

Radius Health, Inc.  
Form 10-Q  
November 01, 2018  
Table of Contents

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 September 30, 2018

Or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_.

Commission File Number 001-35726

Radius Health, Inc.  
(Exact name of registrant as specified in its charter)  
Delaware 80-0145732  
(State or other jurisdiction of (IRS Employer  
Incorporation or organization) 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)

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

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

---

Table of Contents

Number of shares of the registrant's Common Stock, \$.0001 par value per share, outstanding as of October 31, 2018:  
45,539,516 shares

---

Table of Contents

RADIUS HEALTH, INC.  
FORM 10-Q  
FOR THE QUARTER ENDED SEPTEMBER 30, 2018

TABLE OF CONTENTS

PART I FINANCIAL INFORMATION

<u>Item 1.</u>	<u>Condensed Consolidated Financial Statements (Unaudited)</u>	<u>4</u>
	<u>Condensed Consolidated Balance Sheets as of September 30, 2018 and December 31, 2017</u>	<u>4</u>
	<u>Condensed Consolidated Statements of Operations and Comprehensive Loss for the three and nine months ended September 30, 2018 and 2017</u>	<u>5</u>
	<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and 2017</u>	<u>6</u>
	<u>Notes to Condensed Consolidated Financial Statements</u>	<u>7</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>21</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>41</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>	<u>42</u>

PART II OTHER INFORMATION 43

<u>Item 1.</u>	<u>Legal Proceedings</u>	<u>43</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>43</u>
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>44</u>
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	<u>44</u>
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	<u>44</u>
<u>Item 5.</u>	<u>Other Information</u>	<u>44</u>
<u>Item 6.</u>	<u>Exhibits</u>	<u>44</u>

SIGNATURES 46

---

Table of Contents

## Item 1. Condensed Consolidated Financial Statements

Radius Health, Inc.

Condensed Consolidated Balance Sheets

(Unaudited, in thousands, except share and per share amounts)

	September 30, 2018 (unaudited)	December 31, 2017
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 62,014	\$ 118,564
Restricted cash	558	55
Marketable securities	172,120	134,714
Accounts receivable, net	12,908	4,441
Inventory	5,546	4,366
Prepaid expenses	10,097	5,175
Other current assets	1,193	2,191
Total current assets	264,436	269,506
Investments	42,235	176,978
Property and equipment, net	4,561	6,195
Intangible assets	7,581	8,180
Other assets	589	799
Total assets	\$ 319,402	\$ 461,658
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 6,294	\$ 3,915
Accrued expenses and other current liabilities	41,759	49,512
Total current liabilities	48,053	53,427
Other non-current liabilities	118	189
Notes payable	176,180	166,006
Total liabilities	\$ 224,351	\$ 219,622
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.0001 par value; 200,000,000 shares authorized, 45,539,516 shares and 44,616,586 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	5	4
Additional paid-in-capital	1,158,417	1,124,630
Accumulated other comprehensive loss	(848	) (314
Accumulated deficit	(1,062,523	) (882,284
Total stockholders' equity	95,051	242,036
Total liabilities and stockholders' equity	\$ 319,402	\$ 461,658

See accompanying notes to unaudited condensed consolidated financial statements.



Table of Contents

Radius Health, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
<b>REVENUES:</b>				
Product revenue, net	\$27,639	\$3,469	\$64,815	\$4,449
License revenue	—	10,000	—	10,000
<b>OPERATING EXPENSES:</b>				
Cost of sales - product	2,193	253	4,884	358
Cost of sales - intangible amortization	200	200	599	200
Research and development	26,804	20,997	75,979	60,176
Selling, general and administrative	43,661	47,723	140,266	135,943
Other operating expenses	—	—	10,801	—
Loss from operations	(45,219 )	(55,704 )	(167,714 )	(182,228 )
<b>OTHER (EXPENSE) INCOME:</b>				
Other income (expense)	17	(195 )	83	(212 )
Interest expense	(5,793 )	(2,763 )	(17,041 )	(2,763 )
Interest income	1,193	819	4,433	1,983
<b>NET LOSS</b>	<b>\$(49,802)</b>	<b>\$(57,843 )</b>	<b>\$(180,239)</b>	<b>\$(183,220)</b>
<b>OTHER COMPREHENSIVE LOSS:</b>				
Unrealized gain (loss) from available-for-sale debt securities	442	(1 )	(534 )	(70 )
<b>COMPREHENSIVE LOSS</b>	<b>\$(49,360)</b>	<b>\$(57,844 )</b>	<b>\$(180,773)</b>	<b>\$(183,290)</b>
<b>LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED (Note 11)</b>	<b>\$(49,802)</b>	<b>\$(57,843 )</b>	<b>\$(180,239)</b>	<b>\$(183,220)</b>
<b>LOSS PER SHARE:</b>				
Basic and diluted	<b>\$(1.09 )</b>	<b>\$(1.31 )</b>	<b>\$(3.98 )</b>	<b>\$(4.21 )</b>
<b>WEIGHTED AVERAGE SHARES:</b>				
Basic and diluted	45,498,909	43,999,451	45,291,176	43,535,874

See accompanying notes to unaudited condensed consolidated financial statements.

Table of Contents

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

	Nine Months Ended September 30,	
	2018	2017
<b>CASH FLOWS USED IN OPERATING ACTIVITIES:</b>		
Net loss	\$(180,239)	\$(183,220)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,005	1,385
Amortization of discount on marketable securities, net	(199)	(100)
Amortization of debt discount and debt issuance costs	10,174	1,568
Stock-based compensation	22,270	28,785
Changes in operating assets and liabilities:		
Inventory	(1,180)	(3,074)
Accounts receivable, net	(8,467)	(11,682)
Prepaid expenses and other current assets	(4,922)	(5,493)
Other current assets	998	—
Other long-term assets	210	(7)
Accounts payable	2,379	(2,414)
Accrued expenses and other current liabilities	(7,455)	7,327
Other non-current liabilities	(71)	(166)
Net cash used in operating activities	(164,497)	(167,091)
<b>CASH FLOWS PROVIDED BY INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(70)	(2,950)
Payments for capitalized milestones	—	(8,712)
Purchases of marketable securities	(499)	(117,441)
Sales and maturities of marketable securities	97,501	170,208
Net cash provided by investing activities	96,932	41,105
<b>CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:</b>		
Proceeds from exercise of stock options and warrant exercises	8,953	16,167
Proceeds from issuance of convertible debt	—	305,000
Payment of debt issuance costs	—	(9,360)
Proceeds from issuance of shares under employee stock purchase plan	2,565	2,550
Net cash provided by financing activities	11,518	314,357
<b>NET DECREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH</b>	<b>(56,047)</b>	<b>188,371</b>
<b>CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF YEAR</b>	<b>118,619</b>	<b>258,614</b>
<b>CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF PERIOD</b>	<b>\$62,572</b>	<b>\$446,985</b>
<b>SUPPLEMENTAL DISCLOSURES:</b>		
Cash paid for income taxes	\$22	\$26
Property and equipment purchases in accrued expenses at period end	\$298	\$487

See accompanying notes to unaudited condensed consolidated financial statements.



