expense for the year ended December 31, 2018. We expect our research and development expenses to continue to increase as the result of conducting our elacestrant Phase 3 study and the expected launch in 2019 of our abaloparatide-patch Phase 3 study and related manufacturing scale up activities.

Selling, General and administrative expenses—For the year ended December 31, 2018, general and administrative expense was $184.2 million compared to $186.7 million for the year ended December 31, 2017, a decrease of $2.5 million, or 1%. This decrease was primarily due to a $3.3 million decrease in professional fees related to commercial operations and general and administrative activities and a $0.5 million in compensation and travel entertainment costs. This decrease was offset by a $1.3 million increase in other operating costs.

Other operating expenses—For the year ended December 31, 2018, other operating expenses were approximately $10.8 million compared to $0.0 million for the year ended December 31, 2017, an increase of $10.8 million. This increase was the result of a $10.8 million payment made to Ipsen pursuant to a final decision in arbitration proceedings with Ipsen during the second quarter of 2018.

Other (expense) income, net—For the year ended December 31, 2018, other expense, net of other income, was $0.1 million, as compared to $0.2 million during the year ended December 31, 2017. Other expense, net of other income, of $0.1 million for the year ended December 31, 2018 consisted primarily of other taxes. The $0.2 million of other expense, net of income, for the year ended December 31, 2017 was primarily due to other taxes and foreign currency revaluation losses.

Interest (expense) income—For the year ended December 31, 2018, interest expense was $17.3 million, as compared to $5.1 million in interest income during the year ended December 31, 2017, a total change of $12.3 million, or 242%. This change was a result of the issuance of the convertible notes during the year ended December 31, 2018, 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.

Liquidity and Capital Resources

From inception to December 31, 2019, we have incurred an accumulated deficit of $1.2 billion, 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, 2019 was $160.9 million. We have financed our operations since inception primarily through the public offerings of our common stock, private sale of preferred stock, convertible debt, and borrowing under credit facilities. Following our U.S. commercial launch of TYMLOS in May 2017, we have begun financing a portion of our operations through product revenue.

Based upon our cash, cash equivalents, marketable securities, and investments balance as of December 31, 2019 and funds available to us through our credit facilities, we believe that, prior to the consideration of potential proceeds from partnering and/or collaboration activities, we have sufficient capital to fund our development plans, U.S. commercial and other operational activities for at least twelve months from the date of this filing. We expect to finance the future U.S. commercial activities and development costs of our clinical product portfolio with our existing cash, cash equivalents, marketable securities, and investments, as well as through future product sales, 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, the incurrence of additional debt, or other alternative financing arrangements, which may involve a combination of the foregoing. On January 10, 2020, we entered into entered into a secured, non-dilutive credit facility for up to an aggregate amount of $95 million, comprised of a term loan of up to $55.0 million and a $20.0 million revolving credit facility based on accounts receivable and inventory, with the right, subject to certain conditions, to increase the revolver by $20.0 million.

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. Our future capital requirements will depend on many factors, including the scope of and progress 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 or other foreign regulatory authorities. The successful development of our 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 commercialization activities or complete preclinical and clinical trials and obtain approval of any of our product candidates from the FDA and foreign regulatory authorities.

TYMLOS is our only approved product and our business currently depends heavily on its successful commercialization. Successful commercialization of an approved product is an expensive and uncertain process. See “Risk Factors - Risks Related to the Commercialization and Development of Our Product Candidates” set forth in Part I, “Item 1A. Risk Factors” in this Annual Report.

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,		
	2019	2018	2017
Net cash (used in) provided by:			
Operating activities	$ (82,414)	$ (204,726)	$ (206,677)
Investing activities	87,277	134,316	(248,986)
Financing activities	5,709	11,672	315,668
Net increase in cash and cash equivalents	$ 10,572	$ (58,738)	$ (139,995)

Cash Flows from Operating Activities

Net cash used in operating activities during the year ended December 31, 2019 was $82.4 million, which was primarily the result of a net loss of $133.0 million, partially offset by net changes in working capital of $8.7 million and $41.9 million of net non-cash adjustments to reconcile net loss to net cash used in operations. The $41.9 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of $23.6 million, amortization of the value of debt discount and issuance costs of $15.8 million, and depreciation and amortization of $2.3 million, impairment charge for the right of use operating lease of $0.3 million, and loss of fixed assets disposal of $0.2 million offset by amortization of premiums (discounts) on marketable securities of $0.4 million.

Net cash used in operating activities during the year ended December 31, 2018 was $204.7 million, which was primarily the result of a net loss of $221.3 million, partially offset by net changes in working capital of $28.4 million and $45.0 million of net non-cash adjustments to reconcile net loss to net cash used in operations. The $221.3 million net loss was primarily due to costs related to the continued commercial operations for TYMLOS such as compensation costs, professional support costs, and consulting fees as well as ongoing research and development costs. The $45.0 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of $28.7 million, amortization of debt discount and issuance costs of $13.8 million, depreciation and amortization of $2.9 million, offset by amortization of premiums (discounts) on marketable securities of $0.4 million.

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 $6.1 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 ongoing research and development expenses, particularly for elacestrant and RAD140 programs, along with costs related to the launch and continued commercial operations for TYMLOS such as 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 amortization of premiums (discounts) on marketable securities of $2.0 million, offset by amortization of discounts on marketable securities of $0.3 million.

Cash Flows from Investing Activities

Net cash provided by investing activities for the year ended December 31, 2019 was $87.3 million, as compared to net cash used in investing activities of $134.3 million for the year ended December 31, 2018.

The net cash provided by investing activities during the year ended December 31, 2019 was primarily a result of $206.8 million of net proceeds received from the sale or maturity of marketable securities, offset by $119.5 million in purchases of marketable securities. The net cash used in investing activities during the year ended December 31, 2018 was primarily a result of $0.5 million in purchases of marketable securities and $0.2 million of purchases of property and equipment, offset by $135.0 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, 2019 was $5.7 million as compared to $11.7 million of net cash provided by financing activities for the year ended December 31, 2018.

Net cash provided by financing activities during the year ended December 31, 2019 consisted of $3.9 million of proceeds as the result of stock option exercises and $1.8 million of proceeds received from the issuance of stock in connection with the employee stock purchase plan.

Net cash provided by financing activities during the year ended December 31, 2018 consisted of $9.1 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.

Borrowings and Other Liabilities

In August 2017, we issued $300.0 million aggregate principal amount of the Convertible Notes, as discussed in more detail in Note 9, “Notes Payable,” to our consolidated financial statements included in this Annual Report on Form 10-K. We received net proceeds of approximately $290.8 million from the sale of the Convertible Notes, after deducting fees and expenses of $9.2 million. In addition, in September 2017, we issued an additional $5.0 million aggregate principal amount of the Convertible Notes pursuant to the exercise of an over-allotment option granted to the underwriters in the offering. We

received net proceeds of approximately $4.8 million from the exercise of the over-allotment option, after deducting fees and expenses of $0.2 million.

Future minimum payments on our long-term debt as of December 31, 2019 were as follows (in thousands):

Year ended December 31,	Future Minimum Payments	
2020	$	9,150
2021		9,150
2022		9,150
2023		9,150
2024 and thereafter		314,150
Total minimum payments	$	350,750
Less: interest		(45,750)
Less: unamortized discount		(109,409)
Less: current portion		—
Long Term Debt	$	195,591

Leases

We adopted ASC 842 effective January 1, 2019, as discussed in more detail in Note 16, “Leases,” to our consolidated financial statements included in this Annual Report on Form 10-K.

Future payments of operating lease liabilities as of December 31, 2019 are as follows (in thousands):

Year ending December 31,		
2020	$	2,551
2021		1,413
2022		1,038
2023		980
2024		1,005
Thereafter		857
Total Lease payments	$	7,844
Less: effect of discounted cash flows during the period		(1,065)
Total	$	6,779

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 agreed to maintain the additional headcount through at least December 31, 2020. Failure to do so could result 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.

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 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.

Supply and Manufacturing Agreements—In June 2016, we entered into a Supply Agreement with Ypsomed AG ("Ypsomed"), pursuant to which Ypsomed agreed to supply commercial and clinical supplies of a disposable pen injection device customized for subcutaneous injection of abaloparatide. We agreed to purchase a minimum number of devices at prices per device that decrease with an increase in quantity supplied. In addition, we made milestone payments for Ypsomed's capital developments in connection with the initiation of the commercial supply of the device and paid 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 which began on June 1, 2017, after which, it automatically renews for two-year terms unless either party terminates the agreement upon 18 months' notice prior to the end of the then-current term. 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, we entered into a Commercial Supply Agreement with Vetter Pharma International GmbH ("Vetter"), pursuant to which Vetter has agreed to formulate the finished abaloparatide-SC drug product, to fill cartridges with the drug product, to assemble the pen delivery device, and to package 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, 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, we entered into a Manufacturing Services Agreement with Polypeptide Laboratories Holding AB ("PPL"), 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.

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 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, we 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, 2019. 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, we paid Ipsen a milestone of €8.0 million (approximately $8.7 million) under the License Agreement, which we 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 License Agreement provides that we are obligated to pay to Ipsen a fixed five percent royalty based on net sales of products containing abaloparatide by us or our 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 approximately $8.7 million for the year ended December 31, 2019. 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 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.

Prior to executing the License Agreement for abaloparatide with Radius, Ipsen licensed the Japanese rights for abaloparatide to Teijin. Teijin has initiated a Phase 3 clinical trial of abaloparatide-SC in Japan for the treatment of postmenopausal osteoporosis. We maintain full global rights to our development program for abaloparatide-patch.

Pursuant to a final decision in arbitration proceedings with Ipsen in connection with the License Agreement, we are obligated to pay Ipsen $5.0 million if abaloparatide receives marketing approval in Japan and a fixed mid single-digit royalty based on net sales of abaloparatide in Japan.

Abaloparatide-SC (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 our know-how that is necessary for the manufacture of active pharmaceutical ingredient and abaloparatide-SC, (v) a right to request that we 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) a right to request that we arrange for Teijin to directly enter into commercial supply agreements with our existing contract manufacturers on the same pricing terms and on substantially similar commercial terms to those set forth in our 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.

Teijin granted us (i) an exclusive license under certain of Teijin’s intellectual property to develop, manufacture and commercialize abaloparatide-SC outside Japan and (ii) a right of reference to certain of Teijin’s regulatory data related to abaloparatide-SC for purposes of developing, manufacturing and commercializing abaloparatide-SC outside Japan. We maintain full global rights to our 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.

Abaloparatide-patch

In February 2018, we entered into a Scale-Up and Commercial Supply Agreement (the “Supply Agreement”) with 3M Company and 3M Innovative Properties Company (collectively with 3M Company, “3M”), pursuant to which 3M agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-coated transdermal patch product (“Product”) and associated applicator devices (“Applicator”). Under the Supply Agreement, 3M agreed to manufacture Product and Applicator for us according to agreed-upon specifications in sufficient quantities to meet our projected supply requirements. 3M agreed to manufacture commercial supplies of Product at unit prices that decrease with an increase in the quantity we order. We are obligated to 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. In October 2018, the Company committed to fund 3M's purchase of capital equipment totaling approximately $9.6 million in preparation for manufacturing Phase 3 and potential commercial supplies of Product. Milestone payments for the equipment commenced in the fourth quarter of 2018 and are expected to be paid in full in the second quarter of 2021.

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. We 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 $28.9 million, in the aggregate, through December 31, 2019 with respect to services and deliverables delivered pursuant to the Development Agreement.

Elacestrant (RAD1901)

In June 2006, we entered into a license agreement with Eisai Co. Ltd.(the "Eisai Agreement'). Under the Eisai Agreement, Eisai granted us 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, we paid Eisai an initial license fee of $0.5 million, which was expensed during 2006. In March 2015, we entered into an amendment to the Eisai Agreement (the "Eisai Amendment") in which Eisai granted us the exclusive right and license to research, develop, manufacture and commercialize elacestrant in Japan. In consideration for the rights to elacestrant in Japan, we 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 Agreement, as amended, also provides for additional payments of up to $22.3 million, payable upon the achievement of certain clinical and regulatory milestones. To date, the Company has paid Eisai approximately $1.0 million in connection with the achievement of certain 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, 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 us the right to grant sublicenses 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 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.

