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

**FORM 10-Q**

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

For the quarterly period ended March 31, 2019  
Or

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

For the transition period from            to            .

Commission File Number 001-35726

**Radius Health, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
Incorporation or organization)

**80-0145732**  
(IRS Employer  
Identification Number)

**950 Winter Street**  
**Waltham, Massachusetts 02451**  
(Address of Principal Executive Offices and Zip Code)

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

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

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 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

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

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
<b>Common Stock, \$0.0001 par value per share</b>	<b>RDUS</b>	<b>The NASDAQ Global Market</b>

Number of shares of the registrant's Common Stock, \$0.0001 par value per share, outstanding as of May 6, 2019: 46,107,383 shares

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**RADIUS HEALTH, INC.**  
**FORM 10-Q**  
**FOR THE QUARTER ENDED MARCH 31, 2019**

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**Item 1. Condensed Consolidated Financial Statements**

**Radius Health, Inc.**  
**Condensed Consolidated Balance Sheets**  
(Unaudited, in thousands, except share and per share amounts)

	March 31, 2019	December 31, 2018
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 71,504	\$ 59,321
Restricted cash	562	560
Marketable securities	132,679	177,140
Accounts receivable, net	20,750	16,758
Inventory	5,646	6,210
Prepaid expenses	12,372	13,842
Other current assets	2,651	1,202
Total current assets	246,164	275,033
Property and equipment, net	3,570	4,003
Intangible assets	7,182	7,382
Right of use assets - operating leases	7,450	—
Other assets	501	544
Total assets	\$ 264,867	\$ 286,962
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 9,880	\$ 4,226
Accrued expenses and other current liabilities	35,632	42,203
Operating lease liability, current	2,168	—
Total current liabilities	47,680	46,429
Notes payable	183,556	179,806
Operating lease liability, long term	5,556	—
Other non-current liabilities	71	95
Total liabilities	236,863	226,330
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.0001 par value; 200,000,000 shares authorized, 45,967,080 shares and 45,563,693 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	5	5
Additional paid-in-capital	1,174,661	1,165,003
Accumulated other comprehensive loss	(281)	(755)
Accumulated deficit	(1,146,381)	(1,103,621)
Total stockholders' equity	28,004	60,632
Total liabilities and stockholders' equity	\$ 264,867	\$ 286,962

See accompanying notes to unaudited condensed consolidated financial statements.

**Radius Health, Inc.**  
**Condensed Consolidated Statements of Operations and Comprehensive Loss**  
(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2019	2018
<b>REVENUES:</b>		
Product revenue, net	\$ 29,844	\$ 14,547
<b>OPERATING EXPENSES:</b>		
Cost of sales - product	3,030	1,088
Cost of sales - intangible amortization	200	200
Research and development	23,259	22,851
Selling, general and administrative	41,186	48,025
Loss from operations	(37,831)	(57,617)
<b>OTHER (EXPENSE) INCOME:</b>		
Other income (expense)	4	(104)
Interest expense	(6,037)	(5,566)
Interest income	1,104	1,732
<b>NET LOSS</b>	<u>\$ (42,760)</u>	<u>\$ (61,555)</u>
<b>OTHER COMPREHENSIVE LOSS:</b>		
Unrealized gain (loss) from available-for-sale debt securities	474	(1,169)
<b>COMPREHENSIVE LOSS</b>	<u>\$ (42,286)</u>	<u>\$ (62,724)</u>
<b>LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED</b> (Note 11)	<u>\$ (42,760)</u>	<u>\$ (61,555)</u>
<b>LOSS PER SHARE:</b>		
Basic and diluted	<u>\$ (0.94)</u>	<u>\$ (1.37)</u>
<b>WEIGHTED AVERAGE SHARES:</b>		
Basic and diluted	<u>45,671,502</u>	<u>44,937,776</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**Radius Health, Inc.**  
**Condensed Consolidated Statements of Cash Flows**  
(Unaudited, in thousands)

	Three Months Ended March 31,	
	2019	2018
<b>CASH FLOWS USED IN OPERATING ACTIVITIES:</b>		
Net loss	\$ (42,760)	\$ (61,555)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	633	671
Amortization of discount on marketable securities, net	(65)	(180)
Amortization of debt discount and debt issuance costs	3,750	3,278
Impairment loss on operating lease right of use assets	339	—
Stock-based compensation	6,114	7,549
Changes in operating assets and liabilities:		
Inventory	564	(1,072)
Accounts receivable, net	(3,992)	(3,607)
Prepaid expenses	1,470	(1,254)
Other current assets	446	(50)
Operating lease right of use assets	500	—
Other long-term assets	43	43
Accounts payable	5,654	610
Accrued expenses and other current liabilities	(6,571)	(14,641)
Lease liability, operating leases	(565)	—
Other non-current liabilities	(24)	(24)
Net cash used in operating activities	(34,464)	(70,232)
<b>CASH FLOWS PROVIDED BY INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	—	(61)
Purchases of marketable securities	—	(500)
Sales and maturities of marketable securities	45,000	—
Net cash provided by (used in) investing activities	45,000	(561)
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options and warrant exercises	622	6,576
Proceeds from issuance of shares under employee stock purchase plan	1,027	1,741
Net cash provided by financing activities	1,649	8,317
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	12,185	(62,476)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF YEAR	59,881	118,619
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF PERIOD	\$ 72,066	\$ 56,143
<b>SUPPLEMENTAL DISCLOSURES:</b>		
Cash paid for interest	4,575	—
Property and equipment purchases in accrued expenses at period end	—	287
Receivable due from stock options exercises	1,895	—
Cash paid for amounts included in the measurement of operating lease liabilities	685	—
Right of use assets obtained in exchange for operating lease liability	8,289	—

See accompanying notes to unaudited condensed consolidated financial statements.

**Radius Health, Inc.**  
**Condensed Consolidated Statements of Stockholders' Equity**  
(Unaudited, 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
	Shares	Amount	Amount	Amount	Amount	Amount
Balance at December 31, 2017	44,616,586	\$ 4	\$ 1,124,630	\$ (314)	\$ (882,284)	\$ 242,036
Net loss					(61,555)	(61,555)
Unrealized loss from available-for-sale securities				(1,169)		(1,169)
Vesting of restricted shares	16,111					—
Exercise of options	413,686	1	6,575			6,576
Exercise of warrants	113,314					—
Share-based compensation expense related to share-based awards for employee stock purchase plan			162			162
Issuance of common stock upon purchase by employee stock purchase plan	54,690		1,741			1,741
Share-based compensation expense			7,387			7,387
Balance at March 31, 2018	<u>45,214,387</u>	<u>\$ 5</u>	<u>\$ 1,140,495</u>	<u>\$ (1,483)</u>	<u>\$ (943,839)</u>	<u>\$ 195,178</u>
Balance at December 31, 2018	45,563,693	5	1,165,003	(755)	(1,103,621)	60,632
Net loss					(42,760)	(42,760)
Unrealized gain from available-for-sale securities				474		474
Vesting of restricted shares	73,113					—
Exercise of options	185,438		1,517			1,517
Exercise of warrants	81,104		1,000			1,000
Share-based compensation expense related to share-based awards for employee stock purchase plan			181			181
Issuance of common stock upon purchase by employee stock purchase plan	63,732		1,027			1,027
Share-based compensation expense			5,933			5,933
Balance at March 31, 2019	<u>45,967,080</u>	<u>\$ 5</u>	<u>\$ 1,174,661</u>	<u>\$ (281)</u>	<u>\$ (1,146,381)</u>	<u>\$ 28,004</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**Radius Health, Inc.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**1. Organization**

Radius Health, Inc. (“Radius” or the “Company”) is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics in the areas of osteoporosis and oncology. In April 2017, the Company’s first commercial product, TYMLOS® (abaloparatide) injection, was approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In March 2018, the Committee for Medicinal Products for Human Use (“CHMP”) of the European Medicines Agency (“EMA”) adopted a negative opinion on the Company’s European Marketing Authorisation Application (“MAA”) for abaloparatide-SC. In July 2018, following a re-examination procedure, the CHMP maintained its negative opinion and on January 7, 2019, the European Commission adopted a decision refusing approval of the MAA on the basis of the negative opinion of the Committee. In July 2017, the Company entered into a license and development agreement with Teijin Limited (“Teijin”) for abaloparatide for subcutaneous injection (“abaloparatide-SC”) in Japan, under which the Company received an upfront payment and is entitled to receive milestone payments upon the achievement of certain regulatory and sales milestones, and a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term. In addition, the Company has an option to negotiate for a co-promotion agreement with Teijin for abaloparatide-SC in Japan. The Company is developing an abaloparatide transdermal patch, or abaloparatide-patch, for potential use in the treatment of postmenopausal women with osteoporosis. The Company is also developing an investigational product candidate, elacestrant (“RAD1901”), a selective estrogen receptor degrader (“SERD”), for potential use in the treatment of hormone receptor-positive breast cancer. The Company is developing its internally discovered investigational product candidate, RAD140, a non-steroidal selective androgen receptor modulator (“SARM”) for potential use in the treatment of hormone receptor-positive breast cancer.

The Company is subject to the risks associated with biopharmaceutical companies with a limited operating history, including dependence on key individuals, a developing business model, the necessity of securing regulatory approvals to market its investigational product candidates, market acceptance and the successful commercialization of TYMLOS, or any of the Company’s investigational product candidates following receipt of regulatory approval, competition for TYMLOS or any of the Company’s investigational product candidates following receipt of regulatory approval, and the continued ability to obtain adequate financing to fund the Company’s future operations. The Company has incurred losses and expects to continue to incur additional losses for the foreseeable future. As of March 31, 2019, the Company had an accumulated deficit of \$1,146.4 million, and total cash, cash equivalents, restricted cash, marketable securities, and investments of \$204.7 million.

Based upon its cash, cash equivalents, marketable securities, and investments as of March 31, 2019, the Company believes that, prior to the consideration of revenue from the potential future sales of any of its investigational product candidates that may receive regulatory approval or proceeds from partnering and/or collaboration activities, it has sufficient capital to fund its development plans, U.S. commercial scale-up and other operational activities, for at least one year from the date of this filing. The Company expects to finance the future development costs of its clinical product portfolio with its existing cash and cash equivalents, marketable securities, and investments, or through strategic financing opportunities that could include, but are not limited to collaboration agreements, future offerings of its equity, or the incurrence of debt. However, there is no guarantee that any of these strategic or financing opportunities will be executed or executed on favorable terms, and some could be dilutive to existing stockholders. If the Company fails to obtain additional future capital, it may be unable to complete its planned preclinical studies and clinical trials and obtain approval of certain investigational product candidates from the FDA or foreign regulatory authorities.