Table of Contents

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 April 2018, the Company submitted a request for re-examination of the negative opinion adopted by the Committee for Medicinal Products for Human Use (“CHMP”) of the European Medicines Agency (“EMA”) on the Company’s European Marketing Authorisation Application (“MAA”) for abaloparatide for subcutaneous administration (“abaloparatide-SC”) and in July 2018, following a re-examination procedure, the CHMP maintained its negative opinion. The Company's clinical pipeline includes an investigational abaloparatide transdermal patch (“abaloparatide-patch”) for potential use in the treatment of postmenopausal women with osteoporosis; the investigational drug elacestrant (RAD1901), a selective estrogen receptor degrader for potential use in the treatment of hormone-receptor positive breast cancer; and the investigational drug RAD140, a non-steroidal, selective androgen receptor modulator 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 September 30, 2018, the Company had an accumulated deficit of \$1,062.5 million, and total cash, cash equivalents, restricted cash, marketable securities, and investments of \$276.9 million.

Based upon its cash, cash equivalents, marketable securities, and investments as of September 30, 2018, the Company believes that, prior to the consideration of potential proceeds from partnering and/or collaboration activities, it has sufficient capital to fund its development plans, U.S. commercial activities and other operational activities for at least twelve months from the date of this filing. The Company expects to finance its commercial activities in the United States and development costs of its clinical product portfolio with its existing cash and cash equivalents, marketable securities and investments, as well as future product sales or through strategic financing opportunities that could include, but are not limited to, partnering or other collaboration agreements, future offerings of its equity, royalty based financing arrangements, or the incurrence of debt or other alternative financing arrangements which may include a combination of the foregoing. 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 capital, it may be unable to conduct its ongoing commercialization activities or complete its planned preclinical studies and clinical trials and obtain approval of certain of its 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 nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2018. 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

Table of Contents

statements and notes, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 ("2017 Form 10-K"), filed with the Securities and Exchange Commission ("SEC") on March 1, 2018. 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 2017 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 nine months ended September 30, 2018, except for the adoption of three Accounting Standards Updates ("ASU") issued by the Financial Accounting Standards Board ("FASB"), which are detailed below.

**Accounting Standards Updates, Recently Adopted**—In August 2016, the FASB issued ASU No. 2016-15, Classification of Certain Cash Receipts and Cash Payments ("ASU 2016-15"). ASU 2016-15 addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. ASU 2016-15 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. The Company adopted this ASU as of January 1, 2018 and it did not have a material impact on its condensed consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows: Restricted Cash ("ASU 2016-18"). The amendments in this update require that amounts generally described as restricted cash and restricted cash equivalents be included within cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 became effective January 1, 2018. As a result of adopting ASU 2016-18, the Company includes its restricted cash balance in the cash and cash equivalents reconciliation of operating, investing and financing activities. The following table provides a reconciliation of cash, cash equivalents, and restricted cash within the consolidated balance sheet that sum to the total of the same such amounts shown in the statement of cash flows.

	As of September 30, 2018	As of September 30, 2017
Cash and cash equivalents	\$ 62,014	\$ 446,938
Restricted cash	558	47
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	\$ 62,572	\$ 446,985

In May 2017, the FASB issued ASU 2017-09, Compensation-Stock Compensation (Topic 718) Scope of Modification Accounting ("ASU 2017-09"). ASU 2017-09 provides clarification on when modification accounting should be used for changes to the terms or conditions of a share-based payment award. The amendments in ASU 2017-09 are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017, with early adoption permitted, applied prospectively to an award modified on or after the adoption date.

This ASU does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The Company adopted this ASU as of January 1, 2018 and it did not have a material impact on its condensed consolidated financial statements.

**Accounting Standards Updates, Recently Issued**—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 the FASB Accounting Standards Codification ("ASC") to expand the scope of FASB ASC Topic 718, Compensation-Stock Compensation, 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 is currently assessing the potential impact of adopting ASU 2018-07 on its financial statements and related disclosures

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 ASC Topic 842, Leases. ASU 2016-02 requires a lessee to recognize in the statement of financial position a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term for both finance and operating

leases.

In July 2018, the FASB issued ASU 2018-10, Codification Improvements to Topic 842, Leases (“ASU 2018-10”) and ASU No. 2018-11, Target Improvements to Topic 842, Leases (“ASU 2018-11”). The amendments in ASU 2018-10 provide additional clarification and implementation guidance on certain aspects of ASU 2016-02 and have the same effective and transition requirements as ASU 2016-02. ASU 2018-11 gives entities the option to not provide comparative period financial statements and instead apply the transition requirements as of the effective date of the new standard. ASU 2016-02, ASU 2018-10 and

8

---

Table of Contents

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 plans to adopt the new standard using the optional method under ASU 2018-11 and is currently working through lease contract scoping, design and implementation of transition related controls, and finalization of accounting elections. The Company is still assessing the impact that this standard will have on its condensed consolidated financial statements and related disclosures; however, it anticipates that the new standard will result in the Company recording additional right of use assets and corresponding liabilities on its consolidated balance sheet.

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 is currently evaluating the effects the adoption of ASU 2018-09 will have on its consolidated financial statements, results of operations and cash flows.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement - Disclosure Framework-Changes to the Disclosure Requirement for Fair Value Measurement, or (“ASU 2018-13”). The amendments in this ASU 2018-13 modify the disclosure requirements on fair value measurements in Topic 820, Fair Value Measurement, based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The 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.

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 plans to implement this updated disclosure requirement beginning with the first quarter 2019 Form 10-Q.

### 3. Marketable Securities

Available-for-sale marketable securities and cash and cash equivalents as of September 30, 2018 and December 31, 2017 consist of the following (in thousands):

	September 30, 2018			
	Amortized Cost	Gross Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	\$ 15,236	\$ —	\$ —	\$ 15,236
Money market funds	46,778	—	—	46,778
Total	\$ 62,014	\$ —	\$ —	\$ 62,014
Marketable securities:				
Domestic corporate debt securities	\$ 155,346	\$ —	\$ (643)	\$ 154,703
Agency bonds	59,981	—	(329)	59,652
Total	\$ 215,327	\$ —	\$ (972)	\$ 214,355



Table of Contents

	December 31, 2017			
	Amortized Cost	Gross Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	\$73,302	\$ —	\$ —	\$ 73,302
Money market funds	325	—	—	325
Domestic corporate commercial paper	44,937	—	—	44,937
Total	\$118,564	\$ —	\$ —	\$ 118,564

## Marketable securities:

Domestic corporate debt securities	\$207,320	\$ 1	\$ (235 )	\$ 207,086
Domestic corporate commercial paper	29,844	—	(7 )	29,837
Agency bonds	74,842	—	(73 )	74,769
Total	\$312,006	\$ 1	\$ (315 )	\$ 311,692

There were no available-for-sale marketable securities that had been in an unrealized loss position for more than 12 months as of September 30, 2018 or December 31, 2017, respectively. There were 29 marketable securities with an aggregate fair value of \$214.4 million in an unrealized loss position for less than 12 months as of September 30, 2018. There were 38 marketable securities with an aggregate fair value of \$299.2 million in an unrealized loss position for less than 12 months as of December 31, 2017. 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 September 30, 2018.