Elacestrant (Duke)

In December 2017, we and Duke University ("Duke") entered into a License Agreement (the "Duke Agreement") pursuant to which we 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, we incurred non-refundable, non-creditable obligations to pay Duke, totaling $1.3 million, which were expensed as research and development costs during 2017. The Duke 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 we 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 we sublicense the Duke Patents to a third party, the agreement provides that we will pay Duke a percentage of certain payments we received from such sublicensee(s). The applicable percentage is in the high single-digit range on certain payments received in excess of a pre-specified amount. The Duke Agreement may be terminated by either party upon an uncured material breach of the agreement by the other party. We may terminate the agreement upon 60 days written notice to Duke, if we suspend our manufacture, use and sale of the licensed products.

Net Operating Loss Carryforwards

As of December 31, 2019, we had federal and state net operating loss carryforwards of approximately $974.3 million and $681.8 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 of 1986, or Section 382, 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. 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. A full valuation allowance has been recorded against our net operating loss carryforwards and other deferred tax assets, 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 condensed consolidated statements 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, "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.

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, 2019, we had cash, cash equivalents and short-term marketable securities of $160.9 million, consisting of cash, money market funds, domestic corporate debt securities, and agency bonds. 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, 2019, 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

To the Shareholders and the 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, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with 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, 2019, 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 February 27, 2020 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 the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Product Revenue Reserves and Allowances

Description of the Matter

As summarized in Note 11 to the consolidated financial statements, the Company had product revenue reserves and allowances of $24.6 million as of December 31, 2019. Such amounts include chargebacks, prompt pay discounts, wholesaler fees, and returns, which are recorded net of trade receivables on the consolidated balance sheets, as well as government and other rebates, which are recorded within accrued expenses and other current liabilities on the consolidated balance sheets, as disclosed in Notes 2 and 11 to the consolidated financial statements.

Auditing the Company’s measurement of the reserves for product returns and exposure under the Medicare Part D coverage gap is complex because the estimates involve subjective management assumptions about (i) current contractual and statutory requirements, (ii) specific known market events and trends, (iii) industry data, and (iv) forecasted customer buying and payment patterns, including units of product in the distribution channel as of the balance sheet date.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls that address the identified risks related to the Company's process used in determining the reserves for product returns and exposure under the Medicare Part D coverage gap, including controls over the subjective management assumptions in estimating the reserves.

To test the adequacy of the Company's reserves for product returns and exposure under the Medicare Part D coverage gap, our audit procedures included, among other procedures, evaluating the significant assumptions used by management to estimate the reserves. To assess the reasonableness of the significant assumptions, we (i) reviewed contracts and modifications thereto with certain of the Company’s customers, and further confirmed the terms of the Company’s contracts with certain customers, to evaluate if there were any provisions that would allow for extended rights of return or other similar provisions beyond the Company’s standard policies, (ii) compared cash receipts against product sales to review for unexpected trends and other information, (iii) performed revenue cutoff testing to assess if there were unusual patterns at period end not considered in the Company’s analyses, (iv) developed independent expectations of the estimated accrual rates for the reserves, (v) performed lookback analyses using actual historical data to evaluate the forecasted amounts, which included testing credits issued and payments made throughout year, (vi) assessed subsequent events to determine whether there was any new information that would require adjustment to the reserves, and (iv) evaluated overall trends in the reserves.

Accrued Research and Development Expenses

Description of the Matter

The Company's accrued costs for research and development expenses totaled $13.0 million at December 31, 2019, including accruals related to clinical trials. As discussed in Note 2 to the consolidated financial statements, the Company is required to estimate such accruals using judgment based on certain information, including actual costs incurred or level of effort expended, as provided by its vendors. Payments for such activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheet as accrued or prepaid research and development expense.

Auditing the Company's accruals for research and development expenses is complex, as certain of the amounts recorded thereon within the Company's consolidated financial statements are based on estimates from third-party vendors, as well as other inputs evaluated internally by members of management, such as the number of active sites, patient enrollment, and project timeline. Furthermore, due to the duration of the Company's ongoing clinical trials, as well as the related manufacturing activity, and the timing of invoicing received from third parties, the actual amounts incurred are not typically known by the report date.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls that address the identified risks related to the Company's process used in determining the completeness and valuation of accrued research and development expenses.

To evaluate the accrual for research and development expenses, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used in the estimates and evaluating the significant assumptions that are used by management to estimate the recorded accruals and prepayments. To test the significant assumptions, we corroborated the progress of research and development activities through discussion with the Company's research and development personnel that oversee the research and development projects, inspection of the Company's contracts with third parties and any pending change orders to assess the impact on amounts recorded, and review of certain information received by the Company directly from certain third parties, which indicated the third parties' estimate of costs incurred to date. We also performed analytics over fluctuations in accruals by vendor throughout the period subject to audit and tested subsequent invoicing received from such third parties.

/s/ Ernst & Young LLP

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

Boston, Massachusetts
February 27, 2020

Radius Health, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 69,886	$ 59,321
Restricted cash	567	560
Marketable securities	91,015	177,140
Accounts receivable, net	23,289	16,758
Inventory	5,323	6,210
Prepaid expenses	12,131	13,842
Other current assets	846	1,202
Total current assets	203,057	275,033
Property and equipment, net	2,293	4,003
Intangible assets	6,583	7,382
Right of use assets - operating leases	6,704	—
Other assets	514	544
Total assets	$ 219,151	$ 286,962
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 6,030	$ 4,226
Accrued expenses and other current liabilities	53,030	42,203
Operating lease liability, current	2,198	—
Total current liabilities	61,258	46,429
Notes payable	195,591	179,806
Operating lease liability, long term	4,581	—
Other non-current liabilities	—	95
Total liabilities	$ 261,430	$ 226,330
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, $.0001 par value; 200,000,000 shares authorized, 46,189,870 shares and 45,563,693 shares issued and outstanding at December 31, 2019 and 2018, respectively	5	5
Additional paid-in-capital	1,194,327	1,165,003
Accumulated other comprehensive income (loss)	3	(755)
Accumulated deficit	(1,236,614)	(1,103,621)
Total stockholders' equity (deficit)	(42,279)	60,632
Total liabilities and stockholders' equity (deficit)	$ 219,151	$ 286,962

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,		
	2019	2018	2017
REVENUES:			
Product revenue, net	$ 173,317	$ 99,239	$ 12,112
License revenue	—	—	10,000
OPERATING EXPENSES:			
Cost of sales - product	15,287	7,627	932
Cost of sales - intangible amortization	798	799	400
Research and development	116,757	99,911	83,076
Selling, general and administrative	152,704	184,164	186,677
Other operating expense	—	10,801	—
Loss from operations	(112,229)	(204,063)	(248,973)
OTHER (EXPENSE) INCOME:			
Other income (expense), net	242	59	(192)
Interest income	3,929	5,622	3,226
Interest expense	(24,935)	(22,955)	(8,298)
NET LOSS	$ (132,993)	$ (221,337)	$ (254,237)
OTHER COMPREHENSIVE LOSS:			
Unrealized gain (loss) from available-for-sale securities	758	(441)	(385)
COMPREHENSIVE LOSS	$ (132,235)	$ (221,778)	$ (254,622)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS—BASIC AND DILUTED (Note 12)	$ (132,993)	$ (221,337)	$ (254,237)
LOSS PER SHARE:			
Basic and diluted	$ (2.89)	$ (4.88)	$ (5.80)
WEIGHTED AVERAGE SHARES:			
Basic and diluted	46,026,217	45,356,263	43,804,660

See accompanying notes to consolidated financial statements.

Radius Health, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
(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 (Deficit)
	Shares	Amount	Amount	Amount	Amount	Amount
Balance at 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 loss from available-for-sale securities				(385)		(385)
Vesting of restricted shares	14,052					—
Exercise of options	1,385		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
Net loss					(221,337)	(221,337)
Unrealized loss from available-for-sale securities				(441)		(441)
Vesting of restricted shares	36,852	—				—
Exercise of options	472,374	1	9,106			9,107
Exercise of warrants	336,059					—
Share-based compensation expense related to share-based awards for employee stock purchase plan			796			796
Issuance of common stock upon purchase by employee stock purchase plan	101,822	—	2,566			2,566
Share-based compensation expense			27,905			27,905
Balance at December 31, 2018	45,563,693	$ 5	$ 1,165,003	$ (755)	$ (1,103,621)	$ 60,632
Net loss					(132,993)	(132,993)
Unrealized gain from available-for-sale securities				758		758
Vesting of restricted shares	92,031	—				—
Exercise of options	341,337	—	2,869			2,869
Exercise of warrants	81,104		1,000			1,000
Share-based compensation expense related to share-based awards for employee stock purchase plan			661			661
Issuance of common stock upon purchase by employee stock purchase plan	111,705	—	1,840			1,840
Share-based compensation expense			22,954			22,954
December 31, 2019	46,189,870	$ 5	$ 1,194,327	$ 3	$ (1,236,614)	$ (42,279)

See accompanying notes to consolidated financial statements.

Radius Health, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2019	2018	2017
CASH FLOWS USED IN OPERATING ACTIVITIES:			
Net loss	$ (132,993)	$ (221,337)	$ (254,237)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,308	2,867	1,951
Amortization of premium (accretion of discount) on marketable securities, net	(394)	(390)	(264)
Impairment loss on operating lease right of use assets	339	—	—
Stock-based compensation expense	23,615	28,701	35,003
Amortization of debt discount and issuance costs	15,785	13,800	4,816
Loss on disposals of property and equipment	201	—	—
Changes in operating assets and liabilities:			
Inventory	887	(1,844)	(4,366)
Accounts receivables, net	(6,531)	(12,317)	(4,441)
Prepaid expenses	1,711	(8,667)	(3,689)
Other current assets	356	989	(1,362)
Operating lease right of use assets	2,034	—	—
Other long-term assets	30	255	(248)
Accounts payable	1,804	311	(2,213)
Accrued expenses and other current liabilities	10,827	(7,000)	22,563
Lease liability, operating leases	(2,298)	—	—
Other non-current liabilities	(95)	(94)	(190)
Net cash used in operating activities	(82,414)	(204,726)	(206,677)
CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES:			
Purchases of property and equipment	—	(185)	(2,341)
Payment of milestone related to intangible asset	—	—	(8,712)
Purchases of marketable securities	(119,502)	(499)	(429,296)
Sales and maturities of marketable securities	206,779	135,000	191,363
Net cash (used in) provided by investing activities	87,277	134,316	(248,986)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:			
Proceeds from exercise of stock options and warrants	3,869	9,106	17,478
Proceeds from issuance of convertible notes	—	—	305,000
Deferred financing costs	—	—	(9,360)
Proceeds from employee stock purchase plan	1,840	2,566	2,550
Net cash provided by financing activities	5,709	11,672	315,668
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	10,572	(58,738)	(139,995)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF YEAR	59,881	118,619	258,614
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF YEAR	$ 70,453	$ 59,881	$ 118,619
SUPPLEMENTAL DISCLOSURES:			
Cash paid for interest	$ 9,150	$ 9,582	$ —
Property and equipment purchases in accrued expense	$ —	$ 309	$ 352
Right of use assets obtained in exchange for operating lease liability	$ 9,077	$ —	$ —

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 April 2017, the Company's 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 January 2019, the European Commission adopted a decision refusing approval of the Company's European Marketing Authorisation Application ("MAA") for abaloparatide-SC. In July 2017, the Company entered into a license and development agreement with Teijin Limited ("Teijin") for abaloparatide for subcutaneous injection ("abaloparatide-SC") in Japan, under which the Company received an upfront payment and is 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. 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 an 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 investigated its 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, 2019, the Company had an accumulated deficit of $1.2 billion, and total cash, cash equivalents, marketable securities, and investments of $160.9 million.

Based upon its cash, cash equivalents, marketable securities, and investments balance as of December 31, 2019, 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 at least one year 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 clinical trials and obtain approval of certain investigational product candidates from the FDA or foreign regulatory authorities. On January 10, 2020, the Company entered into entered into a secured, non-dilutive credit facility for up to an aggregate amount of $95 million, comprised of a term loan of up to $55.0 million and a $20.0 million revolving credit facility based on accounts receivable and inventory, with the right, subject to certain conditions, to increase the revolver by $20.0 million.