**2. Basis of Presentation and Significant Accounting Policies**

*Basis of Presentation*—The accompanying unaudited condensed consolidated financial statements and the related disclosures of the Company have been prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”) for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (including those which are normal and recurring) considered necessary for a fair presentation of the interim financial information have been included.

When preparing financial statements in conformity with U.S. GAAP, the Company must make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the financial statements. Actual results could differ from those estimates. Additionally, operating results for the three months ended March 31, 2019 are not

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necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2019. Subsequent events have been evaluated up to the date of issuance of these financial statements. These interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 ("2018 Form 10-K"), filed with the Securities and Exchange Commission ("SEC") on February 28, 2019.

Certain prior period amounts have been reclassified to conform to the current period presentation.

**Significant Accounting Policies**—The significant accounting policies identified in the Company's 2018 Form 10-K that require the Company to make estimates and assumptions include: revenue recognition, inventory obsolescence, long-lived assets and intangible assets, accounting for stock-based compensation, contingencies, tax valuation reserves, fair value measures, and accrued expenses. There were no changes to significant accounting policies during the three months ended March 31, 2019, except for the adoption of the Accounting Standards Updates ("ASU") issued by the Financial Accounting Standards Board ("FASB") detailed below.

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

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

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

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

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

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

(2) Represents recognition of operating lease liabilities.

The Company implemented internal controls to enable the preparation of financial information upon adoption.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 amends ASC 718, *Compensation-Stock Compensation*, to expand the scope of the standard to include accounting for share-based payment transactions for acquiring goods and services from non-employees. The amendments in ASU 2018-07 are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2018. Early adoption is permitted. The Company

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adopted ASU 2018-07 as of January 1, 2019, and it did not have a material impact on the Company's condensed consolidated financial statements.

In July 2018, the FASB issued ASU 2018-09, *Codification Improvements*, or ("ASU 2018-09"). This amendment makes changes to a variety of topics to clarify, correct errors in, or make minor improvements to the ASC. The majority of the amendments in ASU 2018-09 will be effective for the Company in annual periods beginning after December 15, 2018. The Company adopted ASU 2018-09 as of January 1, 2019 and it did not have a material impact on the Company's condensed consolidated financial statements.

On August 17, 2018, the SEC issued an amendment to Rule 3-04 of Regulation S-X, which extended the annual disclosure requirement of reporting changes in stockholders' equity to interim periods. Such disclosures are to be provided in a note to the financial statements or in a separate financial statement and requires both the year-to-date information and subtotals for each interim period. On September 25, 2018, the SEC issued guidance under a Compliance and Disclosure Interpretation (C&DI 105.09) to clarify the effective date of the requirement. Under the guidance in C&DI 105.09, the Company implemented this updated disclosure requirement beginning with its Form 10-Q for the first quarter 2019 herein, specifically by presenting the Company's condensed consolidated statement of stockholders' equity for the three months ended March 31, 2019 and 2018.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808), Clarifying the Interaction between Topic 808 and Topic 606* ("ASU 2018-18"). The amendments in ASU 2018-18 clarify that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer in the context of a unit of account. The amendments under ASU 2018-18 are effective for interim and annual fiscal periods beginning after December 15, 2019, with early adoption permitted. The amendments in ASU 2018-18 should be applied retrospectively to the date of initial application of ASC 606. The Company adopted ASU 2018-18 as of January 1, 2019 and it did not have a material impact on the Company's condensed consolidated financial statements, as each of the Company's arrangements detailed below within Note 12, "License Agreements," were previously accounted for under ASC 606 and/or other topics of the ASC, not ASC 808, and the Company has no other arrangements within the scope of ASC 808.

*Accounting Standards Updates, Recently Issued*— In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. The amendments under ASU 2016-13 are effective for interim and annual fiscal periods beginning after December 15, 2019. The Company is currently evaluating the effects the adoption of ASU 2016-13 will have on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement - Disclosure Framework-Changes to the Disclosure Requirement for Fair Value Measurement*, or ("ASU 2018-13"). The amendments in ASU 2018-13 modify the disclosure requirements on fair value measurements in Topic 820, *Fair Value Measurement*, based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendment under ASU 2018-13 are effective for interim and annual fiscal periods beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the effects the adoption of ASU 2018-13 will have on its consolidated financial statements and related disclosures.

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

### **3. Marketable Securities**

Available-for-sale marketable securities and cash and cash equivalents as of March 31, 2019 and December 31, 2018 consist of the following (in thousands):

March 31, 2019				
	Amortized Cost Value	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	\$ 60,535	\$ —	\$ —	\$ 60,535
Money market funds	10,969	—	—	10,969
Total	<u>\$ 71,504</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 71,504</u>
Marketable securities:				
Domestic corporate debt securities	\$ 87,940	\$ —	\$ (180)	\$ 87,760
Agency bonds	45,020	—	(101)	44,919
Total	<u>\$ 132,960</u>	<u>\$ —</u>	<u>\$ (281)</u>	<u>\$ 132,679</u>

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

There were 17 marketable securities with an aggregate fair value of \$132.7 million in an unrealized loss position for more than 12 months as of March 31, 2019. There were 24 marketable securities with an aggregate fair value of \$177.1 million in an unrealized loss position for more than 12 months as of December 31, 2018. The Company considered the decrease in market value for these securities to be primarily attributable to current economic conditions. As it was not more likely than not that the Company would be required to sell these securities before the recovery of their amortized cost basis, which may be at maturity, the Company did not consider these investments to be other-than-temporarily impaired as of March 31, 2019.

As of March 31, 2019, the aggregate fair value of marketable securities maturing within one year and after one year through two years was \$132.7 million and \$0, respectively.

#### 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 material transfers between any levels during the three months ended March 31, 2019. There were no material transfers between any levels during 2018.

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The following table summarizes the financial instruments measured at fair value on a recurring basis in the Company's accompanying condensed consolidated balance sheets as of March 31, 2019 and December 31, 2018 (in thousands):

	As of March 31, 2019			
	Level 1	Level 2	Level 3	Total
<b>Assets</b>				
Cash and cash equivalents:				
Cash	\$ 60,535	\$ —	\$ —	\$ 60,535
Money market funds (1)	10,969	—	—	10,969
<b>Total</b>	<b>\$ 71,504</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 71,504</b>
Marketable Securities				
Domestic corporate debt securities (2)	\$ —	\$ 87,760	\$ —	\$ 87,760
Agency bonds (2)	—	44,919	—	44,919
<b>Total</b>	<b>\$ —</b>	<b>\$ 132,679</b>	<b>\$ —</b>	<b>\$ 132,679</b>

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

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

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

## 5. Inventory

Inventory consisted of the following as of March 31, 2019 and December 31, 2018 (in thousands):

	March 31, 2019	December 31, 2018
Raw materials	\$ 4,172	\$ 4,961
Work in process	79	490
Finished goods	1,395	759
<b>Total inventories</b>	<b>\$ 5,646</b>	<b>\$ 6,210</b>

The Company began to capitalize the costs associated with the production of TYMLOS upon receipt of FDA approval on April 28, 2017.

Finished goods manufactured by the Company have a 36-month shelf life from date of manufacture.

## 6. Intangible Assets

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

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	March 31, 2019	December 31, 2018	Estimated useful life
Acquired and in-licensed rights	\$ 8,712	\$ 8,712	11 Years
Less: accumulated amortization	(1,530)	(1,330)	
Total intangible asset, net	<u>\$ 7,182</u>	<u>\$ 7,382</u>	

Acquired and in-licensed rights as of March 31, 2019 consist of the €8.0 million (approximately \$8.7 million on the date paid) milestone paid to Ipsen, which was triggered by FDA approval of TYMLOS on April 28, 2017.

The Company recorded approximately \$0.2 million in amortization expense related to intangible assets, using the straight-line methodology, which is considered the best estimate of economic benefit, during the three months ended March 31, 2019. Estimated future amortization expense for intangible assets as of March 31, 2019 is approximately \$0.6 million for the remainder of 2019, and approximately \$0.8 million per year over the remaining life.

## 7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following for the periods set forth below (in thousands):

	March 31, 2019	December 31, 2018
Commercial costs	\$ 3,967	\$ 2,884
Product revenue reserves	13,014	7,620
Royalty payable	1,505	1,735
Research and development costs	5,931	10,403
Payroll and employee benefits	6,456	12,230
Interest	763	3,050
Professional fees	3,481	3,465
Restructuring costs	420	613
Other current liabilities	95	203
Total accrued expenses and other current liabilities	<u>\$ 35,632</u>	<u>\$ 42,203</u>

## 8. Convertible Notes Payable

On August 14, 2017, in a registered underwritten public offering, the Company issued \$300 million aggregate principal amount of 3% Convertible Senior Notes due September 1, 2024 (the “Convertible Notes”). In addition, on September 12, 2017, the Company issued an additional \$5.0 million principal amount of Convertible Notes pursuant to the exercise of an over-allotment option granted to the underwriters in the offering. In accordance with accounting guidance for debt with conversion and other options, the Company separately accounted for the liability component (“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 condensed consolidated balance sheet. The portion allocated to the liability component is amortized to interest expense using the effective interest method over seven years.

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

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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) during any calendar quarter commencing after the calendar quarter ending on December 31, 2017 (and only during such calendar quarter), if the last reported sale price of the Company's common stock for at least 20 trading days (whether consecutive or not) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;
- (2) during the five-business day period after any five-consecutive trading day period (the "measurement period") in which the "trading price" per \$1,000 principal amount of the Convertible Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day;
- (3) if the Company calls the Convertible Notes for redemption, until the close of business on the business day immediately preceding the redemption date; or
- (4) upon the occurrence of specified corporate events.

As of March 31, 2019, none of the above circumstances had occurred and as such, the Convertible Notes were not convertible.

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

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 \$166.3 million on their respective dates of issuance. The excess of the principal amount of the Liability Component over its carrying amount (the "Debt Discount") is amortized to interest expense using the effective interest method over seven years. The Equity Component is not remeasured as long as it continues to meet the conditions for equity classification. In connection with issuance of the Convertible Notes, the Company also incurred certain offering costs directly attributable to the offering. Such costs are deferred and amortized over the term of the debt to interest expense using the effective interest method. A portion of the deferred financing costs incurred in connection with the Convertible Notes was deemed to relate to the Equity Component and was allocated to additional paid-in capital.