As of September 30, 2018, the aggregate fair value of marketable securities maturing within one year and after one year through two years was \$172.1 million and \$42.2 million, 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 nine months ended September 30, 2018.

There were no material transfers between any levels during 2017.

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 September 30, 2018 and December 31, 2017 (in thousands):

Table of Contents

As of September 30, 2018  
Level 1 Level 2 Level 3 Total

Assets				
Cash and cash equivalents:				
Cash	\$15,236	\$—	\$	—\$15,236
Money market funds (1)	46,778	—	—	46,778
Total	\$62,014	\$—	\$	—\$62,014
Marketable Securities				
Domestic corporate debt securities (2)	\$—	\$154,703	\$	—\$154,703
Agency bonds (2)	—	59,652	—	59,652
Total	\$—	\$214,355	\$	—\$214,355

As of December 31, 2017  
Level 1 Level 2 Level 3 Total

Assets				
Cash and cash equivalents:				
Cash	\$73,302	\$—	\$	—\$73,302
Money market funds (1)	325	—	—	325
Domestic corporate commercial paper (2)	—	44,937	—	44,937
Total	\$73,627	\$44,937	\$	—\$118,564
Marketable Securities				
Domestic corporate debt securities (2)	\$—	\$207,086	\$	—\$207,086
Domestic corporate commercial paper (2)	—	29,837	—	29,837
Agency bonds (2)	—	74,769	—	74,769
Total	\$—	\$311,692	\$	—\$311,692

(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 at September 30, 2018 and December 31, 2017 (in thousands):

	September 30, December 31,	
	2018	2017
Raw materials	\$ 4,257	\$ 3,852
Work in process	636	313
Finished goods	653	201
Total inventories	\$ 5,546	\$ 4,366

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

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

## 6. Intangible Assets

The following table presents intangible assets as of September 30, 2018 (in thousands):



Table of Contents

	September 30, 2018	Estimated useful life
Acquired and in-licensed rights	\$ 8,712	11 Years
Less: accumulated amortization	(1,131 )	
Total intangible asset, net	\$ 7,581	

Acquired and in-licensed rights as of September 30, 2018 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 and \$0.6 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 and nine months ended September 30, 2018. Estimated future amortization expense for intangible assets as of September 30, 2018 is approximately \$0.2 million for the remainder of 2018, 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):

	September 30, 2018	December 31, 2017
Commercial costs and product revenue reserves	\$ 13,567	\$ 14,300
Research and development costs	11,212	8,406
Payroll and employee benefits	11,619	16,934
Interest	763	3,482
Restructuring costs	628	—
Professional fees	3,875	6,295
Other current liabilities	95	95
Total accrued expenses and other current liabilities	\$ 41,759	\$ 49,512

#### 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, the Convertible Notes may be

converted at an initial conversion rate of 20.4891 shares of common stock per \$1,000 principal

12

---

Table of Contents

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:

- 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 (1) (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;
- 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;
- if the Company calls the Convertible Notes for redemption, until the close of business on the business day immediately preceding the redemption date; or
- upon the occurrence of specified corporate events.

As of September 30, 2018, none of the above circumstances had occurred and as such, the Convertible Notes may not be converted.

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 September 30, 2018 consisted of the following (in thousands):

	2024 Convertible Notes
Liability component:	
Principal	\$ 305,000
Less: debt discount and issuance costs, net	\$(128,820 )

Net carrying amount	\$ 176,180
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 September 30, 2018

13

---

Table of Contents

was 13.04%. As of September 30, 2018, 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 September 30, 2018 was approximately \$234.0 million.

The following table sets forth total interest expense recognized related to the Convertible Notes during the three and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Contractual interest expense	\$2,287	\$1,195	\$6,863	\$1,195
Amortization of debt discount	3,379	1,568	9,804	1,568
Amortization of debt issuance costs	127	—	370	—
Total interest expense	\$5,793	\$2,763	\$17,037	\$2,763

Future minimum payments on the Company’s long-term debt as of September 30, 2018 are as follows (in thousands):

Years ended December 31,	Future Minimum Payments
2019	\$9,150
2020	9,150
2021	9,150
2022	9,150
2023	9,150
2024 and Thereafter	314,150
Total minimum payments	\$359,900
Less: interest	(54,900 )
Less: unamortized discount	(128,820 )
Less: current portion	—
Long Term Debt	\$176,180

## 9. Stock-Based Compensation

## Stock Options

A summary of stock option activity during the nine months ended September 30, 2018 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, 2017	5,648	\$ 37.71		
Granted	1,388	34.43		
Exercised	(461 )	16.14		
Canceled	(407 )	42.53		
Expired	(409 )	52.04		
Options outstanding at September 30, 2018	5,759	\$ 37.29	7.48	\$ 5,728
Options exercisable at September 30, 2018	3,121	\$ 36.56	6.38	\$ 5,728



Table of Contents

The weighted-average grant-date fair value per share of options granted during the three and nine months ended September 30, 2018 was \$12.86 and \$19.07, respectively. As of September 30, 2018, there was approximately \$49.3 million of total unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.64 years.

**Restricted Stock Units**

A summary of RSU activity during the nine months ended September 30, 2018 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, 2017	147	\$ 36.69
Granted	221	37.83
Vested	(24 )	41.37
Forfeited	(82 )	37.37
RSUs Outstanding at September 30, 2018	262	\$ 37.00

As of September 30, 2018, there was approximately \$7.3 million of total unrecognized compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 2.84 years.

**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 September 30, 2018, 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 and \$0.6 million for the three and nine-month periods ended September 30, 2018, respectively.

**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 nine months ended September 30, 2018 and 2017 (in thousands):

Table of Contents

	Chargebacks, Government Discounts, and Fees		and other rebates	Returns	Total
Beginning balance at December 31, 2017	\$ 1,986	\$ 1,231	\$ 421	\$ 3,638	
Provision related to sales in the current year	9,750	15,350	229	25,329	
Adjustments related to prior period sales	(76 )	(106 )	(111 )	(293 )	
Credits and payments made	(8,971 )	(9,257 )	(236 )	(18,464 )	
Ending balance at September 30, 2018	\$ 2,689	\$ 7,218	\$ 303	\$ 10,210	
Beginning balance at December 31, 2016	\$ —	\$ —	\$ —	\$ —	
Provision related to sales in the current year	688	459	296	1,443	
Adjustments related to prior period sales				—	
Credits and payments made				—	
Ending balance at September 30, 2017	\$ 688	\$ 459	\$ 296	\$ 1,443	

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. The total provision related to sales for 2018 of \$25.3 million is comprised of \$6.1 million, \$8.6 million, and \$10.6 million, respectively, for activity during the quarters ended March 31, June 30, and September 30, 2018. The total adjustments related to prior period sales in 2018 of \$293 thousand is comprised of \$245 thousand, \$(29) thousand, and \$77 thousand, respectively, for the quarters ended March 31, June 30, and September 30, 2018. The total credits and payments made for 2018 of \$18.5 million is comprised of \$3.0 million, \$6.7 million, and \$8.8 million, respectively, for activity during the quarters ended March 31, June 30, and September 30, 2018.

