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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, 2021

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.)

22 Boston Wharf Road, 7th Floor
Boston, Massachusetts 02210
(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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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, 2021 was $0.9 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 18, 2022: 47,382,754

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2022 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, 2021
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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- *our expectations regarding commercialization of TYMLOS® in the U.S., including our market access coverage expectations;*
- *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;*
- *the direct and indirect impact of the COVID-19 pandemic on the U.S. and global economies and our business and operations, including sales, expenses, supply chain, manufacturing, research and development costs, clinical trials and employees;*
- *our plans with respect to collaborations and licenses related to the development, manufacture or sale of TYMLOS and our investigational product candidates;*
- *our goals and expectations with respect to development and commercialization of RAD011, our cannabidiol oral solution asset ("CBD");*
- *our expectations with respect to development and commercialization of elacestrant by Berlin-Chemie;*
- *our plans with respect to expanding our product portfolio;*
- *our plans and expectations with respect to our intellectual property profile;*
- *our expectations regarding the timing of our regulatory submissions;*
- *our expectations for our clinical trials, including projected costs, study designs or the timing for initiation, recruitment, completion, or reporting top-line data;*
- *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;*
- *our expectations regarding federal, state and foreign regulatory and other legal requirements;*
- *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 Annual Report on Form 10-K.*

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 commercializing pharmaceutical products 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 and patent and trademark authorities and offices, 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 global biopharmaceutical company focused on addressing unmet medical needs in the areas of bone health, neuroscience, and oncology.

In April 2017, our first commercial product, TYMLOS (abaloparatide) injection, was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In May 2017, we commenced U.S. commercial sales of TYMLOS and as of January 1, 2022, TYMLOS was available and covered for approximately 288 million U.S. insured lives, representing approximately 99% of U.S. Commercial and 74% of Medicare Part D insured lives.

During 2021, we completed three potentially pivotal Phase 3 clinical trials and announced their results, as follows:

- In October 2021, we announced positive topline results from our Phase 3 clinical trial evaluating abaloparatide for subcutaneous injection ("abaloparatide-SC") for use in males with osteoporosis (the "ATOM Trial"). The ATOM Trial met its primary and secondary endpoints and demonstrated a safety profile consistent with previous trials.
- In October 2021, together with our licensee, Berlin-Chemie AG ("Berlin-Chemie"), a company of the Menarini Group, we announced positive topline results from our Phase 3 clinical trial of elacestrant, a selective estrogen receptor degrader (SERD) we investigated as a monotherapy versus the standard of care for treatment of ER+/HER2- advanced or metastatic breast cancer (the "EMERALD Trial"). The EMERALD Trial met both primary endpoints and demonstrated a safety profile consistent with previous trials. We presented data from the EMERALD Trial at the San Antonio Breast Cancer Symposium in December 2021.
- In December 2021, we announced the results of our Phase 3 clinical trial of the abaloparatide transdermal system ("abaloparatide-TD"), a different formulation of abaloparatide delivered using Kindeva Drug Delivery's ("Kindeva") patented microstructured transdermal system technology (the "wearABLe Trial"). The wearABLe Trial did not meet its primary or secondary endpoints.

We are also developing RAD011, a pharmaceutical-grade synthetic cannabidiol oral solution, manufactured utilizing traditional pharmaceutical manufacturing processes. Based on feedback received from a Type C meeting with the FDA in June 2021, we are moving forward with a potentially pivotal Phase 2/3 study for treatment of hyperphagia-related behavior in patients with Prader-Willi Syndrome ("PWS") in the first half of 2022.

We out licensed our oncology assets in 2020. In July 2020, we entered into a license agreement with Berlin-Chemie under which we granted Berlin-Chemie an exclusive license to develop and commercialize products containing elacestrant worldwide.

In September 2020 we sold RAD140, our internally discovered non-steroidal selective androgen receptor modulator ("SARM") to Ellipses Pharma. Ellipses Pharma will be responsible for the clinical development and commercialization of the asset and is obligated to pay us royalties.

Our Marketed Product and Investigational Product Candidates

The success of our business is primarily dependent upon our ability to maximize the commercialization of TYMLOS and abaloparatide-SC, develop and commercialize our current and future product candidates, and benefit from Berlin-Chemie's potential commercialization of elacestrant. With respect to abaloparatide-SC, we hold worldwide commercialization rights, except in Japan and Canada, where we have entered into exclusive license, supply and development relationships with our partners. With respect to elacestrant, Berlin-Chemie holds worldwide commercialization rights.

Our Strategy

To achieve our corporate and strategic goals, we plan to:

- **Expand use of TYMLOS and abaloparatide-SC**. We remain focused on growing our U.S.-based sales through a refined focus on patients with a high risk of fracture. In December 2021, we announced the removal of the boxed warning regarding the risk of osteosarcoma from the TYMLOS label. We intend to continue to expand our global abaloparatide footprint, including through our collaboration with Teijin Limited ("Teijin") in Japan.

- **Expand abaloparatide's market potential through continued research, development and regulatory initiatives.** We announced top-line data from the ATOM Trial in October 2021 and expect to file a supplemental New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") ") for abaloparatide for use in males with osteoporosis during the first quarter of 2022. We may continue to pursue additional formulations of and indications for abaloparatide, as well as any and all improvements to the TYMLOS product that we may identify in the future.

- **Develop RAD011 in our initial target indication, Prader-Willi Syndrome, as well as other indications we may identify in the future.** Based on feedback from a Type C meeting with the FDA in June 2021, we intend to initiate a potentially pivotal study of RAD011 in the first half of 2022. This Synthetic Cannabidiol Oral Solution 015 study will be a randomized double-blind placebo-controlled seamless Phase 2/3 trial (the "SCOUT-015 Trial") designed to support a (505(b)(2) NDA submission to the FDA for RAD011 for the treatment of hyperphagia in patients with PWS. Our efforts to identify additional indications for RAD011 are ongoing, and we expect to identify additional indications in 2022.

- **Continue to expand our product portfolio**. We may consider opportunistically expanding our product portfolio within these areas through in-licensing, acquisitions or partnerships.

Abaloparatide

We have developed or targeted two formulations of abaloparatide: abaloparatide-SC and abaloparatide-TD.

Abaloparatide-SC

In April 2017, the FDA approved TYMLOS for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. The first commercial sales of TYMLOS in the United States occurred in May 2017 and as of January 1, 2022, TYMLOS was available and covered for approximately 288 million U.S. insured lives, representing approximately 99% of U.S. Commercial and 74% of Medicare Part D insured lives.

We are commercializing TYMLOS in the United States through our internal commercial organization. We hold worldwide commercialization rights to abaloparatide-SC, except for Japan and Canada, where we are entitled to receive milestones and royalties based on the development and commercialization of abaloparatide-SC under our license and development agreements.

In July 2017, we entered into a license and development agreement with Teijin for abaloparatide-SC in Japan. In May 2020, we announced that Teijin submitted an NDA for abaloparatide-SC in Japan for the treatment of osteoporosis in patients who are at high risk for fracture and in March 2021, we announced the approval in Japan of Ostabalo® abaloparatide acetate for the treatment of osteoporosis and promotion of bone formation in both female and male patients with high risk of fracture in Japan. Pursuant to the agreement, we have received an upfront payment and a regulatory milestone upon the approval of Ostabalo. We may receive additional milestone payments upon the achievement of certain 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.

In October 2021, we announced positive top-line results of our ATOM Trial. This study met its primary endpoint of change in lumbar spine bone mineral density ("BMD") at 12 months compared to placebo, demonstrating statistical significance after 12 months. It also met secondary endpoints of change in lumbar spine BMD at 6 months compared to placebo, change in total hip BMD at 12 months compared to placebo, and change in femoral neck BMD at 12 months compared to placebo. We expect that these results will form the basis of a supplemental NDA seeking to expand the use of TYMLOS to increase bone mass in men with osteoporosis at high risk for fracture. The ATOM Trial was a randomized, double-blind, placebo-controlled trial that has enrolled 228 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 ATOM Trial 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.

Abaloparatide-TD

In December 2021, we announced Phase 3 top-line results from the wearABLe Trial, which evaluated the non-inferiority of abaloparatide-TD as compared to TYMLOS. The trial did not meet its primary endpoint, as patients treated with abaloparatide-TD demonstrated an increase of 7.1% in lumbar spine BMD versus an increase of 10.9% for those treated with TYMLOS. The wearABLe Trial similarly did not meet its secondary endpoint. The wearABLe study was a single, pivotal, randomized, open label, active-controlled, BMD non-inferiority bridging study with an enrollment of approximately 500 patients with postmenopausal osteoporosis at high risk of fracture.

We, along with our partner, Kindeva, continue to evaluate all strategic options for the abaloparatide-TD program.

RAD011

We are also developing RAD011 with PWS as our initial target indication. We acquired RAD011 from Fresh Cut Development, LLC and Benuvia Therapeutics Inc. in December 2020. Prior to the Company's acquisition of RAD011 in December 2020, it was granted fast track designation by the FDA in 2017 and orphan drug designation in August 2020 for the treatment of hyperphagia behavior and weight loss in patients with PWS. In June 2021, we participated in a Type C meeting with the FDA and, based on feedback from that meeting, intend to initiate the SCOUT Trial in the first half of 2022. The SCOUT-015 Trial will be a randomized double-blind placebo-controlled seamless Phase 2/3 trial designed to support a 505(b)(2) NDA submission for RAD011 for the treatment of hyperphagia in patients with PWS.

Our Oncology Portfolio

Given our focus on growing our TYMLOS and abaloparatide-SC business, developing RAD011 and expanding our product portfolio, we evaluated all strategic options for our oncology assets in 2020. In July 2020, we entered into a license agreement with Berlin-Chemie for the exclusive license of elacestrant.

In October 2021, we and Berlin-Chemie AG together announced positive top-line results from the EMERALD Trial of elacestrant. The EMERALD Trial was designed to evaluate elacestrant as a second or third-line monotherapy versus the standard of care for treatment of patients with estrogen receptor-positive ("ER+") and human epidermal growth factor receptor 2-negative ("HER2-") advanced or metastatic breast cancer. The study met both primary endpoints, demonstrating statistically significant progression-free survival in the overall population and in patients with tumors harboring estrogen receptor 1 ("ESR1") mutations. Based on these results, we expect to proceed with applications for marketing approval in the United States and the European Union in collaboration with Berlin-Chemie.

In 2020, we also sold RAD140, our internally discovered SARM, to Ellipses Pharma.

Manufacturing

We do not own or operate manufacturing facilities for the production of 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-TD, is manufactured for us on a contract basis by Polypeptide Laboratories Holding (PPL) AB ("PPL") 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 TYMLOS 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-TD drug product is manufactured by Kindeva, based on their patented microneedle technology to administer drugs through the skin, as an alternative to subcutaneous injection.

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

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 and Canada, to certain patents, data and technical information related to abaloparatide through a license agreement with an affiliate of Ipsen Pharma SAS ("Ipsen"). Patents covering the composition of matter of abaloparatide (e.g., U.S. Patent No. 5,969,095), expired in 2016. The subcutaneous formulation of abaloparatide for use in treating osteoporosis is covered by Orange Book-listed U.S. Patent No. 7,803,770, which expires on April 28, 2031. The therapeutic formulation for abaloparatide-SC is covered by Orange Book-listed U.S. Patent No. 8,148,333 until November 8, 2027 and Orange Book-listed U.S. Patent No. 8,748,382 until October 3, 2027. Related patents granted in Australia, Brazil, China, Europe, Hong Kong, Israel, Japan, South Korea, Mexico, Norway, New Zealand, and Singapore and additional patent applications pending in Brazil and Canada, 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 the United States and additional patent applications are currently pending in the United States, Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, Japan, South Korea, Mexico, New Zealand, and Singapore. These patents and applications are co-owed with, and licensed from, Kindeva. The issued patents and any patents that might issue from the pending applications will have a statutory expiration dates of 2036, not taking into account extension under any applicable laws. Finally, the therapeutic formulation for abaloparatide-SC also is covered by Orange Book-listed U.S. Patent No. 10,996,208 (the "'208 patent") which expires on April 30, 2038. The 208 patent is exclusively owned by Radius and does not have any foreign counterparts.

We own federal trademark registrations in the United States for RADIUS® and TYMLOS® for pharmaceuticals for use in the treatment of bone diseases. In addition, we own registrations for TYMLOS in Canada, the European Union, the United Kingdom, and Mexico; Radius in Mexico, Japan, the United Kingdom, Bermuda, and the European Union; and trademark applications for these and other potential brand names for our product candidates in the U.S. and in other countries.

Elacestrant (RAD1901)

In July 2020, we entered into a license agreement with Berlin-Chemie AG, a company of the Menarini Group ("Berlin-Chemie"), under which we granted Berlin-Chemie an exclusive license to develop and commercialize products containing elacestrant worldwide.

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 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). Patents that may issue from corresponding applications pending in Europe and Canada will have a statutory expiration date in 2035 if granted. Polymorphic forms of elacestrant are covered in U.S. Patent No. 10,385,008, U.S. Patent No. 10,745,343, and U.S. Patent No. 11,148,996 (statutory terms expire 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, Hong Kong, 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+ would be covered by patents that may issue from applications pending in the U.S., Australia, Brazil, Canada, China, Europe, Hong Kong, 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). Elacestrant combination therapy with abemaciclib for treatment of breast cancer would be covered by patents that may issue from applications pending in the U.S., the United Arab Emirates, Australia, Azerbaijan, Brazil, Canada, China, Algeria, Eurasia, Egypt, Europe, Guatemala, Hong Kong, Israel, India, Indonesia, Iran, Jordan, Japan, South Korea, Kazakhstan, Morocco, Moldova, Mexico, Malaysia, New Zealand, Panama, Philippines, Russia, Saudi Arabia, Singapore, Thailand, Tunisia, Ukraine, Venezuela, and South Africa.

RAD011

In December 2020, we entered into an Asset Purchase Agreement with Fresh Cut Development, LLC and Benuvia Therapeutics Inc. for the acquisition of certain assets related to formulations of cannabidiol ("CBD") related to the oral administration of a liquid formulation of CBD for therapeutic use in humans or animals ("RAD011").

We acquired and maintain exclusive worldwide rights to certain patents and pending patent applications related to oral RAD011. Patents covering a therapeutic formulation of RAD011 are granted in Australia, New Zealand and Japan, and additional patent applications pending in the United States, Europe, Canada, the People's Republic of China, Israel, Mexico, and South Africa will have patent expiration dates of 2035-2036, not taking into account extension under any applicable laws. Patent applications covering related CBD formulations have been granted in the United States (e.g., U.S. Patent No. 11,224,660), Australia and Japan and are currently pending in Canada, the People's Republic of China, Europe, Israel, Mexico, New Zealand and South Africa. The issued patents and pending applications that may issue from the pending applications will have statutory expiration dates of 2035, not taking into account extension under any applicable law.

We also acquired worldwide rights to certain patent applications directed to methods of synthesizing CBD, nanocrystal compositions of CBD and self-emulsifying compositions of CBD. These applications are currently pending in the United States, Canada and Europe. These applications are licensed from Fresh Cut Development, LLC and Benuvia Therapeutics Inc. Any patents that might issue from these applications will have statutory expiration dates extending to 2040, not taking into account extension under any applicable laws.

Competition

The development and commercialization of new products to treat the targeted indications of our marketed and investigational product candidates faces 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 comparable resources to us, including financial, manufacturing, marketing, research and drug development resources. In addition, some of these companies have longer operating histories and more experience than us in preclinical and clinical development, manufacturing, regulatory and global commercialization, while others have less experience.

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 one of two other anabolic drug targeting the PTH receptor approved in the United States for the treatment of osteoporosis. In 2020, Pfenex, Inc., which was acquired by Ligand Inc., along with its commercialization partner Alvogen began marketing another teriparatide injection drug, Bonsity. We are aware of companies pursuing development in the United States of teriparatide through various regulatory pathways, including 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-TD, if approved.

RAD011

We expect to develop RAD011 for treatment of hyperphagia related to Prader-Willi syndrome. While there is no treatment for Prader-Willi syndrome ("PWS") currently approved in the United States, there have been select competitive molecules in development, including intranasal carbetocin for the treatment of hyperphagia and behavior associated with PWS, by Levo Therapeutics Inc.; intranasal oxytocin for the treatment of hyperphagia in PWS by Montefiore Medical Center; cannabidivarin for treatment of irritability, restricted/repetitive behaviors, hyperphagia in PWS, by GW Pharmaceuticals plc; CSTI-500 for the treatment of hyperphagia in PWS, by ConSynance Therapeutics Inc.; HM04 for the treatment of hyperphagia in PWS, by Helsinn Group; GDD3898 for the treatment of etabolic conditions associated with PWS, by Lipidio Pharmaceuticals Inc.; NS200 to suppress food intake and mood disorders in PWS, by Neuracle Science; OPN-300 for the treatment of PWS, by OptiNose Inc.; RM-853 for the treatment of PWS, by Rhythm Pharmaceuticals; and Tesomet for the treatment of hyperphagia in PWS, by Saniona AB.

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

Kindeva

The Company is a party to a Scale-Up and Commercial Supply Agreement (the "Supply Agreement") with Kindeva Drug Delivery ("Kindeva"), as successor to 3M Company and 3M Innovative Properties Company (collectively with 3M Company, "3M"), pursuant to which Kindeva has agreed to exclusively manufacture Phase 3 and global commercial supplies of an abaloparatide-coated transdermal system ("abaloparatide-TD"). Under the Supply Agreement, Kindeva will manufacture abaloparatide-TD for the Company according to agreed-upon specifications in sufficient quantities to meet the Company's projected supply requirements. If abaloparatide-TD is commercialized, Kindeva would manufacture commercial supplies of abaloparatide-TD at unit prices that decrease with an increase in the quantity the Company orders. The Company would pay Kindeva a mid-to-low single-digit royalty on worldwide net sales of abaloparatide-TD and reimburse Kindeva for certain capital expenditures incurred to establish a commercial supply of abaloparatide-TD. The Company is responsible for providing, at its expense, supplies of abaloparatide drug substance to be used in manufacturing abaloparatide-TD. During the term of the Supply Agreement, Kindeva 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 abaloparatide-TD. 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 abaloparatide-TD, if it is unable to obtain U.S. regulatory approval for abaloparatide-TD within a certain time period, or if it ceases development or commercialization of abaloparatide-TD. Kindeva may terminate the Supply Agreement upon the occurrence of certain events, including if there are certain safety issues related to abaloparatide-TD, if the Company is unable to obtain U.S. regulatory approval for abaloparatide-TD within a certain time period, or if the Company fails to order abaloparatide-TD for a certain period of time after commercial launch of abaloparatide-TD in the U.S. Upon certain events of termination, Kindeva is required to transfer the manufacturing processes for abaloparatide-TD to the Company or a mutually agreeable third party and continue supplying abaloparatide-TD for a period of time pursuant to the Company's projected supply requirements.