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, 2019 and 2018.

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, 2019 and 2018.

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. The Company records unrealized gains and losses on available-for-sale debt securities as a component of Accumulated other comprehensive (loss), which is a separate component of shareholders' equity on its consolidated balance sheet, until such gains and losses are realized. 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, 2019 and 2018.

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 marketplace.

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 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. 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, 2019 and 2018.

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. Forfeitures are recognized as they occur.

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 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 grant date fair value of the options issued, as determined by the Black-Scholes option pricing model.

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 had 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, 2019 and 2018.

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, 2019 and, therefore, the transaction price was not reduced further during the twelve months ended December 31, 2019 and 2018. 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, 2019, 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 us;
- Quantity delivered that is greater than the quantity ordered;
- Product distributed by us that is damaged in transit prior to receipt by the customer;
- Expired product, previously purchased directly from us, 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 we, at our sole discretion, have specified to be returned.

In addition, our limited right of return policy allows for eligible returns of TYMLOS from indirect purchasers in the following circumstances:

- Expired product 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 we, at our sole discretion, have 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.

Licenses of Intellectual Property— We enter into out-licensing agreements within the scope of Topic 606, under which we license certain rights to our product candidates to third parties. Such agreements may include the transfer of intellectual property rights in the form of licenses, transfer of technological know-how, delivery of drug substances, research and development services, and participation on certain committees with the counterparty. Payments made by the customers may include one or more of the following: non-refundable, up-front license fees; payments upon the exercise of customer options; development, regulatory, and commercial milestone payments; payments for manufacturing supply services we provide through our contract manufacturers; and royalties on net sales of licensed products if they are successfully approved and commercialized. 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 we fulfill our obligations under each of our out-licensing agreements, we perform 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) we satisfy each performance obligation. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from the transaction price allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. We evaluate all other promised goods or services in the agreement to determine if they are distinct. If they are not distinct, they are combined with other promised goods or services to create a bundle of promised goods or services that is distinct. Optional future services where any additional consideration paid to us reflects their standalone selling prices do not provide the customer with a material right and, therefore, are not considered performance obligations. If optional future services are priced in a manner which provides the customer with a significant or incremental discount, they are material rights, and are accounted for as performance obligations.

We utilize judgment to determine the transaction price. In connection therewith, we evaluate contingent milestones at contract inception to estimate the amount which is not probable of a material reversal to include in the transaction price using the most likely amount method. Milestone payments that are not within our control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received and, therefore, the variable consideration is constrained. At the end of each reporting period, we re-evaluate the probability of achieving development milestone payments which may not be subject to a material reversal and, if necessary, adjust our estimate of the overall transaction price. Any such

adjustments are recorded on a cumulative catch-up basis, which would affect license and other revenue, as well as earnings, in the period of adjustment.

The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied.

We then determine whether the performance obligations or combined performance obligations are 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, upfront fees. We evaluate the measure of progress, as applicable, each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

When consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services to the customer under the terms of a contract, a contract liability is recorded within deferred revenue. Contract liabilities within deferred revenue are recognized as revenue after control of the goods or services is transferred to the customer and all revenue recognition criteria have been met.

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

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.

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.

Accrued Clinical Expenses—The Company estimates its accrued clinical expenses, which involves reviewing open contracts and purchase orders, communicating with Company personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of actual cost. Payments under some of the contracts the Company has 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 trial materials.

When accruing clinical expenses, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If possible, the Company obtains information regarding unbilled services directly from its service providers. However, the Company may be required to estimate the cost of these services based only on internally developed estimates. If the Company underestimates or overestimates 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, the Company's estimated accrued clinical expenses have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in the Company's accruals.

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. 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 was allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed.

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, and warrants. 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 February 2016, the FASB issued ASU 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 supersedes the lease guidance under FASB ASC Topic 840, Leases, resulting in the creation of FASB Accounting Standards Codification ("ASC") Topic 842, Leases. ASU 2016-02 requires a lessee to recognize a liability to make lease payments and a right-of-use asset in the statement of financial position, representing its right to use the underlying asset for the lease term for both finance and operating leases.

In July 2018, the FASB issued ASU 2018-10, Codification Improvements to Topic 842, Leases ("ASU 2018-10") and ASU No. 2018-11, Target Improvements to Topic 842, Leases ("ASU 2018-11"). The amendments in ASU 2018-10 provide additional clarification and implementation guidance on certain aspects of ASU 2016-02 and have the same effective and transition requirements as ASU 2016-02. ASU 2018-11 gives entities the option to not provide comparative period financial statements and instead apply the transition requirements as of the effective date of ASU 2016-02. ASU 2016-02, ASU 2018-10 and ASU 2018-11 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. Early adoption is permitted. The Company adopted the standard effective January 1, 2019 using the optional method under ASU 2018-11 and therefore, prior period financial information has not been retrospectively adjusted.

The Company applied the package of practical expedients to leases that commenced prior to the effective date whereby it elected to not reassess: (i) whether any expired or existing contracts contain leases; (ii) the lease classification for any expired or existing leases; and (iii) initial direct costs for any existing leases. The Company also elected the short-term lease recognition exemption for all leases that qualify, where a right-of-use asset or lease liability will not be recognized for short term leases. Furthermore, for all leases entered into or modified after the effective date, the Company has made an accounting policy

election, by class of underlying asset, to not separate nonlease components from lease components. The Company did not elect the use-of-hindsight to estimate the lease term or to assess impairment of right-of-use assets for existing leases.

As summarized in the table below, the standard had a material impact on the Company's consolidated balance sheet as of December 31, 2019, specifically through recognition of right-of-use assets and lease liabilities for operating leases of $8.3 million on the effective date. However, the standard did not have a material impact on the Company's consolidated statement of operations and comprehensive loss, as expense for the Company's existing operating leases continues to be recognized consistent with the recognition pattern before adoption.

Consolidated Balance Sheet Data (in thousands)	January 1, 2019 *Prior to ASC 842 Adoption*	ASC 842 Adjustment	January 1, 2019 *As Adjusted*
Right of use assets - operating leases [1]	$ —	$ 8,289	$ 8,289
Operating lease liability, current [2]	$ —	$ 2,245	$ 2,245
Operating lease liability, long term [2]	$ —	$ 6,044	$ 6,044

(1) Represents capitalization of operating lease right of use assets.

(2) Represents recognition of operating lease liabilities.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 amends ASC 718, *Compensation-Stock Compensation*, to expand the scope of the standard to include accounting for share-based payment transactions for acquiring goods and services from non-employees. The amendments in ASU 2018-07 are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2018. Early adoption is permitted. The Company adopted ASU 2018-07 on January 1, 2019, and it did not have a material impact on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808), Clarifying the Interaction between Topic 808 and Topic 606* ("ASU 2018-18"). The amendments in ASU 2018-18 clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. The amendments under ASU 2018-18 are effective for interim and annual fiscal periods beginning after December 15, 2019, with early adoption permitted. The amendments in ASU 2018-18 should be applied retrospectively to the date of initial application of Topic 606. The Company adopted ASU 2018-18 as of January 1, 2019 and it did not have a material impact on the Company's consolidated financial statements, as each of the Company's arrangements detailed within Note 13, "License Agreements," were previously accounted for under Topic 606 and/or other topics of the ASC, not ASC 808, and the Company has no other arrangements within the scope of ASC 808.

Accounting Standards Updates—Recently Issued

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. These amendments under ASU 2016-13 are effective for interim and annual fiscal periods beginning after December 15, 2019. The Company does not expect the adoption of ASU 2016-13 to have a material impact of its results of operations, financial position, or cash flows.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement - Disclosure Framework-Changes to the Disclosure Requirement for Fair Value Measurement*, or ("ASU 2018-13"). The amendments in this ASU 2018-13 modify the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement, based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments under ASU 2018-13 are effective for interim and annual fiscal periods beginning after December 15, 2019, with early adoption permitted. The Company does not expect the adoption of ASU 2018-13 to have a material impact on its results of operations, financial position or cash flows.

In August 2018, the FASB issued ASU 2018-15, *Intangible-Goodwill and Other Internal-Use Software (Subtopic 350-40* ("ASU 2018-15"). ASU 2018-15 updates guidance regarding accounting for a cloud computing arrangement that is a service contract. The amendments under ASU 2018-15 are effective for interim and annual fiscal periods beginning after December 15, 2019, with early adoption permitted. The Company does not expect the adoption of ASU 2018-15 to have a material impact on its results of operations, financial position or cash flows.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). ASU 2019-12 eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interest period and the recognition of deferred tax liabilities for outside basis differences, and also clarifies and simplifies other aspects of the accounting for income taxes. The amendments under ASU 2010-12 are effective for interim and annual fiscal periods beginning after December 15, 2020. The Company is currently evaluating the effects the adoption of ASU 2019-12 will have on its consolidated financial statements and related disclosures.

3. Marketable Securities

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

	December 31, 2019			
	Amortized Cost Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 34,726	$ —	$ —	$ 34,726
Money market	35,160	—	—	35,160
Domestic corporate commercial paper	—	—	—	—
Total	$ 69,886	$ —	$ —	$ 69,886
Marketable securities:				
Domestic corporate debt securities	$ 41,229	$ 3	$ (3)	$ 41,229
Domestic corporate commercial paper	24,900	5	—	24,905
Agency bonds	12,391	1	(3)	12,389
US treasury bonds	12,492	—	—	12,492
Total	$ 91,012	$ 9	$ (6)	$ 91,015

	December 31, 2018			
	Amortized Cost Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 20,448	$ —	$ —	$ 20,448
Money market	38,873	—	—	38,873
Domestic corporate commercial paper	—	—	—	—
Total	$ 59,321	$ —	$ —	$ 59,321
Marketable securities:				
Domestic corporate debt securities	$ 132,886	$ —	$ (530)	$ 132,356
Domestic corporate commercial paper	—	—	—	—
Agency bonds	45,009	—	(225)	44,784
Total	$ 177,895	$ —	$ (755)	$ 177,140

There were no securities in a loss position for more than 12 months at December 31, 2019 and 2018. There were eight debt securities in an unrealized loss position for less than 12 months at December 31, 2019 and there was one debt security that had been in an unrealized loss position for less than 12 months at December 31, 2018. The aggregate unrealized loss on these securities as of December 31, 2019 and 2018 was approximately $6.0 thousand and $0.8 million, respectively, and the fair value was $42.5 million and $177.1 million, respectively. The aggregate unrealized gain on these securities as of December 31, 2019 and 2018 was approximately $9.0 thousand and $0.0, respectively, and the fair value was $48.5 million and $0.0, 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, 2019 and 2018.

As of December 31, 2019, all marketable securities, which had an aggregate fair value of $91.0 million, are maturing within one year.

4. Fair Value Measurements

The Company determines the fair value of its financial instruments based upon the fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Below are the three levels of inputs that may be used to measure fair value:

- Level 1—Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- 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 other 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.

Transfers into or out of any hierarchy level are recognized at the end of the reporting period in which the transfers occurred. There were no transfers between any levels during the twelve months ended December 31, 2019 and 2018.

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, 2019 and December 31, 2018 (in thousands):

	As of December 31, 2019			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
Cash and cash equivalents:				
Cash	$ 34,726	$ —	$ —	$ 34,726
Money market funds (1)	35,160	—	—	35,160
Domestic corporate commercial paper (2)	—	—	—	—
Total	$ 69,886	$ —	$ —	$ 69,886
Marketable Securities				
Domestic corporate debt securities (2)	$ —	$ 41,229	$ —	$ 41,229
Domestic corporate commercial paper (2)	—	24,905	—	24,905
Agency bonds (2)		12,389		12,389
US treasury bonds (2)	—	12,492	—	12,492
Total	$ —	$ 91,015	$ —	$ 91,015

	As of December 31, 2018			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
Cash and cash equivalents:				
Cash	$ 20,448	$ —	$ —	$ 20,448
Money market funds (1)	38,873	—	—	38,873
Domestic corporate commercial paper (2)	—	—	—	—
Total	$ 59,321	$ —	$ —	$ 59,321
Marketable securities:				
Domestic corporate debt securities (2)	$ —	$ 132,356	$ —	$ 132,356
Domestic corporate commercial paper (2)	—	—	—	—
Agency bonds (2)	—	44,784	—	44,784
Total	$ —	$ 177,140	$ —	$ 177,140

(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.