## 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 September 30, 2018		Nine Months Ended September 30, 2018	
	2017	2018	2017	2018
Numerator:				
Net loss	\$(49,802)	\$(57,843 )	\$(180,239)	\$(183,220)
Denominator:				
Weighted-average number of common shares used in loss per share - basic and diluted	45,498,909	43,999,451	45,291,176	43,535,874
Loss per share - basic and diluted	\$(1.09 )	\$(1.31 )	\$(3.98 )	\$(4.21 )

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 and nine months ended September 30, 2018 and 2017, 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 and Nine Months Ended September 30, 2018		2017
Options to purchase common stock	5,759,140	6,233,398	
Warrants	120,532	605,415	
Restricted stock units	262,002	108,940	





Table of Contents

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 September 30, 2018, 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 and nine-month periods ended September 30, 2018 and 2017, 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 has agreed to exclusively manufacture Phase 3 and global commercial supplies of an abaloparatide-coated transdermal patch product ("Product") and associated applicator devices ("Applicator"). Under the Supply Agreement, 3M will manufacture Product and Applicator for 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 are expected to be made between the fourth quarter of 2018 and 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 \$24.0 million, in the aggregate, through September 30, 2018 with respect to services and deliverables delivered pursuant to the Development Agreement.

## Ipsen

In September 2005, the Company entered into a license agreement (the "License Agreement"), as amended, with an affiliate of Ipsen Pharma SAS ("Ipsen") under which the Company exclusively licensed certain Ipsen compound technology and related patents covering abaloparatide to research, develop, manufacture, and commercialize certain compounds and related products in all countries, except Japan (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

Table of Contents

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 September 30, 2018. The License Agreement provides for further payments upon the achievement of certain future regulatory and commercial milestones. Total additional milestone payments that could be payable under the agreement are €24.0 million (approximately \$28.0 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 \$1.4 million and \$3.2 million for the three and nine months ended September 30, 2018, respectively, and is included within cost of sales. 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 final decision in arbitration proceedings with Ipsen in connection with the License Agreement, the Company is 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.

Eisai Co. Ltd.

In June 2006, the Company entered into a license agreement (the "Eisai Agreement"), with Eisai Co. Ltd. ("Eisai"). Under the Eisai Agreement, Eisai granted to the Company an exclusive right and license to research, develop, manufacture and commercialize elacestrant (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

Table of Contents

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 entered into a patent license agreement (the “Duke Agreement”) with Duke University (“Duke”). 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 an aggregate of \$1.3 million, which were expensed as research and development costs during 2017. The Duke Agreement provides for additional payments upon the achievement of certain 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 licensed patent rights to expire in a country. The latest licensed patent is expected to expire, barring any extension thereof, 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 either party upon an uncured material breach of the agreement by the other party. The Company may terminate the agreement upon 60 days written notice to Duke, if the Company suspends its manufacture, use and sale of the licensed products.

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.

Upon execution of the Teijin Agreement, the transaction price included only the \$10.0 million up-front payment owed to the Company. The Company received this amount in October 2017. As referenced above, the Company may receive further

Table of Contents

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.

## 13. Income Taxes

The Company did not record a federal or state income tax provision or benefit for the three and nine months ended September 30, 2018 and 2017 due to the expected loss before income taxes to be incurred for the years ended December 31, 2018 and 2017, as well as the Company's continued maintenance of a full valuation allowance against its net deferred tax assets.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the U.S. Tax Cuts and Jobs Act (the "Tax Reform Act"), which was enacted in December 2017. The Company has recognized the provisional tax impacts related to the revaluation of the deferred tax assets and liabilities and included these amounts in its consolidated financial statements for the year ended December 31, 2017. The ultimate impact may differ from these provisional amounts due to, among other things, additional analysis, changes in interpretations and assumptions the Company has made, additional regulatory guidance that may be issued, and actions the Company may take as a result of the Tax Reform Act. The accounting was completed when the Company's 2017 U.S. corporate income tax return was filed in October 2018.

## 14. Commitments and Contingencies

## Litigation

The Company may be subject to legal proceedings and claims which arise in the ordinary course of its business. In the Company's opinion, the ultimate resolution of these matters is not expected to have a material effect on its consolidated financial statements. The Company records a liability in its consolidated financial statements for these matters when a loss is known or considered probable and the amount can be reasonably estimated. The Company reviews these estimates each accounting period as additional information is known and adjusts the loss provision when appropriate. If a matter is both probable to result in a liability and the amounts of loss can be reasonably estimated, the Company estimates and discloses the possible loss or range of loss to the extent necessary to make the consolidated financial statements not misleading. If the loss is not probable or cannot be reasonably estimated, a liability is not recorded in its consolidated financial statements. As of September 30, 2018, 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 active pharmaceutical ingredient ("API") for TYMLOS. The Company agreed to purchase a minimum number of devices at prices per device that decrease with an increase in quantity supplied. In addition, the Company has made milestone payments for Ypsomed's capital developments in connection with the initiation of the commercial supply of the device and paid a one-time capacity fee. All costs and payments under the agreement are delineated in Swiss Francs. The agreement has an initial term of three years, which began on June 1, 2017, after which it automatically renews for two-year terms unless either party terminates the agreement upon 18 months' notice prior to the end of the then-current term. The Company agreed to purchase the devices at prices that decrease based on the quantity ordered, subject to an annual increase by Ypsomed and 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 equal to approximately CHF 0.5 million (approximately \$0.5 million) per year and CHF 2.9 million (approximately \$3.0 million) in total, subject to any annual price adjustments, during the initial term.

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 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,

Table of Contents

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 \$3.4 million) per year and approximately €16.1 million (approximately \$18.7 million) in total, subject to any annual price adjustments, during the initial term.

Restructuring

In March 2018, the Company implemented a restructuring plan to consolidate operations into its two main offices in Waltham, Massachusetts and Wayne, Pennsylvania to achieve operational efficiencies. As part of that effort, the Company will shut down its Parsippany, New Jersey office. Costs incurred in connection with the restructuring comprise one-time benefits to employees who are involuntarily terminated, costs related to the early termination of contracts, and retention costs for certain employees who will continue to work remotely for the Company after the Parsippany office is closed. Employee termination and retention related costs are generally recognized ratably over the future service period and contract termination costs are generally recognized as of the cease-use date. During the nine months ended September 30, 2018, the Company incurred \$1.5 million of employee termination and retention costs, with related cash payments to be made through the first quarter of 2019.

In June 2018, the Company implemented a restructuring plan designed to increase the impact and efficiency of its field sales by re-allocating commercial resources across certain territories. Costs incurred in connection with the restructuring comprise one-time benefits to employees who are involuntarily terminated. During the nine months ended September 30, 2018, the Company incurred \$0.5 million of employee termination costs, and made related cash payments in the third quarter of 2018.