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 abaloparatide-TD. Milestone payments for the equipment commenced in the fourth quarter of 2018 and are expected to be paid in full in the first quarter of 2022. 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 and Kindeva approximately $63.0 million, in the aggregate, through December 31, 2021 with respect to performance under the Supply Agreement, including the purchase of capital equipment. In addition, there are cancellable purchase commitments in place to fund certain facility build out and future purchases of capital equipment. In addition, there are cancellable purchase commitments in place to fund certain facility build out and future purchases of capital equipment.

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, 2021. 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 $29.5 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 License Agreement also provides that the Company is obligated to pay to Ipsen a fixed five percent royalty based on net sales of the products containing abaloparatide 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 $10.9 million, $10.4 million and $8.7 million for the twelve months ended December 31, 2021, 2020 and 2019, 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, after patent term extension, is expected to be April 28, 2031.

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 License 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 the 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.

Prior to executing the License Agreement for abaloparatide with Radius, Ipsen licensed the Japanese rights for abaloparatide to Teijin.

Pursuant to a 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). Under the final decision, we are obligated to pay Ipsen a fixed mid-single-digit royalty based on net sales of abaloparatide in Japan. In March 2021, Teijin received approval for Ostabalo® abaloparatide acetate for the treatment of osteoporosis and for promotion of bone formation in both female and male patients with high risk fracture. As a result, the Company recognized a liability of $5.0 million which was recorded as accrued expenses and other current liabilities within the condensed consolidated balance sheet as of March 31, 2021.

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.

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 has received and may receive further payments upon the achievement of certain regulatory and sales milestones, as well as a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term, as defined below. In addition, the Company has an option to negotiate a co-promotion agreement with Teijin for abaloparatide-SC in Japan upon commercialization. In March 2021, Teijin received approval for Ostabalo® abaloparatide acetate for the treatment of osteoporosis and for promotion of bone formation in both female and male patients with high risk fracture. Upon achievement of this regulatory milestone, the Company received a payment of $10.0 million from Teijin.

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-TD, 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.

Berlin-Chemie

In July 2020, the Company entered into a license agreement ("License Agreement") with Berlin-Chemie under which the Company granted Berlin-Chemie an exclusive license to develop and commercialize products containing elacestrant (RAD1901) worldwide.

Pursuant to the terms of the License Agreement, Berlin-Chemie made a nonrefundable initial license fee payment to the Company of $30.0 million in July 2020. The Company is also eligible to receive up to $20.0 million in development and regulatory milestone payments and up to $300.0 million in sales milestone payments, with such payments contingent on the achievement of specified milestones with respect to the licensed products. The Company is also eligible to receive tiered royalties on sales of licensed products at percentages ranging from low to mid-teens, subject to certain reductions. Royalties on net sales will be payable on a product-by-product and country-by-country basis until the latest of the expiration date of the last to expire of the relevant patent rights, the expiration of regulatory exclusivity, or ten years from such first commercial sale.

The License Agreement will continue on a licensed product-by-licensed product and country-by-country basis until the last to expire royalty term. Either party may terminate the License Agreement for an uncured material breach by the other party or upon the bankruptcy or insolvency of the other party. The Company may terminate the License Agreement for certain patent challenges or if no development, manufacture or commercialization activity occurs in any given 24-month period. Berlin-Chemie may terminate the License Agreement at its discretion for any reason by delivering 180 days' prior written notice to the Company; provided that such termination will not be effective prior to the third anniversary of the effective date.

The Company and Berlin-Chemie simultaneously entered into a Transition Services Agreement (the "TSA"), pursuant to which the Company agreed to perform certain services for Berlin-Chemie related to the EMERALD Phase 3 monotherapy study until the earlier of the completion of the contemplated services or the filing with the FDA of a New Drug Application for elacestrant. Pursuant to the TSA, Berlin-Chemie agreed to reimburse the Company for all out-of-pocket and full-time employee costs in performing the services, for total estimated reimbursements of $111.5 million. The Company will continue to incur research and development expenses in support of scale up costs under the TSA.

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 renewed for a two-year term. Following its current term, the agreement automatically renews for additional two-year terms unless either party terminates the agreement upon 18 months' notice prior to the end of the then-current term. During the two-year term beginning May 2020, we are required to purchase a minimum number of batches CHF 1.9 million ($2.0 million).

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 term of the agreement automatically renewed on January 1, 2021 for an additional two-year term and will automatically renew for additional two-year terms thereafter 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 ($3.2 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.

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 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 have active investigational new drug ("IND") applications for abaloparatide, elacestrant and RAD011 in the United States, with the goal of filing an NDA for each product candidate.

Approval Process—We are not permitted to market our product candidates in the United States until we receive 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 GMPs 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 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—Phase 1 clinical trials involve initial introduction of the study drug in a limited population of healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the study drug in humans, evaluate the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- Phase 2—Phase 2 clinical trials typically involve administration of the study drug to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—Phase 3 clinical trials typically involve administration of the study drug to an expanded patient population to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the study drug and to provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

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.

Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific time frames to the National Institutes of Health for public dissemination on the Clinicaltrials.gov data registry.

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.

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 "user fee" payment to the FDA. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product in the proposed patient population to the satisfaction of the FDA. 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, but is not bound by the recommendations of the advisory committee.

Before approving an NDA, the FDA usually will inspect the facility or the facilities at which the drug is manufactured and determine whether the manufacturing and production and testing facilities are in compliance with cGMP regulations. The FDA also may audit the clinical trial sponsor and one or more sites at which clinical trials have been conducted to determine compliance with GCPs and data integrity. 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 ("CRL"). An approval letter authorizes commercial marketing of the drug with specific prescribing information for a specific indication(s). A CRL indicates that the review cycle of the application is complete and the application is not ready for approval. A CRL 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, or 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. 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.

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— Even after a drug has been approved by the FDA, the FDA may impose certain post-approval requirements, 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 comply with ongoing regulatory requirements governing manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, as well as continued compliance with current GCP regulations for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents. Future FDA inspections may identify compliance issues at the facilities of our third-party 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.

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 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, for example, abaloparatide-TD is approved prior to the expiration to the NCE exclusivity granted to TYMLOS, we would expect abaloparatide-TD to be protected by any remaining NCE exclusivity period.

Additionally, 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).

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 EU has adopted Regulation (EU) No 536/2014, which replaced the prior Directive 2001/20/EC and 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 came into effect in each EU Member State on January 31, 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, the commercial success of any products we market, or may market in the future, is dependent, in significant part, on the scope of coverage and amount of reimbursement from third-party payors such as government health programs and private health insurance. Third-party payors are increasingly focused on controlling the costs of drug products by managing utilization and reducing payments for drugs. Third party payor initiatives to do so include establishing formularies that limit coverage of drug products and create financial incentives for patients to use lower cost drugs (through implementation of differential cost-sharing) or requiring prescribing physicians to demonstrate medical necessity for a drug product for a particular patient before coverage will be authorized (prior authorization). Pharmaceutical manufacturers may be required by law or market conditions to provide discounts or rebates to third party payors or purchasers in order to ensure coverage or sales of drug products. Coverage and payment of drug products is subject to ongoing scrutiny and reform efforts. Future legislation or other action by government authorities in the United States and other jurisdictions could affect pricing, coverage and reimbursement for the products we market and may develop in the future. Any such legislation could impact, in a significant way, our ability to generate revenues from sales of products that, if successfully developed, we bring to market.

Within the United States, coverage and reimbursement for products can differ significantly from third-party payor to third-party payor. One third party payor's decision to cover a particular drug product does not ensure that other payors will also provide coverage for the drug product. As a result, the coverage determination process usually requires manufacturers to provide scientific and clinical support for the use of their products to each payor separately and can be a time consuming process. Additionally, obtaining coverage does not mean that reimbursement for covered drugs will be adequate. A significant proportion of patients eligible for TYMLOS are Medicare beneficiaries. Drugs like TYMLOS that are dispensed by pharmacies to patients for self-administration are potentially eligible for coverage under Medicare Part D. Medicare Part D is a voluntary program that offers prescription drug coverage through private plans to members enrolled with the plan. Medicare Part D coverage may vary from plan to plan and the plans may implement formularies and certain utilization management activities as well as negotiate rebates with pharmaceutical manufacturers to manage access and costs. Manufacturers must also provide discounts on Medicare Part D brand name prescription drugs sold to Medicare beneficiaries in the Medicare Part D coverage gap (i.e., the so called "donut hole").

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 proposals 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. If a product is approved, we must also comply with post-marketing requirements, including, but not limited to, compliance with advertising and promotion requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as ‘‘off-label use’’), monitoring and record-keeping activities, reporting of adverse events, product sampling and distribution restrictions, and limitations on industry sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Promotional materials for approved drugs must be submitted to the FDA in conjunction with their first use or first publication. If there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new NDA or an NDA supplement, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials.

Within the United States, we are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry, including anti-kickback and false claims laws. Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and/or exclusion from federal health care programs (including Medicare and Medicaid). Federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry, and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the federal civil False Claims Act (“FCA”). Violations of these laws can result in imprisonment, criminal fines, penalties or exclusion from participation in government health care programs. Given the broad scope of these laws, our activities could be subject to scrutiny under the laws. If we were subject to allegations concerning, or were convicted of violating, these laws, our business could be harmed.

The federal anti-kickback statute generally prohibits, among other things, a pharmaceutical manufacturer from directly or indirectly soliciting, offering, receiving, or paying any remuneration in cash or in kind where one purpose is either to induce the referral of an individual for, or the purchase or prescription of, a particular drug that is payable by a federal health care program. A person or entity does not need to have actual knowledge of the statute or a specific intent to violate the statute. A claim arising from a violation of the federal Anti-Kickback Statute also constitutes a false or fraudulent claim for purposes of the FCA.

Federal and state false claims laws generally prohibit anyone from knowingly and willfully, among other activities, presenting, or causing to be presented for payment to third party payors (including Medicare and Medicaid) claims for drugs or services that are false or fraudulent (which may include claims for services not provided as claimed or claims for medically unnecessary services). There is also a criminal FCA statute by which individuals or entities that submit false claims can face criminal penalties. In addition, under the federal civil monetary penalty law, the Department of Health and Human Services Office of Inspector General has the authority to exclude from participation in federal health care programs or to impose civil penalties against any person who, among other things, knowingly presents, or causes to be presented, certain false or otherwise improper claims. A federal healthcare fraud statute prohibits the knowing and willful execution, or attempt to execute, a

scheme to defraud a health care benefit program, including private health plans, or obtain, through false or fraudulent pretenses, money or property owned by, or under the custody or control of, such a health care benefit program.

The majority of states also have anti-kickback, false claims, and similar fraud and abuse laws and although the specific provisions of these laws vary, their scope is generally broad, and there may not be regulations, guidance or court decisions that apply the laws to particular industry practices.

Laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers; require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government; and/or require disclosure to the government and/or public of financial interactions (so-called "sunshine laws"). State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Manufacturers must also submit information to the FDA on the identity and quantity of drug samples requested and distributed by a manufacturer during each year. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our activities could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

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.

Human Capital

At Radius, attracting and developing high-performing team members is key to our success. As of December 31, 2021, we employed 293 full-time employees. Of the total 293 employees, 103 were engaged in research and development activities, 64 were engaged in support administration, including business development and finance, and 126 were 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.

We also seek to build a diverse and inclusive workplace. Our employee base was comprised of 57% females and 43% males, and was comprised of the following ethnicities as of December 31, 2021: 73% White, 11% Asian, 5% Hispanic, 6% Black, 2% two or more races, and 0.7% additional groups (including American Indian or Alaska Native). We will continue to support the diversification of our workforce through recruiting, retention, employee development and inclusion efforts.

We believe our compensation package is competitive and designed to attract, retain, and motivate talented and high-performing team members who have relevant, critical skills and experience which are important to the achievement of our business objectives. Our employees' total compensation package includes market-competitive salary, bonuses or sales commissions, and equity. We also offer a wide range of benefits across areas such as health, family, and finance, which include but are not limited to healthcare, financial wellness and retirement planning programs, employee assistance programs, generous paid time off, and fitness benefits.

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, 2022, 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.

Risk Factors Summary

The following is a summary of the principal risks that could adversely affect our business, conditions and financial results.

Risks Related to Our Financial Position and Need for Capital

- We are not currently profitable and may never become profitable.
- 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.

Risks Related to the Commercialization and Development of Our Product Candidates

- We are heavily dependent on the commercial success of TYMLOS; 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 current and future product candidates may never receive regulatory approval.
- We may never receive approval for, or commercialize, our products outside of the United States.
- 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 our product candidates.
- Pre-clinical studies and clinical trials are very expensive, time-consuming and difficult to design and implement.
- We have sold or licensed our oncology assets; however there can be no assurance that those or other transactions will yield additional value for stockholders.
- The results of clinical trials may not support our product candidate claims.
- 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.
- Any product candidate for which we have or 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.
- 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.
- We may expend 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.

Risks Related to Our Dependence on Third Parties

- 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 entered into, and in the future may enter into, licenses and/or collaborations with third parties for the development and commercialization of our product candidates. If those licenses and/or collaborations, are not successful, we may not be able to capitalize on the market potential of these product candidates.

Risks Related to Marketing and Sale of Our Products

- If we are unable to maintain appropriate and effective commercial capabilities on our own or through partnerships or collaborations, we may not be able to continue to successfully commercialize TYMLOS or any of our product candidates or generate product revenue.
- If we cannot compete successfully against other drug companies, we may not achieve sufficient product revenues and our business will suffer.
- We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

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.
- If our efforts to protect our intellectual property related to TYMLOS/abaloparatide-SC, 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.
- Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.
- Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Risks Related to Legislation and Administrative Actions

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

Risks Related to Employee Matters and Managing Our Workforce

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

Risks Relating to Our Securities

- Our stock price may be volatile, and the value of an investment in our common stock may decline.
- Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

For a more complete discussion of the material risks facing our business, see below.

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 $70.2 million, $109.2 million, and $133.0 million for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021, we had an accumulated deficit of $1.4 billion. Even if we succeed in our efforts in continuing to commercialize TYMLOS and our collaboration partners succeed in their efforts to commercialize abaloparatide-SC outside the U.S., we may incur losses and never achieve or maintain profitability. We also may incur additional operating and capital expenses as we:

- continue to maintain and build our internal infrastructure, including 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.

Unless and until we become profitable, we may 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.

Unless and until we become profitable, we may need to raise additional capital, which may not be available on favorable terms, if at all, in order to continue operating our business.

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. 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. For the foreseeable future, we expect to fund our operations and capital expenditures with our product revenues, existing cash and cash equivalents and short and long-term marketable securities, or through strategic financing opportunities.

Based upon our cash and cash equivalents balance as of December 31, 2021 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, should we need it, 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.

Our existing and any future indebtedness could adversely affect our ability to operate our business.

As of December 31, 2021, we had $150 million of outstanding long-term debt under the Amended and Restated Credit and Security Agreement (“Term Credit Agreement”) and none outstanding debt under the Amended and Restated Credit and Security Agreement (Revolving Loan) (the “Revolving Credit Agreement,” together with the Term Credit Agreement, the “Credit Agreements”), each by and between Radius Pharmaceuticals, Inc. and Radius Health Ventures, Inc. (collectively with the Company, the “Borrowers”) and MidCap Financial Trust (“MidCap”), as lender. We could incur additional indebtedness in the future. Our payment obligations under the Credit Agreements reduce cash available to fund working capital, capital expenditures, research and development and general corporate needs. In addition, indebtedness under the Credit Agreements bears interest at a variable rate, making us vulnerable to increases in market interest rates. If market rates increase substantially, we will have to pay additional interest on this indebtedness, which would further reduce cash available for our other business needs.

Our obligations under the Credit Agreement are secured by substantially all of the assets of the Borrowers and their wholly-owned subsidiaries. The security interest granted over these assets could limit our ability to obtain additional debt financing. In addition, 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 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. In addition, we are required to maintain an amount of unrestricted cash of at least $50.0 million and to achieve net revenue for each preceding twelve month period of at least certain specified amounts. Failure to comply with the covenants in the Credit Agreements, including the minimum cash and minimum net revenue covenants, could result in the acceleration of our obligations under the Credit Agreements, and, if such acceleration were to occur, it would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

The obligations under the Credit Agreements are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to regulatory actions relating to abaloparatide and a material adverse change in our business, operations or other financial condition. If an event of default occurs, MidCap may declare all or any portion of the outstanding principal amount of the borrowings plus accrued and unpaid interest to be due and payable.

In addition, as of December 31, 2021, we had outstanding $192.8 million principal amount of our 3% Convertible Senior Notes due September 1, 2024 (the "Convertible Notes"). The Convertible Notes are senior unsecured obligations of us and upon conversion the notes are convertible into cash, shares of our common stock or a combination of cash and shares, at the our election.

While the indenture governing our Convertible Notes does not include covenants restricting the operation of our business, except in certain limited circumstances, in the event of a default under any of the Convertible Senior Notes, the applicable noteholders or the trustee under the indenture governing the applicable Convertible Senior Notes may accelerate our payment obligations under such Convertible Senior Notes, which could have a material adverse effect on our business, financial condition and results of operations. The indenture governing our Convertible Notes also includes cross-default features providing that certain failures to pay for outstanding indebtedness would result in a default under the indenture governing our Convertible Notes. We are also required to offer to repurchase the Convertible Notes upon the occurrence of a fundamental change, which could include, among other things, any acquisition of our company (other than an acquisition in which at least 90% of the consideration is common stock listed on The Nasdaq Global or Global Select Market or The New York Stock Exchange), subject to the terms of the indenture governing the Convertible Notes.

Our outstanding indebtedness and any future indebtedness, combined with our other financial obligations, could increase our vulnerability to adverse changes in general economic, industry and market conditions, limit our flexibility in planning for, or reacting to, changes in our business and the industry and impose a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

If we do not generate sufficient cash flows from operations or if future borrowings are not available to us in an amount sufficient to pay our indebtedness, including payments of principal when due on our outstanding indebtedness or, in the case of our Convertible Notes, in connection with a transaction involving us that constitutes a fundamental change under the indenture governing the Convertible Notes, or to fund our liquidity needs, we may be forced to refinance all or a portion of our indebtedness on or before the maturity dates thereof, sell assets, reduce or delay currently planned activities or curtail operations, seek to raise additional capital or take other actions. We may not be able to execute any of these actions on commercially reasonable terms or at all. This, together with any of the factors described above, could materially and adversely affect our business, financial condition and results of operations.

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.

If we are unable to generate substantial product revenues, we may need 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. 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 the Credit Agreement, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties or royalty-based financing arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or we may need to grant licenses on terms that may not be favorable to us. 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.

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.

We are subject to foreign currency risk.

A portion of our commercial activities, including a significant portion of contract manufacturing processes in support of TYMLOS is 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, regulatory inquires or actions 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; 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 continue to successfully commercialize TYMLOS, our first and currently only approved product, is critical to the execution of our business strategy. TYMLOS may not maintain market acceptance in the United States, or in any international markets where it may subsequently be approved, among physicians, patients, and third-party payors, and may not be 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 GMP 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 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 continue 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, 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 by comparable foreign regulatory authorities. 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.