5. Inventory

Inventory consists of the following at December 31, 2019 and 2018 (in thousands):

	December 31, 2019	**December 31, 2018**
Raw materials	$ 4,093	$ 4,961
Work in process	—	490
Finished goods	1,230	759
Total inventories	$ 5,323	$ 6,210

Finished goods manufactured by the Company have a 36-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, 2019	December 31, 2018
Furniture and fixtures, lab and office equipment	5	$ 1,262	$ 1,262
Computer equipment and software	3	2,726	3,445
Manufacturing equipment	10	1,616	1,616
Leasehold improvements	Shorter of useful life or remaining lease term	1,915	1,915
Construction in progress	-	—	—
		7,519	8,238
Less: accumulated depreciation		(5,226)	(4,235)
Property and equipment, net		$ 2,293	$ 4,003

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, 2019 and 2018. Depreciation expense related to property and equipment was approximately $1.5 million, $1.9 million and $1.4 million for the years ended December 31, 2019, 2018, and 2017, respectively.

7. Intangible Assets

The following table presents intangible assets as of December 31, 2019 and 2018 (in thousands):

	December 31, 2019	December 31, 2018	Estimated useful life (years)
Acquired and in-licensed rights	$ 8,712	$ 8,712	11
Less: accumulated amortization	(2,129)	(1,330)	
Total intangible asset, net	$ 6,583	$ 7,382	

The acquired and in-licensed rights relate 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 $0.8 million, $0.8 million, and $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 each of the twelve months ended December 31, 2019, 2018, and 2017, respectively. Estimated future amortization expense for intangible assets as of December 31, 2019 is approximately $0.8 million per year over the remaining life of 8.25 years.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses as of December 31, 2019 and 2018 consist of the following (in thousands):

	December 31, 2019	December 31, 2018
Commercial costs	$ 3,514	$ 2,884
Product revenue reserves	17,280	7,620
Royalty payable	2,797	1,735
Research costs	13,049	10,403
Payroll and employee benefits	11,551	12,230
Interest	3,050	3,050
Professional fees	1,439	3,465
Restructuring	255	613
Other current liabilities	95	203
Total accrued expenses and other current liabilities	$ 53,030	$ 42,203

9. Convertible Notes Payable

On August 14, 2017, in a registered underwritten public offering, the Company issued $300.0 million aggregate principal amount of 3% Convertible Senior Notes due September 1, 2024 (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). As of December 31, 2019, the Notes were not convertible.

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 consisted of the following (in thousands):

	December 31, 2019	December 31, 2018
Liability component:		
Principal	$ 305,000	$ 305,000
Less: debt discount and issuance costs, net	(109,409)	(125,194)
Net carrying amount	$ 195,591	$ 179,806
Equity component:	$ 134,450	$ 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, 2019 was 13.04%. As of December 31, 2019, 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, 2019 was approximately $259.0 million.

The following table sets forth total interest expense recognized related to the Convertible Notes during the twelve months ended December 31, 2019, 2018, and 2017 (in thousands):

	Twelve Months Ended December 31,		
	2019	2018	2017
Contractual interest expense	$ 9,150	$ 9,150	$ 3,482
Amortization of debt discount	15,213	13,300	4,641
Amortization of debt issuance	572	505	175
Total interest expense	$ 24,935	$ 22,955	$ 8,298

Future minimum payments on our long-term debt as of December 31, 2019 are as follows (in thousands):

Years ended December 31,	Future Minimum Payments
2020	$ 9,150
2021	9,150
2022	9,150
2023	9,150
2024 and thereafter	314,150
Total minimum payments	$ 350,750
Less: interest	(45,750)
Less: unamortized discount	(109,409)
Less: current portion	—
Long Term Debt	$ 195,591

10. Employee Stock Benefit Plans

Employee Stock Purchase Plan

In September 2016, the Company initiated the first offering period under the Company's 2016 Employee Stock Purchase Plan (the "ESPP"), pursuant to which eligible employees may purchase shares of the Company's common stock on the last day of each predetermined six-month offering period at 85% of the lower of the fair market value per share at the beginning or end of the applicable offering period. The offering periods run from March 1 through August 31 and from September 1 through February 28 (or February 29, in a leap year) of each year.

At December 31, 2019, there were 1,473,247 shares available for future sale to employees under this plan. As of December 31, 2019, the Company recorded a liability of $0.8 million related to employee withholdings under this plan.

Stock Options under Equity Incentive Plans

The Company has granted awards to employees, directors and consultants under the following compensation plans. The Company's 2018 Stock Option and Incentive Plan (the "2018 Plan") is the current plan under which the Company grants awards.

2003 Long-Term Incentive Plan—The Company's 2003 Long-Term Incentive Plan (the "2003 Plan) provided 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, was required to 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 limited the exercise of incentive stock options, but in no case could 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 granted under the 2003 Plan generally vest over a four-year period.

2011 Equity Incentive Plan—The Company's 2011 Equity Incentive Plan (the "2011 Plan") replaced the 2003 Plan when the Company's board of directors approved the 2011 Plan on November 7, 2011 and the shares that remained available for issuance under the 2003 Plan were assumed as shares authorized under the 2011 Plan. The 2011 Plan provided 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, was required to 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 limited the exercise of incentive stock options, but in no case could 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 granted under the 2011 Plan generally vest over a four-year period, subject to continued employment with, or services to, the Company.

2018 Stock Option and Incentive Plan—The 2018 Plan replaced the 2011 Plan when the Company's stockholders approved the new plan on June 6, 2018 and the shares that remained available for issuance under the 2011 Plan were assumed as shares authorized under the 2018 Plan. The 2018 Plan provides for the granting of equity awards, including incentive and non-qualified stock options and restricted stock units, to employees, non-employee 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 2018 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 and restricted stock units granted under the 2018 plan generally vest over a four-year period, subject to continued employment with, or services to, the Company.

As of December 31, 2019, an aggregate of 4,834,255 common shares remained outstanding under all of the Company's stock based compensation plans. The number of common shares remaining available for granting of future awards under these plans was approximately 5,684,071 at December 31, 2019.

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 2019, 2018, and 2017 was $12.97, $18.69, and $22.74 respectively. The weighted-average assumptions used in the Black-Scholes option-pricing model were as follows:

	Years Ended December 31,		
	2019	2018	2017
Expected term (years)	6.13	6.23	6.02
Volatility	72%	56%	57%
Expected dividend yield	0%	0%	0%
Risk-free interest rates	2.35%	2.68%	2.01%

A summary of stock option activity for the year ended December 31, 2019 is as follows (in thousands, except for share, 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, 2018	5,462,787	$ 36.88		
Granted	1,110,100	19.88		
Exercised	(341,337)	8.40		
Canceled	(558,747)	33.91		
Expired	(838,548)	40.59		
Options outstanding at December 31, 2019	4,834,255	$ 34.69	6.76	$ 4,167
Options exercisable at December 31, 2019	2,951,940	$ 39.49	5.56	$ 3,166

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, 2019 and 2018 was $4.2 million and $9.1 million, respectively.

As of December 31, 2019, there was approximately $25.1 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 2.41 years.

Restricted Stock Units

A summary of RSU activity during the year ended December 31, 2019 is as follows:

	RSUs	Weighted-Average Grant Date Fair Value (in dollars per share)
RSUs Outstanding at December 31, 2018	227,088	$ 37.69
Granted	613,650	20.04
Vested	(92,031)	35.79
Forfeited	(134,434)	26.17
RSUs Outstanding at December 31, 2019	614,273	$ 22.83

As of December 31, 2019, there was approximately $9.8 million of total unrecognized compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 2.55 years.

Performance Units

During the twelve months ended December 31, 2019, the Company awarded 79,000 performance restricted stock units (“PSUs”) to employees. Each PSU entitles the holder to receive one share of the Company’s common stock if and when the PSU vests. The PSUs vest upon achievement of certain performance targets within a pre-specified period from the grant date. The vesting of any earned units is subject to the employee’s continued service relationship with the Company through each vesting date.

A summary of PSU activity during the twelve months ended December 31, 2019 is as follows:

	PSUs	Weighted-Average Grant Date Fair Value (in dollars per share)
PSUs Outstanding at December 31, 2018	—	$ —
Granted	79,000	19.20
Vested	—	—
Forfeited	—	
PSUs Outstanding at December 31, 2019	79,000	$ 19.20

As the performance condition must be met for the awards to vest, compensation cost will be recognized over the implicit service period and only if the performance condition is assessed as probable of achievement. As of December 31, 2019, the achievement of the performance condition was not probable and, therefore, no expense has been recognized to date.

The following table summarizes stock-based compensation expense by financial statement line (in thousands):

	Years Ended December 31,		
	2019	2018	2017
Research and development	$ 8,768	$ 11,657	$ 14,699
General and administrative	14,847	17,044	20,304
Share-based compensation expense included in operating expenses	$ 23,615	$ 28,701	$ 35,003

Warrants

At December 31, 2018, the Company had outstanding warrants to purchase 120,532 shares of the Company's common stock at prices ranging from $14.00 to $16.97 per share. The warrants became exercisable at various dates between 2011 and 2014. No warrants were outstanding as of December 31, 2019.

11. 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, 2019 and 2018 (in thousands):

	Chargebacks, Discounts, and Fees	Government and Other Rebates	Returns	Total
Ending balance at December 31, 2017	$ 1,986	$ 1,231	$ 421	$ 3,638
Provision related to sales in the current year	15,281	24,156	355	39,792
Adjustment related to prior periods sales	(140)	254	(111)	3
Credits and payments made	(13,929)	(18,021)	(254)	(32,204)
Ending balance at December 31, 2018	$ 3,198	$ 7,620	$ 411	$ 11,229
Provision related to sales in the current year	30,960	62,271	1,673	94,904
Adjustment related to prior periods sales	(81)	337	(10)	246
Credits and payments made	(28,338)	(52,948)	(491)	(81,777)
Ending balance at December 31, 2019	$ 5,739	$ 17,280	$ 1,583	$ 24,602

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.

12. 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,		
	2019	2018	2017
Numerator:			
Net loss	$ (132,993)	$ (221,337)	$ (254,237)
Loss attributable to common stockholders—basic	(132,993)	(221,337)	(254,237)
Loss attributable to common stockholders—diluted	$ (132,993)	$ (221,337)	$ (254,237)
Denominator:			
Weighted-average number of common shares used in loss per share— basic and diluted	46,026,217	45,356,263	43,804,660
Loss per share—basic and diluted	$ (2.89)	$ (4.88)	$ (5.80)

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, 2019, 2018, and 2017 all of the Company's options to purchase common stock, warrants and stock units outstanding were assumed to be anti-dilutive as earnings attributable to common stockholders was in a loss position.

	Year Ended December 31		
	2019	2018	2017
Options to purchase common stock	4,834,255	5,462,787	5,647,895
Warrants	—	120,532	605,415
Restricted stock units	614,273	227,088	146,451
Performance units	79,000	—	—

13. License Agreements

3M

In February 2018, the Company entered into a Scale-Up and Commercial Supply Agreement (the "Supply Agreement") with 3M Company and 3M Innovative Properties Company (collectively with 3M Company, "3M"), pursuant to which 3M has agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-coated transdermal patch product ("Product") and associated applicator devices ("Applicator"). Under the Supply Agreement, 3M will manufacture Product and Applicator for the Company according to agreed-upon specifications in sufficient quantities to meet the Company's projected supply requirements. 3M will manufacture commercial supplies of Product at unit prices that decrease with an increase in the quantity the Company orders. The Company 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. The Company is responsible for providing, at its expense, supplies of abaloparatide drug substance to be used in manufacturing Product. During the term of the Supply Agreement, 3M and the Company 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, February 27, 2018, 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. The Company may terminate the Supply Agreement upon the occurrence of certain events, including for certain clinical, technical, or commercial reasons impacting Product, if it is unable to obtain U.S. regulatory approval for Product within a certain time period, or if it ceases 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 the Company is unable to obtain U.S. regulatory approval for Product within a certain time period, or if the Company fails 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 the Company or a mutually agreeable third party and continue supplying Product and Applicator for a period of time pursuant to the Company's projected supply requirements.