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

Cautionary Statement

This Quarterly Report on Form 10-Q, 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 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 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. and the impact of the CHMP’s adoption of a negative opinion on our European Marketing Authorisation Application for abaloparatide-SC;
- our expectations regarding the timing of our regulatory submissions;
- our expectations for our Phase 3 study of elacestrant or other clinical trials, including projected costs, study designs or the timing for initiation, recruitment or completion;
- our ability to compete with other companies that are or may be developing or selling products that are competitive with TYMLOS or our investigational product candidates;
- anticipated trends and challenges in the market in which TYMLOS will compete and in other potential markets in which we may compete;
- our plans with respect to collaborations and licenses related to the development, manufacture or sale of TYMLOS and our investigational product candidates;
- the progress of, timing of and amount of expenses associated with our research, development and commercialization activities;
- the safety profile and related adverse events of TYMLOS and our investigational product candidates;
- the ability of our investigational product candidates to meet existing or future regulatory standards;

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

Table of Contents

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, 2017. 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” 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 October 16, 2018, TYMLOS was available and covered for approximately 265 million U.S. insured lives, representing approximately 95% of U.S. commercial and 44% of Medicare insured lives. Effective January 1, 2019, we project TYMLOS will be available and covered for approximately 274 million U.S. insured lives, representing approximately 95% of U.S. commercial and 64% of Medicare insured lives. In May 2017, we announced positive top-line results from our completed 24-month ACTIVEExtend 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. We submitted a labeling supplement to the FDA in connection with the results from our ACTIVEExtend trial 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 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 April 2018, we submitted a request for re-examination of the CHMP’s opinion and in July 2018, following a re-examination procedure, the CHMP maintained its negative opinion. 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 pursuant to which 3M has agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-patch. 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 are expected to be made between the fourth quarter of 2018 and the third quarter of 2020.

Table of Contents

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. In October 2017, the FDA granted Fast Track designation for our elacestrant breast cancer program. We have completed enrollment in our ongoing dose escalation Part A, and dose expansion Part B and C, and in the 18F fluoroestradiol positron emission tomography (“FES-PET”) imaging Phase 1 studies of elacestrant in advanced metastatic breast cancer. We currently intend to conduct 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+/HER2- advanced/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. We expect to initiate this Phase 3 study in the fourth quarter of 2018 with a planned recruitment period of 18 to 21 months. In September 2018, we submitted a request to the FDA for an additional Fast Track designation for elacestrant for the population to be included in the Phase 3 study.

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

Abaloparatide

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

Abaloparatide-SC

TYMLOS was approved in the United States in April 2017 for the treatment of postmenopausal women with osteoporosis at high risk for fracture. The first commercial sales of TYMLOS in the United States occurred in May 2017 and as of October 16, 2018, TYMLOS was available and covered for approximately 265 million U.S. insured lives, representing approximately 95% of U.S. commercial and 44% of Medicare insured lives. Effective January 1, 2019, we project TYMLOS will be available and covered for approximately 274 million U.S. insured lives, representing approximately 95% of U.S. commercial and 64% 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 April 2018, we submitted a request for re-examination of the CHMP’s opinion and in July 2018, following a re-examination procedure, the CHMP maintained its negative opinion.

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-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

Table of Contents

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.

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 will be a randomized, double-blind, placebo-controlled trial that will enroll approximately 225 men with osteoporosis. The primary endpoint is change in lumbar spine BMD at 12 months compared with placebo. In previous clinical trials, TYMLOS has demonstrated increases in BMD in postmenopausal women. The study 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 we are developing abaloparatide-patch toward future global regulatory submissions to build upon the potential success of TYMLOS. Our development strategy for abaloparatide patch is to bridge to the established efficacy and safety of our approved abaloparatide-SC formulation.

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

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



study in mid-2019 and to complete it in 2020. In February 2018, we entered into a scale-up and commercial supply agreement with 3M Company pursuant to which 3M has agreed to exclusively manufacture Phase 3 and global commercial supplies of abaloparatide-patch. 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 are expected to be made between the fourth quarter of 2018 and the third quarter of 2020.

Elacestrant (RAD1901)

Table of Contents

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.

In October 2017, the FDA granted Fast Track designation for our elacestrant breast cancer program. In February 2018, we received scientific advice from the EMA regarding a potential single-arm monotherapy Phase 2 trial of elacestrant in patients with ER+, HER2- advanced or metastatic breast cancer. In addition, we had a meeting in February 2018 with the FDA regarding the registrational pathway for elacestrant at which we confirmed FDA's guidance for a single-arm study and gained alignment with the agency on an alternative potential comparator study design for our monotherapy program. Following further review and additional input from the FDA, we currently intend to conduct 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+/HER2- advanced/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 would 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. We expect to initiate the Phase 3 study in the fourth quarter of 2018 with a planned recruitment period of 18 to 21 months. In September 2018, we submitted a request to the FDA for an additional 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 on a more homogeneous patient population to support our overall elacestrant clinical development program and anticipated regulatory submissions. We discontinued recruitment in the Part D cohort because the outcome is no longer relevant to the revised study population for 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 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. Ten patients were enrolled in the Part D cohort, and as of June 30, 2018, three patients remained on treatment.

Phase 1 - FES-PET Study

In December 2015, we commenced a FES-PET study in patients with metastatic breast cancer in the EU, which includes the use of FES-PET imaging to assess estrogen receptor occupancy in tumor lesions following elacestrant treatment.

In December 2016, we reported positive results from the Phase 1 FES-PET study. The first three enrolled patients dosed at the 400-mg cohort had a tumor FES-PET signal intensity reduction ranging from 79% to 91% at day 14 compared to baseline. This study enrolled five additional patients in the 400-mg daily oral cohort, followed by eight patients in the 200-mg daily oral cohort. In December 2017, we reported updated data from the Phase 1 FES-PET study showing that elacestrant demonstrated robust reduction in tumor ER availability in patients with advanced ER+ breast cancer who progressed on prior endocrine

Table of Contents

therapy. Seven out of eight patients dosed at the 400-mg cohort, and four out of seven patients dosed at the 200-mg cohort, had a tumor FES-PET signal intensity reduction equal to, or greater than, 75% at day 14 compared to baseline. The reduction in FES uptake supports flexibility for both 200-mg and 400-mg elacestrant dose selection for further clinical development in combination studies with various targeted agents and was similar in patients harboring mutant or wild-type ESR1. The most commonly reported adverse events reported were grade 1 and 2 nausea and dyspepsia.

Potential for use in Combination Therapy

In July 2015, we announced that early but promising preclinical data showed that our investigational drug elacestrant, in combination with Pfizer's palbociclib, a cyclin-dependent kinase, 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.

Collaborations

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

In January 2016, we entered into a worldwide clinical collaboration with Novartis Pharmaceuticals to evaluate the safety and efficacy of combining elacestrant with Novartis' investigational agent LEE011 (ribociclib), a CDK 4/6 inhibitor, and BYL719 (alpelisib), an investigational phosphoinositide 3-kinase inhibitor. In January 2018, we terminated this collaboration following the completion of preclinical studies. We are evaluating additional opportunities to collaborate with companies to evaluate the safety and efficacy of combining elacestrant with other targeted 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 July 2016, we reported that RAD140 in preclinical xenograft models of breast cancer demonstrated potent tumor growth inhibition when administered alone or in combinations with CDK4/6 inhibitors. It is estimated that 77% of breast cancers show expression of the androgen receptor. Our data suggest that RAD140 activity at the androgen receptor leads to activation of AR signaling pathways including an AR-specific tumor suppressor and suppression of ER signaling. In April 2017, we presented these RAD140 preclinical results at a major scientific congress.