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 comparable foreign regulatory authorities;
- the results of our clinical studies may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory activities for marketing approval;
- the FDA or comparable foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical studies;
- we may be unable to demonstrate that the product candidate’s clinical and other benefits outweigh its safety risks;
- the FDA or comparable 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;
- we may experience delays in testing, validation, manufacturing and delivery of our product candidates to the clinical sites;
- we may experience delays in having patients complete participation in a study or return for post-treatment follow-up;
- we may experience delays or difficulties in initiating clinical study sites;
- the FDA may not accept clinical data from clinical trials conducted by individual investigators or in countries where the standard of care is potentially different from the United States; and
- the FDA or comparable 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.

The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in policy or guidance that occur prior to or during the FDA or comparable foreign regulatory authority’s review. Delays in obtaining regulatory approvals may prevent us from commercializing our product candidates.

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

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 additional risks not detailed in these Risk Factors. 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.

Our collaboration agreements, including with Teijin, or 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 our product candidates.

The continued development and commercialization of our product candidates will require substantial cash to fund expenses. For some of our product candidates, we have and may again decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. For example, in July 2017, the Company entered into Teijin Agreement with Teijin for abaloparatide-SC in Japan. 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 require us to divert capital from our other business strategies and initiatives, or may not be available to us at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate additional product revenue.

Our current and any future collaborations or other arrangement 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.

Pre-clinical studies and clinical trials are very expensive, time-consuming and difficult to design and implement.

Pre-clinical studies and human clinical trials are very time consuming, expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Furthermore, failure can occur at any stage of the trials. Events that may prevent successful completion of pre-clinical studies and clinical trials include:

- changes in government regulation or guidance with respect to pre-clinical studies or clinical trials that change the requirements for approval, including the size of any such trials;
- unforeseen safety issues or lack of effectiveness during clinical trials;
- unforeseen issues with drug supply, including batch failures and other supply chain issues;
- actions, or failures to act, by clinical research organizations or other organizations contracted to perform services for pre-clinical studies or clinical trials;
- slower than expected rates of patient recruitment and enrollment in the overall population or other prespecified populations;
- 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.

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. 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 sold or licensed our oncology assets; however there can be no assurance that those or other transactions will yield additional value for stockholders.

In 2020, we entered into an exclusive license agreement with Berlin-Chemie AG – Menarini Group (“Berlin-Chemie”) for elacestrant. We also sold RAD140 to Ellipses Pharma (“Ellipses”). While both the Berlin-Chemie and Ellipses transactions provided for certain upfront payments, much of the consideration payable to us is in the form of development and sales milestones and royalties. There can be no assurances that we, Berlin-Chemie or Ellipses will be able to meet the conditions

necessary for such milestones or royalties to be paid. Further, under our license agreement with Berlin-Chemie we retained certain ongoing obligations with respect to elacestrant, which 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.

Any strategic acquisition or divestment decision involves risks and uncertainties, and we cannot guarantee that any completed or 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. The success of any completed or 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 assets, which may be in the early stages of clinical development.

Any uncertainties related to consummating any future transaction 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. Alternatively, even if we obtain regulatory approval, that approval may be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional or unanticipated clinical trials to obtain approval or be subject to additional post-marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution in the form of a modified REMS. 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.

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 and potential product liability claims. 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, abaloparatide-SC or any product candidate that may receive marketing approval, a number of potentially significant negative consequences could result, including:

- our clinical trials may be put on hold;
- regulatory authorities may withdraw or limit approvals of such product;
- regulatory authorities may require additional warnings on the label;
- regulatory authorities may require us to adopt REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools;
- regulatory authorities may require us to conduct additional post-market studies, including clinical studies, to assess the safety of the product;
- 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 have or 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 have or obtain marketing approval are subject to continuing requirements of and review by the FDA and foreign regulatory authorities. These requirements include, but are not limited to 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 may be subject to limitations on the indicated uses for which the product candidate may be marketed or to the conditions of approval, or 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 the marketing or manufacturing of a product, withdrawal of a product from the market, or voluntary or mandatory product recalls;
- restrictions on the labeling of a product;
- requirements to conduct post-marketing clinical trials;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications that we submit;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention; 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 may not prescribe our products and patients may not 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;
- the efficacy and safety of the product as demonstrated in clinical trials;
- cost-effectiveness of our product relative to competing products;
- the prevalence and severity of adverse side effects;
- 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 any product candidate is approved but does not achieve or maintain an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and we may not become or remain profitable, which would have a material adverse 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 authorities and health benefit programs, private health insurers and other organizations.

Our ability to continue to successfully commercialize TYMLOS or any of our product candidates, if approved, will depend in large part on the scope of coverage and amount of reimbursement by third-party payors. Government authorities and third-party payors, such as private health plans, decide which drugs they will cover and establish reimbursement levels. Coverage and reimbursement may vary among third-party payors. Coverage may not be available, and reimbursement may not be adequate, for our current and any future products that we may develop and commercialize. Also, coverage and reimbursement policies may reduce the demand for, or the price paid for, our products. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use our or our partners' products unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of such products. Third-party payors may limit coverage or impose conditions on coverage. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will apply or patient copayment will be at an acceptable level. In addition, pharmaceutical manufacturers are required by law to offer certain purchasers discounts and rebates and often also need to offer third party payors discounts or rebates on the cost of drugs dispensed to the payors' members in order to increase the possibility of favorable coverage and adequate cost sharing thresholds for patients. We may be required to provide such rebates to some third-party payors in relation to our product(s). Adequate third-party reimbursement, taking into account such rebates as applicable, may not be available and we may not be able to maintain price levels sufficient to realize an appropriate profit, including a return on our investment in product development. See "Government Regulation-Pricing and Reimbursement".

We expect to experience pricing pressures in connection with the sale of our current and any future products due to the healthcare reforms discussed below, the trend toward initiatives aimed at reducing healthcare costs, the increasing influence of managed care, the scrutiny of pharmaceutical pricing, the ongoing debates on reducing government spending and additional legislative proposals. There has been significant scrutiny of pharmaceutical pricing and the resulting costs of pharmaceutical products that could cause significant operational and reimbursement changes for the pharmaceutical industry. There have been a number of federal and state efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices, price increases or other related costs. Healthcare reform efforts or any future legislation or regulatory actions aimed at controlling and reducing healthcare costs, including through measures designed to limit reimbursement, restrict access or impose unfavorable pricing modifications on pharmaceutical products, could impact our ability to obtain or maintain reimbursement for our products at satisfactory levels, or at all, which could materially harm our business and financial results.

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 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.

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.

Interim, "topline," and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to confirmation, audit, and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval or commercialization of the particular product candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

If we experience delays in the enrollment of patients in our clinical trials, our clinical trials and 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. In addition, our ability to enroll patients may be significantly delayed by the evolving COVID-19 pandemic and we do not know the extent and scope of such delays at this point.

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.

The ongoing COVID-19 pandemic is having and is expected to continue to have an adverse impact on our business, financial condition and results of operations, including our commercial operations and sales, clinical trials, preclinical studies, and employees.

The Coronavirus disease 2019 ("COVID-19") pandemic continues to evolve, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions, vaccine rollouts and other public health safety measures. It has also had a substantial effect on worldwide economies, causing fluctuations in the capital markets and significant supply chain issues.

Since March 2020, our employees have worked remotely and will continue to do so indefinitely. We have selectively resumed in-person interactions by our customer-facing personnel in compliance with local and state restrictions. We also continue to engage with customers virtually as we seek to continue to support healthcare professionals and patient care.

However, our ability to engage in personal interactions with physicians and customers remains limited, and it is unknown when in-person interactions will be fully resumed.

Notwithstanding the various measures we have taken to address the pandemic, COVID-19 could affect the health and availability of our workforce as well as those of the third parties we rely on taking similar measures. If members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to COVID-19, we may not be able to execute on our business strategy and/or our operations may be negatively impacted.

Business interruptions from the current COVID-19, or any future, pandemic may also adversely impact the third parties we solely rely on to sufficiently manufacture TYMLOS and to produce our product candidates in quantities we require, which may adversely impact the commercialization of TYMLOS and our research and development activities and potential commercialization of our product candidates.

The COVID-19 pandemic could worsen in countries that are afflicted with COVID-19, could continue to spread to additional countries, or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to commercialize TYMLOS, or conduct clinical trials and our business generally, and could have a material adverse impact on our operations and financial condition and results. In addition, the trading prices for our common stock and other biopharmaceutical companies have been, and will likely continue to be, highly volatile as a result of the COVID-19 pandemic, and may limit our ability to raise additional capital.

Separately, in response to the global pandemic of COVID-19, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. In July 2021, the FDA stated that it had begun transitioning back to standard operations for domestic inspections, while continuing to prioritize mission-critical work for foreign inspections. However, further delays or setbacks are possible in the future. As a result, review, inspection, and other timelines for our product candidates may be materially delayed for an unknown period of time. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our marketing applications, clinical trial authorizations, or other regulatory submissions, which could have a material adverse effect on our business.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will inevitably depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, such as the existence of additional variants of the disease, the actions taken to contain it or treat its impact and the economic impact on local, regional, and national markets.

Risks Related to Our Dependence on Third Parties

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. This reliance on third parties increases the risk that we do not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

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 or our product candidates to meet our needs, 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-TD 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, Kindeva for the production of abaloparatide-TD. If our relationship with any of these contract manufacturers is terminated, or if they are unable to produce abaloparatide or related components in required quantities, on a timely basis or at all, and/or in compliance with the terms of our agreements, our business and financial condition would be materially harmed. Because the manufacturing process for abaloparatide-TD requires the use of Kindeva's proprietary technology, Kindeva is the sole source for supplies of abaloparatide-TD.

Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks, among others:

- 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 inspect any manufacturers for cGMP compliance as part of our application.
- 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.
- 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 we do not have control over third-party manufacturers' compliance with these regulations and standards.
- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates.
- 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.

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. 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 ("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 these third parties 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 delay ongoing or planned clinical trials or require us to repeat clinical trials, which would delay the regulatory approval process. Failure by us or by third parties we engage to comply with regulatory requirements can also result in fines, adverse publicity, and civil and criminal sanctions. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. 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 have entered into, and in the future may enter into, licenses and/or collaborations with third parties for the development and commercialization of our product candidates. If those licenses and/or collaborations, are not successful, we may not be able to capitalize on the market potential of these product candidates.

We have in the past, currently have, and may in the future, seek third-party licensees and/or collaborators for the development and commercialization of some of our products and product candidates on a selective basis. Our likely licensees and/or collaborators for any arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

To the extent we have, and if we do enter into any further such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our licensees and/or collaborators dedicate to such development or commercialization activities. Our ability to generate revenues from our license and/or collaboration arrangements will depend on our licensees' and/or collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Licenses and collaborations involving our product candidates would pose numerous risks to us, including the following:

- licensees and/or collaborators have significant discretion in determining the efforts and resources that they will apply to these arrangements and may not perform their obligations as expected;
- licensees and/or collaborators may deemphasize or not pursue development and commercialization of our products or product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- licensees and/or collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- licensees and/or collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if they believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; license or collaboration arrangements may subject us to exclusivity provisions which could restrict our ability to compete in certain territories, including those licensed to the licensee and/or collaborator;
- a licensee or collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- licensees or collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the licensees and/or collaborators and us that result in the delay or termination of the research, development or commercialization of our products or product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- licenses and/or collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- license and/or collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- if a licensee or collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

If our license or collaboration arrangements are not successful, our business, financial condition, results of operations, prospects and development and commercialization efforts may be adversely affected. Any termination or expiration of our

license or collaboration agreements could adversely affect us financially or harm our business reputation, development and commercialization efforts.

Risks Related to Marketing and Sale of Our Products

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

We established an internal sales force to market and sell TYMLOS in the United States to specialists and continue to pursue collaborative arrangements to market and sell abaloparatide-SC outside of the United States. 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 our products and product candidates and such collaborators' or partners' ability to successfully develop, market, and sell any such products.

In addition, our ability to 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 commercial and medical affairs personnel, including a 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.

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

The market for our products and 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.

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. 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 order to compete successfully, we will have to demonstrate to patients, physicians and third-party payors that treatment 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 Abbreviated New Drug Application ("ANDA").

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 or may compete against new or 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, 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, and our other product candidates. We could encounter challenges or difficulties in maintaining and/or defending our intellectual property both in the United States and abroad.

We and Ipsen are also co-assignees to U.S. Patent No. 7,803,770 that we believe provides exclusivity until April 28, 2031 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 November 8, 2027 and October 3, 2027, respectively.

We and Kindeva are co-assignees to several foreign and corresponding U.S. patents and patent applications, which cover various aspects of abaloparatide for microneedle application. Any issued patents resulting from these applications will have a statutory expiration date of 2036, 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-TD 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-TD. 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-TD even if it were to be successfully developed and approved by the FDA.

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 in litigation, it is possible that the patent(s) will be found invalid, unenforceable and/or not infringed in the course of that litigation or other proceedings. 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 post grant or inter partes reviews, reexaminations, or other proceedings before the USPTO. Third parties also may assert infringement claims against us in courts in various jurisdictions. 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.

Trade secret protection is available only for trade secrets as defined by applicable laws. Trade secret laws may vary depending upon the jurisdiction and various statutes. Trade secrets do not prevent reverse engineering by competitors. We cannot assure you that information that we have sought or will seek to maintain secret is or will be a trade secret under the applicable law or 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 ANDA or a 505(b)(2) Application 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 law for a generic company to file an ANDA and 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 against the Paragraph IV filer 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 unadjusted or unextended 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. 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 or misappropriate our trademarks or trade secrets. To counter infringement, misappropriation, or unauthorized use, we may be required to file proceedings, which can be expensive and time consuming. In addition, in such a proceeding, a court may decide that a patent of ours is invalid and/or unenforceable, confidential information is not a trade secret under the appropriate statute or was not misappropriated, a trademark was not protectable or misappropriated, 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 or other intellectual property rights at risk, such as by 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.

In the U.S., federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, health care, which include initiatives to reduce the cost of healthcare. For example, in March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (the "Healthcare Reform Act"), which expanded health care coverage through Medicaid expansion, implemented the "individual mandate" for health insurance coverage (by imposing a tax penalty on individuals who did not obtain insurance) and changed the coverage and reimbursement of drug products under government healthcare programs.

Based upon efforts by the Trump administration, there have been ongoing attempts to modify or repeal all or certain provisions of the Healthcare Reform Act. For example, tax reform legislation was enacted at the end of 2017 that eliminated the tax penalty established under the Healthcare Reform Act for individuals who do not maintain mandated health insurance coverage beginning in 2019. The Healthcare Reform Act has also been subject to judicial challenge. On June 17, 2021, the U.S. Supreme Court dismissed the latest judicial challenge to the Healthcare Reform Act brought by several states without specifically ruling on the constitutionality of the Healthcare Reform Act.

Beyond the Healthcare Reform Act, there have been ongoing health care reform efforts. Some recent healthcare reform efforts have sought to address certain issues related to the COVID-19 pandemic, including an expansion of telehealth coverage under Medicare and accelerated or advanced Medicare payments to healthcare providers. Other reform efforts affect pricing or payment for drug products. For example, the Medicaid Drug Rebate Program has been subject to statutory and regulatory changes and the discount that manufacturers of Medicare Part D brand name drugs must provide to Medicare Part D beneficiaries during the coverage gap increased from 50% to 70%. Additional reform efforts are likely. The Biden administration has focused on reforms that would address the high cost of drugs. In response to an Executive Order from President Biden, the Secretary of the Department of Health and Human Services issued a comprehensive plan for addressing high drug prices that describes a number of legislative approaches and identifies administrative tools to address the high cost of drugs. In addition, Democrats included drug pricing reform provisions reflecting elements of the plan in a broader proposed spending package in late 2021 - such as capping Medicare Part D patients out-of-pocket costs; establishing penalties for drug prices that increase faster than inflation in Medicare; and authorizing the federal government to negotiate prices on certain, select high cost drugs under Medicare Parts B and D.

Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. For example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. Pursuant to court order, the removal was delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026.

There have also been efforts by government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices. Adoption of new legislation regulating drug pricing at the federal or state level could further affect demand for, or pricing of, our products.

General legislative cost control measures may also affect reimbursement for our products. The Budget Control Act of 2011, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and remains in effect through 2030 (except May 1, 2020 to March 31, 2022) unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

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.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations now or in the future. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Within the U.S., such laws include:

- The federal anti-kickback statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term “remuneration” has been broadly interpreted to include anything of value.
- Federal false claims and false statement laws, including the federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent.
- The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended, which prohibits executing a scheme to defraud any healthcare benefit program, including private health plans, or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information on certain types of entities, which include many healthcare providers and health plans with which we interact;
- The Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products prior to approval or for unapproved indications and regulates the distribution of samples;
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- Federal laws, including the Medicaid Drug Rebate Program, that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs; and
- The so-called “federal sunshine” law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians, certain non-physician practitioners and teaching hospitals to the federal government for re-disclosure to the public.

Also, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply to claims reimbursed by private payors as well as government programs or regardless of reimbursement. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government’s and/or pharmaceutical industry’s voluntary compliance guidelines, impose specific restrictions on interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Other state laws may require pharmaceutical companies to file reports relating to pricing and marketing information and state and local laws that require the registration of pharmaceutical sales representatives. Finally, there are state laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA. Many of these laws and regulations also contain ambiguous requirements or require administrative guidance for implementation.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our operations and commercial activities in connection with TYMLOS or any product candidate that may be approved may not comply with such laws. If our operations are found to be in violation of any of these laws or any other

governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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.

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.

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 ("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 are subject to the General Data Protection Regulation, (EU) 2016/679, ("GDPR"), which became effective on May 25, 2018. GDPR 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 Our Workforce

We may encounter difficulties with managing the size and makeup of our workforce, 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 to grow our TYMLOS business and expand into other therapeutic areas. In particular, we may need to grow or transition our internal sales, marketing, and distribution capabilities to market TYMLOS and any other drug that we may successfully develop. That growth or transition would 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.

In connection with our development of RAD011, our cannabidiol oral solution asset, we have hired or entered into consulting agreements with certain individuals who will provide assistance with the management and oversight of the assets' development and commercialization. There can be no guarantee that these individuals will smoothly and successfully integrate into our workforce or workstreams or accomplish the development or commercialization activities assigned to them within the desired timelines.

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 our workforce effectively. In particular, as our commercialization plans and strategies change and develop, we will recruit and train new personnel. To that end, we must be able to:

- manage our development efforts effectively;
- integrate additional management, administrative and manufacturing personnel; 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.

If we are unable to successfully maintain and further develop internal commercialization capabilities, sales of TYMLOS or other future approved products 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 our continued commercialization of TYMLOS or the commercialization of any other product we may launch. 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 new sales personnel, who may have limited experience with our company or our products, to deliver a consistent and compliant message regarding our products that will be compelling to physicians who may prescribe them;
- an inability to equip sales personnel with effective materials, including medical and sales literature to help them educate physicians and our healthcare providers regarding our products 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 maintaining an effective commercial infrastructure, we may have difficulty generating product revenue, which could adversely affect our business and financial condition.