In partnership with 3M, the Company selected Thermo Fisher to conduct the abaloparatide-patch coating process and packaging operations. In October 2018, the Company committed to fund 3M's purchase of capital equipment totaling approximately $9.6 million in preparation for manufacturing Phase 3 and potential commercial supplies of Product. Milestone payments for the equipment commenced in the fourth quarter of 2018 and are expected to be paid in full in the second quarter of 2021. In addition, there are cancelable purchase commitments in place to fund the facility build out and future purchases of capital equipment. The Company has paid 3M approximately $14.4 million, in the aggregate, through December 31, 2019 with respect to performance under the Supply Agreement.

In June 2009, the Company 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 on an exclusive basis. The initial term of the Development Agreement remained in effect until June 2019, after which it automatically renews for successive 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. The Company pays 3M for services delivered pursuant to the agreement on a fee-for-service or a fee-for-deliverable basis as specified in the agreement. The Company has paid 3M approximately $28.9 million, in the aggregate, through December 31, 2019 with respect to services and deliverables delivered pursuant to the Development Agreement.

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 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, 2019. 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 $8.7 million and $5.0 million for the years ended December 31, 2019 and 2018, respectively, which is recorded in cost of sales within the consolidated statement of operations and comprehensive loss. 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.

Pursuant to a June 2018 final decision in arbitration proceedings with Ipsen in connection with the License Agreement, the Company paid Ipsen $10.0 million (and pre-award interest of $0.8 million) and is obligated to pay Ipsen (i) $5.0 million if abaloparatide receives marketing approval in Japan, and (ii) a fixed mid single-digit royalty based on net sales of abaloparatide in Japan. The Company recorded the $10.8 million payment to other operating expenses in the consolidated statement of operations and comprehensive loss in the second quarter of 2018. The $5.0 million payment upon abaloparatide receiving marketing approval in Japan will be accrued in the period in which the approval is determined to be probable. Royalties based on net sales of abaloparatide in Japan will be accrued during the period that revenue for such sales, which is subject to a royalty arrangement, is recognized and will be presented as cost of sales within the consolidated statement of operations and comprehensive loss.

The arbitration decision does not impact the Company's rights under the License Agreement or its license agreement with Teijin for abaloparatide-SC in Japan, under which the Company previously received a $10.0 million upfront payment and is entitled to 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.

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 Agreement, as amended, also provides for additional payments of up to $22.3 million, payable upon the achievement of certain clinical and regulatory milestones. To date, the Company has paid Eisai approximately $1.0 million in connection with the achievement of certain 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 and Duke University (“Duke”) entered into a License Agreement with (the “Duke 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 Agreement provides for further payments upon the achievement of certain future regulatory and commercial milestones totaling up to $3.8 million. To date, the Company has paid Duke approximately $0.5 million in connection with the achievement of certain milestones. 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.

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 its 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 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 Company notes that these milestone and royalty payments represent variable consideration and amounts subject to the sales and usage-based royalty exception under ASC 606, respectively. The regulatory milestone payments representing variable consideration were fully constrained through December 31, 2019, and no amount will be recognized until the applicable regulatory milestones are achieved. The sales-based milestones and royalty payments subject to the sales and usage-based royalty exception will not be included in the transaction price until the underlying sales or sales-based milestones have been achieved.

14. Income Taxes

For the year ended December 31, 2019, 2018, and 2017 no income tax expense was recorded due to the Company's net operating losses (NOLs) and full valuation allowance.

The components of loss before provision for (benefit from) income taxes during the three years ended December 31, 2019 consisted of the following:

	Year Ended December 31,		
	2019	2018	2017
United States	$ (116,749)	$ (208,735)	$ (245,264)
Foreign	(16,244)	(12,602)	(8,973)
	(132,993)	(221,337)	(254,237)

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,		
	2019	2018	2017
Income tax benefit using U.S. federal statutory rate	$ (27,918)	$ (46,464)	$ (86,426)
State income taxes, net of federal benefit	(5,486)	(6,694)	(5,570)
Stock-based compensation	4,379	(12)	(5,909)
Research and development tax credits	(2,491)	(3,743)	(2,468)
Effect of federal tax law change	—	—	86,035
Other adjustments - ASU 2016-09 adoption	—	—	6,135
Change in the valuation allowance	26,918	49,550	(39,045)
Convertible note	(128)	(128)	47,016
Permanent items	457	883	543
Uncertain Tax Positions	—	—	3,056
Foreign rate differential	3,414	2,649	—
Other	855	3,959	(3,367)
Income tax expense	$ —	$ —	$ —

The principal components of the Company's deferred tax assets are as follows (in thousands):

	December 31,	
	2019	2018
Deferred tax assets:		
NOL carryforwards	$ 243,063	$ 225,285
Capitalized research and development	4,099	3,919
Research and development credits	9,608	8,380
Interest Expense	2,729	1,125
Accrued expenses	5,342	2,644
Stock-based compensation	14,952	14,377
UNICAP	103	86
Allowance for bad debt	1,832	840
Operating lease liability	1,696	—
Other	119	106
Gross non-current deferred tax assets	283,543	256,762
Valuation allowance	(255,242)	(228,322)
Net non-current deferred tax assets	$ 28,301	$ 28,440
Deferred tax liabilities:		
Depreciation	$ (216)	$ (347)
Right-of-Use asset	(1,677)	—
Convertible debt	(26,408)	(28,093)
Gross non-current deferred tax liabilities	(28,301)	(28,440)
Net non-current deferred tax assets (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 net deferred tax assets in each of the years ended December 31, 2019, 2018, and 2017, 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 of $26.9 million in 2019 primarily relates to the net loss incurred by the Company.

As of December 31, 2019, the Company had federal and state net operating loss ("NOL") carryforwards of approximately $974.3 million and $681.8 million, respectively, which may be used to offset future taxable income. Of the federal NOL amount, approximately $754.2 million will expire at various dates through 2037 and $220.1 million will carryforward indefinitely. The state NOLs will expire at various dates through 2039.

As of December 31, 2019, the Company also had federal and state tax credits of $8.0 million and $2.1 million, respectively, to offset future tax liabilities. The federal general business credits will expire at various dates through 2039 and the state research and development tax credits will expire at various dates through 2034.

In 2016, the Company 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 its NOL and credit carryforwards. The Company has adjusted its NOL and credit carryforwards, and the related valuation allowance, according to the results of this evaluation. As no additional evaluations have been completed since 2016, the NOLs could be subject to further limitations.

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, 2019, the unrecognized tax benefit was $2.6 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, 2018	$ 2,239
Decreases related to prior year tax positions	(285)
Increases related to prior year tax positions	92
Decreases related to current year tax positions	—
Increases related to current year tax positions	517
Balance at December 31, 2019	$ 2,563

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 2016 through 2018 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 material interest or penalties have been recorded for the years ended December 31, 2019, 2018, or 2017. The Company does not expect any significant change in its uncertain tax positions in the next 12 months.

15. Commitments and Contingencies

Litigation

From time to time, the Company may become subject to legal proceedings and claims which arise in the ordinary course of its business. 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.

As of December 31, 2019, the Company was not party to any significant litigation.

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 which began on June 1, 2017, after which, it automatically renews for two-year terms unless either party terminates the agreement upon 18 months' notice prior to the end of the then-current term. 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.

Related Party Transactions

Beginning in December 2019, a member of our Board of Directors had a familial relationship with an executive officer of one of our customers, AmerisourceBergen Corporation ("ABC"). The activities with ABC and its affiliates are in the ordinary course of business and are primarily for commercial distribution of TMYLOS and service fees. As of December 31, 2019, the Company recognized net revenues of approximately $93.8 million from ABC in connection with product sales of TYMLOS and paid ABC and its affiliates approximately $1.1 million for services under various commercial and services agreements. In addition, accounts receivable due from ABC of approximately $12.4 million is recorded within the consolidated balance sheets as of December 31, 2019.

16. Leases

The Company determines if an arrangement is a lease at inception. For operating leases, amounts recorded in connection therewith are included in right-of-use assets and lease liabilities in the condensed consolidated balance sheets. Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the leases and are recognized on the lease commencement date based on the present value of lease payments over the lease term. As the Company's leases have not historically provided an implicit rate, the Company's incremental borrowing rate based on information available at the commencement date is used in determining the present value of lease payments. However, the implicit rate is used when readily determinable. The operating lease right-of-use assets also include any lease payments made and excludes lease incentives. Options to extend the lease term or terminate the leases are incorporated into the determination of the lease term if it is reasonably certain that the Company will exercise such options based on assessment of economic factors, such as contractual terms, market rates and locations, and costs associated with negotiation of new leases or termination of leases. Lease expense for operating lease payments is recognized on a straight-line basis over the lease term.

In addition, as a practical expedient, for all leases entered into or modified after the effective date of ASC 842, the Company, as the lessee, has made an accounting policy election, by class of underlying asset, to not separate nonlease components from lease components. The Company will account for each separate lease component and the nonlease components associated with that lease component as a single lease component.

The Company has operating leases for corporate offices in Waltham, MA, Wayne, PA and Parsippany, NJ and for research laboratories in Cambridge, MA. These leases have remaining lease terms of less than one year to six years, some of which

include options to extend the leases for additional years, and of which includes the option to terminate the lease upon default by the Company. The options to extend and terminate the leases were not incorporated into the determination of the lease term as the exercise of such options was not reasonably certain at the lease commencement date based on assessment of economic factors.

In addition to the operating leases, the Supply Agreement with 3M is a multiple-element arrangement covering Phase 3 clinical materials and related services, potential commercial materials, and potential future royalty payments, as well as the construction of certain equipment, an isolator, to be used in the manufacture of the Phase 3 and potential commercial supplies of Product. The contractually stated cost of the isolator, as well as the costs of the other elements, represent the estimated standalone selling price and, therefore, no initial allocation was required to separate the cost of the isolator from the other elements. Under ASC 840, *Leases*, which was the standard under which the Company accounted for leases through December 31, 2018, the Company was considered the accounting owner of the isolator equipment during construction and costs were recognized to research and development expense as incurred through December 31, 2018, since the equipment was assessed to not have alternative future use to the Company. Upon transition to ASC 842 on January 1, 2019, the Company continues to control the isolator during construction and costs will be recognized to research and development expense as incurred, which is expected to be completed in 2020, since the equipment was again assessed to not have alternative future use to the Company and/or 3M.

On March 27, 2018, the Company announced organizational changes which included the closure of its Parsippany, NJ office and, on January 4, 2019, the Company ceased use of the office, triggering an impairment assessment. In connection with this assessment, the Company recorded an impairment loss of $0.3 million during the twelve months ended December 31, 2019.

The Company's operating leases also include such costs as real estate taxes and common area maintenance charges. Such amounts have been recorded as variable lease costs within the consolidated statement of operations. During the twelve months ended December 31, 2019, the components of lease expense were as follows (in thousands):

	Year ended December 31, 2019
Operating lease cost	$ 2,742
Variable lease cost	124
Total lease cost	$ 2,866

As of December 31, 2019, the weighted average remaining lease term for the Company's operating leases was 4.60 years.

As a discount rate was not directly observable for the operating leases, the discount rate used to calculate the net present value of future payments was the Company's incremental borrowing rate calculated at transition based on the remaining lease term for each operating lease. The incremental borrowing rate is the rate of interest that the Company would have to pay to borrow, on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. In determining the incremental borrowing rate, the Company considered the following: (i) the Company's public credit rating, (ii) observable debt yields of the Company, as well as other bonds in the market issued by other companies with similar credit ratings as the Company, and (iii) adjustments necessary for collateral, lease term and inflation or foreign currency. As of December 31, 2019, the weighted average discount rate for the Company's operating leases was 6.07%.

The following table summarizes activity of the operating lease liabilities for the twelve months ended December 31, 2019 (in thousands):

	Lease Liability
Beginning balance at December 31, 2018	$ —
Transition adjustment recorded upon adoption	8,289
Operating lease liability recognized	788
Payments during the period	(2,742)
Effect of discounted cash flows during the period	444
Ending balance at December 31, 2019	$ 6,779

Future payments of operating lease liabilities as of December 31, 2019 are as follows (in thousands):

Year ending December 31,		
2020	$	2,551
2021		1,413
2022		1,038
2023		980
2024		1,005
Thereafter		857
Total Lease payments	$	7,844
Less: effect of discounted cash flows during the period		(1,065)
Total	$	6,779

Rent expense for the years ended December 31, 2019, 2018, and 2017 was $2.9 million, and $3.5 million, and $3.4 million, respectively.