The outstanding balances of the Convertible Notes as of March 31, 2019 consisted of the following (in thousands):

	<b>2024 Convertible Notes</b>	
Liability component:		
Principal	\$	305,000
Less: debt discount and issuance costs, net	\$	(121,444)
Net carrying amount	\$	183,556
Equity component:	\$	134,450

The Company determined the expected life of the Convertible Notes was equal to its seven-year term. The effective interest rate on the Liability Components of the Convertible Notes for the period from the date of issuance through March 31, 2019 was

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13.04%. As of March 31, 2019, the “if-converted value” did not exceed the remaining principal amount of the Convertible Notes. 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, and, therefore, the Convertible Notes are classified within Level 2 in the fair value hierarchy. The fair value of the Convertible Notes, which differs from their carrying value, is influenced by interest rates, the Company’s stock price and stock price volatility. The estimated fair value of the Convertible Notes as of March 31, 2019 was approximately \$254.3 million.

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

	Three Months Ended March 31,	
	2019	2018
Contractual interest expense	\$ 2,287	\$ 2,288
Amortization of debt discount	3,614	3,159
Amortization of debt issuance costs	136	119
<b>Total interest expense</b>	<b>\$ 6,037</b>	<b>\$ 5,566</b>

Future minimum payments on the Company’s long-term debt as of March 31, 2019 are as follows (in thousands):

Years ended December 31,	Future Minimum Payments	
2019	\$	4,575
2020		9,150
2021		9,150
2022		9,150
2023		9,150
2024 and Thereafter		314,150
<b>Total minimum payments</b>	<b>\$</b>	<b>355,325</b>
Less: interest		(50,325)
Less: unamortized discount		(121,444)
Less: current portion		—
<b>Long Term Debt</b>	<b>\$</b>	<b>183,556</b>

## 9. Stock-Based Compensation

### Stock Options

A summary of stock option activity during the three months ended March 31, 2019 is as follows (in thousands, except for per share amounts):

	Shares	Weighted- Average Exercise Price (in dollars per share)	Weighted- Average Contractual Life (in years)	Aggregate Intrinsic Value
Options outstanding at December 31, 2018	5,463	\$ 36.88		
Granted	808	18.96		
Exercised	(185)	8.18		
Canceled	(176)	38.81		

Expired	(136)	48.48		
Options outstanding at March 31, 2019	5,774	\$ 34.96	7.39	\$ 5,775
Options exercisable at March 31, 2019	3,226	\$ 38.13	6.17	\$ 4,791

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The weighted-average grant-date fair value per share of options granted during the three months ended March 31, 2019 was \$12.45. As of March 31, 2019, there was approximately \$41.1 million of total unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.67 years.

*Restricted Stock Units*

A summary of RSU activity during the three months ended March 31, 2019 is as follows (in thousands, except for per share amounts):

	RSUs	Weighted-Average Grant Date Fair Value (in dollars per share)
RSUs Outstanding at December 31, 2018	227	\$ 37.69
Granted	422	19.17
Vested	(73)	38.75
Forfeited	(19)	37.32
RSUs Outstanding at March 31, 2019	557	\$ 23.48

As of March 31, 2019, there was approximately \$12.4 million of total unrecognized compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 3.20 years.

*Performance Units*

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

A summary of PSU activity during the three months ended March 31, 2019 is as follows (in thousands, except for per share amounts):

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

As the performance condition must be met for the awards to vest, compensation cost will be recognized over the implicit service period and only if the performance condition is assessed as probable of achievement.

*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.

As of March 31, 2019, the Company had recorded a liability of \$0.2 million related to its ESPP obligations. In accordance with the terms of its ESPP, the Company recorded stock-based compensation expense of \$0.2 million for the three-month period ended March 31, 2019.

## 10. 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 three months ended March 31, 2019 and 2018 (in thousands):

	Chargebacks, Discounts, and Fees	Government and other rebates	Returns	Total
Ending balance at December 31, 2017	\$ 1,986	\$ 1,231	\$ 421	\$ 3,638
Provision related to sales in the current year	2,194	3,835	76	6,105
Adjustments related to prior period sales	(25)	(96)	(124)	(245)
Credits and payments made	(1,798)	(1,159)	(24)	(2,981)
Ending balance at March 31, 2018	<u>\$ 2,357</u>	<u>\$ 3,811</u>	<u>\$ 349</u>	<u>\$ 6,517</u>
Ending balance at December 31, 2018	\$ 3,198	\$ 7,620	\$ 411	\$ 11,229
Provision related to sales in the current year	5,589	13,903	35	19,527
Adjustments related to prior period sales	(19)	(45)	(141)	(205)
Credits and payments made	(4,738)	(8,464)	(86)	(13,288)
Ending balance at March 31, 2019	<u>\$ 4,030</u>	<u>\$ 13,014</u>	<u>\$ 219</u>	<u>\$ 17,263</u>

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

## 11. Net Loss Per Share

Basic and diluted net loss per share for the periods set forth below is calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended March 31,	
	2019	2018
Numerator:		
Net loss	\$ (42,760)	\$ (61,555)
Denominator:		
Weighted-average number of common shares used in loss per share - basic and diluted	45,671,502	44,937,776
Loss per share - basic and diluted	<u>\$ (0.94)</u>	<u>\$ (1.37)</u>

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 three months ended March 31, 2019 and 2018, respectively, all the Company's options to purchase common stock, warrants, and restricted stock units outstanding were assumed to be anti-dilutive as earnings attributable to common stockholders was in a loss position.

	Three Months Ended March 31,	
	2019	2018
Options to purchase common stock	5,773,654	5,886,348
Warrants	—	425,283
Restricted stock units	557,150	336,240
Performance units	79,000	—

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 March 31, 2019, 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 during the three-month periods ended March 31, 2019 and 2018, respectively.

## 12. License Agreements

### 3M

In February 2018, the Company entered into a Scale-Up And Commercial Supply Agreement (the "Supply Agreement") with 3M Company and 3M Innovative Properties Company (collectively with 3M Company, "3M"), pursuant to which 3M agreed to exclusively manufacture Phase 3 and global commercial supplies of an abaloparatide-coated transdermal patch product ("Product") and associated applicator devices ("Applicator"). Under the Supply Agreement, 3M will manufacture Product and Applicator for the Company according to agreed-upon specifications in sufficient quantities to meet the Company's projected supply requirements. 3M will manufacture commercial supplies of Product at unit prices that decrease with an increase in the quantity the Company orders. The Company will pay 3M a mid-to-low single-digit royalty on worldwide net sales of Product and reimburse 3M for certain capital expenditures incurred to establish commercial supply of Product. The Company is responsible for providing, at its expense, supplies of abaloparatide drug substance to be used in manufacturing Product. During the term of the Supply Agreement, 3M and the Company have agreed to work exclusively with each other with respect to the delivery of abaloparatide, parathyroid hormone ("PTH"), and/or PTH related proteins via active transdermal, intradermal, or microneedle technology. In October 2018, the Company committed to fund 3M's purchase of capital equipment totaling approximately \$9.6 million in preparation for manufacturing Phase 3 and potential commercial supplies of Product. Milestone payments for the equipment commenced in the fourth quarter of 2018 and are expected to be completed in the third quarter of 2020.

The initial term of the Supply Agreement began on its effective date, February 27, 2018, and will continue for five years after the first commercial sale of Product. The Supply Agreement then automatically renews for successive three-year terms, unless earlier terminated pursuant to its terms or upon either party's notice of termination to the other 24 months prior to the end of the then-current term. The Supply Agreement may be terminated by either party upon an uncured material breach of its terms by the other party, or due to the other party's bankruptcy, insolvency, or dissolution. The Company may terminate the Supply Agreement upon the occurrence of certain events, including for certain clinical, technical, or commercial reasons impacting Product, if it is unable to obtain U.S. regulatory approval for Product within a certain time period, or if it ceases development or commercialization of Product. 3M may terminate the Supply Agreement upon the occurrence of certain events, including if there are certain safety issues related to Product, if the Company is unable to obtain U.S. regulatory approval for Product within a certain time period, or if the Company fails to order Product for a certain period of time after commercial launch of the Product in the U.S. Upon certain events of termination, 3M is required to transfer the manufacturing processes for Product and Applicator to the Company or a mutually agreeable third party and continue supplying Product and Applicator for a period of time pursuant to the Company's projected supply requirements.

In June 2009, the Company entered into a Development and Clinical Supplies Agreement with 3M, as amended (the "Development Agreement"), under which Product and Applicator development activities occur and 3M has manufactured phase 1 and 2 clinical trial supplies on an exclusive basis. The term of the Development Agreement runs until June 2019 and then automatically renews for additional one-year terms, unless earlier terminated, until the earliest of (i) the expiration or termination of the Supply Agreement, (ii) the mutual written agreement of the parties, or (iii) prior written notice by either party to the other party at least ninety days prior to the end of the then-current term of the Development Agreement that such party declines to extend the term. Either party may terminate the agreement in the event of an uncured material breach by the other party. The Company pays 3M for services delivered pursuant to the agreement on a fee-for-service or a fee-for-deliverable basis as specified in the agreement. The Company has paid 3M approximately \$26.7 million, in the aggregate, through March 31, 2019 with respect to services and deliverables delivered pursuant to the Development Agreement.

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### *Ipsen*

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

In consideration for these rights, 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 March 31, 2019. The License Agreement provides for further payments upon the achievement of certain future regulatory and commercial milestones. Total additional milestone payments that could be payable under the agreement are €24.0 million (approximately \$26.9 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 condensed consolidated balance sheet and will amortize over the remaining patent life or the estimated useful life of the underlying product. The agreement also provides that the Company will pay to Ipsen a fixed five percent royalty based on net sales of the product by the Company or its sublicensees on a country-by-country basis until the later of the last to expire of the licensed patents or for a period of 10 years after the first commercial sale in such country. The royalty expense was \$1.5 million and \$0.7 million for the three months ended March 31, 2019 and 2018, respectively, and is included within cost of sales within the condensed consolidated statement of operation and comprehensive loss. The date of the last to expire of the abaloparatide patents licensed from or co-owned with Ipsen, barring any extension thereof, is expected to be March 26, 2028.

If the Company sublicenses abaloparatide to a third party, then the agreement provides that the Company would pay Ipsen a percentage of certain payments received from such sublicensee (in lieu of milestone payments not achieved at the time of such sublicense). The applicable percentage is in the low double-digit range. In addition, if the Company or its sublicensees commercialize a product that includes a compound discovered by it based on or derived from confidential Ipsen know-how, then the agreement provides that the Company would pay to Ipsen a fixed low single-digit royalty on net sales of such product on a country-by-country basis until the later of the last to expire of licensed patents that cover such product or for a period of 10 years after the first commercial sale of such product in such country.