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 as part of our broader business strategy, including the continued expansion of our product portfolio. We have limited experience in such activities, which are typically accompanied by a number of risks, including:

- the difficulty of integrating the operations and personnel;
- 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 business combinations or 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 these activities. 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.

During the fourth quarter of 2021, following announcement of results from various clinical trials discussed elsewhere in this Annual Report on Form 10-K, our stock price fluctuated substantially, reaching a high of $22.31 and a low of $6.74 in

closing price on The NASDAQ Global Market. The trading price of our common stock may be subject to future 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.

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.

We may be required to pay severance benefits to our employees who are terminated under certain circumstances, 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 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 under certain circumstances. 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, 2021, we had $1,033.8 million of federal and $710.5 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.

General Risk Factors

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.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Details of each of our principal properties as of December 31, 2021, are provided below:

Location	Function	Size (approximate square feet)	Property Interest
Boston, MA, USA	Corporate Headquarters	2,500	Leased
Waltham, MA, USA	Office space	26,553	Leased
Wayne, PA, USA	Office space	2,404	Leased
Durham, NC, USA	Office space	3,944	Leased
Chandler, AZ, USA	Lab space	3,930	Leased

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, 2022, 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.

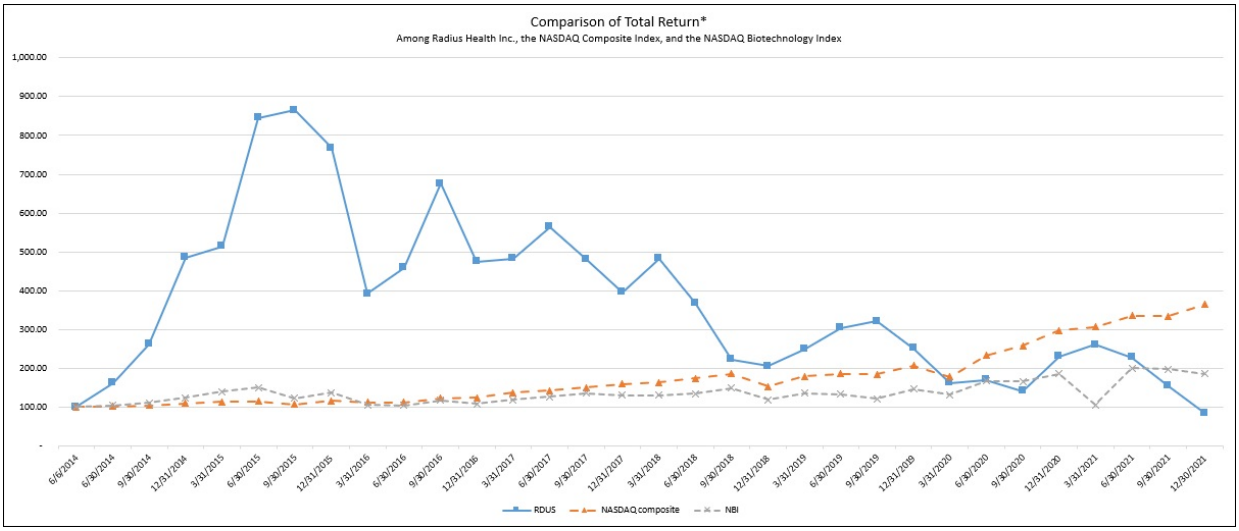
On February 18, 2022, the closing price of our common stock was $6.93 per share as reported on The Nasdaq Global Market.

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, 2021, 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 18, 2022, there were 12 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, 2021.

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, 2021.

ITEM 6. SELECTED FINANCIAL DATA

None.

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 global biopharmaceutical company focused on addressing unmet medical needs in the areas of bone health, neuroscience, and oncology.

In April 2017, our first commercial product, TYMLOS (abaloparatide) injection, was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In May 2017, we commenced U.S. commercial sales of TYMLOS and as of January 1, 2022, TYMLOS was available and covered for approximately 288 million U.S. insured lives, representing approximately 99% of U.S. Commercial and 74% of Medicare Part D insured lives.

During 2021, we completed three potentially pivotal Phase 3 clinical trials and announced their results, as follows:

- In October 2021, we announced positive topline results from our Phase 3 clinical trial evaluating abaloparatide for subcutaneous injection ("abaloparatide-SC") for use in males with osteoporosis (the "ATOM Trial"). The ATOM Trial met its primary and secondary endpoints and demonstrated a safety profile consistent with previous trials.

- In October 2021, together with our licensee, Berlin-Chemie AG ("Berlin-Chemie"), a company of the Menarini Group, we announced positive topline results from our Phase 3 clinical trial of elacestrant, a selective estrogen receptor degrader (SERD) we investigated as a monotherapy versus the standard of care for treatment of ER+/HER2- advanced or metastatic breast cancer (the "EMERALD Trial"). The EMERALD Trial met both primary endpoints and demonstrated a safety profile consistent with previous trials. We presented data from the EMERALD Trial at the San Antonio Breast Cancer Symposium in December 2021.

- In December 2021, we announced the results of our Phase 3 clinical trial of the abaloparatide transdermal system ("abaloparatide-TD"), a different formulation of abaloparatide delivered using Kindeva Drug Delivery's ("Kindeva") patented microstructured transdermal system technology (the "wearABLe Trial"). The wearABLe Trial did not meet its primary or secondary endpoints.

We are also developing RAD011, a pharmaceutical-grade synthetic cannabidiol oral solution, manufactured utilizing traditional pharmaceutical manufacturing processes. Based on feedback from a Type C meeting with the FDA held in June 2021, we are moving forward with a potentially pivotal Phase 2/3 study for treatment of hyperphagia-related behavior in patients with Prader-Willi Syndrome ("PWS") in the first half of 2022.

We out licensed our oncology assets in 2020. In July 2020, we entered into a license agreement with Berlin-Chemie, under which we granted Berlin-Chemie an exclusive license to develop and commercialize products containing elacestrant worldwide.

In September 2020 we sold RAD140, our internally discovered non-steroidal selective androgen receptor modulator ("SARM") to Ellipses Pharma. Ellipses Pharma will be responsible for the clinical development and commercialization of the asset and is obligated to pay us royalties.

Abaloparatide

We have developed or targeted two formulations of abaloparatide: abaloparatide-SC and abaloparatide-TD.

Abaloparatide-SC

In April 2017, the FDA approved TYMLOS for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. The first commercial sales of TYMLOS in the United States occurred in May

2017 and as of January 1, 2022, TYMLOS was available and covered for approximately 288 million U.S. insured lives, representing approximately 99% of U.S. Commercial and 74% of Medicare Part D insured lives.

We are commercializing TYMLOS in the United States through our internal commercial organization. We hold worldwide commercialization rights to abaloparatide-SC, except for Japan and Canada, 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 agreements.

In July 2017, we entered into a license and development agreement with Teijin for abaloparatide-SC in Japan. In May 2020, we announced that Teijin submitted an NDA for abaloparatide-SC in Japan for the treatment of osteoporosis in patients who are at high risk for fracture and in March 2021, announced the approval of Ostabalo® abaloparatide acetate for the treatment of osteoporosis and promotion of bone formation in both female and male patients with high risk of fracture in Japan. Pursuant to the agreement, we have received an upfront payment and a regulatory milestone upon the approval of Ostabalo. We may receive additional milestone payments upon the achievement of certain 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.

In October 2021, we announced positive top-line results of our ATOM Trial. This study met its primary endpoint of change in lumbar spine bone mineral density (“BMD”) at 12 months compared to placebo, demonstrating statistical significance after 12 months. It also met secondary endpoints of change in lumbar spine BMD at 6 months compared to placebo, change in total hip BMD at 12 months compared to placebo, and change in femoral neck BMD at 12 months. We expect that these results will form the basis of a supplemental NDA seeking to expand the use of TYMLOS to increase bone mass in men with osteoporosis at high risk for fracture. The ATOM Trial was a randomized, double-blind, placebo-controlled trial that has enrolled 228 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 included specialized high-resolution imaging to examine the effect of abaloparatide on bone structure, such as the hip, in a subset of the study participants.

Abaloparatide-TD

In December 2021, we announced Phase 3 topline results from the wearABLe Trial, which evaluated the non-inferiority of abaloparatide-TD as compared to TYMLOS. The trial did not meet its primary endpoint as patients treated with abaloparatide-TD demonstrated an increase of 7.1% in lumbar spine BMD versus an increase of 10.9% for those treated with TYMLOS. The wearABLe Trial similarly did not meet its secondary endpoints. The wearABLe study was a single, pivotal, randomized, open label, active-controlled, BMD non-inferiority bridging study with an enrollment of approximately 500 patients with postmenopausal osteoporosis at high risk of fracture.

We, along with our partner Kindeva continue to evaluate all strategic options for the abaloparatide-TD program.

RAD011

We are also developing RAD011, with PWS as our initial target indication. We acquired RAD011 from Fresh Cut Development, LLC and Benuvia Therapeutics Inc. in December 2020. Prior to the Company’s acquisition of RAD011, it was granted fast track designation by the FDA in 2017 and orphan drug designation in August 2020 for the treatment of hyperphagia behavior and weight loss in patients with PWS. In June 2021, we participated in a Type C meeting with the FDA and, based on feedback from that meeting, intend to initiate the SCOUT Trial in the first half of 2022. The SCOUT Trial will be a randomized double-blind placebo-controlled seamless Phase 2/3 trial designed to support a 505(b)(2) NDA submission for RAD011 for the treatment of hyperphagia in patients with Prader-Willi Syndrome.

Oncology Portfolio

Given our focus on growing our TYMLOS and abaloparatide-SC business, developing RAD011 and expanding our product portfolio, we evaluated all strategic options for our oncology assets in 2020. In July 2020, we entered into a license agreement with Berlin-Chemie for the exclusive license of elacestrant.

In October 2021, we and Berlin-Chemie together announced positive top-line results from the EMERALD Trial of elacestrant. The EMERALD Trial was designed to evaluate elacestrant as a second or third-line monotherapy versus the standard of care for treatment of patients with estrogen receptor-positive (“ER+”) and human epidermal growth factor receptor 2-negative (“HER2-”) advanced or metastatic breast cancer. The study met both primary endpoints, demonstrating statistically significant progression-free survival in the overall population and in patients with tumors harboring estrogen receptor 1 (“ESR1”) mutations. Based on these results, we expect to proceed with applications for marketing approval in the United States and the European Union in collaboration with Berlin-Chemie.

In 2020, we also sold RAD140, our internally discovered SARM, to Ellipses Pharma.

Financial Overview

Product Revenue

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

License Revenue

License revenue is derived from payments received from contracts with customers, which include upfront payments for licenses.

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, 2021 were approximately $259.2 million. We began tracking program expenses for abaloparatide-TD in 2007, and program expenses from inception to December 31, 2021 were approximately $191.9 million. We began tracking program expenses for elacestrant in 2006, and program expenses from inception to December 31, 2021 were approximately $133.0 million, net of reimbursable expenses. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to December 31, 2021 were approximately $18.0 million. We began tracking program expenses for RAD011 in 2020, and program expenses from inception to December 31, 2021 were approximately $25.3 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-TD, elacestrant, RAD140, and RAD011 for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Program-specific costs - external:			
Abaloparatide-SC	$ 19,530	$ 9,252	$ 8,234
Abaloparatide-TD	47,386	66,133	26,185
Elacestrant, net of amounts reimbursable	4,882	15,366	27,267
RAD140	(255)	1,143	2,126
RAD011	9,335	16,000	—
Total program-specific costs - external	$ 80,878	$ 107,894	$ 63,812
Shared-services costs - external:			
R&D support costs	21,502	14,264	13,217
Other operating costs	771	765	2,152
Total shared-services costs - external:	$ 22,273	$ 15,029	$ 15,369
Shared-services costs - internal:			
Personnel-related costs	24,021	28,530	26,114
Share-based compensation	6,164	6,654	8,769
Occupancy costs	1,141	1,083	1,853
Depreciation	149	522	840
Total shared-services costs - internal:	$ 31,475	$ 36,789	$ 37,576
Total R&D costs	$ 134,626	$ 159,712	$ 116,757

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 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.

Interest Income and Other Income

Interest income reflects interest earned on our cash, cash equivalents and marketable securities. Other income reflects rental income, other income, and foreign exchange revaluation gains offset by other taxes.

Interest Expense

Interest expense consists of interest expense related to the Convertible Notes the Company issued in a registered underwritten public offering on August 14, 2017 (“Convertible Notes”) and the Amended and Restated Credit and Security Agreement with MidCap (“Term Loan”) the Company refinanced on March 3, 2021. A portion of the interest expense on the Convertible Notes and Term Loan 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 long-lived assets and intangible assets, revenue recognition, inventory obsolescence, 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. In accordance with Accounting Standards Codification (“ASC”) Topic 606 - Revenue from Contracts with Customers (“Topic 606”), revenue is recognized 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, 2021.

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, 2021 and, therefore, the transaction price was not reduced further during the twelve months ended December 31, 2021. 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.

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 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, 2021 and December 31, 2020

	Years Ended December 31,		Change	
	2021	2020	$	%
	(in thousands)			
Revenues:				
Product revenue, net	$ 218,973	$ 208,395	$ 10,578	5 %
License revenue	11,000	30,250	(19,250)	(64)%
Total revenue	229,973	238,645	(8,672)	(4)%
Operating expenses:				
Cost of sales - product	18,352	16,403	1,949	12 %
Cost of sales - intangible amortization	798	798	—	— %
Research and development	134,626	159,712	(25,086)	(16)%
Selling, general and administrative	130,514	144,154	(13,640)	(9)%
Loss from operations	(54,317)	(82,422)	28,105	(34)%
Other (expense) income:				
Other income (expense), net	361	(212)	573	(270)%
Interest (expense) / income, net	(18,180)	(26,574)	8,394	(32)%
Gain on extinguishment of debt	$ 1,960	$ —	1,960	100 %
Net loss	$ (70,176)	$ (109,208)	$ 39,032	(36)%

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, 2021 we recorded approximately $219.0 million of net product revenue compared to $208.4 million for the year end December 31, 2020. The increase in product revenue was primarily driven by a combination of price and sales volume.

License revenue—For the year ended December 31, 2021, we recorded $11.0 million of license revenue compared to $30.3 million for the year end December 31, 2020. This decrease is due to the contracted license fee in the Berlin-Chemie agreement during the year ended December 31, 2020 being higher than the contracted amounts for the Teijin and other licenses agreements recognized during the year ended December 31, 2020.

Cost of sales—For the year ended December 31, 2021, cost of sales was $19.2 million compared to $17.2 million for the year end December 31, 2020. 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, 2021, research and development expense was $134.6 million, as compared to $159.7 million for the year ended December 31, 2020, a decrease of $25.1 million, or 16%. This decrease was primarily a result of by a decrease of $18.7 million in abaloparatide-TD program costs, a $6.6 million decrease in RAD011 program costs, a decrease of $1.4 million in RAD140 expenses, a $5.0 million decrease in compensation expense, which is comprised of a $1.6 million decrease in compensation expense related to headcount, $0.5 million decrease in stock compensation and $2.9 million of billed reimbursable expenses, and a $19.8 million decrease in elacestrant program costs, which is comprised of a $10.2 million decrease in gross program expenses as well as an increase of $9.6 million in billed reimbursable expenses that offset these expenses. These decreases were offset by a $10.2 million increase in abaloparatide-SC program costs and a $7.2 million increase in professional fees and other expenses.

Selling, general and administrative expenses—For the year ended December 31, 2021, selling, general, and administrative expense was $130.5 million, as compared to $144.2 million for the year ended December 31, 2020, a decrease of $13.6 million, or 9%. This decrease was primarily due to a $0.3 million decrease in professional fees related to commercial operations and general and administrative activities, a $10.1 million decrease in compensation and travel entertainment costs, and a $3.2 million decrease in other operating costs including impairment on leases, depreciation and amortization, and loss on fixed asset disposals.

Other Income, net— For the year ended December 31, 2021, other income, net of expenses, was $0.4 million, as compared to other expense, net of income, of $0.2 million during the year ended December 31, 2020. Other income, net of other expenses, of $0.4 million for the year ended December 31, 2021 consisted primarily of rental income, other income, and foreign exchange revaluation gains offset by other taxes. The $0.2 million of other expense, net of income, for the year ended December 31, 2020 consisted primarily of other foreign currency revaluation losses.

Interest income (expense), net—For the year ended December 31, 2021, net interest expense was $18.2 million, as compared to net interest expense of $26.6 million during the year ended December 31, 2020, a total change of $8.4 million, or 32%. This change was primarily the result of the decreasing interest expense incurred due to the repurchase of the convertible notes that was partially offset by increase in interest expense for the issuance of the Term Loans and interest income.

Years Ended December 31, 2020 and December 31, 2019

	Years Ended December 31,		Change	
	2020	2019	$	%
	(in thousands)			
Revenues:				
Product revenue, net	$ 208,395	$ 173,317	35,078	20 %
License revenue	30,250	—	30,250	100 %
Total revenue	238,645	173,317	65,328	38 %
Operating expenses:				
Cost of sales - product	16,403	15,287	1,116	7 %
Cost of sales - intangible amortization	798	798	—	— %
Research and development	159,712	116,757	42,955	37 %
Selling, General and administrative	144,154	152,704	(8,550)	(6)%
Loss from operations	(82,422)	(112,229)	29,807	(27)%
Other (expense) income:				
Other income / (expense), net	(212)	242	(454)	(188)%
Interest (expense) / income, net	(26,574)	(21,006)	(5,568)	27 %
Net loss	$ (109,208)	$ (132,993)	23,785	(18)%

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, 2020 we recorded approximately $208.4 million of net product revenue compared to $173.3 million for the year end December 31, 2019. The increase in product revenue was primarily driven by an increase in sales volume as a result of greater market penetration.

License revenue—We entered into the License Agreement with Berlin-Chemie on July 23, 2020. For the year ended December 31, 2020, we recorded $30.0 million of license revenue in connection with this agreement compared to none for the year end December 31, 2019.

Cost of sales—For the year ended December 31, 2020, cost of sales of $17.2 million compared to $16.1 million for the year end December 31, 2019. The increase in cost of sales was driven by the increase in product revenue.

Research and development expenses—For the year ended December 31, 2020, research and development expense was $159.7 million compared to $116.8 million for the year ended December 31, 2019, an increase of $43.0 million, or 37%. This increase was primarily a result of an increase of $39.9 million in program spending for the abaloparatide-TD program, a $1.1 million increase in professional services, a $1.0 million increase in program spending for the abaloparatide-SC program, and an increase of $16.0 million in other costs due to the Benuvia licensing expense. These increases were partially offset by a $0.9 million decrease in program spending for RAD-140 program, a $1.0 million decrease in occupancy and depreciation, a $1.3 million decrease in compensation related costs, and a $11.9 million decrease in program spending for elacestrant research which is a result of $39.3 million of reimbursable expenses offsetting year to date expenses. We are being reimbursed for the costs incurred in connection with the elacestrant project pursuant to the terms of the TSA with Berlin-Chemie, under which the Company will perform certain services for Berlin-Chemie related to the EMERALD Phase 3 monotherapy study until the earlier of the completion of the contemplated services or the filing with the FDA of a NDA for elacestrant.