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

development program by the end of 2018.

Financial Overview

Product Revenue

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

26

---

Table of Contents

## 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 September 30, 2018 were approximately \$219.2 million. We began tracking program expenses for abaloparatide-patch in 2007, and program expenses from inception to September 30, 2018 were approximately \$48.3 million. We began tracking program expenses for elacestrant (RAD1901) in 2006, and program expenses from inception to September 30, 2018 were approximately \$81.8 million. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to September 30, 2018 were approximately \$14.7 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 and nine months ended September 30, 2018 and 2017 (in thousands):

	Three Months Ended September 30, 2018		Nine Months Ended September 30, 2017	
Program-specific costs - external:				
Abaloparatide-SC*	\$1,344	\$311	\$4,561	\$608
Abaloparatide-patch	3,636	1,308	6,163	2,340
Elacestrant (RAD1901)	6,656	4,083	13,817	6,990
RAD140	1,001	245	3,658	1,566
Total program-specific costs - external	\$12,637	\$5,947	\$28,199	\$11,504
Shared-services costs - external:				
R&D support costs	2,790	2,972	9,171	8,990
Other operating costs	519	529	1,965	1,992
Total shared-services costs - external	\$3,309	\$3,501	\$11,136	\$10,982
Shared-services costs - internal				
Personnel-related costs	7,886	7,486	25,013	23,663
Stock-based compensation	2,389	3,261	9,310	11,829
Occupancy costs	332	548	1,562	1,616
Depreciation expense	251	254	759	582
Total shared-services costs - internal	\$10,858	\$11,549	\$36,644	\$37,690
Total research and development costs	\$26,804	\$20,997	\$75,979	\$60,176

\*2017 expenses were net of the FDA's refund of NDA fees of \$2.4 million previously paid and expensed in the first quarter of 2016.

Selling, General and Administrative Expenses

27

---

## Table of Contents

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 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).

### Other Operating Expenses

Other operating expenses reflects a payment made to Ipsen pursuant to a final decision in arbitration proceedings with Ipsen.

### 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 Convertible Notes. A portion of the interest expense on the Convertible Notes is non-cash expense relating to accretion of the debt discount and amortization of issuance costs.

### Critical Accounting Policies and Estimates

Our management's discussion and analysis of 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, 2017. 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.

We have reviewed our policies and estimates to determine our critical accounting policies for the three and nine months ended September 30, 2018. Significant accounting policies over revenue are detailed below. There were no changes to significant accounting policies during the three and nine months ended September 30, 2018, except for the adoption of three Accounting Standards Updates issued by the Financial Accounting Standards Board, 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.

Revenue recognition—On April 28, 2017, the FDA approved TYMLOS in the U.S. Subsequent to receiving FDA approval, we entered into a limited number of arrangements with wholesalers in the U.S. (collectively, our "Customers") to distribute TYMLOS. These arrangements are our initial contracts with customers and, as a result, we adopted Accounting Standards Codification ("ASC") Topic 606 - Revenue from Contracts with Customers ("Topic 606"). There is no transition to Topic 606 because we had no historical revenue. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements, and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled in exchange for those goods or services.

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



the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net—We sell TYMLOS to our Customers. These Customers subsequently resell our products to specialty pharmacy providers, as well as other retail pharmacies and certain medical centers or hospitals. In addition to distribution

Table of Contents

agreements with Customers, we enter into arrangements with specialty pharmacies, health care providers and payors that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of our products.

We recognize revenue on product sales when the Customer obtains control of our product, which occurs at a point in time (upon delivery). Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances. Payment from Customers is typically due within 31 calendar days of the invoice date.

If taxes should be collected from Customers relating to product sales and remitted to governmental authorities, they will be excluded from revenue. We expense incremental costs of obtaining a contract when incurred, if the expected amortization period of the asset that we would have recognized is one year or less. However, no such costs were incurred during the three and nine months ended September 30, 2018.

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

The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. Our analyses also contemplated application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of September 30, 2018 and, therefore, the transaction price was not reduced further during the three and nine months ended September 30, 2018. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

**Trade Discounts and Allowances**—We generally provide Customers with discounts which include incentive fees that are explicitly stated in our contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, we compensate (through trade discounts and allowances) our Customers for sales order management, data, and distribution services. However, we have determined such services received to date are not distinct from the sale of our products to the Customer and, therefore, these payments have been recorded as a reduction of revenue within the statement of operations and comprehensive loss through September 30, 2018, as well as a reduction to trade receivables, net on the condensed consolidated balance sheets.

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

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

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

Table of Contents

Product that we, at our sole discretion, have specified to be returned.

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

Expired product that is returned during the period beginning six months prior to the product's expiration date and ending twelve months after the product's expiration date;

Product subject to a recall; and

Product that we, at our sole discretion, have specified to be returned.

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

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

**Payor Rebates**—We contract with certain private payor organizations, primarily insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. We estimate these rebates and record such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

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

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

**Licenses of Intellectual Property**—We enter into out-licensing agreements within the scope of Topic 606, under which we license certain rights to our product candidates to third parties. Such agreements may include the transfer of intellectual property rights in the form of licenses, transfer of technological know-how, delivery of drug substances, research and development services, and participation on certain committees with the counterparty. Payments made by the customers may include one or more of the following: non-refundable, up-front license fees; payments upon the exercise of customer options; development, regulatory, and commercial milestone payments; payments for manufacturing supply services we provide through our contract manufacturers; and royalties on net sales of licensed products if they are successfully approved and commercialized. Each of these payments may result in license,

collaboration, or other revenue, except revenue from royalties on net sales of licensed products, which would be classified as royalty revenue.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of our out-licensing agreements, we perform the following steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations including whether they are distinct in the

30

---

Table of Contents

context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and determines those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

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

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

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

We then determine whether the performance obligations or combined performance obligations are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. We evaluate the measure of progress, as applicable, each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

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

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

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

## Results of Operations

Three Months Ended September 30, 2018 and 2017 (in thousands, except percentages)



Table of Contents

	Three Months Ended		Change	
	September 30, 2018	September 30, 2017	\$	%
Revenues:				
Product revenue, net	\$27,639	\$3,469	\$24,170	697 %
License revenue	—	10,000	(10,000 )	(100)%
Operating expenses:				
Cost of sales - product	2,193	253	1,940	767 %
Cost of sales - intangible amortization	200	200	—	—
Research and development	26,804	20,997	5,807	28 %
Selling, general and administrative	43,661	47,723	(4,062 )	(9 )%
Loss from operations	(45,219 )	(55,704 )	(10,485 )	(19 )%
Other (expense) income:				
Other expense	17	(195 )	212	109 %
Interest expense	(5,793 )	(2,763 )	3,030	110 %
Interest income	1,193	819	374	46 %
Net loss	\$(49,802)	\$(57,843)	\$(8,041 )	(14 )%

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 September 30, 2018 we recorded approximately \$27.6 million of net product revenue compared to \$3.5 million for the three months ended September 30, 2017. 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, 2017.