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

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

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commercialize elacestrant (RAD1901) and related products from Eisai in all countries, except Japan. In consideration for the rights to elacestrant, the Company paid Eisai an initial license fee of \$0.5 million, which was expensed during 2006. In March 2015, the Company entered into an amendment to the Eisai Agreement (the “Eisai Amendment”) in which Eisai granted to the Company the exclusive right and license to research, develop, manufacture and commercialize elacestrant in Japan. In consideration for the rights to elacestrant in Japan, the Company paid Eisai an initial license fee of \$0.4 million upon execution of the Eisai Amendment, which was recognized as research and development expense in 2015. The Eisai Agreement, as amended, also provides for additional payments of up to \$22.3 million, payable upon the achievement of certain clinical and regulatory milestones. To date, the Company has paid Eisai approximately \$1.0 million in connection with the achievement of certain milestones.

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

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

### *Duke University*

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

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

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

### *Teijin Limited*

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

Pursuant to the Teijin Agreement, the Company granted Teijin: (i) an exclusive payment-bearing license under certain of the Company’s intellectual property to develop and commercialize abaloparatide-SC in Japan, (ii) a non-exclusive payment-bearing license under certain of the Company’s intellectual property to manufacture abaloparatide-SC for commercial supply in Japan, (iii) a right of reference to certain of the Company’s regulatory data related to abaloparatide-SC for purposes of developing, manufacturing and commercializing abaloparatide-SC in Japan, (iv) a manufacture transfer package, upon Teijin’s request, consisting of information and the Company’s know-how that is necessary for the manufacture of active pharmaceutical ingredient and abaloparatide-SC, (v) a right to request that the Company manufacture (or arrange for a third party to

manufacture) and supply (or arrange for a third party to supply) the active pharmaceutical ingredient for the clinical supply of abaloparatide-SC in sufficient quantities to enable Teijin to conduct its clinical trials in Japan, and (vi) a right to request that the Company arrange for Teijin to directly enter into commercial supply agreements with the Company's existing contract manufacturers on the same pricing terms and on substantially similar commercial terms to those set forth in the Company's existing agreements with such contract manufacturers. In consideration for these rights, the Company received an upfront payment of \$10.0 million, and may receive further payments upon the achievement of certain regulatory and sales milestones, as well as a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term, as defined below. In addition, the Company has an option to negotiate a co-promotion agreement with Teijin for abaloparatide-SC in Japan upon commercialization.

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

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

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

The Company further determined that the up-front payment of \$10.0 million constituted the entirety of the consideration to be included in the transaction price, which was allocated to the performance obligations based on the Company's best estimate of their relative stand-alone selling prices. For the commercialization and manufacturing licenses, including the right of reference to certain regulatory information, the stand-alone selling price was calculated using the expected cost approach by leveraging the direct costs incurred by the Company in its recently completed ACTIVEExtend 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 which the Company received in October 2017. 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 March 31, 2019, and no amount will be recognized until the applicable regulatory milestones are achieved. The sales-based milestones and royalty payments subject to the sales and usage-based royalty exception will not be included in the transaction price until the underlying sales or sales-based milestones have been achieved.

### **13. Income Taxes**

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The Company did not record a federal or state income tax provision or benefit for each of the three months ended March 31, 2019 and 2018 due to the expected loss before income taxes to be incurred for the years ended December 31, 2019 and 2018, as well as the Company's continued maintenance of a full valuation allowance against its net deferred tax assets.

### **14. 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 condensed 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 condensed 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 March 31, 2019, the Company was not party to any significant litigation.

#### Manufacturing Agreements

In June 2016, the Company entered into a Supply Agreement with Ypsomed AG ("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 Company has agreed to purchase a minimum number of devices at prices per device that decrease with an increase in quantity supplied. In addition, the Company has agreed to make milestone payments for Ypsomed's capital developments in connection with the initiation of the commercial supply of the device and to pay a one-time capacity fee. All costs and payments under the agreement are delineated in Swiss Francs. The agreement has an initial term of three years, which began on June 1, 2017, after which it automatically renews for two-year terms unless either party terminates the agreement upon 18 months' notice prior to the end of the then-current term. The Company will purchase the devices subject to minimum annual quantity requirements over the initial three-year term of the agreement. The Company is required to purchase a minimum number of batches for CHF 2.4 million (approximately \$2.4 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"), pursuant to which Vetter has agreed to formulate the finished abaloparatide-SC drug product containing the active pharmaceutical ingredient of abaloparatide API, to fill cartridges with the drug product, to assemble the pen delivery device, and to package the pen for commercial distribution. The Company 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 agreement has an initial term of five years, which began on January 1, 2016, after which, it automatically renews for two-year terms unless either party notifies the other party two years before the end of the then-current term that it does not intend to renew.

In July 2016, the Company entered into a Manufacturing Services Agreement with Polypeptide Laboratories Holding AB ("PPL"), as successor-in-interest to Lonza Group Ltd., pursuant to which PPL 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 agreement has an initial term of six years, which began on June 28, 2016, 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. The Company is also required to purchase a minimum number of batches annually, equal to approximately €2.9 million (approximately \$3.3 million) per year, subject to any annual price adjustments, during the initial term, except in calendar years 2019 and 2020.

### **15. Leases**

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

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such options based on assessment of economic factors, such as contractual terms, market rates and locations, and costs associated with negotiation of new leases or termination of leases. Lease expense for operating lease payments is recognized on a straight-line basis over the lease term.

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

The Company has operating leases for corporate offices in Waltham, MA, Wayne, PA and Parsippany, NJ and for research laboratories in Boston, MA. These leases have remaining lease terms of one to seven years, excluding the lease in Boston, MA, which, at adoption, had a remaining lease term of less than one year, some of which include options to extend the leases for additional years, and some of which include options to terminate the lease upon default by the Company. The options to extend and terminate the leases were not incorporated into the determination of the lease term as the exercise of such options was not reasonably certain at the lease commencement date based on assessment of economic factors.

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

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

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

	<b>March 31, 2019</b>
Operating lease cost	\$ 685
Variable lease cost	16
Total lease cost	<u>\$ 701</u>

As of March 31, 2019, the weighted average remaining lease term for the Company's operating leases was 5.10 years.

As a discount rate was not directly observable for the operating leases, the discount rate used to calculate the net present value of future payments was the Company's incremental borrowing rate calculated at transition based on the remaining lease term for each operating lease. The incremental borrowing rate is the rate of interest that the Company would have to pay to borrow, on a collateralized basis over a similar term, an amount equal to the lease payments in a similar economic environment. In determining the incremental borrowing rate, the Company considered the following: (i) the Company's public credit rating, (ii) observable debt yields of the Company, as well as other bonds in the market issued by other companies with similar credit ratings as the Company, and (iii) adjustments necessary for collateral, lease term and inflation or foreign currency. As of March 31, 2019, the weighted average discount rate for the Company's operating leases was 6.06%.

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

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	Lease Liability
Beginning balance at December 31, 2018	\$ —
Transition adjustment recorded upon adoption	8,289
Payments during the period	(685)
Effect of discounted cash flows during the period	120
Ending balance at March 31, 2019	\$ 7,724

Maturities of operating lease liabilities as of March 31, 2019 are as follows (in thousands):

Year ending December 31,	
2019	\$ 1,998
2020	2,136
2021	1,060
2022	1,038
2023	980
Thereafter	1,863
Total Lease payments	\$ 9,075
Less: effect of discounted cash flows during the period	(1,351)
Total	\$ 7,724

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

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

### Cautionary Statement

*This Quarterly Report on Form 10-Q, including in the sections titled "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," and including the information incorporated by reference herein, 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 Quarterly Report on Form 10-Q may include, among other things, statements about:*

- our expectations regarding commercialization of TYMLOS in the U.S., including our market access coverage expectations, and our ability to successfully commercialize TYMLOS in the U.S.;*
- the therapeutic benefits and effectiveness of TYMLOS and our 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, including the approval of abaloparatide-SC outside of the U.S.;*
- our ability to compete with other companies that are or may be developing or selling products that are competitive with TYMLOS or our investigational product candidates;*
- anticipated trends and challenges in the market in which TYMLOS will compete and in other potential markets in which we may compete;*
- our plans with respect to collaborations and licenses related to the development, manufacture or sale of TYMLOS and our investigational product candidates, including our plans to enter into a global partnership for elacestrant;*
- our expectations regarding the timing of our regulatory submissions;*
- our expectations for our Phase 3 studies of elacestrant and abaloparatide-patch or our other clinical trials, including projected costs, study designs or the timing for initiation, recruitment or completion;*
- the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;*
- the safety profile and related adverse events of TYMLOS and our investigational product candidates;*
- the ability of our investigational product candidates to meet existing or future regulatory standards;*

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- our expectations regarding federal, state and foreign regulatory requirements;
- the success of our clinical studies for our investigational product candidates;
- our expectations as to future financial performance, expense levels, future payment obligations and liquidity sources;
- our ability to attract, motivate, and retain key personnel; and
- other factors discussed elsewhere in this Quarterly Report on Form 10-Q.

The outcome of the events described in these forward-looking statements is subject to known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from the results anticipated by these forward-looking statements. These important factors include our financial performance, the uncertainties inherent in the early stages of commercializing any new pharmaceutical product or the initiation, execution and completion of clinical trials, uncertainties surrounding the timing of availability of data from our clinical trials, ongoing discussions with and actions by regulatory authorities, our ability to attract and retain customers, our development activities and those other factors we discuss under the caption "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q and in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2018. You should read these factors and the other cautionary statements made in this Quarterly Report on Form 10-Q as being applicable to all related forward-looking statements wherever they appear in this Quarterly Report on Form 10-Q. These important factors are not exhaustive and other sections of this Quarterly Report on Form 10-Q may include additional factors which could adversely impact our business and financial performance.

You should read the following discussion of our financial condition and results of operations in conjunction with our financial statements and related notes set forth in this report. Unless the context otherwise requires, "we," "our," "us," "Radius," "Company," and similar expressions used in this Management's Discussion and Analysis of Financial Condition and Results of Operations section refer to Radius Health, Inc. and our consolidated entities.