As of December 31, 2019, the Company had no operating or finance leases that have not yet commenced. In addition, upon adoption, and as of December 31, 2019, the Company had no short-term leases.

17. Subsequent Events

On January 10, 2020, the Company and Radius Pharmaceuticals, Inc., a wholly-owned subsidiary of the Company (collectively, the "Borrowers"), entered into a (i) Credit and Security Agreement (Term Loan) (the "Term Credit Agreement") with MidCap Financial Trust, in its capacity as administrative agent (the "Agent") and as a lender, and the financial institutions or other entities from time to time parties thereto and (ii) Credit and Security Agreement (Revolving Loan) (the "Revolving Credit Agreement", together with the Term Credit Agreement, the "Credit Agreements"), with the Agent, and the financial institutions or other entities from time to time parties thereto.

The Credit Agreements consist of a secured term loan facility (the "Term Facility") in an aggregate amount of $55.0 million, which will be made available to the Borrowers under the following four tranches: (i) Tranche 1 – $10.0 million, available at closing; (ii) Tranche 2 – $15.0 million, available no later than March 31, 2020; (iii) Tranche 3 – $15.0 million, available no later than December 31, 2021, subject to the Company's satisfaction of certain conditions described in the Term Credit Agreement; and (iv) Tranche 4 – $15.0 million, available no later than December 31, 2021, subject to the Company's satisfaction of certain conditions described in the Term Credit Agreement.

The Credit Agreements also consist of a secured revolving credit facility (the "Revolving Facility", together with the Term Facility, the "Facilities") under which the Borrowers may borrow up to $20.0 million, the availability of which is determined based on a borrowing base as follows: (i) up to 85% of the net collectible value of the Borrowers' domestic accounts receivable due from eligible direct and third-party payors, plus (ii) up to 40% of the Borrowers' domestic eligible inventory, provided that the availability from eligible inventory may not exceed 20% of the total availability at any time. The Borrowers also have the right, subject to certain customary conditions, to increase the Revolving Facility by $20.0 million.

The Facilities have a maturity date of June 1, 2024. The Borrowers guarantee their obligations under the Credit Agreements. The obligations are secured by first priority liens on substantially all of the assets of the Borrowers, including, with certain exceptions, all of the capital stock of the Borrowers' subsidiaries.

The proceeds of the Term Facility may be used for (i) transaction fees in connection with the transactions contemplated by the Credit Agreements, (ii) the payment in full on the closing date of certain existing debt, and (iii) working capital needs and general corporate purposes of the Borrowers and their subsidiaries. The proceeds of the Revolving Facility may be used for (i) transaction fees in connection with the transactions contemplated by the Credit Agreements and (ii) working capital needs and general corporate purposes of the Borrowers and their subsidiaries.

Borrowings under the Term Facility will bear interest through maturity at a variable rate based upon the LIBOR rate plus 5.75%, subject to a LIBOR floor of 2.00%. Borrowings under the Revolving Facility will bear interest through maturity at a variable rate based upon the LIBOR rate plus 3.50%, subject to a LIBOR floor of 2.00%.

Subject to the terms and conditions set forth in the Credit Agreements, the Borrowers may be required to make certain mandatory prepayments prior to maturity.

The Credit Agreements contain affirmative and negative covenants customarily applicable to senior secured credit facilities, including covenants that, among other things, will limit or restrict the ability of the Borrowers, subject to negotiated exceptions, to incur additional indebtedness and additional liens on their assets, engage in mergers or acquisitions or dispose of assets, pay dividends or make other distributions, voluntarily prepay other indebtedness, enter into transactions with affiliated persons, make investments, and change the nature of their businesses. The Credit Agreements also contains customary events of default, including subject to thresholds and grace periods, among others, payment default, covenant default, cross default to other material indebtedness, and judgment default. In addition, the Credit Agreements require the Borrowers to maintain a minimum level of net revenue, or in the case where the Borrowers fail to maintain a minimum level of net revenue, certain levels of market capitalization and unrestricted cash.

18. Selected Quarterly Financial Data (Unaudited)

Selected quarterly financial data for the years ended December 31, 2019 and 2018 is as follows (in thousands, except for share and per share data):

	Three Months Ended			
	March 31,	June 30,	September 30,	December 31,
2019:				
Net revenue	$ 29,844	$ 41,042	$ 46,766	$ 55,665
Gross profit	26,614	37,034	42,595	50,989
Net loss	(42,760)	(35,474)	(30,044)	(24,715)
Net loss applicable to common stock	(42,760)	(35,474)	(30,044)	(24,715)
Net loss per share—basic and diluted	(0.94)	(0.77)	(0.65)	(0.54)
Weighted-average common shares outstanding—basic and diluted	45,671,502	46,109,193	46,141,217	46,176,145
2018:				
Net revenue	$ 14,547	$ 22,629	$ 27,639	$ 34,424
Gross profit	13,259	20,826	25,246	31,482
Net loss	(61,555)	(68,882)	(49,802)	(41,098)
Net loss applicable to common stock	(61,555)	(68,882)	(49,802)	(41,098)
Net loss per share—basic and diluted	(1.37)	(1.52)	(1.09)	(0.90)
Weighted-average common shares outstanding—basic and diluted	44,937,776	45,430,678	45,498,909	45,549,972

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, 2019.

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, 2019, 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, 2019.

The effectiveness of our internal control over financial reporting as of December 31, 2019 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, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the 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, 2019, 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, 2019, 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 2019 consolidated financial statements of the Company and our report dated February 27, 2020 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 the 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
February 27, 2020

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 4, 2020. 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 2020 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 2020 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 2020 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 2020 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 2020 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) 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:

(b) 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.

(c) 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	8-K		3.1	3/2/2018	
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	
4.5	Description of Securities					*
	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. 2018 Stock Option and Incentive Plan, together with forms of Incentive Stock Option Agreement, Non-Qualified Stock Option Agreement for Employees, Non-Qualified Stock Option Agreement for Non-Employee Directors, Restricted Stock Unit Agreement for Employees, and Restricted Stock Unit Agreement for Non-Employee Directors.	10-Q	10.5	8/7/2018	
10.3(a)	Form of Restricted Stock Unit Agreement for Employees under Radius Health, Inc. 2018 Stock Option and Incentive Plan				*
10.4	Radius Health, Inc. 2016 Employee Stock Purchase Plan	8-K	10.2	5/27/2016	
10.5	Radius Health, Inc. Amended and Restated Non-Employee Director Compensation Program	10-K	10.5	02/28/2019	
10.6	Form of Executive Severance Agreement between the Company and Jose Carmona	10-K	10.13	2/24/2017	
10.7	Form of Executive Severance Agreement between the Company and Joseph Kelly and Charles Morris	10-K	10.12(a)	3/1/2018	
10.8	Employment Letter Agreement, dated May 9, 2017, between the Company and Jose Carmona	8-K	10.1	5/15/2017	
10.8(a)	Employment Inducement Stock Option Agreement, dated May 15, 2017, between the Company and Jose Carmona	8-K	10.2	5/15/2017	
10.9	Employment Agreement, dated June 23, 2017, between the Company and Jesper Hoeiland	8-K	10.1	7/17/2017	
10.9(a)	First Amendment to Employment Agreement between the Company and Jesper Hoeiland	8-K	10.1	11/16/2017	
10.9(b)	Employment Inducement Stock Option Agreement, dated July 17, 2017, between the Company and Jesper Hoeiland	8-K	10.2	7/17/2017	
10.10	Employment Letter Agreement, dated November 10, 2017, between the Company and Joseph Kelly	10-K	10.15	3/1/2018	
10.10(a)	Employment Inducement Stock Option Agreement, dated November 27, 2017, between the Company and Joseph Kelly	10-K	10.15(a)	3/1/2018	
10.11	Employment Letter Agreement, dated June 28, 2018, between the Company and Charles Morris	10-K	10.17	2/28/2019	
10.11(a)	Employment Inducement Stock Option Agreement, dated September 4, 2018, between the Company and Charles Morris	10-K	10.17(a)	2/28/2019	
10.12	Form of Indemnification Agreement between the Company and its Directors	10-K	10.18	2/28/2019	
10.13	Form of Indemnification Agreement between the Company and its Officers	10-K	10.19	2/28/2019	
10.14	Radius Health, Inc. Form of Employment Inducement Stock Option Agreement	10-Q	10.4	8/7/2018	

	Other Agreements					
10.15^	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	
10.16^	Scale-Up and Commercial Supply Agreement, dated February 27, 2018, between the Company, 3M Company and 3M Innovative Properties Company	10-Q		10.1	5/10/2018	
10.17^	License Agreement, dated June 29, 2006, between the Company and Eisai Co., Ltd.	8-K/A	000-53173	10.25	10/24/2011	
10.17(a)	License Agreement Amendment No. 1, dated March 9, 2015, between the Company and Eisai Co., Ltd.	10-Q		10.3	5/6/2015	
10.18^	License and Development Agreement, dated July 13, 2017, between the Company and Teijin Limited	10-Q		10.1	11/2/2017	
10.19^	Supply Agreement, dated June 23, 2016, between the Company and Ypsomed AG	10-Q		10.1	8/4/2016	
10.19(a)	Amendment No. 1, dated February 7, 2017, to Supply Agreement, dated June 23, 2016, between the Company and Ypsomed AG	10-Q		10.11	8/7/2019	
10.19(b)	Amendment No. 2, dated June 18, 2019, to Supply Agreement, dated June 23, 2016, between the Company and Ypsomed AG	10-Q		10.2	8/7/2019	
10.20^	Commercial Supply Agreement, dated June 28, 2016, between the Company and Vetter Pharma International GmbH	10-Q		10.2	8/4/2016	
10.20(a)^^	Amendment No. 1, dated December 1, 2019, to Commercial Supply Agreement, dated June 28, 2016, between the Company and Vetter Pharma International GmbH					*
10.21^	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	
10.21(a)^	Amendment No. 1, dated December 1, 2018, to 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	5/8/2019	
10.21(b)	Amendment No. 2, dated June 10, 2019, to Manufacturing Services Agreement, dated July 13, 2016, between the Company and Polypeptide Laboratories Holding (PPL) AB, as successor to Lonza Sales Ltd	10-Q		10.3	8/7/2019	
10.22	Indenture of Lease, dated May 14, 2014, between the Company and BP Bay Colony LLC	8-K		10.1	5/20/2014	

10.22(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	
10.22(b)	Second Amendment, dated April 22, 2016, to Lease, dated May 14, 2014, between the Company and BP Bay Colony LLC	10-Q	10.2	5/10/2018	
10.22(c)	Third Amendment, dated May 23, 2018, to Lease, dated May 14, 2014, between the Company and BP Bay Colony LLC	10-Q	10.1	8/7/2018	
10.22(d)	Fourth Amendment, dated January 28, 2020, to Lease, dated May 14, 2014, between the Company and BP Bay Colony LLC				*
10.23	Lease, dated June 28, 2017, between the Company and KBSIII Crosspoint at Valley Forge Trust	10-Q	10.1	8/4/2017	
10.24	Sublease, dated March 11, 2016, between the Company and Rovi Corporation	10-Q	10.2	8/4/2017	
10.24(a)	First Amendment to Sublease, dated July 7, 2017, between the Company and Rovi Corporation	10-Q	10.3	8/4/2017	
10.24(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	
10.25	Credit and Security Agreement (Term Loan), dated as of January 10, 2020, by and among the Company, Radius Pharmaceuticals, Inc., and any additional borrower from time to time, MidCap Financial Trust, as a lender and the administrative agent, and the financial institutions or other entities from time to time parties thereto	8-K	10.1	1/13/2020	
10.26	Credit and Security Agreement (Revolving Loan), dated as of January 10, 2020, by and among the Company, Radius Pharmaceuticals, Inc., and any additional borrower from time to time, MidCap Financial Trust, as a lender and the administrative agent, and the financial institutions or other entities from time to time parties thereto	8-K	10.2	1/13/2020	
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.SCH	Inline XBRL Taxonomy Extension Schema Document				

101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101. DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)

---

^ 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.

^^ Certain confidential information contained in this exhibit, marked by brackets in the exhibit, has been omitted, because it is both not material and would likely cause competitive harm if publicly disclosed.