Cost of sales— Cost of sales of \$2.4 million for the three months ended September 30, 2018 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 \$0.5 million for the three months ended September 30, 2017. The increase in cost of sales was driven by the increase in product revenue. In addition, based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of TYMLOS units recognized as revenue during the three months ended September 30, 2018 were expensed prior to the April 2017 FDA approval and, therefore, are not included in cost of sales during this period. Such amounts totaled \$0.2 million and \$0.1 million for the three months ended September 30, 2018 and 2017, respectively. We expect cost of sales to increase in relation to product revenues as we deplete these inventories, which total approximately \$0.1 million as of September 30, 2018.

Research and development expenses— For the three months ended September 30, 2018, research and development expense was \$26.8 million compared to \$21.0 million for the three months ended September 30, 2017, an increase of \$5.8 million, or 28%. This increase was primarily driven by a \$2.8 million increase in elacestrant project costs, a \$2.3 million increase in abaloparatide-patch project costs, a \$1.0 million increase in abaloparatide-SC project costs, and a \$0.8 million increase in RAD140 project costs. These increases were partially offset by a \$0.2 million decrease in other project related spending, and \$0.5 million decrease in personnel related spending attributed to a decrease in headcount from 105 research and development employees as of September 30, 2017 to 95 research and development employees as of September 30, 2018.

Selling, general and administrative expenses— For the three months ended September 30, 2018, selling, general and administrative expense was \$43.7 million compared to \$47.7 million for the three months ended September 30, 2017, a decrease of \$4.1 million, or 9%. This decrease was primarily the result of \$2.8 million and \$0.9 million decreases in compensation and travel related expenses, respectively.

Interest income—For the three months ended September 30, 2018, interest income was approximately \$1.2 million compared to \$0.8 million for the three months ended September 30, 2017, an increase of \$0.4 million, or 46%. This increase was primarily due to the combined effects of an increase in the balance of our investments coupled with an



increase in the rate of return on investments in the three months ended September 30, 2018 as compared to those of the three months ended September 30, 2017.

Interest expense—For the three months ended September 30, 2018, interest expense was approximately \$5.8 million compared to \$2.8 million for the three months ended September 30, 2017, an increase of \$3.0 million. This increase was the result of the

Table of Contents

issuance of the Convertible Notes during the three months ended September 30, 2017, while debt was outstanding for the entire three months ended September 30, 2018.

Nine Months Ended September 30, 2018 and 2017 (in thousands, except percentages)

	Nine Months Ended		Change	
	September 30, 2018	2017	\$	%
<b>Revenues:</b>				
Product revenue, net	\$64,815	\$4,449	\$60,366	1,357 %
License revenue	—	10,000	(10,000 )	(100 )%
<b>Operating expenses:</b>				
Cost of sales - product	4,884	358	4,526	1,264 %
Cost of sales - intangible amortization	599	200	399	200 %
Research and development	75,979	60,176	15,803	26 %
Selling, general and administrative	140,266	135,943	4,323	3 %
Other operating expenses	10,801	—	10,801	100 %
Loss from operations	(167,714 )	(182,228 )	(14,514 )	(8 )%
<b>Other (expense) income:</b>				
Other expense	83	(212 )	(295 )	(139 )%
Interest expense	(17,041 )	(2,763 )	14,278	517 %
Interest income	4,433	1,983	2,450	124 %
Net loss	\$(180,239)	\$(183,220)	\$(2,981 )	(2 )%

**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 nine months ended September 30, 2018 we recorded approximately \$64.8 million of net product revenue compared to \$4.4 million for the nine months ended September 30, 2017. 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, 2017.

**Cost of sales**— Cost of sales of \$5.5 million for the nine months ended September 30, 2018, 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 \$0.6 million for the nine months ended September 30, 2017. The increase in cost of sales was driven by the increase in product revenue. Based on our policy to expense costs associated with the manufacture of our products prior to regulatory approval, certain of the costs of TYMLOS units recognized as revenue during the nine months ended September 30, 2018 were expensed prior to the April 2017 FDA approval and, therefore, are not included in cost of sales during this period. Such amounts totaled \$0.5 million and \$0.1 million for the nine months ended September 30, 2018 and 2017, respectively. We expect cost of sales to increase in relation to product revenues as we deplete these inventories, which total approximately \$0.1 million as of September 30, 2018.

**Research and development expenses**— For the nine months ended September 30, 2018, research and development expense was \$76.0 million compared to \$60.2 million for the nine months ended September 30, 2017, an increase of \$15.8 million, or 26%. This increase was primarily driven by a \$7.6 million increase in elacestrant project costs, a \$4.0 million increase in abaloparatide-SC project costs, a \$3.8 million increase in abaloparatide-patch project costs, and a \$2.1 million increase in RAD140 project costs. These increases were partially offset by a \$0.7 million decrease in other project related spending and a \$0.9 million decrease in compensation and travel related expenses attributed to a decrease in headcount from 105 research and development employees as of September 30, 2017 to 95 research and development employees as of September 30, 2018.

**Selling, general and administrative expenses**— For the nine months ended September 30, 2018, selling, general and administrative expense was \$140.3 million compared to \$135.9 million for the nine months ended September 30, 2017, an increase of \$4.3 million, or 3%. This increase was primarily the result of \$2.5 million and \$0.7 million increases in compensation and travel related expenses, respectively attributed to an increase in headcount from 361

selling, general and administrative employees as of September 30, 2017 to 384 selling, general and administrative employees as of September 30, 2018. Additionally, there was a \$0.8 million increase in professional fees and other operating expenses.

Table of Contents

Other operating expenses—For the nine months ended September 30, 2018, other operating expenses were approximately \$10.8 million compared to \$0 for the nine months ended September 30, 2017, an increase of \$10.8 million. This increase was the result of a \$10.8 million payment made to Ipsen pursuant to a final decision in arbitration proceedings with Ipsen during the nine months ended September 30, 2018.

Interest income—For the nine months ended September 30, 2018, interest income was approximately \$4.4 million compared to \$2.0 million for the nine months ended September 30, 2017, an increase of \$2.5 million, or 124%. This increase was primarily due to the combined effects of an increase in the balance of our investments coupled with an increase in the rate of return on investments in the nine months ended September 30, 2018 as compared to those of the nine months ended September 30, 2017.

Interest expense—For the nine months ended September 30, 2018, interest expense was approximately \$17.0 million compared to \$2.8 million for the nine months ended September 30, 2017, an increase of \$14.3 million. This increase was the result of the issuance of the Convertible Notes during September 2017, while debt was outstanding for the entire nine months ended September 30, 2018.