### **Executive Overview**

We are a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics in the areas of osteoporosis and oncology. In April 2017, our first commercial product, TYMLOS (abaloparatide) injection, was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In May 2017, we commenced U.S. commercial sales of TYMLOS and as of April 29, 2019, TYMLOS was available and covered for approximately 283 million U.S. insured lives, representing approximately 99% of U.S. commercial and 67% of Medicare insured lives. In May 2017, we announced positive top-line results from our completed 24-month ACTIVExtend clinical trial for TYMLOS, which met all of its primary and secondary endpoints. In July 2017, we entered into a license and development agreement with Teijin Limited ("Teijin") for abaloparatide for subcutaneous injection ("abaloparatide-SC") in Japan. Under this agreement, we received an upfront payment and are entitled to receive milestone payments upon the achievement of certain regulatory and sales milestones, and a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term. In addition, we have an option to negotiate for a co-promotion agreement with Teijin for abaloparatide-SC in Japan. In October 2018, the FDA approved a labelling supplement for TYMLOS in connection with the results from our ACTIVExtend trial to reflect that after 24 months of open-label alendronate therapy, the vertebral fracture risk reduction achieved with TYMLOS therapy was maintained. In March 2018, the Committee for Medicinal Products for Human Use ("CHMP") of the European Medicines Agency ("EMA") adopted a negative opinion on our European Marketing Authorisation Application ("MAA") for abaloparatide-SC. In July 2018, following a re-examination procedure, the CHMP maintained its negative opinion and on January 7, 2019, the European Commission adopted a decision refusing approval of the MAA on the basis of the negative opinion of the Committee. In March 2018, we initiated a clinical trial in men with osteoporosis which, if successful, will form the basis of a supplemental NDA seeking to expand the use of TYMLOS to treat men with osteoporosis at high risk for fracture. In July 2018, we initiated a bone histomorphometry study, which will enroll approximately 25 postmenopausal women with osteoporosis to evaluate the early effects of TYMLOS on tissue-based bone remodeling and structural indices.

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

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and global commercial supplies of abaloparatide-patch. In partnership with 3M, we selected Patheon N.V. (part of Thermo Fisher Scientific) to conduct the abaloparatide-patch coating process and packaging operations. We have made significant progress scaling up to support our planned Phase 3 study and, if abaloparatide-patch is approved, potential commercial batches. In October 2018, we committed to fund 3M's purchase of capital equipment totaling approximately \$9.6 million in preparation for manufacturing Phase 3 and potential commercial supplies of abaloparatide-patch. Milestone payments for the equipment commenced in the fourth quarter of 2018 and are expected to be paid in full in the third quarter of 2020.

We are also developing our investigational product candidate, elacestrant (RAD1901), a selective estrogen receptor degrader ("SERD"), for potential use in the treatment of hormone receptor-positive breast cancer. We initiated our Phase 3 EMERALD study of elacestrant in late November 2018 with a planned recruitment period of 18 to 21 months. The Phase 3 study is a single, randomized, open label, active-controlled Phase 3 trial of elacestrant as a second or third-line monotherapy in approximately 460 patients with estrogen receptor-positive ("ER+") and human epidermal growth factor receptor 2-negative ("HER2-") advanced or metastatic breast cancer who have received prior treatment with one or two endocrine therapies, including a cyclin-dependent kinase ("CDK") 4/6 inhibitor. Patients in the study will be randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent. The primary endpoint of the study will be progression-free survival ("PFS"), which we will analyze in the overall patient population and in patients with estrogen receptor 1 gene ("ESR1") mutations. Secondary endpoints will include evaluation of overall survival ("OS"), objective response rate ("ORR"), and duration of response ("DOR"). We believe that, depending on results, this single trial would support applications for marketing approvals for elacestrant as a second- and third-line monotherapy in the U.S., European Union ("EU"), and other markets. In November 2018, the FDA granted Fast Track designation for elacestrant for the population to be included in the Phase 3 study. We previously completed enrollment in our ongoing dose escalation Part A, and dose expansion Parts B and C, and in the 18F fluoroestradiol positron emission tomography ("FES-PET") imaging Phase 1 studies of elacestrant in advanced metastatic breast cancer. Enrollment in Part D of the Phase 1 dose-escalation and expansion study was discontinued as the data was no longer required to support the final design of our Phase 3 study. We plan to enter into a worldwide co-development and co-commercialization strategic collaboration with a global oncology partner to broaden development of elacestrant to potentially address earlier lines of treatment in combination with other anti-cancer agents.

We are developing our internally discovered investigational product candidate, RAD140, a non-steroidal selective androgen receptor modulator ("SARM") for potential use in the treatment of hormone-receptor positive breast cancer. In September 2017, we initiated a Phase 1 dose escalation study of RAD140 in patients with locally advanced or metastatic breast cancer. In November 2018, we provided an update on the study, noting that we had identified a provisional maximum tolerated dose and an additional cohort had been opened to further confirm tolerability, pharmacokinetics, and on-treatment pharmacodynamics effects of RAD140 at that dose.

### ***Abaloparatide***

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

### ***Abaloparatide-SC***

TYMLOS was approved in the United States in April 2017 for the treatment of postmenopausal women with osteoporosis at high risk for fracture. The first commercial sales of TYMLOS in the United States occurred in May 2017 and as of January 17, 2019, TYMLOS was available and covered for approximately 283 million U.S. insured lives, representing approximately 99% of U.S. commercial and 67% of Medicare insured lives. We are commercializing TYMLOS in the United States through our commercial organization. We have built a distribution network for TYMLOS in the United States, comprised of well-established distributors and specialty pharmacies. Under our distribution model, both the distributors and specialty pharmacies take physical delivery of TYMLOS and the specialty pharmacies dispense TYMLOS directly to patients.

We hold worldwide commercialization rights to abaloparatide-SC, except for Japan, where we have an option to negotiate a co-promotion agreement with Teijin for abaloparatide-SC. We intend to enter a collaboration for the commercialization of abaloparatide-SC outside of the United States and Japan. In March 2018, the CHMP of the EMA adopted a negative opinion on our European MAA for abaloparatide-SC. In July 2018, following a re-examination procedure, the CHMP maintained its negative opinion and on January 7, 2019, the European Commission adopted a decision refusing approval of the MAA on the basis of the negative opinion of the Committee.

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

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label alendronate. For the subset of ACTIVE trial patients (n=1139) that enrolled in the ACTIVEExtend trial, the previous TYMLOS-treated patients had a significant 84% relative risk reduction ( $p<0.0001$ ) in the incidence of new vertebral fractures compared with patients who received placebo followed by alendronate. They also demonstrated a 39% risk reduction in nonvertebral fractures ( $p=0.038$ ), a 34% risk reduction clinical fractures ( $p=0.045$ ) and a 50% risk reduction in major osteoporotic fractures ( $p=0.011$ ) compared with patients who received placebo followed by alendronate. At the 43-month timepoint, for all patients (n=1645) that enrolled in the ACTIVE trial, TYMLOS-treated patients had a statistically significant risk reduction in new vertebral fractures ( $p<0.0001$ ), nonvertebral fractures ( $p=0.038$ ), clinical fractures ( $p=0.045$ ), and major osteoporotic fractures ( $p<0.001$ ), compared with patients who received placebo followed by alendronate. While not a pre-specified endpoint, there was also a statistically significant risk reduction in hip fractures ( $p=0.027$ ) at the 43-month time point in the TYMLOS-treated patients, compared with patients who received placebo followed by alendronate. The adverse events reported during the alendronate treatment period were similar between the previous TYMLOS-treated patients and the previous placebo group. The incidences of cardiovascular adverse events including serious adverse events were similar between groups. There have been no cases of osteonecrosis of the jaw or atypical femoral fracture in the entire TYMLOS development program. The results from the completed ACTIVEExtend trial were presented at a major scientific meeting in September 2017 and we submitted a labeling supplement in connection with this data to the FDA in December 2017. In October 2018, the FDA approved a labelling supplement for TYMLOS to reflect that after 24 months of open-label alendronate therapy, the vertebral fracture risk reduction achieved with TYMLOS therapy was maintained.

In July 2017, we entered into a license and development agreement with Teijin for abaloparatide-SC in Japan. Pursuant to the agreement, we received an upfront payment and may receive additional milestone payments upon the achievement of certain regulatory and sales milestones, and a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term. In addition, we have an option to negotiate for a co-promotion agreement with Teijin for abaloparatide-SC in Japan. Teijin is conducting a Phase 3 clinical trial of abaloparatide in Japan for the treatment of postmenopausal osteoporosis.

In March 2018, we initiated a clinical trial in men with osteoporosis which, if successful, will form the basis of a supplemental NDA seeking to expand the use of TYMLOS to treat men with osteoporosis at high risk for fracture. The study is a randomized, double-blind, placebo-controlled trial that will enroll approximately 225 men with osteoporosis. The primary endpoint is change in lumbar spine BMD at 12 months compared with placebo. In previous clinical trials, TYMLOS has demonstrated increases in BMD in postmenopausal women. The study includes specialized high-resolution imaging to examine the effect of abaloparatide on bone structure, such as the hip, in a subset of the study participants.

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

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

### *Abaloparatide-patch*

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

We commenced a human replicative clinical evaluation of the optimized abaloparatide-patch in December 2015, with the goal of achieving comparability to abaloparatide-SC. In September 2016, we presented results from this evaluation of the first and second abaloparatide-patch prototypes, demonstrating that formulation technology can modify the pharmacokinetic profile of abaloparatide, including  $T_{max}$ , half-life (" $T_{1/2}$ "), and area under the curve (" $AUC$ "). In March 2018, we announced that through further optimization we had achieved comparability to the abaloparatide-SC profile with a third prototype (the "current abaloparatide-patch"). The current abaloparatide-patch optimized the drug-device combination through process improvements, a finalized formulation, selection of a dose (300  $\mu$ g), and the introduction of a new clinical applicator, which were designed to improve the ease of use and patient experience. In the second half of 2018, we completed further evaluation confirming that a five minute application of the current abaloparatide-patch to the thigh resulted in a pharmacokinetic exposure highly similar ( $AUC >90\%$ ) to abaloparatide-SC.

In January 2018, we met with the FDA to align on a regulatory and development path for registration of abaloparatide-patch. We gained alignment with the agency on a single, pivotal BMD non-inferiority bridging study to support an NDA submission. The FDA agreed that, depending on the study results, a randomized, open label, active-controlled, non-inferiority Phase 3 study of up to 500 patients with postmenopausal osteoporosis at high risk of fracture would be sufficient to gain approval for

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abaloparatide-patch. The FDA confirmed that the primary endpoint will be change in lumbar spine BMD at 12 months and that the non-inferiority margin must preserve 75% of the active control (abaloparatide-SC) based on the lower bound of the 95% confidence interval. We expect to initiate this pivotal study in mid-2019 and to complete it in 2020.

In February 2018, we entered into a Scale-Up and Commercial Supply Agreement with 3M Company pursuant to which 3M agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-patch. In partnership with 3M, we selected Patheon to conduct the abaloparatide-patch coating process and packaging operations. In October 2018, we committed to fund 3M's purchase of capital equipment totaling approximately \$9.6 million in preparation for manufacturing Phase 3 and potential commercial supplies of abaloparatide-patch. Milestone payments for the equipment commenced in the fourth quarter of 2018 and are expected to be paid in full in the third quarter of 2020. We have successfully completed development activities associated with the scale up of manufacturing to support our planned Phase 3 study. We continue to progress on a significant portion of analytical method validations, as well as progress on verification activities to support the Phase 3 study. We are working to finalize engineering equipment designs for commercial supplies. Build out of the commercial manufacturing facilities has started and equipment installation at Patheon is planned to start in the first half of 2019.