* 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 HOEILAND

Jesper Hoeiland
President and Chief Executive Officer

Date: February 27, 2020

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 HOEILAND Jesper Hoeiland	Chief Executive Officer and Director (Principal Executive Officer)	February 27, 2020
/s/ JOSE CARMONA Jose Carmona	Chief Financial Officer (Principal Accounting and Financial Officer)	February 27, 2020
/s/ WILLARD H. DERE Willard H. Dere	Director	February 27, 2020
/s/ CATHERINE FRIEDMAN Catherine Friedman	Director	February 27, 2020
/s/ JEAN-PIERRE GARNIER Jean-Pierre Garnier	Director	February 27, 2020
/s/ KURT C. GRAVES Kurt C. Graves	Director	February 27, 2020
/s/ OWEN HUGHES Owen Hughes	Director	February 27, 2020
/s/ JESSICA HOPFIELD Jessica Hopfield	Director	February 27, 2020
/s/ ANTHONY ROSENBERG Anthony Rosenberg	Director	February 27, 2020

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of February 25, 2020, Radius Health, Inc. has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common stock.

Description of Common Stock

General

Our authorized capital stock consists of 200,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share. The following description of our common stock and provisions of our restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to our restated certificate of incorporation and amended and restated bylaws.

Common Stock

Each holder of our common stock is entitled to one vote for each share held on all matters submitted to a vote of stockholders. Our stockholders do not have cumulative voting rights. Accordingly, the holders of a majority of the voting shares are able to elect all of the directors then up for election, except that in the case of a contested election, which occurs where the number of director nominees exceeds the number of directors to be elected, the election will be determined by a plurality of the votes cast. Any incumbent director who is not re-elected must tender his or her resignation to our board of directors. Our nominating and corporate governance committee will make a recommendation to our board of directors as to whether to accept or reject the resignation, or whether other action should be taken. Our board of directors will act on the recommendation and publicly disclose its decision within 90 days following certification of the voting results. An incumbent director who tenders his or her resignation may not participate in such decisions of our nominating and corporate governance committee or our board of directors.

Subject to preferential dividend rights of any series of preferred stock that we may designate and issue in the future, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. In the event of our liquidation or dissolution, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock. Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Anti-Takeover Provisions

Our restated certificate of incorporation provides for our board of directors to be divided into three classes, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors then up for election, except that in the case of a contested election, which occurs where the number of director nominees exceeds the number of directors to be elected, the election will be determined by a plurality of the votes cast. Our restated certificate of incorporation and amended and restated bylaws provide that all stockholder action must be effected at a duly called meeting of stockholders and not by a consent in writing, and that only our board of directors, chairman of the board, chief executive officer or president (in the absence of a chief executive officer) may call a special meeting of stockholders.

Our restated certificate of incorporation requires a two-thirds stockholder vote for the amendment, repeal or modification of certain provisions of our restated certificate of incorporation and amended and restated bylaws relating to the classification of our board of directors, the requirement that stockholder actions be effected at a duly called meeting, and the designated parties entitled to call a special meeting of the stockholders. The combination of the classification of our board of directors, the lack of cumulative voting and the two-thirds stockholder voting requirements make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty, or other wrongdoing, by any of our directors, officers, employees or agents to us or our stockholders, creditors or other of constituents; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. Our restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

These provisions may have the effect of deterring hostile takeovers or delaying changes in our control or management. These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts. These provisions may also have the effect of preventing changes in our management.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- if, before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested holder;

- if, upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- if, on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or is an affiliate or associate of the corporation and within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Listing

Our common stock is listed on the Nasdaq Global Market under the symbol “RDUS.”

Exhibit 10.20(a)

Certain information identified in this document, marked by "[*]", has been excluded pursuant to Regulation S-K, Item 601(b)(10) because it is not material and would likely cause competitive harm to the registrant if publicly disclosed.

AMENDMENT #1 TO

COMMERCIAL SUPPLY AGREEMENT

This Amendment #1 to the Commercial Supply Agreement is made and entered into the 1st day of December 2019 (the "Amendment #1 Effective Date") by and between Vetter Pharma International GmbH, a company duly organized and existing under the laws of Germany, having its principal place of business at Eywiesenstraβe 5, 88212 Ravensburg, Germany ("Vetter") and Radius Health, Inc., a Delaware corporation having its principal office at 950 Winter Street, Waltham, Massachusetts, 02139, USA ("Radius)". The Parties agree as follows:

WHEREAS, Vetter and Radius previously entered into that certain Commercial Supply Agreement effective January 1, 2016, as amended, (the "Agreement"); and

WHEREAS, the Parties desire to amend the Agreement to reflect the purchase of back-ups of certain critical equipment set forth herein, on the terms and conditions in this Amendment #1.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and agreements herein contained, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

ARTICLE 1: AMENDMENTS

1. Appendix A, "Radius Equipment," is hereby amended by adding the following equipment set forth below:

- [*] ([*] Euro)
- [*] ([*] Euro)
- [*] ([*] Euro)
- [*] ([*] Euro)
- [*] ([*] Euro)
- [*] ([*] Euro)
- [*] ([*] Euro)
- [*] ([*] Euro)

2. Upon execution of this Amendment #1 and receipt of a purchase order from Radius, Vetter shall order and purchase the above-listed equipment. Radius shall reimburse Vetter within thirty (30) calendar days of the date of Vetter's respective invoice. For the avoidance of doubt, in the absence of any provision in this Amendment #1, the "Prices and Payments" terms Article 8 of the Agreement shall apply.

ARTICLE 2: MISCELLANEOUS

1. Capitalized terms used but not defined in this Amendment #1 shall have the meanings given to such terms in the Agreement.

2. In the event of any conflict between the provisions of this Amendment #1 and any of the provisions of the Agreement, the provisions of this Amendment #1 shall govern in all respects.

3. Except as specifically modified herein, the terms and conditions of the Agreement including its appendices are hereby affirmed, confirmed and ratified and the Agreement, as amended, shall remain in full force and effect. For the avoidance of doubt, anything which is not covered in this Amendment #1, shall be subject to the provisions of the Agreement.

(Page remainder left blank intentionally, immediately followed by the signatures page.)

IN WITNESS WHEREOF, the Parties have caused this Amendment #1 to be duly executed by their duly authorized representatives as of the Amendment #1 Effective Date.

Radius Health, Inc.

Waltham, MA, United States of America, dated this 5th day of January, 2020

(signed)	/s/ Judson Taylor
Name:	Judson Taylor
Title	Executive Director, Supply Chain

Vetter Pharma International GmbH

Ravensburg, Germany, dated this 4th day of December, 2019

(signed)	/s/ Jeffrey C. Ellenburg	(signed)	/s/ Hermann Klein
Name:	Jeffrey C. Ellenburg	Name:	Hermann Klein
Title	Director, Key Account Management Europe	Title:	Key Account Manger

Exhibit 10.22(d)

FOURTH AMENDMENT TO LEASE

FOURTH AMENDMENT TO LEASE dated as of this 28th day of January 2020 by and between BP BAY COLONY LLC, a Delaware limited liability company ("**Landlord**"), and RADIUS HEALTH, INC., a Delaware corporation ("**Tenant**").

RECITALS

By Lease dated May 14, 2014 (the "**Lease**"), Landlord did lease to Tenant, and Tenant did hire and lease from Landlord, certain premises containing approximately 8,490 square feet of rentable floor area located on the first (1st) floor (referred to in the First Amendment (hereinafter defined) as the "Initial Premises") of the building known and numbered as 950 Winter Street, Waltham, Massachusetts (the "**Building**").

By First Amendment to Lease dated as of September 9, 2015 (the "**First Amendment**"), Tenant (i) leased from Landlord an additional 8,176 square feet of rentable floor area located on the first (1st) floor of the Building (referred to in the First Amendment as the "Expansion Premises 1"), (ii) leased from Landlord an additional 10,542 square feet of rentable floor area (referred to in the First Amendment as the "Rentable Floor Area of the Expansion Premises 2") located on the first (1st) floor of the Building (referred to in the First Amendment as the "Expansion Premises 2", the Initial Premises, the Expansion Premises 1, and the Expansion Premises 2, hereinafter collectively referred to as the "**Premises**"), and (iii) extended the Term of the Lease, upon all of the same terms and conditions set forth in the Lease except as set forth in the First Amendment.

By Second Amendment to Lease dated as of April 22, 2016 (the "**Second Amendment**"), Landlord and Tenant agreed to increase the size of Expansion Premises 1 by 432 square feet of rentable floor area, upon all of the same terms and conditions set forth in the Lease except as set forth in the Second Amendment.

By Third Amendment to Lease dated as of May 23, 2018 (the "**Third Amendment**"), Landlord and Tenant agreed that the Expansion Premises 2 contains 9,455 square feet of rentable floor area, which is 1,087 square feet less than the 10,542 square feet of rentable floor area that is set forth as the "Rentable Floor Area of the Expansion Premises 2" in the First Amendment.

Landlord and Tenant have agreed to extend the Term of the Lease for one (1) period of one (1) year upon all of the same terms and conditions set forth in the Lease except as set forth in this Fourth Amendment to Lease (this "**Fourth Amendment**").

NOW THEREFORE, in consideration of One Dollar ($1.00) and other good and valuable consideration in hand this date paid by each of the parties to the other, the receipt and sufficiency of which are hereby severally acknowledged, and in further consideration of the mutual promises herein contained, Landlord and Tenant hereby agree to and with each other as follows:

1. Term. The Term of the Lease, which but for this Fourth Amendment is scheduled to expire on January 31, 2021 (the "**Scheduled Expiration Date**"), is hereby extended for one (1) period of one (1) year commencing on February 1, 2021 and expiring on January 31, 2022 (the "**Second Extended Term**"), unless sooner terminated in accordance with the provisions of the Lease, upon all the same terms and conditions contained in the Lease as herein amended.

2. Extension Option. Landlord and Tenant acknowledge and agree that the extension option contained in Section 9.18 of the Lease shall be deleted in its entirety, and Tenant's only option to extend the Term upon the expiration of the Second Extended Term shall be as set forth in this Section 2.

(A) On the conditions (which conditions Landlord may waive by written notice to Tenant) that both at the time of exercise of the herein described option to extend and as of the commencement of the Third Extended Term (as hereinafter defined) (i) there exists no "Event of Default" (defined in Section 7.1 of the Lease) and there have been no more than two (2) Event of Default occurrences during the Term, (ii) the Lease is still in full force and effect, and (iii) Tenant has neither assigned the Lease nor sublet more than twenty-five percent (25%) of the Rentable Floor Area of the Premises (except for an assignment or subletting permitted without Landlord's consent under Section 5.6.4 hereof), Tenant shall have the right to extend the Term hereof upon all the same terms, conditions, covenants and agreements herein contained (except for the Annual Fixed Rent, which shall be as set forth in Section 2(B) below and except that there shall be no further option to extend) for one (1) period of one (1) year commencing on February 1, 2022 and expiring on January 31, 2023 (the "**Third Extended Term**") as hereinafter set forth. Notwithstanding any implication to the contrary, Landlord has no obligation to make any additional payment to Tenant in respect of any construction allowance or the like or to perform any work to the Premises as a result of the exercise by Tenant of any such option.

(B) If Tenant desires to exercise said option to extend the Term, then Tenant shall give notice (the "**Exercise Notice**") to Landlord, not later than January 31, 2021 exercising such option to extend. During the Third Extended Term, the Annual Fixed Rent for the Premises shall be payable by Tenant at the annual rate of $1,115,226.00 (being the product of (i) $42.00 and (ii) the Rentable Floor Area of the Premises (being 26,553 square feet)). Upon the giving of the Exercise Notice by Tenant to Landlord exercising Tenant's option to extend the Lease Term in accordance with the provisions of this Section 2(B), then the Lease and the Lease Term hereof shall automatically be deemed extended, for the Third Extended Term, without the necessity for the execution of any additional documents; and in such event all references herein to the Lease Term or the term of the Lease shall be construed as referring to the Lease Term, as so extended, unless the context clearly otherwise requires, and except that there shall be no further option to extend the Lease Term.

3. Annual Fixed Rent.

(A) Annual Fixed Rent for the Premises through the Scheduled Expiration Date shall continue to be payable by Tenant as set forth in the Lease.