Selling, General and administrative expenses—For the year ended December 31, 2020, general and administrative expense was $144.2 million compared to $152.7 million for the year ended December 31, 2019, a decrease of $8.6 million, or 6%. This decrease was primarily due to a $6.3 million decrease in professional fees related to commercial operations and general and administrative activities, a $4.0 million decrease in compensation and travel entertainment costs. These decrease were partially offset by an increase of $1.7 million in other costs.

Other (expense) income, net—For the year ended December 31, 2020, other expense, net of other income, was $0.2 million, as compared to $0.2 million during the year ended December 31, 2019. Other expense, net of other income, of $0.2

million for the year ended December 31, 2020 consisted primarily of other foreign currency revaluation losses. The $0.2 million of other expense, net of income, for the year ended December 31, 2019 was primarily due to other foreign currency revaluation gains.

Interest (expense) income—For the year ended December 31, 2020, net interest expense was $26.6 million, as compared to net interest expense of $21.0 million during the year ended December 31, 2019, a total change of $5.6 million, or 27%. 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.

Liquidity and Capital Resources

From inception to December 31, 2021, we have incurred an accumulated deficit of $1.4 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 and cash equivalents balance as of December 31, 2021 was $111.5 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 and cash equivalents balance as of December 31, 2021 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 and cash equivalents 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.

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,		
	2021	2020	2019
Net cash (used in) provided by:			
Operating activities	$ (22,434)	$ (73,948)	$ (82,414)
Investing activities	23,212	67,485	87,277
Financing activities	19,319	28,013	5,709
Net increase in cash and cash equivalents	$ 20,097	$ 21,550	$ 10,572

Cash Flows from Operating Activities

Net cash used in operating activities during the year ended December 31, 2021 was $22.4 million, which was primarily the result of a net loss of $70.2 million, partially offset by net changes in working capital of $25.0 million and $22.7 million of net non-cash adjustments to reconcile net loss to net cash used in operations. The $22.7 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of $22.8 million, amortization of the value of debt discount and issuance costs of $1.6 million, and depreciation and amortization of $1.2 million, offset by a gain on the termination of a lease of $0.9 million and a gain on the extinguishment of debt of $2.0 million.

Net cash used in operating activities during the year ended December 31, 2020 was $73.9 million, which was primarily the result of a net loss of $109.2 million, partially offset by net changes in working capital of $12.5 million and $47.7 million of net non-cash adjustments to reconcile net loss to net cash used in operations. The $47.7 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of $24.7 million, amortization of debt discount and issuance costs of $18.1 million, depreciation and amortization of $1.7 million, impairment charge for the right of use operating lease of $2.4 million, and loss on disposal of fixed assets of $0.6 million offset by amortization of premiums (discounts) on marketable securities of $0.3 million.

Net cash used in operating activities during the year ended December 31, 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 $133.0 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 $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 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 on disposal of fixed assets of $0.2 million offset by amortization of discounts on marketable securities of $0.4 million.

Cash Flows from Investing Activities

Net cash provided by investing activities for the year ended December 31, 2021 was $23.2 million, as compared to net cash provided by investing activities of $67.5 million for the year ended December 31, 2020 and $87.3 million for the year ended December 31, 2019.

The net cash provided by investing activities during the year ended December 31, 2021 was primarily a result of $23.2 million of net proceeds received from the sale or maturities of marketable securities.

The net cash provided by investing activities during the year ended December 31, 2020 was primarily a result of $107.4 million of net proceeds received from the sale or maturities of marketable securities, offset by $39.9 million in purchases of marketable securities.

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 maturities of marketable securities, offset by $119.5 million in purchases 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, 2021 was $19.3 million as compared to $28.0 million of net cash provided by financing activities for the year ended December 31, 2020 and $5.7 million for the year ended December 31, 2019.

Net cash provided by financing activities during the year ended December 31, 2021 consisted of $125.0 million of proceeds received from the issuance of the term loan offset by issuance costs of $2.3 million, $4.0 million of proceeds as the result of stock option exercises, and $1.2 million of proceeds received from the issuance of stock in connection with the employee stock purchase plan off set by $108.6 million of cash used or repurchase of convertible notes.

Net cash provided by financing activities during the year ended December 31, 2020 consisted of $25.0 million of proceeds received from the issuance of the term loan offset by issuance costs,$1.5 million of proceeds as the result of stock option exercises, and $1.6 million of proceeds received from the issuance of stock in connection to the stock purchase plan.

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 to the stock purchase plan.

Borrowings and Other Liabilities

Convertible Notes Payable

In August 2017, we issued $300.0 million aggregate principal amount of the Convertible Notes, as discussed in more detail in Note 9, “Convertible 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. In March 2021, we repurchased approximately $112.2 million aggregate principal amount of the Convertible Notes in separate, privately negotiated transactions with certain holders thereof.

Future minimum payments on our convertible notes payable as of December 31, 2021 were as follows (in thousands):

Year ended December 31,	Future Minimum Payments
2022	5,783
2023	5,783
2024 and thereafter	198,535
Total minimum payments	$ 210,101
Less: interest	(17,348)
Less: unamortized discount	(2,274)
Less: current portion	—
Convertible notes payable	$ 190,479

Term Loan and Credit Facility

In March 2021, we entered into the Term Loan, as discussed in more detail in Note 10, “Term Loan and Credit Facility,” to our condensed consolidated financial statements included in this Annual Report on Form 10-K.

Future minimum payments on our Term Loan as of December 31, 2021 were as follows (in thousands):

Years ended December 31,	**Future Minimum Payments**
2022	11,625
2023	61,302
2024	102,260
Total minimum payments	$ 175,187
Less: interest	(25,187)
Less: unamortized issuance costs	(1,735)
Less: current portion	—
Term loan	$ 148,265

Leases

Future payments of operating lease liabilities as of December 31, 2021 are as follows (in thousands):

Year ending December 31,	
2022	633
2023	176
2024	120
Thereafter	30
Total Lease payments	$ 959
Less: effect of discounted cash flows during the period	(31)
Total	$ 928

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 cancellable 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 cancellable upon written notice by us and therefore, not long-term liabilities. Additionally, the expected timing of payment of the obligations discussed 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 two-year term of the agreement. The Company is required to purchase a minimum number of batches for CHF 1.9 million ($2.0 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 had an initial term of fivefive years, which began on January 1, 2016, after which it automatically renewed for a two-year term and will automatically renew for additional two-year terms thereafter 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 ($3.2 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.

R&D Tax Credit—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. As we failed to maintain the headcount requirement, we are required to repay a portion of the incentive received, equal to $0.1 million. This amount has been accrued for as of December 31, 2021 in Accrued expenses and other current liabilities on our consolidated balance sheet.

License Agreement Obligations

TYMLOS (Abaloparatide)

In September 2005, we entered into a license agreement (the "License Agreement"), as amended with and affiliate of Ipsen Pharma SAS (Ipsen) 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, 2021. 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 $29.5 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 also provides that we will 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 $10.9 million for the year ended December 31, 2021. The date of the last to expire of the abaloparatide patents licensed from or co-owned with Ipsen, after patent term extension, is expected to be April 28, 2031.

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. In March 2021, Teijin received approval in Japan for Ostabalo® abaloparatide acetate for the treatment of osteoporosis and for promotion of bone formation in both female and male patients with high risk of fracture.

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

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 described below.

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 in March 2021, received approval for Ostabalo. 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, and are entitled to receive up to an aggregate of $40.0 million 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.

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.

Pursuant to the Teijin Agreement, we and Teijin may further collaborate on new indications for abaloparatide-SC. We also maintain full global rights to our development program for abaloparatide-TD, 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 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-TD

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 system ("abaloparatide-TD"). In May 2020, 3M announced that it completed its sale of its drug delivery business, which manufactures clinical trial supplies of abaloparatide-TD, to Kindeva Drug Delivery ("Kindeva"), an affiliate of Altaris Capital Partners, LLC ("Altaris"). Under the Supply Agreement, Kindeva will manufacture abaloparatide-TD for us according to agreed-upon specifications in sufficient quantities to meet our projected supply requirements. If abaloparatide-TD is commercialized, Kindeva would manufacture commercial supplies of abaloparatide-TD at unit prices that decrease with an increase in the quantity we order. We would pay Kindeva a mid-to-low single-digit royalty on worldwide net sales of abaloparatide-TD and reimburse Kindeva for certain capital expenditures incurred to establish commercial supply of abaloparatide-TD. We are responsible for providing, at our expense, supplies of abaloparatide drug substance to be used in manufacturing abaloparatide-TD. During the term of the Supply Agreement, Kindeva 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 abaloparatide-TD. Milestone payments for the equipment commenced in the fourth quarter of 2018 and are expected to be paid in full in the first quarter of 2022.

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 abaloparatide-TD. 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 abaloparatide-TD, if we are unable to obtain U.S. regulatory approval for abaloparatide-TD within a certain time period, or if we cease development or commercialization of abaloparatide-TD. Kindeva may terminate the Supply Agreement upon the occurrence of certain events, including if there are certain safety issues related to abaloparatide-TD, if we are unable to obtain U.S. regulatory approval for abaloparatide-TD within a certain time period, or if we fail to order Product for a certain period of time after commercial launch of the abaloparatide-TD in the U.S. Upon certain events of termination, Kindeva is required to transfer the manufacturing processes for abaloparatide-TD to us or a mutually agreeable third party and continue supplying abaloparatide-TD for a period of time pursuant to our projected supply requirements.

Elacestrant (RAD1901)

Pursuant to a license agreement with Eisai Co. Ltd. (as amended, the "Eisai Agreement'), Eisai has granted us an exclusive right and license to research, develop, manufacture and commercialize elacestrant and related products from Eisai in all countries. 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. In connection with the Berlin-Chemie exclusive license, we granted to Berlin-Chemie to develop and commercialize products containing elacestrant (RAD1901) worldwide and paid Eisai a fee of $3.0 million in August 2020 in accordance with the Eisai Agreement. 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, 2021, we had federal and state net operating loss carryforwards of approximately $1,033.8 million and $710.5 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 consolidated statements of operations.

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, 2021, we had cash and cash equivalents of $111.5 million, consisting of cash and money market funds. 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, 2021, we do not have any hard to value investment securities or securities for which a market is not readily available or active.

We are also exposed to interest rate volatility with regard to existing debt issuances. As of December 31, 2021, we had a term loan balance of $148.3 million and borrowings under this Term Facility bear interest through maturity at a variable rate based upon the LIBOR rate plus 5.75%, subject to a LIBOR floor of 2.00% and borrowings under the Revolving Facility bear interest through maturity at a variable rate based upon the LIBOR rate plus 3.50%, subject to a LIBOR floor of 2.00%. An immediate 10% change in interest rates would not have a material effect on the fair value of our term loan, and would not have a significant impact on our financial statements as we do not record debt at fair value.

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 stockholders 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. and subsidiaries (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

We have also 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, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 24, 2022, expressed an unqualified opinion on the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company changed its method of accounting for convertible debt in 2021 due to the adoption of ASU 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, using the modified retrospective approach.

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 Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates 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 financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Reserves for variable consideration for Medicare Part D, Medicare Part D coverage gap, third-party payor rebates, and product returns - Refer to "Note 2 – Revenue Recognition" and "Note 12 – Product Revenue Returns and Allowances" to the financial statements

Critical Audit Matter Description

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. These reductions are offered within contracts between the Company and its customers, payors, and other indirect customers relating to the Company's sale of its products. The reserves 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). Chargebacks, discounts, fees, and returns are recorded as reductions of accounts

receivables, net on the consolidated balance sheets. Government and other rebates are recorded as a component of accrued expenses and other current liabilities on the consolidated balance sheets.

Certain of the reserves for variable consideration related to Medicare Part D, Medicare Part D coverage gap, third-party payor rebates, and product returns (the "Reserves") involve the use of significant assumptions and judgments in their calculation. These significant assumptions and judgments include consideration of (i) current contractual and statutory requirements, (ii) expected rebate or return rate, (iii) expected utilization of rebates by plan participants, and (iv) payor mix of the Company's product sales.

Given the complexity and significant management judgment in determining the significant assumptions used in calculating the Reserves, auditing these estimates involved especially subjective judgment in performing the audit procedures related to these estimates.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the Reserves included the following, among others:

- We tested the effectiveness of internal controls over the Company's estimate of the Reserves, including underlying assumptions and key inputs into the Company's models used to calculate the Reserves.
- We evaluated the appropriateness and consistency of the Company's methods and assumptions used to calculate the Reserves.
- We tested significant assumptions and key inputs used to calculate the Reserves by:
  - Performing sensitivity analyses addressing certain assumptions and subjective inputs utilized in the calculations of the Reserves.
  - Reviewing contracts and modifications thereto with certain of the Company's customers.
  - Developing an independent expectation of the estimated Reserves, including a comparison of rates used in management's calculation to rates in underlying contracts.
  - Performing lookback analyses by comparing amounts invoiced to and paid by the Company to corresponding Reserves recorded by the Company.
  - Performing testing, on a sample basis, of the activity within accounts receivable and current liabilities made throughout the year and evaluating whether such activity was recorded in accordance with the contractual terms of the Company's rebate programs, returns policy, and if applicable, statutory requirements.
- We tested the mathematical accuracy of the Reserve models.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 24, 2022

We have served as the Company's auditor since 2020.

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 statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for the year 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 results of its operations and its cash flows for the year ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

Adoption of ASU No. 2016-02

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, Leases, and related amendments.

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.

/s/ Ernst & Young LLP
We served as the Company's auditor from 2005 until August 2020.

Boston, Massachusetts
February 27, 2020

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

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 111,533	$ 91,436
Restricted cash	567	567
Marketable securities	—	23,280
Accounts receivable, net	23,355	20,310
Inventory	11,373	9,174
Prepaid expenses	10,050	13,279
Other current assets	16,201	22,502
Total current assets	173,079	180,548
Property and equipment, net	647	796
Intangible assets	4,986	5,785
Right of use assets - operating leases	835	3,933
Other assets	1,995	520
Total assets	$ 181,542	$ 191,582
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 17,625	$ 9,925
Accrued expenses and other current liabilities	76,549	59,758
Deferred revenue	—	1,000
Operating lease liability, current	613	2,490
Total current liabilities	94,787	73,173
Convertible notes payable	190,479	213,645
Term loan	148,265	24,905
Operating lease liability, long term	315	3,518
Total liabilities	$ 433,846	$ 315,241
Commitments and contingencies		
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 200,000,000 shares authorized, 47,359,573 shares and 46,779,479 shares issued and outstanding at December 31, 2021 and 2020, respectively	5	5
Additional paid-in-capital	1,115,672	1,222,137
Accumulated other comprehensive income (loss)	—	21
Accumulated deficit	(1,367,981)	(1,345,822)
Total stockholders' equity (deficit)	(252,304)	(123,659)
Total liabilities and stockholders' equity (deficit)	$ 181,542	$ 191,582

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,		
	2021	2020	2019
REVENUES:			
Product revenue, net	$ 218,973	$ 208,395	$ 173,317
License revenue	11,000	30,250	—
Total revenue	229,973	238,645	173,317
OPERATING EXPENSES:			
Cost of sales - product	18,352	16,403	15,287
Cost of sales - intangible amortization	798	798	798
Research and development, net of amounts reimbursable (a)	134,626	159,712	116,757
Selling, general and administrative	130,514	144,154	152,704
Loss from operations	(54,317)	(82,422)	(112,229)
OTHER (EXPENSE) INCOME:			
Other income (expense), net	361	(212)	242
Interest income	75	1,403	3,929
Interest expense	(18,255)	(27,977)	(24,935)
Gain on extinguishment of debt	1,960	—	—
NET LOSS	$ (70,176)	$ (109,208)	$ (132,993)
OTHER COMPREHENSIVE LOSS:			
Unrealized gain (loss) from available-for-sale securities	(21)	18	758
COMPREHENSIVE LOSS	$ (70,197)	$ (109,190)	$ (132,235)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS—BASIC AND DILUTED (Note 14)	$ (70,176)	$ (109,208)	$ (132,993)
LOSS PER SHARE:			
Basic and diluted	$ (1.49)	$ (2.35)	$ (2.89)
WEIGHTED AVERAGE SHARES:			
Basic and diluted	47,216,754	46,459,366	46,026,217

(a) Amounts reimbursable were $51.5 million, $39.3 million, and $0 for the years ended December 31, 2021, 2020, and 2019.

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	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Amount	Amount	Amount	Amount
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 loss 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
Balance at December 31, 2019	46,189,870	$ 5	$ 1,194,327	$ 3	$ (1,236,614)	$ (42,279)
Net loss					(109,208)	(109,208)
Unrealized gain from available-for-sale securities				18		18
Vesting of restricted shares	281,099	—				—
Exercise of options	193,153	—	1,491			1,491
Share-based compensation expense related to share-based awards for employee stock purchase plan			759			759
Issuance of common stock upon purchase by employee stock purchase plan	115,357	—	1,621			1,621
Share-based compensation expense			23,939			23,939
Balance at December 31, 2020	46,779,479	$ 5	$ 1,222,137	$ 21	$ (1,345,822)	$ (123,659)
Net loss					(70,176)	(70,176)
Adjustment due to adoption of ASU 2020-06			(134,450)		48,017	(86,433)
Unrealized gain from available-for-sale securities				(21)		(21)
Vesting of restricted shares	263,236					—
Share-based compensation expense related to share-based awards for employee stock purchase plan			418			418
Exercise of options	210,091		4,046			4,046
Issuance of common stock upon purchase by employee stock purchase plan	106,767		1,154			1,154
Share-based compensation expense			22,367			22,367
Balance at December 31, 2021	47,359,573	$ 5	$ 1,115,672	$ —	$ (1,367,981)	$ (252,304)

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2021	2020	2019
CASH FLOWS USED IN OPERATING ACTIVITIES:			
Net loss	$ (70,176)	$ (109,208)	$ (132,993)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,160	1,693	2,308
Amortization of premium (accretion of discount) on marketable securities, net	19	268	(394)
Impairment loss on operating lease right of use assets	—	2,410	339
Share-based compensation expense	22,785	24,698	23,615
Amortization of debt discount and issuance costs	1,602	18,058	15,785
Loss on disposals of property and equipment	—	602	201
Gain on lease termination	(901)	—	—
Gain on extinguishment of debt	(1,960)	—	—
Changes in operating assets and liabilities:			
Inventory	(2,199)	(3,851)	887
Accounts receivables, net	(3,045)	2,979	(6,531)
Prepaid expenses	3,229	(1,148)	1,711
Other current assets	6,301	(21,656)	356
Operating lease right of use assets	1,066	1,752	2,034
Other long-term assets	(1,659)	(6)	30
Accounts payable	7,700	3,895	1,804
Accrued expenses and other current liabilities	16,791	6,728	10,827
Lease liability, operating leases	(2,147)	(2,162)	(2,298)
Deferred revenue	(1,000)	1,000	—
Other non-current liabilities	—	—	(95)
Net cash used in operating activities	(22,434)	(73,948)	(82,414)
CASH FLOWS PROVIDED BY INVESTING ACTIVITIES:			
Purchases of property and equipment	(28)	—	—
Purchases of marketable securities	—	(39,915)	(119,502)
Sales and maturities of marketable securities	23,240	107,400	206,779
Net cash provided by investing activities	23,212	67,485	87,277
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:			
Proceeds from exercise of stock options and warrants	4,046	1,491	3,869
Proceeds from issuance of term loan	125,000	25,000	—
Deferred financing costs	(2,313)	(99)	—
Repurchase of convertible notes	(108,568)	—	—
Proceeds from employee stock purchase plan	1,154	1,621	1,840
Net cash provided by financing activities	19,319	28,013	5,709
NET INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	20,097	21,550	10,572
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF YEAR	92,003	70,453	59,881
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF YEAR	$ 112,100	$ 92,003	$ 70,453
SUPPLEMENTAL DISCLOSURES:			
Cash paid for interest	$ 16,475	$ 9,854	$ 9,150
Cash paid for amounts included in the measurement of operating lease liabilities	$ 2,311	$ 2,551	$ 2,720
Right of use assets obtained in exchange for operating lease liability	$ 826	$ 1,391	$ 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 global biopharmaceutical company focused on addressing unmet medical needs in the areas of bone health, neuroscience, and oncology. 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. We are also developing certain assets we acquired related to formulations of cannabidiol related to the oral administration of a solution of CBD for therapeutic use in humans or animals ("RAD011"), for which the Company intends to seek FDA approval for a Phase 2/3 trial for treatment of hyperphagia behavior and weight loss in patients with Prader-Willi Syndrome ("PSW").