### ***Elacestrant (RAD1901)***

Elacestrant is a SERD that we are evaluating for potential use as a once daily oral treatment for hormone receptor-positive breast cancer. We hold worldwide commercialization rights to elacestrant. Elacestrant is currently being investigated in women with advanced ER-positive and HER2-negative breast cancer, the most common subtype of the disease. Studies completed to date indicate that the compound has the potential for use as a single agent or in combination with other therapies for the treatment of breast cancer. We have completed enrollment in our FES-PET imaging study and dose-escalation Part A and expansion study parts B and C Phase 1 breast cancer trials. These studies have identified a single oral dose of 400 mg per day for evaluation in subsequent monotherapy trials.

We initiated our Phase 3 EMERALD study of elacestrant in late November 2018 with a planned recruitment period of 18 to 21 months. The Phase 3 study is a single, randomized, open label, active-controlled Phase 3 trial of elacestrant as a second- or third-line monotherapy in approximately 460 patients with ER+ and HER2- advanced or metastatic breast cancer who have received prior treatment with one or two endocrine therapies, including a CDK 4/6 inhibitor. Patients in the study will be randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent. The primary endpoint of the study will be PFS, which we will analyze in the overall patient population and in patients with ESR1 mutations. Secondary endpoints will include evaluation of OS, ORR, and DOR. We believe that, depending on results, this single trial would support applications for marketing approvals for elacestrant as a second- and third-line monotherapy in the U.S., EU and other markets. In November 2018, the FDA granted Fast Track designation for elacestrant consistent with the population to be included in the Phase 3 study.

### ***Phase 1 - Dose-Escalation and Expansion Study***

In December 2014, we commenced a Phase 1, multicenter, open-label, multiple-part, dose-escalation study of elacestrant in postmenopausal women with ER-positive and HER2-negative advanced breast cancer in the United States to determine the recommended dose for a Phase 2 clinical trial and to make a preliminary evaluation of the potential anti-tumor effect of elacestrant. Part A of this Phase 1 study was designed to evaluate escalating doses of elacestrant. The Part B expansion cohort was initiated at 400-mg daily dosing in March 2016 to allow for an evaluation of additional safety, tolerability and preliminary efficacy. The patients enrolled in this study are heavily pretreated ER-positive, HER2-negative advanced breast cancer patients who have received a median of 3 prior lines of therapy including fulvestrant and CDK4/6 inhibitors, and about 50% of the patients had ESR1 mutations. We have completed enrollment in the ongoing dose-escalation Part A and expansion study parts B and C. In December 2017, we opened a Part D cohort in this study to provide additional data to support the elacestrant clinical development program anticipated at that time. We discontinued recruitment in the Part D cohort as the data was no longer required to support the final design of our Phase 3 study.

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

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We initiated Part D of the Phase 1 dose-escalation and expansion study to evaluate the safety and preliminary efficacy of elacestrant at a 400 mg tablet dose in a population with different eligibility requirements from Parts A, B, and C of this study. In Part D, patients were required to have at least two prior lines of endocrine therapy for advanced/metastatic breast cancer, including fulvestrant, and prior treatment with a CDK 4/6 inhibitor. Ten patients of an originally planned thirty-six were enrolled in Part D, and as of January 3, 2019, one patient remained on treatment. A preliminary review of the data as of December 27, 2018 showed that overall the patients in Part D were more heavily pretreated and more likely to have visceral metastases than patients in Parts A through C of this study. In addition, out of the nine patients with measurable disease, four had a best response of stable disease, two of them for greater than 24 weeks. Combined data, as of December 27, 2018, from all four study Parts (A through D) at 400 mg showed that the overall elacestrant single agent ORR was 19.4% and the median PFS was 4.5 months.

### *Phase 1 - FES-PET Study*

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

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

### *Potential for use in Combination Therapy*

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

In December 2017, we announced additional preclinical data that continues to demonstrate elacestrant anti-tumor activity, as a single agent and in combination, in multiple models. In these preclinical models, elacestrant demonstrated marked tumor growth inhibition, as a single agent in models treated with multiple rounds of fulvestrant and in combination with CDK 4/6 inhibitors such as palbociclib and abemaciclib and with a phosphoinositide 3-kinase inhibitor, alpelisib. In December 2018, we announced additional preclinical data that showed that elacestrant demonstrated marked tumor growth inhibition as a single agent in models harboring ESR1 point mutations, models insensitive to fulvestrant, and models insensitive to CDK 4/6 inhibitors such as palbociclib, ribociclib, or abemaciclib.

### *Collaborations*

We plan to enter into a worldwide co-development and co-commercialization strategic collaboration with a global oncology partner to broaden development of elacestrant to potentially address earlier lines of treatment in combination with other anti-cancer agents.

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

In January 2016, we entered into a worldwide clinical collaboration with Novartis Pharmaceuticals to evaluate the safety and efficacy of combining elacestrant with Novartis’ investigational agent LEE011 (ribociclib), a CDK 4/6 inhibitor, and BYL719 (alpelisib), an investigational phosphoinositide 3-kinase inhibitor. In January 2018, we terminated this collaboration following

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the completion of pre-clinical studies. We are evaluating additional opportunities to collaborate with companies to evaluate the safety and efficacy of combining elacestrant with other agents for the treatment of breast cancer. We believe that such combinations may be suitable in earlier lines of treatment for patients with advanced disease.

### ***RAD140***

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

In September 2017, we initiated a Phase I study of RAD140 in patients with locally advanced or metastatic breast cancer. The clinical trial is designed to evaluate the safety and maximum tolerated dose of RAD140 in approximately 40 patients. Primary safety outcomes from the trial include rate of dose-limiting toxicities, adverse events related to treatment, and tolerability as measured by dose interruptions or adjustments. In addition, pharmacokinetics, pharmacodynamics and tumor response will also be evaluated. In November 2018, we provided an update on the Phase I study, noting that we had identified a provisional maximum tolerated dose and an additional cohort had been opened to further confirm tolerability, pharmacokinetics, and on-treatment pharmacodynamics effects of RAD140 at that dose. Recruitment in the additional cohort is complete and we anticipate reviewing the data in the second quarter of 2019 to guide the decision whether to continue to the Phase 1b portion of the study.

In July 2016, we reported that RAD140 in preclinical xenograft models of breast cancer demonstrated potent tumor growth inhibition when administered alone or in combinations with CDK 4/6 inhibitors. It is estimated that 77% of breast cancers show expression of the androgen receptor. Our data suggest that RAD140 activity at the androgen receptor leads to activation of AR signaling pathways including an AR-specific tumor suppressor and suppression of ER signaling. In April 2017, we presented these RAD140 preclinical results at a major scientific congress. In December 2018, we presented a preclinical poster further demonstrating anti-tumor activity of RAD140 in breast cancer models resistant to standard-of-care endocrine treatments.

### **Financial Overview**

#### ***Product Revenue***

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

#### ***Cost of Product Revenue***

Cost of product revenue consist 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 trial costs made to contract research organizations (“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 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. TYMLOS (abaloparatide-SC) historically has represented the largest portion of our research and development expenses for our development programs. We began tracking program expenses for TYMLOS (abaloparatide-SC) in 2005, and program expenses from inception to March 31, 2019 were approximately \$224.1 million. We began tracking program expenses for abaloparatide-patch in 2007, and program expenses from inception to March 31, 2019 were approximately \$54.8 million. We began tracking program expenses for elacestrant (RAD1901) in 2006, and program expenses from inception to March 31, 2019 were approximately \$91.1 million. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to March 31, 2019 were approximately \$15.5 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 that are directly attributable to the programs listed below for the three months ended March 31, 2019 and 2018 (in thousands):

	Three Months Ended March 31,	
	2019	2018
<b>Program-specific costs - external:</b>		
Abaloparatide-SC	\$ 1,924	\$ 1,539
Abaloparatide-patch	2,615	806
Elacestrant (RAD1901)	5,667	2,599
RAD140	438	1,649
<b>Total program-specific costs - external</b>	<b>\$ 10,644</b>	<b>\$ 6,593</b>
<b>Shared-services costs - external:</b>		
R&D support costs	2,855	2,875
Other operating costs	544	723
<b>Total shared-services costs - external</b>	<b>\$ 3,399</b>	<b>\$ 3,598</b>
<b>Shared-services costs - internal</b>		
Personnel-related costs	6,708	8,488
Stock-based compensation	2,072	3,257
Occupancy costs	197	661
Depreciation expense	239	254
<b>Total shared-services costs - internal</b>	<b>\$ 9,216</b>	<b>\$ 12,660</b>
<b>Total research and development costs</b>	<b>\$ 23,259</b>	<b>\$ 22,851</b>

***Selling, General and Administrative Expenses***

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

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

***Interest Income***

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

***Interest Expense***

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

### **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of financial condition and results of operations is based upon our consolidated financial statements, which have been 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 financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, as well as related disclosures. We evaluate our policies and estimates on an ongoing basis, including those related to revenue recognition, accrued clinical expenses, research and development expenses, stock-based compensation and fair value measures, among others, which we discussed in our Annual Report on Form 10-K for the year ended December 31, 2018. We base our estimates on historical experience and various other assumptions that we believe are reasonable under the circumstances. Our actual results may differ from these estimates under different assumptions or conditions.

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We have reviewed our policies and estimates to determine our critical accounting policies for the three months ended March 31, 2019. There were no changes to significant accounting policies during the three months ended March 31, 2019, except for the adoption of certain ASUs issued by the FASB, as disclosed above within Note 2, “Basis of Presentation and Significant Accounting Policies,” in the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

**Results of Operations**

*Three Months Ended March 31, 2019 and 2018 (in thousands, except percentages)*

	Three Months Ended		Change	
	March 31,		\$	%
	2019	2018		
<b>Revenues:</b>				
Product revenue, net	\$ 29,844	\$ 14,547	\$ 15,297	105 %
<b>Operating expenses:</b>				
Cost of sales - product	3,030	1,088	1,942	178 %
Cost of sales - intangible amortization	200	200	—	—
Research and development	23,259	22,851	408	2 %
Selling, general and administrative	41,186	48,025	(6,839)	(14)%
Loss from operations	(37,831)	(57,617)	(19,786)	(34)%
<b>Other (expense) income:</b>				
Other expense	4	(104)	108	104 %
Interest expense	(6,037)	(5,566)	471	8 %
Interest income	1,104	1,732	(628)	(36)%
Net loss	\$ (42,760)	\$ (61,555)	\$ (18,795)	(31)%

*Product revenue*— We began U.S. commercial sales of TYMLOS in May 2017, following receipt of FDA marketing approval on April 28, 2017. For the three months ended March 31, 2019 we recorded approximately \$29.8 million of net product revenue compared to \$14.5 million for the three months ended March 31, 2018. The increase in product revenue was driven by an increase in sales volume as a result of greater market penetration. For further discussion regarding our revenue recognition policy, see Note 2, “Summary of Significant Accounting Policies”, in the Notes to Consolidated Financial Statements included in Part II, Item 8 of the Annual Report on Form 10-K for the year ended December 31, 2018.