(B) During the Second Extended Term, Annual Fixed Rent for the Premises shall be payable by Tenant at the annual rate of $1,088,673.00 (being the product of (i) $41.00 and (ii) the Rentable Floor Area of the Premises (being 26,553 square feet)).

4. Condition of the Premises. Tenant shall accept the Premises in its as-is condition during the Second Extended Term without any obligation on the Landlord's part to perform any additions, alterations, improvements, demolition or other work therein or pertaining thereto, provided, however, that the foregoing shall not relieve Landlord of its maintenance and repair obligations under the Lease.

5. Brokerage.

(A) Tenant warrants and represents that Tenant has not dealt with any broker in connection with the consummation of this Fourth Amendment other than Colliers ("Broker") and in the event any claim is made against Landlord relative to dealings by Tenant with any brokers other than Broker with respect to this Fourth Amendment, Tenant shall defend the claim against Landlord with counsel of Tenant's selection first approved by Landlord (which approval will not be unreasonably withheld) and save harmless and indemnify Landlord on account of loss, cost or damage which may arise by reason of such claim.

(B) Landlord warrants and represents that Landlord has not dealt with any broker in connection with the consummation of this Fourth Amendment other than Broker, and in the event any claim is made against Tenant relative to dealings by Landlord with any brokers other than Broker, Landlord shall defend the claim against Tenant with counsel of Landlord's selection first approved by Tenant (which approval will not be unreasonably withheld) and save harmless and indemnify Tenant on account of loss, cost or damage which may arise by reason of such claim. Landlord agrees that is shall be solely responsible for the payment of brokerage commissions to Broker for this Fourth Amendment.

6. Defined Terms. Except as otherwise expressly provided herein, all capitalized terms used herein without definition shall have the same meanings as are set forth in the Lease.

7. Ratification of Lease. Except as herein amended, the Lease shall remain unchanged and in full force and effect. All references to the "Lease" shall be deemed to be references to the Lease, as previously amended by the First Amendment, the Second Amendment, and the Third Amendment and as further amended by this Fourth Amendment.

8. Authority. Each of Landlord and Tenant hereby represents and warrants to the other that all necessary action has been taken to enter this Fourth Amendment and that the person signing this Fourth Amendment on its behalf has been duly authorized to do so.

9. Counterparts. This Fourth Amendment may be executed in counterparts, and such counterparts together shall constitute but one original of the Fourth Amendment. Each counterpart shall be equally admissible in evidence, and each original shall fully bind each party who has executed it. Provided it is accompanied by the final version of this Fourth Amendment (including

all exhibits, if any), an executed signature page of this Fourth Amendment delivered by facsimile or as a PDF or a similar attachment to an email shall constitute effective delivery of this Fourth Amendment by the party so delivering the same for all purposes with the same force and effect as the delivery of an executed original counterpart.

--SIGNATURE PAGE FOLLOWS --

EXECUTED as of the date and year first above written.

WITNESS: /s/ Casey Jorta

LANDLORD:

BP BAY COLONY LLC, a Delaware limited liability company

By: BP BAY COLONY HOLDINGS LLC, a Delaware limited liability company, its sole member

By: BOSTON PROPERTIES LIMITED PARTNERSHIP, a Delaware limited partnership, its member

By: BOSTON PROPERTIES, INC., a Delaware corporation, its general partner

By: /s/ Patrick Mulvihill

Name: Patrick Mulvihill

Title: VP, Leasing

TENANT:

WITNESS:

/s/ Jon Mahlowitz

RADIUS HEALTH, INC., a Delaware corporation

By: /s/ Jesper Hoeiland

Name: Jesper Hoeiland

Title: President & Chief Executive Officer

Exhibit 10.3(a)

RESTRICTED STOCK UNIT AWARD AGREEMENT
FOR COMPANY EMPLOYEES
2018 STOCK OPTION AND INCENTIVE PLAN

(Form amended as of February 20, 2020)

Name of Grantee: __

No. of Restricted Stock Units: __

Grant Date: __

Vesting Commencement Date: __

Pursuant to the Radius Health, Inc. 2018 Stock Option and Incentive Plan, as amended through the date hereof (the "Plan"), Radius Health, Inc. (the "Company") hereby grants an award of the number of Restricted Stock Units listed above (an "Award") to the Grantee named above. Each Restricted Stock Unit shall relate to one share of Common Stock, par value $0.0001 per share (the "Stock") of the Company.

1. Restrictions on Transfer of Award. This Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of by the Grantee, and any shares of Stock issuable with respect to the Award may not be sold, transferred, pledged, assigned or otherwise encumbered or disposed of until (i) the Restricted Stock Units have vested as provided in Paragraph 2 of this Agreement and (ii) shares of Stock have been issued to the Grantee in accordance with the terms of the Plan and this Agreement.

2. Vesting of Restricted Stock Units. The restrictions and conditions of Paragraph 1 of this Agreement shall lapse, and the Restricted Stock Units shall vest in [three (3) substantially equal annual installments] on each of the [first three (3) anniversaries of the vesting commencement date set forth above] (the "Vesting Commencement Date"), such that the Restricted Stock Units will be fully vested on the [third (3rd) anniversary of the Vesting Commencement Date], so long as the Grantee has a continuing Service Relationship with the Company or a Subsidiary or any successor entity on such dates. The restrictions and conditions in Paragraph 1 shall lapse only with respect to the number of Restricted Stock Units vested on such vesting date.

The Administrator may at any time accelerate the vesting schedule specified in this Paragraph 2.

3. Termination of Service Relationship. If the Grantee's Service Relationship with the Company or a Subsidiary or any successor entity terminates for any reason (including death or disability) prior to the satisfaction of the vesting conditions set forth in Paragraph 2 above, any Restricted Stock Units that have not vested as of such date shall automatically and without notice terminate and be forfeited, and neither the Grantee nor any of his or her successors, heirs,

assigns, or personal representatives will thereafter have any further rights or interests in such unvested Restricted Stock Units.

4. Issuance of Shares of Stock. As soon as practicable following each Vesting Date (but in no event later than two and one-half months after the end of the year in which the Vesting Date occurs), the Company shall issue to the Grantee the number of shares of Stock equal to the aggregate number of Restricted Stock Units that have vested pursuant to Paragraph 2 of this Agreement on such date and the Grantee shall thereafter have all the rights of a stockholder of the Company with respect to such shares.

5. Incorporation of Plan. Notwithstanding anything herein to the contrary, this Agreement shall be subject to and governed by all the terms and conditions of the Plan, including the powers of the Administrator set forth in Section 2(b) of the Plan. Capitalized terms in this Agreement shall have the meaning specified in the Plan, unless a different meaning is specified herein.

6. Tax Withholding. Notwithstanding any Plan provision to the contrary, unless the Administrator determines otherwise, the requirement for the Grantee to satisfy all withholding obligations arising in connection with the Award will be satisfied by placing a market sell order with a broker acceptable to the Company covering a sufficient number of shares of Stock otherwise then-issuable under the Award as are necessary to satisfy the statutory tax withholding obligations arising in connection with the Award, as determined by the Company. The net proceeds of such sale shall be delivered to the Company or its applicable subsidiary upon the settlement of such sale. The Grantee acknowledges that, unless otherwise determined by the Administrator, such market sell order will be placed automatically and that it is mandatory, binding and non-discretionary on the part of the Grantee. The Company shall have the authority to cause the required tax withholding obligation to be satisfied, in whole or in part, by withholding from shares of Stock to be issued to the Grantee a number of shares of Stock with an aggregate Market Value that would satisfy the withholding amount due.

7. Section 409A of the Code. This Agreement shall be interpreted in such a manner that all provisions relating to the settlement of the Award are exempt from the requirements of Section 409A of the Code as “short-term deferrals” as described in Section 409A of the Code.

8. No Obligation to Continue Service Relationship. Neither the Company nor any Subsidiary is obligated by or as a result of the Plan or this Agreement to continue the Grantee’s Service Relationship with the Company or a Subsidiary or any successor entity, and neither the Plan nor this Agreement shall interfere in any way with the right of the Company or any Subsidiary to terminate the Grantee’s Service Relationship at any time.

9. Integration. This Agreement constitutes the entire agreement between the parties with respect to this Award and supersedes all prior agreements and discussions between the parties concerning such subject matter.

10. Data Privacy Consent. In order to administer the Plan and this Agreement and to implement or structure future equity grants, the Company, its subsidiaries and affiliates and certain agents thereof (together, the “Relevant Companies”) may process any and all personal or

professional data, including but not limited to Social Security or other identification number, home address and telephone number, date of birth and other information that is necessary or desirable for the administration of the Plan and/or this Agreement (the "Relevant Information"). By entering into this Agreement, the Grantee (i) authorizes the Company to collect, process, register and transfer to the Relevant Companies all Relevant Information; (ii) waives any privacy rights the Grantee may have with respect to the Relevant Information; (iii) authorizes the Relevant Companies to store and transmit such information in electronic form; and (iv) authorizes the transfer of the Relevant Information to any jurisdiction in which the Relevant Companies consider appropriate. The Grantee shall have access to, and the right to change, the Relevant Information. Relevant Information will only be used in accordance with applicable law.

11. Notices. Notices hereunder shall be mailed or delivered to the Company at its principal place of business and shall be mailed or delivered to the Grantee at the address on file with the Company or, in either case, at such other address as one party may subsequently furnish to the other party in writing.

12. Acceptance of Award. The Grantee must execute this Agreement by logging on to the Company's administrative agent's website for the Plan. IF THE GRANTEE DOES NOT ELECTRONICALLY ACCEPT THIS AWARD THROUGH THE WEBSITE WITHIN THIRTY (30) DAYS FOLLOWING THE GRANT DATE AND THEREBY ACCEPT THE TERMS AND CONDITIONS OF THIS AGREEMENT AND THE PLAN, THEN THE GRANTEE WILL BE DEEMED TO HAVE DECLINED THE AWARD AND THIS AWARD WILL BE NULL AND VOID (AND THE PARTICIPANT WILL HAVE NO RIGHTS WITH RESPECT TO THE AWARD).

Exhibit 21.1

SUBSIDIARIES OF RADIUS HEALTH, INC.

Legal Name of Subsidiary	Jurisdiction of Organization
Radius Global Support, Inc.	Delaware
Radius Health Securities Corporation	Massachusetts
Radius International Limited	United Kingdom
Radius Pharmaceuticals (Bermuda) Ltd.	Bermuda
Radius Pharmaceuticals, Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-8, File No. 333-177800) pertaining to the 2003 Long-Term Incentive Plan of Radius Health, Inc. and 2011 Equity Incentive Plan of Radius Health, Inc.;

2. Registration Statement (Form S-8, File No. 333-195521) pertaining to the 2011 Equity Incentive Plan of Radius Health, Inc.;

3. Registration Statement (Form S-8, File No. 333-213081) pertaining to the 2011 Equity Incentive Plan, as amended and restated, of Radius Health, Inc.;

4. Registration Statement (Form S-8, File No. 333-213082) pertaining to the 2016 Employee Stock Purchase Plan of Radius Health, Inc.;

5. Registration Statement (Form S-8, File Nos. 333-215552, 333-224882, and 333-231237) pertaining to Inducement Stock Option Agreements between Radius Health, Inc. and certain of its employees; and

6. Registration Statement (Form S-8, File No. 333-226971) pertaining to the 2018 Stock Option and Incentive Plan of Radius Health, Inc.;

of our reports dated February 27, 2020, with respect to the consolidated financial statements of Radius Health, Inc. and the effectiveness of internal control over financial reporting of Radius Health, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2019.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 27, 2020

Exhibit 31.1

CERTIFICATIONS

I, Jesper Hoeiland, certify that:

1. I have reviewed this annual report on Form 10-K of Radius Health, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2020

/s/ Jesper Hoeiland

Jesper Hoeiland

President and Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Jose Carmona, certify that:

1. I have reviewed this annual report on Form 10-K of Radius Health, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2020

/s/ Jose Carmona

Jose Carmona
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Radius Health, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jesper Hoeiland, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 27, 2020

By: /s/ Jesper Hoeiland

Jesper Hoeiland
President and Chief Executive Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Radius Health, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jose Carmona, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

February 27, 2020

By: /s/ Jose Carmona

Jose Carmona

Chief Financial Officer

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.