The Company is subject to risks common to companies in its industry including, but not limited to, the dependence on revenues from a single product, competition, uncertainty about clinical trial outcomes and regulatory approvals, uncertainties relating to pharmaceutical pricing reimbursement, uncertain protection of proprietary technology, and potential product liability. As of December 31, 2021, the Company had an accumulated deficit of $1.4 billion, and total cash and cash equivalents of $111.5 million.

Based upon its cash and cash equivalents balance as of December 31, 2021, 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, or through strategic financing opportunities that could include, but are not limited to collaboration agreements, cash provided by operations 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.

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 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 and Cash Equivalents—Cash and cash equivalents include cash in readily available checking and savings accounts and money market funds. 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, 2021 and 2020.

Restricted Cash—Restricted cash is reported as non-current unless the restrictions are expected to be released in the next twelve months. As of December 31, 2021 and 2020, the Company had restricted cash of $0.6 million, which represents cash held in a depository account at a financial institution to collateralize foreign VAT charges and virtual payables program. The following table provides a reconciliation of cash, cash equivalents, and restricted cash equivalents reported within the condensed consolidated balance sheets to the amounts shown in the condensed consolidated statements of cash flows:

	As of the year ended	
	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 111,533	$ 91,436
Restricted cash	567	567
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 112,100	$ 92,003

Accounts Receivable—Accounts receivable 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 expected credit losses is not deemed necessary at December 31, 2021 and 2020.

Significant Customers—Gross product revenues and accounts receivable from each of the Company's customers who individually accounted for 10% or more of total gross product revenues and/or 10% or more of total accounts receivable consisted of the following:

	Percent of Total Gross Product Revenues					
	Year Ended December 31,					
	2021		2020		2019	
Customer A	—	%	—	%	36	%
Customer B	—	%	—	%	41	%
Customer C(a)	—	%	13	%	11	%
Customer D(a)	41	%	27	%	—	%
Customer E(a)	10	%	11	%	—	%
Customer F(a)	29	%	22	%	—	%
Customer G(a)	14	%	13	%	—	%

(a) The above table has been corrected for certain prior year errors. Previously reported concentrations for Customers C, D, E, F, and G were 0%, 27%, 11%, 0%, and 0%, respectively for the year ended December 31, 2020.

	Percent of Accounts Receivable			
	As of December 31,			
	2021		2020	
Customer C	11	%	—	%
Customer D(a)	32	%	31	%
Customer E	15	%	—	%
Customer F(a)	27	%	29	%
Customer G(a)	15	%	25	%

(a) The above table has been corrected for certain prior year errors. Previously reported concentrations for Customers D, F, G, and H were 0%, 33%, 18%, and 13%, respectively, for the year ended December 31, 2020.

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, 2021 and 2020.

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 cash equivalents, marketable securities, accounts receivable, accounts payable and accrued expenses, approximate their fair values due to the short-term nature of these instruments. The fair value of convertible notes payable and the term loan are 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.

Sales and Marketing Cost—Sales and marketing expenses consist primarily of wages, commissions and benefits for sales and marketing personnel, consulting fees, conferences and seminars, and marketing and advertising costs such as marketing literature, promotional activities, conferences and seminars and branding. Advertising costs are expensed as incurred and included in selling, general and administrative costs in the accompanying consolidated statements of operations.

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.

Other current assets—Research and development costs incurred by the Company that are reimbursable are recorded as other receivables or unbilled receivables and are included in other current assets. As of December 31, 2021 and 2020, total reimbursable research and development costs of $11.8 million and $21.4 million, respectively, was included in other current assets on the consolidated balance sheet.

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, 2021 and 2020.

Share-Based Compensation-Options and market condition awards—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. For awards with market conditions, the Company recognizes compensation expense on an accelerated attribution basis.

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.

The Company estimates the fair value of each market condition award using the Monte Carlo simulation model (a binomial lattice-based valuation model). The fair value of the market condition award at the date of grant is amortized to expense over the performance period.

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. to distribute TYMLOS. In the first quarter of 2020, the Company executed a transition of its external distribution model from full-line wholesalers to specialty distributors and specialty pharmacies (collectively, its "Customers"). 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"). 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 Customers. 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, 2021 and 2020.

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, 2021 and, therefore, the transaction price was not reduced further during the twelve months ended December 31, 2021 and 2020. 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.

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 accounts 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 accounts 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, which is included in accrued expenses and other current liabilities on the consolidated balance sheets.

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 accounts receivables, net on the consolidated balance sheets. Government and other rebates are recorded 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, regulatory, or commercial 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.

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 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. If readily determinable, the Company uses the rate implicit in the lease when determining the present value of lease payments. As the Company's leases have not historically provided an implicit rate, the Company's incremental borrowing rate is based on information available at the commencement date and is used in determining the present value of lease payments. 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.

The operating lease right-of-use assets also include any lease payments made and reduced by 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, *Leases*, the Company, as the lessee, has made an accounting policy election, by class of underlying asset, to not separate non-lease components from lease components. The Company will account for each separate lease component and the non-lease components associated with that lease component as a single lease component.

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 clinical research organizations ("CRO") 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— Prior to the adoption of ASU 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06") on January 1, 2021, 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.

Subsequent to the adoption of ASU 2020-06 on January 1, 2021, which the Company elected to adopt using the modified retrospective method, the Company removed the impact of recognizing the Equity Component of the Convertible Notes (at issuance and the subsequent accounting impact of additional interest expense from debt discount amortization). The cumulative effect of the change was recognized as an adjustment to the opening balance of accumulated deficit at the date of adoption and the convertible notes are no longer bifurcated into separate liability and equity components.

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. Net income available to common shareholders is allocated to each share on an as-converted basis as if all of the earnings for the periods when the Company is in a net income position.

Diluted net income per share is computed using the if-converted method. The weighted-average number of common shares outstanding gives effect to all potentially dilutive common equivalent shares, including outstanding stock options, warrants, and convertible instruments. 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 August 2020, the FASB issued ASU 2020-06. The guidance simplifies the complexity associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. More specifically, the amendments focus on the guidance for convertible instruments and derivative scope exception for contracts in an entity's own equity.

Consequently, a convertible debt instrument, such as the Company's convertible notes, will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The new guidance also requires the if-converted method to be applied for all convertible instruments and requires additional disclosures. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years.

The Company elected to early adopt this guidance effective January 1, 2021 under the modified retrospective adoption approach and the comparative information has not been restated and continues to be presented according to accounting standards in effect for those periods. The cumulative effect of the change was recognized as an adjustment to the opening balance of accumulated deficit at the date of adoption and our convertible notes due September 1, 2024 are no longer bifurcated into separate liability and equity components as described in Note 9 of the Company's Consolidated Financial Statements. The principal amount of our convertible notes due September 2024 is classified as a liability only in the consolidated balance sheet for the period ended December 31, 2021. Upon adoption of ASU 2020-06, we recorded an adjustment to the convertible notes liability component, equity component (additional paid-in-capital) and accumulated deficit. This adjustment was calculated based on the carrying amount of the convertible notes as if it had always been treated as a liability only. Furthermore, we recorded an adjustment to the debt issuance costs contra liability and equity (additional paid-in-capital) components under the same premise, as if debt issuance costs had always been treated as a contra liability only. In addition, we derecognized deferred income tax liabilities associated with the equity component of the convertible notes, which the impact is fully offset by the change in valuation allowance. Lastly, interest expense related to the accretion of our convertible notes due September 1, 2024 is no longer recognized.

The following table summarizes the cumulative effect of the changes to our condensed consolidated balance sheet as of January 1, 2021 as compared to December 31, 2020 from the adoption of ASU 2020-06:

Consolidated Balance Sheet Data (in thousands)	Balance at December 31, 2020	Adjustment due to ASU 2020-06 adoption	Balance at January 1, 2021
Liabilities			
Convertible notes payable (1)	$ 213,645	$ 86,433	$ 300,078
Equity			
Additional paid-in-capital	$ 1,222,137	$ (134,450)	$ 1,087,687
Accumulated deficit	$ (1,345,822)	$ 48,017	$ (1,297,805)

(1) Convertible notes payable is presented net of unamortized discount and debt issuance costs of $88.1 million and $3.2 million, respectively at December 31, 2020. Convertible notes payable is presented net of unamortized discount and debt issuance costs of $4.7 million and $0.3 million at January 1, 2021.

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, with early adoption permitted. The Company adopted this guidance on January 1, 2021 and it did not have a material impact on its financial statements.

Accounting Standards Updates—Recently Issued

There are no applicable material accounting pronouncements recently issued that have not yet been adopted by the Company.

3. Marketable Securities

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

	December 31, 2021			
	Amortized Cost Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 41,285	$ —	$ —	$ 41,285
Money market funds, included in cash equivalents	70,248	—	—	70,248
Total	$ 111,533	$ —	$ —	$ 111,533

	December 31, 2020			
	Amortized Cost Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$ 44,616	$ —	$ —	$ 44,616
Money market funds, included in cash equivalents	46,820	—	—	46,820
Total	$ 91,436	$ —	$ —	$ 91,436
Marketable securities:				
Domestic corporate debt securities	$ 18,266	$ 21	$ (2)	$ 18,285
Domestic corporate commercial paper	4,993	2	—	4,995
Total	$ 23,259	$ 23	$ (2)	$ 23,280

The Company reviews marketable securities whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. The Company evaluates whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency, and adverse conditions specifically related to the security, among other factors. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security are compared to the amortized cost basis of the security. If the present value of cash flows expected to be collected is less than the amortized cost basis, a credit loss exists and an allowance for credit losses is recorded for the credit loss on the condensed consolidated balance sheet, limited by the amount that the fair value is less than the amortized cost basis. Any impairment that is not related to credit is recognized in other comprehensive income.

Changes in the allowance for credit losses are recorded as a provision for (or reversal of) credit loss expense on the condensed consolidated statement of operations. Losses are charged against the allowance when the Company believes the uncollectability of an available-for-sale debt security is confirmed or when either of the criteria regarding intent or requirement to sell is met. There was one available-for-sale debt security in an unrealized loss position at December 31, 2020 for which an allowance for credit losses was not recorded as it was attributable to changes in interest rates and the Company did not believe any unrealized losses represented credit losses. There were no available-for-sale debt securities or unrealized losses at December 31, 2021.

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, 2021 and 2020.

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, 2021 and December 31, 2020 (in thousands):

	As of December 31, 2021			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
Cash and cash equivalents:				
Cash	$ 41,285	$ —	$ —	$ 41,285
Money market funds (1)	70,248	—	—	70,248
Total	$ 111,533	$ —	$ —	$ 111,533

	As of December 31, 2020			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets				
Cash and cash equivalents:				
Cash	$ 44,616	$ —	$ —	$ 44,616
Money market funds (1)	46,820	—	—	46,820
Total	$ 91,436	$ —	$ —	$ 91,436
Marketable securities:				
Domestic corporate debt securities (2)	$ —	$ 18,285	$ —	$ 18,285
Domestic corporate commercial paper (2)	—	4,995	—	4,995
Total	$ —	$ 23,280	$ —	$ 23,280

(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.

The Company's Convertible Notes are classified within Level 2 in the fair value hierarchy. The fair values of the Convertible Notes are based on data from readily available pricing sources which utilize market observable inputs and other characteristics for similar types of instruments. 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, 2021 was $186.2 million.

The Company's Term Loan falls into the Level 2 category within the fair value level hierarchy and the fair value was determined using quoted prices for similar liabilities in active markets, as well as inputs that are observable for the liability (other than quoted prices), such as interest rates that are observable at commonly quoted intervals. The estimated fair value of the Term Loan as of December 31, 2021 was $144.9 million.

As of December 31, 2021, the carrying amounts of the cash and cash equivalents, restricted cash, accounts receivable, prepaid expenses, other current assets, accounts payable, accrued expenses, and operating lease liabilities approximated their estimated fair values.

5. Inventory

Inventory consists of the following at December 31, 2021 and 2020 (in thousands):

	December 31, 2021	December 31, 2020
Raw materials	$ 7,159	$ 5,228
Work in process	1,335	667
Finished goods	2,879	3,279
Total inventories	$ 11,373	$ 9,174

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, 2021	December 31, 2020
Furniture and fixtures, lab and office equipment	5	$ 299	$ 299
Computer equipment and software	3	2,697	2,697
Manufacturing equipment	10	1,616	1,616
Leasehold improvements	Shorter of useful life or remaining lease term	183	183
Construction in progress		28	—
		4,823	4,795
Less: accumulated depreciation		(4,176)	(3,999)
Property and equipment, net		$ 647	$ 796

In the year ended December 31, 2020, 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, and concluded that there were indicators of impairment for property and equipment. As a result of the abandonment of our leases (see Note 18), we disposed leasehold improvements, computer equipment, lab and office equipment, and furniture and fixtures and recorded a $0.6 million loss on disposal for these assets during the year ended December 31, 2020. No triggering events were identified in the year ended December 31, 2021.

Depreciation expense related to property and equipment was approximately $0.2 million, $0.9 million and $1.5 million for the years ended December 31, 2021, 2020, and 2019, respectively.

7. Intangible Assets

The following table presents intangible assets as of December 31, 2021 and 2020 (in thousands):

	December 31, 2021	December 31, 2020	Estimated useful life (years)
Acquired and in-licensed rights	$ 8,712	$ 8,712	11
Less: accumulated amortization	(3,726)	(2,927)	
Total intangible asset, net	$ 4,986	$ 5,785	

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 $0.8 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, 2021, 2020, and 2019, respectively. Estimated future amortization expense for intangible assets as of December 31, 2021 is $0.8 million per year over the remaining life of 6.25.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses as of December 31, 2021 and 2020 consist of the following (in thousands):

	December 31,	
	2021	2020
Commercial costs	$ 3,179	$ 3,901
Product revenue reserves	24,596	14,650
Royalty payable	3,234	2,999
Research costs	25,385	20,061
Payroll and employee benefits	10,133	10,999
Interest	3,101	3,153
Professional fees	3,276	3,235
Restructuring	3,553	665
Other current liabilities	92	95
Total accrued expenses and other current liabilities	$ 76,549	$ 59,758

In December 2021, the Company decided on organizational changes, which would result in a reduction in headcount in the first quarter of 2022. The reduction in workforce focused on the functions that directly or indirectly supported abaloparatide. Costs incurred comprise of contractual termination benefits and one-time termination benefits to employees who are involuntarily terminated. Contractual termination benefits are typically recognized when it is probable the employees will be entitled to benefits and the amount can be reasonably estimated. One-time termination benefits are recognized ratably over the future service period. The Company expects the aggregate of such costs to be approximately $3.7 million. As of December 31, 2021, the Company has recognized $3.6 million in costs, $2.3 million of which are recorded within research and development and $1.3 million of which are selling, general and administrative expenses in the consolidated statement of operations. No amounts have been paid as of December 31, 2021, and $3.6 million of accrued restructuring is included within accrued expenses and other current liabilities on the consolidated balance sheet.

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, and prior to the adoption of ASU 2020-06 on January 1, 2021, the Company separately accounted for the liability component (the “Liability Component”) and embedded conversion option (the “Equity Component”) 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.

Prior to the adoption of ASU 2020-06 on January 1, 2021, the initial 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.

Subsequent to the adoption of ASU 2020-06 on January 1, 2021, which the Company elected to adopt using the modified retrospective method, the Company removed the impact of recognizing the Equity Component of the Convertible Notes (at issuance and the subsequent accounting impact of additional interest expense from debt discount amortization). The cumulative effective of the accounting change as of January 1, 2021 was an increase to the carrying amount of the convertible notes of

$86.4 million, a reduction to accumulated deficit of $48.0 million, and a reduction to additional paid-in capital of $134.5 million. In connection with the adoption the Company calculated an effective interest rate of 3.43%.

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. 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. The Convertible Notes may be redeemed at the Company's option, in whole or in part, if the conditions described below are satisfied. The redemption of the Convertible Notes may also be subject to certain restrictions included in Note 10, "Term Loan and Credit Facility." 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).

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) 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.

As of December 31, 2021, none of the above circumstances had occurred and, as such, the Convertible Notes were not convertible.

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 March 2021, the Company entered into separate, privately negotiated transactions with certain holders of the Convertible Notes to repurchase $112.2 million face amount of the Convertible Notes for a cash purchase of $108.6 million. As the Company only extinguished a portion of the debt, the difference between the reacquisition price and the net carrying amount of the extinguished portion resulted in a gain on extinguishment of $2.0 million. Third party costs associated with the extinguishment of $0.3 million were included in selling, general and administrative expense for the twelve months ended December 31, 2021.

The outstanding balances of the Convertible Notes as of December 31, 2021 consisted of the following (in thousands):

	December 31, 2021
Liability	
Principal	$ 192,753
Less: debt discount and issuance costs, net	(2,274)
Net carrying amount	$ 190,479

The debt issuance costs on the Convertible Notes will be amortized over the remaining period.

Prior to January 1, 2021, the Company separated the Convertible Notes into liability and equity components. On issuance, the carrying amount of the equity components was recorded as a debt discount and subsequently amortized into interest expense. The Company determined the expected life of the Convertible Notes was equal to their seven-year term. Effective January 1, 2021 the effective interest rate on the Convertible Notes for the period from the date of issuance through December 31, 2021 was 3.43%.

As of December 31, 2021, the "if-converted value" did not exceed the remaining principal amount of the Convertible Notes.