*Cost of sales*— Cost of sales of \$3.2 million for the three months ended March 31, 2019 consisted of costs associated with the manufacturing of TYMLOS, royalties owed to our licensor for such sales, and amortization expense for intangible assets compared to \$1.3 million for the three months ended March 31, 2018. The increase in cost of sales was driven by the increase in product revenue.

*Research and development expenses*— For the three months ended March 31, 2019, research and development expense was \$23.3 million compared to \$22.9 million for the three months ended March 31, 2018, an increase of \$0.4 million, or 2%. This increase was primarily driven by a \$3.1 million increase in elacestrant project costs, a \$1.8 million increase in abaloparatide-patch project costs, and a \$0.4 million increase in abaloparatide-SC project costs. These increases were partially offset by a \$1.2 million decrease in other project related spending, a \$0.5 million decrease in occupancy and depreciation costs, a \$0.1 million decrease in other operating and support costs, and a \$3.1 million decrease in personnel related spending attributed to a decrease in headcount from 131 research and development employees as of March 31, 2018 to 95 research and development employees as of March 31, 2019.

*Selling, general and administrative expenses*— For the three months ended March 31, 2019, selling, general and administrative expense was \$41.2 million compared to \$48.0 million for the three months ended March 31, 2018, a decrease of \$6.8 million, or 14%. This decrease was primarily the result of a \$4.6 million decrease in compensation related expenses attributed to a decrease in headcount from 405 selling, general, and administrative employees as of March 31, 2018 to 284 selling, general, and administrative employees as of March 31, 2019, a \$2.5 million decrease in travel and expense related costs, and a \$0.3 million decrease in other operating costs. These decreases were partially offset by a \$0.4 million increase in occupancy and depreciation expenses and a \$0.2 million increase in professional fees and support costs.

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*Other (expenses), net*—For the three months ended March 31, 2019, other income, net of other expense, was \$4 thousand, as compared to \$0.1 million during the year ended March 31, 2018. Other income, net of other expense, of \$4 thousand for the three months ended March 31, 2019 consisted primarily of other tax expenses. The \$0.1 million of other expense, net of income, for the three months ended March 31, 2018 was primarily due to other taxes and foreign currency revaluation losses.

*Interest income*—For the three months ended March 31, 2019, interest income was approximately \$1.1 million compared to \$1.7 million for the three months ended March 31, 2018, a decrease of \$0.6 million, or 36%. This decrease was primarily due to the decrease in the balance of our investments as a result of investment maturities throughout 2018 and in the three months ended March 31, 2019 as compared to a greater amount of investments outstanding during the three months ended March 31, 2018.

*Interest expense*—For the three months ended March 31, 2019, interest expense was approximately \$6.0 million compared to \$5.6 million for the three months ended March 31, 2018, an increase of \$0.4 million. This increase was the result of continued amortization on the Company's Convertible Notes, the balance for which is continuing to accrete to par over the term and resulting in higher interest during the three months ended March 31, 2019 as compared to the three months ended March 31, 2018.

### ***Liquidity and Capital Resources***

From inception to March 31, 2019, we have incurred an accumulated deficit of \$1,146.4 million, primarily as a result of expenses incurred through a combination of research and development activities related to our various product candidates and expenses supporting those activities. Our total cash, cash equivalents, restricted cash, marketable securities, and investments balance as of March 31, 2019 was \$204.7 million. We have financed our operations since inception primarily through the public offerings of our common stock, issuance of convertible debt, private sales of preferred stock, and borrowings under credit facilities. Following our U.S. commercial launch of TYMLOS in May 2017, we have begun financing a portion of our operations through product revenue.

Based upon our cash, cash equivalents, marketable securities, and investments balance as of March 31, 2019, 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 one year from the date of this filing. We expect to finance the future U.S. commercial activities and development costs of our clinical product portfolio with our existing cash, cash equivalents, marketable securities, and investments, as well as through future product sales, or through strategic financing opportunities, that could include, but are not limited to partnering or other collaboration agreements, future offerings of equity, royalty-based financing arrangements, the incurrence of additional debt, or other alternative financing arrangements, which may involve a combination of the foregoing.

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 Discovery, Development and Commercialization of Our Product Candidates" set forth in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2018.

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

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	Three Months Ended			
	March 31,		Change	
	2019	2018	\$	%
Net cash (used in) provided by:				
Operating activities	\$ (34,464)	\$ (70,232)	\$ 35,768	51 %
Investing activities	45,000	(561)	45,561	8,121 %
Financing activities	1,649	8,317	(6,668)	(80)%
Net increase (decrease) in cash, cash equivalents, and restricted cash	\$ 12,185	\$ (62,476)	\$ 74,661	(120)%

*Cash Flows from Operating Activities*

Net cash used in operating activities during the three months ended March 31, 2019 was \$34.5 million, which was primarily the result of a net loss of \$42.8 million, partially offset by \$10.8 million of net non-cash adjustments to reconcile net loss to net cash used in operations and net changes in working capital of \$3.0 million. The \$42.8 million net loss was primarily due to abaloparatide-SC project costs, elacestrant and RAD140 program development expenses along with employee compensation incurred to support the commercialization of TYMLOS in the United States. The \$10.8 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of \$6.1 million, amortization of debt discount of \$3.8 million, and depreciation of \$0.6 million.

Net cash used in operating activities during the three months ended March 31, 2018 was \$70.2 million, which was primarily the result of a net loss of \$61.6 million, partially offset by \$11.3 million of net non-cash adjustments to reconcile net loss to net cash used in operations and net changes in working capital of \$20.0 million. The \$61.6 million net loss was primarily due to abaloparatide-SC and elacestrant program development expenses along with employee compensation and consulting costs incurred to support regulatory submissions and preparation for the commercial launch of TYMLOS in the United States. The \$11.3 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of \$7.5 million, amortization of debt discount of \$3.3 million, and depreciation of \$0.7 million.

*Cash Flows from Investing Activities*

Net cash provided by investing activities during the three months ended March 31, 2019 was \$45.0 million, which was the result of \$45.0 million in sales and maturities of marketable securities.

Net cash used in investing activities during the three months ended March 31, 2018 was \$0.6 million, which was primarily the result of \$0.5 million of purchases of marketable securities and \$0.1 million of payments for property and equipment.

Our investing cash flows will be impacted by the timing of our purchases and sales of our marketable securities. Because our marketable securities are primarily short-term in duration, we would not expect our operational results or cash flows to be significantly affected by a change in market interest rates.

*Cash Flows from Financing Activities*

Net cash provided by financing activities during the three months ended March 31, 2019 was \$1.6 million, which consisted of \$0.6 million of proceeds received from exercises of stock options and \$1.0 million received upon issuance of common stock under the Radius Health, Inc. 2016 Employee Stock Purchase Plan ("ESPP").

Net cash provided by financing activities during the three months ended March 31, 2018 was \$8.3 million, which consisted of \$6.6 million of proceeds received from exercises of stock options and \$1.7 million received upon issuance of common stock under the Radius Health, Inc. 2016 Employee Stock Purchase Plan.

*Borrowings and Other Liabilities*

In August 2017, we issued \$300.0 million aggregate principal amount of the Convertible Notes, as discussed in more detail in Note 8, "Convertible Notes Payable," to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q. 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 sale of the over-allotment option, after deducting fees and expenses of \$0.2 million.

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

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Years ending December 31,	Future Minimum Payments	
2019		4,575
2020		9,150
2021		9,150
2022		9,150
2023		9,150
2024 and Thereafter	\$	314,150
<b>Total minimum payments</b>	<b>\$</b>	<b>355,325</b>
Less: interest		(50,325)
Less: unamortized discount		(121,444)
Less: current portion		—
<b>Long Term Debt</b>	<b>\$</b>	<b>183,556</b>

**Leases**

We adopted ASC 842 effective January 1, 2019, as discussed in more detail in Note 15, “Leases,” to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Maturities of our operating lease liabilities as of March 31, 2019 are as follows (in thousands):

Year ending December 31,		
2019	\$	1,998
2020		2,136
2021		1,060
2022		1,038
2023		980
Thereafter		1,863
<b>Total Lease payments</b>	<b>\$</b>	<b>9,075</b>
Less: effect of discounted cash flows during the period		(1,351)
<b>Total</b>	<b>\$</b>	<b>7,724</b>

**Contractual Obligations**

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

**Supply and Manufacturing Agreements**

In June 2016, we entered into a Supply Agreement with Ypsomed AG (“Ypsomed”), pursuant to which Ypsomed agreed to supply commercial and clinical supplies of a disposable pen injection device customized for subcutaneous injection of abaloparatide. We agreed to purchase a minimum number of devices

at prices per device that decrease with an increase in quantity supplied. In addition, we made milestone payments for Ypsomed's capital developments in connection with the initiation of the commercial supply of the device and paid a one-time capacity fee. All costs and payments under the agreement are delineated in Swiss Francs. The agreement has an initial term of three years which began on June 1, 2017, after which, it

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automatically renews for two-year terms unless either party terminates the agreement upon 18 months' notice prior to the end of the then-current term. We will purchase the devices subject to minimum annual quantity requirements over the initial three-year term of the agreement. We are required to purchase a minimum number of batches for CHF 2.4 million (\$2.4 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, we have agreed to pay a per unit price dependent upon the number of pens loaded with cartridges that are labeled and packaged. These prices are subject to an annual price adjustment. The agreement has an initial term of five years, which began on January 1, 2016, after which, it automatically renews for two-year terms unless either party notifies the other party two years before the end of the then-current term that it does not intend to renew.

In July 2016, we entered into a Manufacturing Services Agreement with Polypeptide Laboratories Holding AB ("PPL"), as successor-in-interest to Lonza Group Ltd., pursuant to which PPL has agreed to manufacture the commercial and clinical supplies of the API for abaloparatide. We have agreed to purchase the API in batches at a price per gram in euros, subject to an annual increase by PPL. We are also required to purchase a minimum number of batches annually, equal to €2.9 million (\$3.3 million) per year through the year ended December 31, 2022. We are not subject to the minimum purchase requirement in 2019 and 2020. The agreement has an initial term of a six years, after which, it automatically renews for three-year terms unless either party provides notice of non-renewal 24 months before the end of the then-current term.