The following table sets forth total interest expense recognized related to the Convertible Notes during the twelve months ended December 31, 2021, 2020, and 2019 (in thousands):

	Twelve Months Ended December 31,		
	2021	2020	2019
Contractual interest expense	$ 6,493	$ 9,150	$ 9,150
Amortization of debt discount	880	17,403	15,213
Amortization of debt issuance costs	49	651	572
Total interest expense	$ 7,422	$ 27,204	$ 24,935

Future minimum payments on our convertible notes payable as of December 31, 2021 is as follows (in thousands):

Years ended December 31,	Future Minimum Payments
2022	5,783
2023	5,783
2024 and thereafter	198,535
Total minimum payments	$ 210,101
Less: interest	(17,348)
Less: debt discount and issuance costs, net	(2,274)
Less: current portion	—
Convertible Notes	$ 190,479

10. Term Loan and Credit Facility

On March 3, 2021, the Company and two of its wholly-owned subsidiaries, Radius Pharmaceuticals, Inc. and Radius Health Ventures, Inc. (collectively with the Company, the "Borrowers"), entered into an (i) Amended and Restated Credit and Security Agreement (Term Loan) (the "Term Credit Agreement"), with MidCap Financial Trust, in its capacity as administrative agent, and the financial institutions or other entities from time to time parties thereto as lenders (the "Term Lenders") and (ii) Amended and Restated Credit and Security Agreement (Revolving Loan) (the "Revolving Credit Agreement," together with the Term Credit Agreement, the "Credit Agreements"), with MidCap Funding IV Trust, in its capacity as administrative agent, and the financial institutions or other entities from time to time parties thereto as lenders.

The Term Credit Agreement provides for a secured term loan facility (the "Term Facility") in an aggregate principal amount of $150.0 million (the "Initial Term Loan"), an increase of $125.0 million from the arrangement entered into in January 2020. In addition, the Borrowers have the right under the Term Credit Agreement to request that the Term Lenders make an additional term loan in an aggregate principal amount of $25.0 million available to the Borrowers within one year of the closing date of the Initial Term Loan (the "Initial Closing Date"). The Term Lenders are not under any obligation to provide any such additional term loan.

The Revolving Credit Agreement provides for a secured revolving credit facility (the "Revolving Facility," together with the Term Facility, the "Facilities") under which the Borrowers may borrow up to $25.0 million, the availability of which is determined based on a borrowing base as follows: (i) up to 85% of the net collectable 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, minus certain reserves; provided that the availability from eligible inventory may not exceed 20% of the borrowing base at any time.

The Facilities have a maturity date of June 1, 2024. The obligations under the Credit Agreements are guaranteed by the Borrowers and are guaranteed by certain future subsidiaries of the Borrowers, subject to certain exceptions. The obligations under the Facilities are secured by substantially all of the assets of the Borrowers, and are secured by substantially all assets of the future subsidiaries of the Borrowers that become borrowers or guarantors under the Facilities, subject to certain exceptions.

Borrowings under the Term Facility 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 bear interest through maturity at a variable rate based upon the LIBOR rate plus 3.50%, subject to a LIBOR floor of 2.00%. The Borrowers are required to pay a monthly commitment fee on the unused commitments under the Revolving Facility of 0.50% per annum.

On March 11, 2021, the Company received proceeds of $122.6 million under the Term Facility, net of fees and expenses of $2.4 million. With the issuance of a new term loan, the Company performed an assessment comparing the discounted cash flows of the original debt and the new debt as of the modification date and concluded that the change is considered a modification. As of the modification date, the Company established a new effective interest rate based on the carrying value of the debt and the revised cash flows. Fees paid to the lender of $2.4 million were capitalized as debt discount and will be amortized to interest expense using the effective interest method over the term of the loan. Third party costs associated with the modification of $2.8 million were included in selling, general and administrative expense for the twelve-months ended December 31, 2021. The outstanding balance of the Term Loan as of December 31, 2021 was (in thousands):

	Term loan
Principal	$ 150,000
Less: debt issuance costs, net	$ (1,735)
Net carrying amount	$ 148,265

The following table sets forth total interest expense recognized related to the Term Facility during the twelve months ended December 31, 2021 and 2020 (in thousands):

	December 31,	
	2021	2020
Contractual interest expense	$ 10,113	$ 771
Amortization of debt discount	720	4
Total interest expense	$ 10,833	$ 775

Future minimum payments on the Term Facility as of December 31, 2021 are as follows (in thousands):

Years ended December 31,	Future Minimum Payments
2022	11,625
2023	61,302
2024	102,260
Total minimum payments	$ 175,187
Less: interest	(25,187)
Less: unamortized issuance costs	(1,735)
Less: current portion	—
Long Term Debt	$ 148,265

11. 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, 2021, there were 2,180,815 shares available for future sale to employees under this plan. As of December 31, 2021, the Company recorded a liability of $0.5 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, 2021, an aggregate of 7,464,256 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 2,830,941 at December 31, 2021.

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 2021, 2020, and 2019 was $10.69, $10.23, and $12.97 respectively. The weighted-average assumptions used in the Black-Scholes option-pricing model were as follows:

	Years Ended December 31,		
	2021	2020	2019
Expected term (years)	6.15	6.17	6.13
Volatility	65 %	67 %	72 %
Expected dividend yield	0 %	0 %	0 %
Risk-free interest rates	0.87 %	0.65 %	2.35 %

A summary of stock option activity for the year ended December 31, 2021 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, 2020	4,258,162	$ 29.50		
Granted	4,196,735	18.25		
Exercised	(210,091)	19.26		
Canceled	(676,162)	19.22		
Expired	(1,139,388)	38.13		
Options outstanding at December 31, 2021	6,429,256	$ 22.03	7.54	$ 1,107
Options exercisable at December 31, 2021	1,945,889	$ 31.44	5.16	$ 1,107

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, 2021, 2020, and 2019 was $0.5 million, $1.6 million, and $4.2 million, respectively.

As of December 31, 2021, there was approximately $38.1 million of total unrecognized compensation expense related to unvested option-based compensation arrangements, which is expected to be recognized over a weighted-average period of approximately 3.08 years.

Restricted Stock Units

A summary of RSU activity during the year ended December 31, 2021 is as follows:

	RSUs	Weighted-Average Grant Date Fair Value (in dollars per share)
RSUs Outstanding at December 31, 2020	596,260	$ 20.52
Granted	243,725	16.98
Vested	(263,236)	20.71
Forfeited	(132,138)	20.47
RSUs Outstanding at December 31, 2021	444,611	$ 18.41

The weighted-average grant date fair value of RSUs granted for the years ended December 31, 2021, 2020, and 2019 was $16.98, $19.38, and $20.04. The total fair value of RSUs vested (measured on the date of vesting) for the years ended December 31, 2021, 2020, and 2019 was $4.8 million, $4.7 million, and $1.8 million respectively.

As of December 31, 2021, there was approximately $4.7 million of total unrecognized compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 1.76 years.

Performance Options

During the twelve months ended December 31, 2021, and 2020 the Company awarded 460,000 performance stock options (“PSOs”) and 575,000 PSOs, respectively, to an employee. Each PSO entitles the holder to receive one share of the Company’s common stock if and when the PSO vests. The 460,000 PSOs vest 100% upon achievement of a stock price hurdle over a

specified performance vesting period, while the 575,000 PSOs vest in 25% increments upon achievement of specific total shareholder return over a prespecified number of consecutive trading days. The PSOs vest upon achievement of certain performance targets within a pre-specified period from the grant date. As these PSOs vest based on the achievement of market conditions, the grant date fair values were determined using a Monte-Carlo valuation model. The Monte-Carlo valuation model considered a variety of potential future share prices for the Company as well as its peer companies in the selected market index. The weighted-average grant date fair value of PSOs granted with market-based vesting conditions in the twelve months ended December 31, 2021, and 2020, were $6.29 and $9.12, respectively, based on the valuation models. No such awards were granted in the twelve months ended December 31, 2019. The vesting of any earned options is subject to the employee's continued service relationship with the Company through each vesting date. During the years ended December 31, 2021, 2020, and 2019, no PSOs vested.

A summary of PSO activity during the twelve months ended December 31, 2021 is as follows:

	PSOs	Weighted-Average Grant Date Fair Value (in dollars per share)
PSOs Outstanding at December 31, 2020 (a)	575,000	$ 9.12
Granted	460,000	6.29
Vested	—	—
Forfeited	—	—
PSOs Outstanding at December 31, 2021	1,035,000	$ 7.86

(a) The above table has been corrected for certain prior year errors. Previously reported weighted-average grant date fair value per share for PSOs outstanding at December 31, 2020 was $16.46.

As the performance condition must be met for the awards to vest, compensation cost will be recognized over the requisite service period. The total expense recognized for these PSOs during the years ended December 31, 2021, 2020, and 2019, was approximately $3.7 million, $2.4 million, and $0, respectively. As of December 31, 2021 there was approximately $2.0 million of total unrecognized compensation expense related to unvested PSOs, which is expected to be recognized over a weighted-average period of approximately 1.02 years.

Share-Based Compensation Expense

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

	Years Ended December 31,		
	2021	2020	2019
Research and development	$ 6,164	$ 6,654	$ 8,768
General and administrative	16,621	18,044	14,847
Share-based compensation expense included in operating expenses	$ 22,785	$ 24,698	$ 23,615

12. Product Revenue Reserves and Allowances

To date, the Company's only source of product revenue has been from the U.S. sales of TYMLOS, which it began shipping to Customers in May 2017. The following table summarizes activity in each of the product revenue allowance and reserve categories for the twelve months ended December 31, 2021 and 2020 (in thousands):

	Chargebacks, Discounts, and Fees	Government and Other Rebates	Returns	Total
Ending balance at December 31, 2019	$ 5,739	$ 17,280	$ 1,583	$ 24,602
Provision related to sales in the current year	20,549	76,166	1,938	98,653
Adjustment related to prior periods sales	(107)	(1,551)	—	(1,658)
Credits and payments made	(24,290)	(77,251)	(949)	(102,490)
Ending balance at December 31, 2020	$ 1,891	$ 14,644	$ 2,572	$ 19,107
Provision related to sales in the current year	21,022	105,986	90	127,098
Adjustment related to prior periods sales	(108)	(2,423)	(2,249)	(4,780)
Credits and payments made	(20,744)	(93,603)	(189)	(114,536)
Ending balance at December 31, 2021	$ 2,061	$ 24,604	$ 224	$ 26,889

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

13. License Revenue and Reimbursable Expenses

General

The Company has generated revenue from contracts with customers, which include upfront payments for licenses.

Berlin-Chemie

In July 2020, the Company entered into a license agreement ("License Agreement") with Berlin-Chemie under which the Company granted Berlin-Chemie an exclusive license to develop and commercialize products containing elacestrant (RAD1901) worldwide.

The Company and Berlin-Chemie simultaneously entered into a Transition Services Agreement (the "TSA"), pursuant to which the Company agreed to perform certain services for Berlin-Chemie related to the EMERALD Phase 3 monotherapy study until the earlier of the completion of the contemplated services or the filing with the FDA of a New Drug Application for elacestrant. Pursuant to the TSA, Berlin-Chemie agreed to reimburse the Company for all out-of-pocket and full-time employee costs in performing the services, for total estimated reimbursements of $111.5 million. The Company will continue to incur research and development expenses in support of scale up costs under the TSA.

Pursuant to the terms of the License Agreement, Berlin-Chemie made a nonrefundable initial license fee payment to the Company of $30.0 million in July 2020. The Company is also eligible to receive up to $20.0 million in development and regulatory milestone payments and up to $300.0 million in sales milestone payments, with such payments contingent on the achievement of specified milestones with respect to the licensed products. The Company is also eligible to receive tiered royalties on sales of licensed products at percentages ranging from low to mid-teens, subject to certain reductions. Royalties on net sales will be payable on a product-by-product and country-by-country basis until the latest of the expiration date of the last to expire of the relevant patent rights, the expiration of regulatory exclusivity, or ten years from such first commercial sale.

The License Agreement will continue on a licensed product-by-licensed product and country-by-country basis until the last to expire royalty term. Either party may terminate the License Agreement for an uncured material breach by the other party or upon the bankruptcy or insolvency of the other party. The Company may terminate the License Agreement for certain patent challenges or if no development, manufacture or commercialization activity occurs in any given 24-month period. Berlin-Chemie may terminate the License Agreement at its discretion for any reason by delivering 180 days' prior written notice to the Company; provided that such termination will not be effective prior to the third anniversary of the effective date.

The Company determined that the License Agreement and TSA should be combined and evaluated as a single arrangement as they were executed on the same date and negotiated as a package. The arrangement with Berlin-Chemie provides for the transfer of the following goods or services: (i) license, (ii) know-how, (iii) regulatory filings, (iv) inventory, (v) transition services, including certain clinical, manufacturing, regulatory and other services associated with the Phase 3 EMERALD monotherapy study, and (vi) participation in various joint committees.

Management applied the guidance in ASC 606 to identify all distinct goods and services within the arrangement to assess whether there is a unit of account that should be accounted for under ASC 606. Management evaluated all of the promised goods or services within the contract and determined which of those were separate performance obligations. The Company

determined that the license granted, at arrangement inception, should be combined with the know-how and regulatory filings as they are not capable of being distinct (the "License"). The Company also concluded that the license rights, know-how, and regulatory filings are capable of being distinct from the supply of inventory, as Berlin-Chemie would be able to benefit from the inventory on its own or with other resources that are readily available, and capable of being distinct from the transition services and participation in joint committees as these are research and development services that can typically be performed by other third parties.

The License is an element of the arrangement that is subject to the revenue recognition accounting guidance, as the performance obligation is an output of the Company's ordinary activities in exchange for consideration. Conversely, the transition services, the participation on joint committees, and transfer of inventory are elements of the arrangements that are outside the scope of the revenue recognition guidance, as the Company is providing goods and services that are not an output of the Company's ordinary activities.

The transaction price at inception is comprised of fixed consideration of $30.0 million. The $30.0 million upfront fee, which represents the fixed consideration in the transaction price, was allocated to the License and the supply of inventory, on a relative standalone selling price basis. The Company estimated the standalone selling price for the license by applying a risk adjusted, net present value, estimate of future potential cash flows approach and determined the standalone selling price for the inventory using a cost approach. Accordingly, the Company has allocated $27.4 million to the license and $2.6 million to the inventory. The Company concluded that the reimbursements for the research and development transition services and participation in the joint steering committees was commensurate with the standalone selling prices of the services, and as such, will be attributed to those services. The reimbursements for these services will be recorded as a reduction of the related research and development expenses as the expenses are incurred.

Under the Berlin-Chemie agreements, the Company is eligible to receive various development and regulatory, and sales milestones. There is uncertainty that the events to obtain the development and regulatory milestones will be achieved. The Company has thus determined that all such milestones will be constrained until it is deemed probable that a significant revenue reversal will not occur. Additional transaction price recognized in future periods related to milestone payments and royalties will be allocated solely to the License.

Sales milestones and sales-based royalties were also excluded from the transaction price as the license is deemed to be the predominant item to which the sales milestones and sales-based royalties relate. The Company will recognize such revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

During the twelve months ended December 31, 2021 and 2020, the Company recognized $0 and $30.0 million, respectively, of license revenue, as it had satisfied its promises under the performance obligation for the license, including the transfer of know-how and regulatory filings, by transferring them at a point in time during the quarter. During the twelve months ended December 31, 2021, 2020, and 2019, the Company recorded $51.5 million, $39.3 million, and $0, respectively, as reductions of research and development expenses for reimbursement of transition services performed under the TSA. As of December 31, 2021 and 2020, we had a receivable of $11.8 million and $21.4 million, respectively, related to reimbursable research and development expenses under this agreement, which is presented in other current assets on the consolidated balance sheet.

14. 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,		
	2021	2020	2019
Numerator:			
Net loss	$ (70,176)	$ (109,208)	$ (132,993)
Loss attributable to common stockholders—basic	(70,176)	(109,208)	(132,993)
Loss attributable to common stockholders—diluted	$ (70,176)	$ (109,208)	$ (132,993)
Denominator:			
Weighted-average number of common shares used in loss per share— basic and diluted	47,216,754	46,459,366	46,026,217
Loss per share—basic and diluted	$ (1.49)	$ (2.35)	$ (2.89)

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, 2021, 2020, and 2019 all of the Company's options to purchase common stock, restricted stock units outstanding, performance units, and performance options were assumed to be anti-dilutive as earnings attributable to common stockholders was in a loss position.

	Year Ended December 31		
	2021	2020	2019
Options to purchase common stock	6,429,256	4,258,162	4,834,255
Restricted stock units	444,611	596,260	614,273
Performance units	—	—	79,000
Performance options	1,035,000	575,000	—

The Company has the option to settle the conversion obligation for the Convertible Notes in cash, shares or any combination of the two. As the Convertible Notes are not convertible as of December 31, 2021, they are not participating securities and they will not have an impact on the calculation of basic earnings or loss per share. Based on the Company's net loss position, there is no impact on the calculation of dilutive loss per share. Effective January 1, 2021, the Company uses the if-converted method for the Convertible Notes as a result of the adoption of ASU 2020-06, as described in Note 2.

15. License Agreements

Ipsen

In September 2005, the Company entered into a license agreement (the "License Agreement"), as amended, with an affiliate of Ipsen Pharma SAS ("Ipsen") under which the Company exclusively licensed certain Ipsen compound technology and related patents covering abaloparatide to research, develop, manufacture, and commercialize certain compounds and related products in all countries, except Japan 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, 2021. 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 $29.5 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 License Agreement provides that the Company would pay to Ipsen a fixed five percent royalty based on net sales of products containing abaloparatide 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 $10.9 million and $10.4 million for the years ended December 31, 2021 and 2020, 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, after patent extension, is expected to be April 28, 2031.

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 $5.0 million upon Teijin's receipt of approval of Ostabalo in Japan. Under the final decision, the Company is obligated to pay Ispen 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.Pursuant to a final decision in arbitration proceedings with Ipsen in connection with the License Agreement, we paid Ipsen $5.0 million upon the approval of Ostabalo. Under the final decision, we are also obligated to pay Ipsen a fixed mid single-digit royalty based on net sales of abaloparatide in Japan. 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-TD, 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, 2021, 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.

16. Income Taxes

For the year ended December 31, 2021, 2020, and 2019 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 years ended December 31, 2021, 2020, and 2019 consisted of the following:

	Year Ended December 31,		
	2021	2020	2019
United States	$ (70,182)	$ (109,208)	$ (116,749)
Foreign	6	—	(16,244)
	(70,176)	(109,208)	(132,993)

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,		
	2021	2020	2019
Income tax benefit using U.S. federal statutory rate	$ (14,737)	$ (22,934)	$ (27,918)
State income taxes, net of federal benefit	(1,752)	(2,108)	(5,486)
Stock-based compensation	5,921	6,315	4,379
Research and development tax credits	(4,301)	(5,222)	(2,491)
Change in the valuation allowance	13,975	28,443	26,918
Convertible note	—	(128)	(128)
Permanent items	110	287	457
Uncertain Tax Positions	15	12	—
Foreign rate differential	—	—	3,414
Capitalized R&D expenses	39	(5,641)	—
Other	730	976	855
Income tax expense	$ —	$ —	$ —

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

	December 31, 2021	December 31, 2020
Deferred tax assets:		
NOL carryforwards	$ 257,080	$ 255,052
Capitalized research and development	14,103	13,615
Research and development credits	17,208	13,773
Interest Expense	8,649	4,614
Accrued expenses	5,662	4,253
Stock-based compensation	9,162	11,696
UNICAP	210	168
Credit loss reserve	546	1,059
Operating lease liability	222	1,431
Collaboration revenue	5,628	—
Convertible debt	937	—
Other	92	98
Gross non-current deferred tax assets	319,499	305,759
Valuation allowance	(318,766)	(283,684)
Net non-current deferred tax assets	$ 733	$ 22,075
Deferred tax liabilities:		
Depreciation	$ (533)	$ (146)
Right-of-Use asset	(200)	(937)
Convertible debt	—	(20,992)
Gross non-current deferred tax liabilities	(733)	(22,075)
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, 2021, 2020, and 2019, 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 $35.1 million in 2021 primarily relates to the net loss incurred by the Company.

As of December 31, 2021, the Company had federal and state net operating loss ("NOL") carryforwards of approximately $1,033.8 million and $710.5 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 $279.6 million will carryforward indefinitely. The state NOLs will expire at various dates through 2041.

As of December 31, 2021, the Company also had federal and state tax credits of $14.8 million and $3.0 million, respectively, to offset future tax liabilities. The federal general business credits will expire at various dates through 2041 and the state research and development tax credits will expire at various dates through 2036.

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, 2021, the unrecognized tax benefit was $4.5 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		
	2021	2020	2019
Balance at January 1	$ 3,592	$ 2,563	$ 2,239
Decreases related to prior year tax positions	—	(1)	(285)
Increases related to prior year tax positions	—	—	92
Decreases related to current year tax positions	—	—	—
Increases related to current year tax positions	880	1,030	517
Balance at December 31	$ 4,472	$ 3,592	$ 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 2018 through 2020 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, 2021, 2020, or 2019. The Company does not expect any significant change in its uncertain tax positions in the next 12 months.

17. 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, 2021, the Company was not party to any significant litigation.

Kindeva

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 system (“abaloparatide-TD”). In May 2020, 3M announced that it completed its sale of its drug delivery business, which manufactures clinical trial supplies of abaloparatide-TD, to Kindeva Drug Delivery (“Kindeva”), an affiliate of Altaris Capital Partners, LLC. The Supply Agreement was assigned to Kindeva as part of the transaction. Under the Supply Agreement, Kindeva will manufacture abaloparatide-TD for the Company according to agreed-upon specifications in sufficient quantities to meet the Company’s projected supply requirements. If abaloparatide-TD is commercialized, Kindeva would manufacture commercial supplies of abaloparatide-TD at unit prices that decrease with an increase in the quantity the Company orders. The Company would pay Kindeva a mid-to-low single-digit royalty on worldwide net sales of abaloparatide-TD and reimburse Kindeva for certain capital expenditures incurred to establish a commercial supply of abaloparatide-TD. The Company is responsible for providing, at its expense, supplies of abaloparatide drug substance to be used in manufacturing abaloparatide-TD. During the term of the Supply Agreement, Kindeva 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 abaloparatide-TD. 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 abaloparatide-TD, if it is unable to obtain U.S. regulatory approval for abaloparatide-TD within a certain time period, or if it ceases development or commercialization of abaloparatide-TD. Kindeva may terminate the Supply Agreement upon the occurrence of certain events, including if there are certain safety issues related to abaloparatide-TD, if the Company is unable to obtain U.S. regulatory approval for abaloparatide-TD within a certain time period, or if the Company fails to order abaloparatide-TD for a certain period of time after commercial launch of abaloparatide-TD in the U.S. Upon certain events of termination, Kindeva is required to transfer the manufacturing processes for abaloparatide-TD to the Company or a mutually agreeable third party and continue supplying abaloparatide-TD for a period of time pursuant to the Company's projected supply requirements.

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 abaloparatide-TD. Milestone payments for the equipment commenced in the fourth quarter of 2018 and are expected to be paid in full in the first quarter of 2022 . 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 and Kindeva approximately $63.0 million, in the aggregate, through December 31, 2021 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 abaloparatide-TD 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 and Kindeva approximately $31.8 million, in the aggregate, through December 31, 2021 with respect to performance under the Development Agreement.

Manufacturing Agreements

In June 2016, the Company 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. The Company agreed to purchase a minimum number of devices at prices per device that decrease with an increase in quantity supplied. In addition, the Company 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 renewed for a two-year term. Following its current term, the agreement automatically renews for additional two-year terms, unless either party terminates the agreement upon 18 months' notice prior to the end of the then-current term. During the two-year term beginning of May 2020, the Company is required to purchase a minimum number of batches for CHF 1.9 million ($2.0 million) through the year ended December 31, 2022.

In June 2016, the Company entered into a Commercial Supply Agreement with Vetter Pharma International GmbH ("Vetter"), as amended, pursuant to which Vetter has agreed to formulate the finished abaloparatide-SC drug product containing the active pharmaceutical ingredient ("API"), 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 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 term of the agreement automatically renewed on January 1, 2021 for an additional two-year term and will automatically renew for additional two-year terms thereafter 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 ("PPL"), as amended, 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 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 ($3.2 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.

Asset Purchase Agreement

In December 2020, the Company entered into an Asset Purchase Agreement with Fresh Cut Development, LLC and Benuvia Therapeutics Inc. for the acquisition of certain assets related to formulations of CBD related to the oral administration of a solution of CBD for therapeutic use in humans or animals. Under the terms of the agreement, the Company may be obligated to make additional payments of up to $60.0 million in future periods, which would become due and payable only upon the achievement of certain development milestones. In addition, the Company may be obligated to pay up to $30.0 million in sales milestones contingent upon the realization of sales revenues and sublicense revenue. As of December 31, 2021, the Company recognized a liability of $2.5 million, which is recorded as accrued expenses and other current liabilities within the consolidated balance sheet for certain development milestones that were deemed probable of achievement.

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 TYMLOS and service fees. As of December 31, 2020, the Company recognized net revenues of approximately $23.7 million from ABC in connection with product sales of TYMLOS and paid ABC and its affiliates approximately $2.7 million for services under various commercial and services agreements. This relationship was terminated in January 2021 due to the departure of the director.

18. Leases

The Company has operating leases for corporate offices in Boston, MA, Waltham, MA, Wayne, PA, Durham, NC and for a research laboratory in Chandler, AZ. These leases have remaining lease terms of less than one year to four 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 Kindeva 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*, 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, 2020, 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. As a result, costs will be recognized to research and development expense as incurred through completion since the equipment was again assessed to not have alternative future use to the Company and/or Kindeva.

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.

On January 28, 2020, the Company amended the Waltham, MA operating lease, extending the lease expiration. In connection with the amendment, the Company remeasured the net present value of the remaining lease payments of the right-of-use assets and lease liabilities to a total of $2.1 million as of January 28, 2020. The Company recorded a total adjustment of $1.1 million to increase both the right-of-use assets and lease liabilities during the twelve months ended December 31, 2020.

On August 10, 2020, the Company announced a shift to a hybrid work model and the plan to vacate its current corporate offices, which triggered the Company to assess the recoverability of its long lived assets, including right-of-use assets. In connection with this assessment, the Company recorded an impairment loss on right-of-use assets of $1.5 million and $0.9 million related to the Waltham, MA and Wayne, PA offices, respectively, during the twelve months ended December 31, 2020.

On October 27, 2020, the Company entered into a fourteen-month operating lease for corporate office space in Boston, Massachusetts (the "Boston Lease"). The Boston Lease commenced in November 2020 when the Company took possession of the space. After the initial two-month free rent period following possession of the space, the operating lease will continue for a term of twelve-months. The lease automatically extends for an additional twelve-month period, unless written notice is provided to the landlord no later than two-months prior to the expiration of the then current Boston Lease term. The Company did not believe the exercise of the extension to be reasonably certain as of the lease commencement date and therefore did not include the extension as part of its recognized lease asset and lease liability. In November 2021, the Company extended the

lease for an additional twelve months, and the Company increased the right-of-use asset and lease liability by approximately $0.3 million.

On May 19, 2021, the Company entered into a Surrender Agreement (the "Surrender Agreement") with Rovi Corporation ("Sublandlord") with respect to certain premises located in Wayne, PA (the "Premises"). The Surrender Agreement provides that the Company surrender the Premises to Sublandlord, and the Sublease Agreement, dated March 11, 2016, by and between the Company and Sublandlord will terminate by May 31, 2021.

In connection with the Surrender Agreement and to accelerate the expiration date of the term of the Sublease, the Company paid the Sublandlord a surrender fee of $1.0 million (the "Surrender Fee") and recorded a gain of $0.9 million related to the termination of the lease during the twelve months ended December 31, 2021. The Surrender Fee serves as the final payment by the Company under the Sublease.

On May 21, 2021, the Company entered into a three-year operating lease for office space in Durham, North Carolina (the "Durham Lease"), and recorded a right-of-use asset and lease liability of approximately $0.3 million. The Company has the right to extend the term of the Durham Lease for one additional three-year term, which the Company did not include in the recognized right-of-use asset and lease liability as the Company did not believe the exercise of the extension to be reasonably certain as of the lease commencement date.

On August 25, 2021, the Company entered into a four-year operating sublease for laboratory and office space in Chandler, AZ (the "Arizona Lease"), and recorded a right-of-use asset and lease liability of approximately $0.2 million. The Company does not have a right to extend the term of the Arizona Lease.

On December 7, 2021, the Company entered into a lease assignment and assumption agreement for the Arizona Lease, where the Company will terminate the sublease agreement and assume the rights, title, and interest in the sublandlord's original lease as of January 1, 2022, the effective date of the lease assignment and assumption agreement. There is no early termination fee in connection with the lease assignment and assumption. The Company will account for the lease assignment and assumption as of the effective date, January 1, 2022, in accordance with ASC 842.

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, 2021, 2020, and 2019 the components of lease expense were as follows (in thousands):

	Year ended December 31,		
	2021	2020	2019
Operating lease cost	$ 2,311	$ 2,555	$ 2,742
Variable lease cost	111	370	124
Total lease cost	$ 2,422	$ 2,925	$ 2,866

As of December 31, 2021, and 2020 the weighted average remaining lease term for the Company's operating leases was 1.90 years and 3.70 years respectively.

As of December 31, 2021, and 2020 the weighted average discount rate for the Company's operating leases was 3.48% and 5.75%.

Future payments of operating lease liabilities as of December 31, 2021 are as follows (in thousands):

Year ending December 31,	
2022	633
2023	176
2024	120
2025	30
Total Lease payments	959
Less: effect of discounted cash flows during the period	(31)
Total	$ 928

As of December 31, 2021, the Company had no short-term leases and there were no operating or finance leases that have not yet commenced.

19. Subsequent Events

The Company has evaluated the subsequent events that have occurred through the date of the report and determined that there are no material subsequent events that require disclosure.

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

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, 2021.

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, 2021, 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, 2021.

The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by Deloitte & Touche 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, 2021 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 stockholders and the Board of Directors of Radius Health, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Radius Health, Inc. and subsidiaries (the "Company") as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013) issued by COSO*.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2021, of the Company and our report dated February 24, 2022, expressed an unqualified opinion on those financial statements and included an explanatory paragraph regarding the Company's change in accounting principle applied to its convertible senior notes effective January 1, 2021.

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/ Deloitte & Touche LLP

Boston, Massachusetts
February 24, 2022

ITEM 9B. OTHER INFORMATION.

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

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 8, 2022. 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 2022 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 2022 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 2022 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 2022 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 2022 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		3.2	9/27/2021	
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	10-K		4.5	2/27/2020	
	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-K		10.3(a)	2/27/2020	

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-Q	10.1	05/07/2021
10.6	Form of Executive Severance Agreement	10-K	10.8	2/25/2021
10.7	Form of Indemnification Agreement between the Company and its Directors	10-K	10.18	2/28/2019
10.8	Form of Indemnification Agreement between the Company and its Officers	10-K	10.19	2/28/2019
10.9	Radius Health, Inc. Form of Employment Inducement Stock Option Agreement	10-Q	10.4	8/7/2018
10.10	Employment Agreement, dated April 24, 2020, between the Company and G. Kelly Martin	8-K	10.1	4/28/2020
10.11	Non-Qualified Stock Option Agreement, Inducement Stock Option Grant (Time-Based), dated April 28, 2020, between the Company and G. Kelly Martin	8-K	10.2	4/28/2020
10.12	Non-Qualified Stock Option Agreement, Inducement Stock Option Grant (Performance-Based), dated April 28, 2020, between the Company and G. Kelly Martin	8-K	10.3	4/28/2020
	Other Agreements			
10.13^^	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-Q	10.1	8/5/2021
10.14^	Scale-Up and Commercial Supply Agreement, dated February 27, 2018, between the Company and Kindeva Drug Delivery L.P., (formerly 3M Company and 3M Innovative Properties Company)	10-Q	10.1	5/10/2018
10.15^^	License Agreement, dated June 29, 2006, between the Company and Eisai Co., Ltd.	10-Q	10.3	8/5/2021
10.15(a)	License Agreement Amendment No. 1, dated March 9, 2015, between the Company and Eisai Co., Ltd.	10-Q	10.3	5/6/2015
10.16^	License and Development Agreement, dated July 13, 2017, between the Company and Teijin Limited	10-Q	10.1	11/2/2017
10.17^	Supply Agreement, dated June 23, 2016, between the Company and Ypsomed AG	10-Q	10.1	8/4/2016
10.17(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
10.17(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

10.18^^	Commercial Supply Agreement, dated June 28, 2016, between the Company and Vetter Pharma International GmbH	10-Q	10.2	8/5/2021
10.18(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-K	10.20(a)	2/27/2020
10.19^	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
10.19(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
10.19(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
10.20	Indenture of Lease, dated May 14, 2014, between the Company and BP Bay Colony LLC	8-K	10.1	5/20/2014
10.20(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
10.20(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
10.20(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
10.20(d)	Fourth Amendment, dated January 28, 2020, to Lease, dated May 14, 2014, between the Company and BP Bay Colony LLC	10-K	10.22(d)	2/27/2020
10.21	Lease, dated June 28, 2017, between the Company and KBSIII Crosspoint at Valley Forge Trust	10-Q	10.1	8/4/2017
10.22	Sublease, dated March 11, 2016, between the Company and Rovi Corporation	10-Q	10.2	8/4/2017
10.22(a)	Surrender Agreement, dated May 19, 2021, by and between Rovi Corporation and Radius Health, Inc.	8-K	10.1	5/21/2021
10.23	Amended and Restated Credit and Security Agreement (Term Loan), dated as of March 3, 2021, by and among the Company, Radius Pharmaceuticals, Inc, Radius Health Ventures, Inc, and any additional borrower thereunder, MidCap Financial Trust, as a lender and administrative agent, and the financial institutions or other entities from time to time parties thereto	8-K	10.1	3/5/2021

10.24	Amended and Restated Credit and Security Agreement (Revolving Loan), dated as of March 3, 2021, by and among Radius Health, Inc., Radius Pharmaceuticals, Inc., Radius Health Ventures, Inc., and any additional borrower from time to time, MidCap Funding IV Trust, as a lender and administrative agent, and the financial institutions or other entities from time to time parties thereto	8-K	10.2	3/5/2021	
10.25	Partial Release and Acknowledgement, dated July 22, 2020, between the Company, Radius Pharmaceuticals, Inc., MidCap Financial Trust and MidCap Funding IV Trust	10-Q	10.2	11/5/2020	
10.26	License Agreement, dated July 23, 2020, between Radius Pharmaceuticals, Inc. and Berlin-Chemie AG – Menarini Group	10-Q	10.1	11/5/2020	
10.27^^	Asset Purchase Agreement, dated December 30, 2020, between Radius Pharmaceuticals, Inc. Benuvia Therapeutics Inc. and Fresh Cut Development LLC	10-K	10.37	2/25/2021	
21.1	Subsidiaries of the Company				*
23.1	Consent of Deloitte LLP, Independent Registered Public Accounting Firm (PCAOB ID #34)				*
23.2	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm (PCAOB ID #42)				*
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 is of the type that Radius Health, Inc. treats as private or confidential.

* 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/ G. Kelly Martin

G. Kelly Martin
President and Chief Executive Officer

Date: February 24, 2022

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/ G. KELLY MARTIN G. Kelly Martin	Chief Executive Officer and Director (Principal Executive Officer)	February 24, 2022
/s/ STEVEN HELWIG Steve Helwig	Principal Financial Officer (Principal Accounting and Financial Officer)	February 24, 2022
/s/ WILLARD H. DERE Willard H. Dere	Director	February 24, 2022
/s/ CATHERINE FRIEDMAN Catherine Friedman	Director	February 24, 2022
/s/ JEAN-PIERRE GARNIER Jean-Pierre Garnier	Director	February 24, 2022
/s/ OWEN HUGHES Owen Hughes	Director	February 24, 2022
/s/ SEAN MURPHY Sean Murphy	Director	February 24, 2022
/s/ MACHELLE SANDERS Machelle Sanders	Director	February 24, 2022
/s/ ANDREW VON ESCHENBACH Andrew von Eschenbach	Director	February 24, 2022

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 Health (Ireland) Limited	Ireland
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 Registration Statement No. 333-201610 on Form S-3 and Registration Statement Nos. 333-177800, 333-195521, 333-213081, 333-213082, 333-215552, 333-224882, 333-231327, 333-238117, and 333-226791 on Form S-8 of our reports dated February 24, 2022, relating to the financial statements of Radius Health, Inc. and subsidiaries (the "Company"), and the effectiveness of the Company's internal control over financial reporting, appearing in this Annual Report on Form 10-K of Radius Health, Inc. for the year ended December 31, 2021.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
February 24, 2022

Exhibit 23.2

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-3, File No. 333-201610) and related Prospectus of Radius Health, Inc. for the registration of common stock, preferred stock, warrants, and units;

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

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

6. Registration Statement (Form S-8, File Nos. 333-215552, 333-224882, and 333-231327, 333-238117) pertaining to Inducement Stock Option Agreements between Radius Health, Inc. and certain of its employees; and

7. Registration Statement (Form S-8, File No. 333-226791) pertaining to the 2018 Stock Option and Incentive Plan of Radius Health, Inc.;

of our report dated February 27, 2020, with respect to the consolidated financial statements of Radius Health, Inc. for the year ended December 31, 2019 included in this Annual Report (Form 10-K) for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 24, 2022

Exhibit 31.1

CERTIFICATIONS

I, G. Kelly Martin, 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 24, 2022

/s/ G. Kelly Martin

G. Kelly Martin
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, Steven Helwig, 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 24, 2022

/s/ Steven Helwig

Steven Helwig
Principal Accounting and 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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, G. Kelly Martin, 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 24, 2022

By: /s/ G. Kelly Martin
G. Kelly Martin
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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven Helwig, 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 24, 2022

By: /s/ Steven Helwig
Steven Helwig
Principal Accounting and 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.