### **License Agreement Obligations**

#### *TYMLOS (abaloparatide)*

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

In consideration for the rights to abaloparatide and in recognition of certain milestones having been met to date, we have paid to Ipsen an aggregate amount of \$13.0 million. The License Agreement further requires us to make payments upon the achievement of certain future regulatory and commercial milestones. Total additional milestone payments that could be payable under the agreement are €24.0 million (approximately \$26.9 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 have recorded as an intangible asset and will amortize over the remaining patent life or the estimated useful life of the underlying product, whichever is shorter. The agreement also provides that we will pay to Ipsen a fixed five percent royalty based on net sales of the product 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 date of the last to expire of the abaloparatide patents licensed from or co-owned with Ipsen, barring any extension thereof, is expected to be March 26, 2028.

If we sublicense abaloparatide to a third party, the agreement provides that we would pay a percentage of certain payments received from such sublicensee (in lieu of milestone payments not achieved at the time of such sublicensee). 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.

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Prior to executing the License Agreement for abaloparatide with Radius, Ipsen licensed the Japanese rights for abaloparatide to Teijin. Teijin has initiated a Phase 3 clinical study of abaloparatide-SC in Japan for the treatment of postmenopausal osteoporosis. We have an option to negotiate a co-promotion agreement with Teijin for abaloparatide-SC in Japan and we maintain full global rights to our development program for abaloparatide-patch.

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

### *Abaloparatide-patch*

In February 2018, we entered into a Scale-Up And Commercial Supply Agreement (the “Supply Agreement”) with 3M Company and 3M Innovative Properties Company (collectively with 3M Company, “3M”), pursuant to which 3M agreed to exclusively manufacture Phase 3 and global commercial supplies of an abaloparatide-coated transdermal patch product (“Product”) and associated applicator devices (“Applicator”). Under the Supply Agreement, 3M agreed to manufacture Product and Applicator for us according to agreed-upon specifications in sufficient quantities to meet our projected supply requirements. 3M agreed to manufacture commercial supplies of Product at unit prices that decrease with an increase in the quantity we order. We are obligated to pay 3M a mid-to-low single-digit royalty on worldwide net sales of Product and reimburse 3M for certain capital expenditures incurred to establish commercial supply of Product. We are responsible for providing, at our expense, supplies of abaloparatide drug substance to be used in manufacturing Product. During the term of the Supply Agreement, 3M and Radius have agreed to work exclusively with each other with respect to the delivery of abaloparatide, parathyroid hormone (“PTH”), and/or PTH related proteins via active transdermal, intradermal, or microneedle technology. In October 2018, the Company committed to fund 3M’s purchase of capital equipment totaling approximately \$9.6 million in preparation for manufacturing Phase 3 and potential commercial supplies of Product. Milestone payments for the equipment commenced in the fourth quarter of 2018 and are expected to be completed in the third quarter of 2020.

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

In June 2009, we entered into a Development and Clinical Supplies Agreement with 3M, as amended (the “Development Agreement”), under which Product and Applicator development activities occur and 3M has manufactured phase 1 and 2 clinical trial supplies for us on an exclusive basis. The term of the Development Agreement runs until June 2019 and then automatically renews for additional one-year terms, unless earlier terminated, until the earliest of (i) the expiration or termination of the Supply Agreement, (ii) the mutual written agreement of the parties, or (iii) prior written notice by either party to the other party at least ninety days prior to the end of the then-current term of the Development Agreement that such party declines to extend the term. Either party may terminate the agreement in the event of an uncured material breach by the other party. We pay 3M for services delivered pursuant to the agreement on a fee-for-service or a fee-for-deliverable basis as specified in the agreement. We have paid 3M approximately \$26.7 million, in the aggregate, through March 31, 2019 with respect to services and deliverables delivered pursuant to the Development Agreement.

### *Elacestrant (Eisai)*

In June 2006, we entered into a license agreement (“Eisai Agreement”), with Eisai Co. Ltd. (“Eisai”). Under the Eisai Agreement, Eisai granted to us an exclusive right and license to research, develop, manufacture and commercialize elacestrant (RAD1901) and related products from Eisai in all countries, except Japan. In consideration for the rights to elacestrant, we paid Eisai an initial license fee of \$0.5 million, which was expensed during 2006. In March 2015, we entered into an amendment to the Eisai Agreement, or the “Eisai Amendment,” in which Eisai granted to us the exclusive right and license to research, develop, manufacture and commercialize elacestrant in Japan. In consideration for the rights to elacestrant in Japan, we paid Eisai an initial license fee of \$0.4 million upon execution of the Eisai Amendment, which was recognized as research and development expense in 2015. The Eisai Agreement, as amended, also provides for additional payments of up to \$22.3 million,

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payable upon the achievement of certain future clinical and regulatory milestones. To date, we have paid Eisai approximately \$1.0 million in connection with the achievement of certain milestones.

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

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

### *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 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.

### *Abaloparatide-SC (Teijin)*

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

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

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Teijin granted us (i) an exclusive license under certain of Teijin's intellectual property to develop, manufacture and commercialize abaloparatide-SC outside Japan and (ii) a right of reference to certain of Teijin's regulatory data related to abaloparatide-SC for purposes of developing, manufacturing and commercializing abaloparatide-SC outside Japan. We maintain full global rights to its development program for abaloparatide-patch, which is not part of the Teijin Agreement. Pursuant to the Teijin Agreement, the parties may further collaborate on new indications for abaloparatide-SC.

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

### ***Net Operating Loss Carryforwards***

As of December 31, 2018, we had federal and state net operating loss carryforwards of approximately \$912.5 million and \$580.1 million, respectively, subject to limitation, 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 subsequent to December 31, 2015 and/or in the future that could further limit the amount of net operating loss and tax credit carryforwards that we can utilize. A full valuation allowance has been recorded against our net operating loss carryforwards and other deferred tax assets, as the realization of the deferred tax asset is uncertain.

As a result, we have not recorded any federal or state income tax benefit in our condensed consolidated statements of operations.

### **Off-Balance Sheet Arrangements**

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

### **New Accounting Standards**

See Note 2 - *Basis of Presentation and Significant Accounting Policies - Accounting Standards Updates* in the accompanying unaudited condensed consolidated financial statements in this Quarterly Report for a discussion of new accounting standards.

**Item 3. Quantitative and Qualitative Disclosures about Market Risk.**

We are exposed to market risk related to changes in the dollar/euro and dollar/Swiss franc exchange rates because a portion of our development and costs of goods expenses are denominated in foreign currencies. We do not hedge our foreign currency exchange rate risk. However, an immediate 10% adverse change in the dollar/euro or dollar/Swiss Franc exchange rate would not have a material effect on our financial results.

We are exposed to market risk related to changes in interest rates. As of March 31, 2019, we had cash, cash equivalents, restricted cash, marketable securities and investments of \$204.7 million, consisting of cash, money market funds, domestic corporate debt securities, domestic corporate commercial paper and agency bonds. This exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable securities. Because our marketable securities are short-term in duration, and have a low risk profile, 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 a change in market interest rates on our investments. We carry our investments based on publicly available information. As of March 31, 2019, we do not have any hard-to-value investment securities or securities for which a market is not readily available or active.

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

**Item 4. Controls and Procedures.**

**Disclosure Controls and Procedures**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated 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, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2019.

**Changes in Internal Control over Financial Reporting**

During the three months ended March 31, 2019, we implemented appropriate changes to our internal control over financial reporting to support the adoption of ASU 2016-02, Leases, as of January 1, 2019, including the preparation of additional lease disclosures. There were no other changes to our internal control over financial reporting during the three months ended March 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II— OTHER INFORMATION

### Item 1. Legal Proceedings.

From time to time, we are party to litigation arising in the ordinary course of our business. As of March 31, 2019, we were not party to any significant litigation.

### 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 carefully consider the discussion of risk factors in Part I, “Item 1A. Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2018, which could materially affect our business, financial condition or future results, in addition to other information contained in or incorporated by reference into this Quarterly Report on Form 10-Q and our other public filings with the Securities and Exchange Commission, or the SEC.*

The risk factor set forth below represents new risk factors or those containing changes, including material changes, to the similarly titled risk factor included in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2018 filed with the Securities and Exchange Commission on February 28, 2019.

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

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

In April 2017, we received FDA approval of TYMLOS for the treatment of postmenopausal women with osteoporosis at high risk for fracture. TYMLOS competes in the U.S. against well-known treatment options, including teriparatide, marketed by Eli Lilly and Company in the U.S. as Forteo. TYMLOS may also face competition from generic or biosimilar versions of teriparatide. For example, we are aware of companies pursuing development of biosimilar and/or generic versions of teriparatide in the U.S. The availability of a generic or biosimilar teriparatide on the market would likely exert pricing and reimbursement pressure on the anabolic class in which abaloparatide-SC would compete. In addition, there are other organizations working to develop new therapies to treat osteoporosis. For example, UCB and Amgen are co-developing an anti-sclerostin anabolic monoclonal antibody for the treatment of osteoporosis, which received Japanese marketing approval in January 2019 and United States regulatory approval in April 2019. In order to compete successfully in this market, we will have to demonstrate to patients, physicians and third-party payors that the treatment of postmenopausal women with osteoporosis at high risk of fracture with TYMLOS is worthwhile and is a better alternative to existing or new therapies.

We 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.

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**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

None.

**Item 5. Other Information.**

On December 1, 2018, the Company and PPL (as successor to Lonza Sales AG) entered into an amendment to the Manufacturing Services Agreement between the parties pursuant to which PPL supplies the Company with abaloparatide active pharmaceutical ingredient (“API”). The amendment eliminated the Company’s minimum annual purchase requirements for 2019 and 2020 in exchange for adjusted API batch pricing during those years. The foregoing description of the amendment does not purport to be complete and is qualified in its entirety by reference to the amendment filed as Exhibit 10.1 to this Quarterly Report on Form 10-Q.

**Item 6. Exhibits.**

A list of exhibits is set forth in the Exhibit Index below, which is incorporated herein by reference.



By:

/s/ Jose Carmona

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**Jose Carmona**

**Chief Financial Officer**

**(Principal Accounting and Financial Officer)**

Date: May 8, 2019



## CERTIFICATIONS

I, Jesper Hoeiland, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: May 8, 2019

/s/ Jesper Hoeiland

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Jesper Hoeiland

President and Chief Executive Officer

## CERTIFICATIONS

I, Jose Carmona, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: May 8, 2019

/s/ Jose Carmona

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Jose Carmona  
Chief Financial Officer