#### Liquidity and Capital Resources

From inception to September 30, 2018, we have incurred an accumulated deficit of \$1,062.5 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 September 30, 2018 was \$276.9 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 September 30, 2018, 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 least than twelve months from the date of this filing. We expect to finance the future U.S. commercial activities and development costs of our clinical product portfolio with our existing cash, cash equivalents, marketable securities, and investments, as well as through future product sales, or through strategic financing opportunities, that could include, but are not limited to partnering or other collaboration agreements, future offerings of equity, royalty-based financing arrangements, the incurrence of additional debt, or other alternative financing arrangements, which may involve a combination of the foregoing.

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, 2017. The following table sets forth the major sources and uses of cash for each of the periods set forth below (in thousands):

	Nine Months Ended		Change	
	September 30, 2018	September 30, 2017	\$	%
Net cash (used in) provided by:				

Edgar Filing: Radius Health, Inc. - Form 10-Q

Operating activities	\$(164,497)	\$(167,091)	\$2,594	2	%
Investing activities	96,932	41,105	55,827	136	%
Financing activities	11,518	314,357	(302,839)	(96)	%
Net decrease in cash, cash equivalents, and restricted cash	\$(56,047)	\$188,371	(244,418)	(130)	%
Cash Flows from Operating Activities					

34

---

Table of Contents

Net cash used in operating activities during the nine months ended September 30, 2018 was \$164.5 million, which was primarily the result of a net loss of \$180.2 million, partially offset by \$34.3 million of net non-cash adjustments to reconcile net loss to net cash used in operations and net changes in working capital of \$18.6 million. The \$180.2 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 \$34.3 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of \$22.3 million, amortization of debt discount of \$10.2 million, and depreciation of \$2.0 million.

Net cash used in operating activities during the nine months ended September 30, 2017 was \$167.1 million, which was primarily the result of a net loss of \$183.2 million, partially offset by \$31.6 million of net non-cash adjustments to reconcile net loss to net cash used in operations and net changes in working capital of \$14.8 million. The \$183.2 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 \$31.6 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of \$28.8 million, amortization of debt discount of \$1.6 million, and depreciation of \$1.4 million.

**Cash Flows from Investing Activities**

Net cash provided by investing activities during the nine months ended September 30, 2018 was \$96.9 million, which was primarily the result of \$97.5 million in sales and maturities of marketable securities, partially offset by \$0.5 million of purchases of marketable securities.

Net cash provided by investing activities during the nine months ended September 30, 2017 was \$41.1 million, which was primarily the result of \$117.4 million of purchases of marketable securities and \$8.7 million payments for capitalized milestone partially offset by \$170.2 million of net proceeds received from the sale or maturity of marketable securities.

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 nine months ended September 30, 2018 was \$11.5 million, which primarily consisted of \$9.0 million of proceeds received from exercises of stock options and \$2.6 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 nine months ended September 30, 2017 was \$314.4 million, which primarily consisted of \$295.6 million of proceeds from our 3% Convertible Senior Notes due 2024, \$16.2 million of proceeds received from exercises of stock options and \$2.6 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 September 30, 2018 were as follows (in thousands):

Table of Contents

Years ended December 31,	Future Minimum Payments
2019	9,150
2020	9,150
2021	9,150
2022	9,150
2023	9,150
2024 and Thereafter	\$314,150
Total minimum payments	\$359,900
Less: interest	(54,900 )
Less: unamortized discount	(128,820 )
Less: current portion	—
Long Term Debt	\$176,180

## Contractual Obligations

## Supply and Manufacturing Agreements

In June 2016, we entered into a Supply Agreement with Ypsomed AG (“Ypsomed”), pursuant to which Ypsomed agreed to supply commercial and clinical supplies of a disposable pen injection device customized for subcutaneous injection of abaloparatide, the active pharmaceutical ingredient (“API”) for TYMLOS. We agreed to purchase a minimum number of devices at prices per device that decrease with an increase in quantity supplied. In addition, we have made milestone payments for Ypsomed’s capital developments in connection with the initiation of the commercial supply of the device and paid a one-time capacity fee. All costs and payments under the agreement are delineated in Swiss Francs. The agreement has an initial term of three years, which began on June 1, 2017, after which, it automatically renews for two-year terms unless either party terminates the agreement upon 18 months' notice prior to the end of the then-current term. We agreed to purchase the devices at prices based on the quantity ordered, subject to an annual increase by Ypsomed and 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 equal to approximately CHF 0.5 million (approximately \$0.5 million) per year and approximately CHF 2.9 million (approximately \$3.0 million) in total, subject to any annual price adjustments, during the initial term.

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 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 agreed to manufacture the commercial and clinical supplies of the API for abaloparatide. We agreed to purchase the API in batches at a price per gram in euros, subject to an annual increase by PPL. The agreement has an initial term of a 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. We are also required to purchase a minimum number of batches annually, equal to approximately €2.9 million (approximately \$3.4 million) per year and approximately €16.1 million (approximately \$18.7 million) in total, subject to any annual price adjustments, during the initial 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,



Table of Contents

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 \$28.0 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 sublicense). The applicable percentage is in the low double-digit range. In addition, if we or our sublicensees commercialize a product that includes a compound discovered by us based on or derived from confidential Ipsen know-how, the agreement provides that we would pay to Ipsen a fixed low single-digit royalty on net sales of such product on a country-by-country basis until the later of the last to expire of our patents that cover such product or for a period of 10 years after the first commercial sale of such product in such country.

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

Prior to executing the License Agreement for abaloparatide with Radius, Ipsen licensed the Japanese rights for abaloparatide to Teijin. Teijin has initiated a Phase 3 clinical 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 has agreed to exclusively manufacture Phase 3 and global commercial supplies of an abaloparatide-coated transdermal patch product ("Product") and associated applicator devices ("Applicator"). Under the Supply Agreement, 3M 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 are expected to be made between the

fourth quarter of 2018 and 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,

37

---

Table of Contents

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 \$24.0 million, in the aggregate, through September 30, 2018 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, 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 entered into a patent license agreement (the “Duke Agreement”) with Duke University (“Duke”). Under the Duke Agreement, we acquired an 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, the “Duke Patents”).

In consideration for these rights, we incurred non-refundable, non-creditable obligations to pay Duke an aggregate of \$1.3 million, which were expensed as research and development costs during 2017. The Duke Agreement provides for additional payments upon the achievement of certain regulatory and commercial milestones totaling up to \$3.8 million. To date, we have

Table of Contents

paid Duke approximately \$0.5 million in connection with the achievement of certain milestones. The agreement provides that we 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 licensed patent rights to expire in a country. The latest licensed patent is expected to expire, barring any extension thereof, on October 10, 2034.

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.

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, 2017, we had federal and state net operating loss carryforwards of approximately \$751.7 million and \$669.3 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 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

39

---

Table of Contents

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.

40

---

Table of Contents

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 September 30, 2018, we had cash, cash equivalents, restricted cash, marketable securities and investments of \$276.9 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 September 30, 2018, 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.



Table of Contents

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 September 30, 2018.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting during the three and nine months ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

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 September 30, 2018, 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, 2017 as modified by the risk factors in Part II, “Item 1A. Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended June 30, 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.

Table of Contents

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.

None.

Item 6. Exhibits.

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

Table of Contents

## EXHIBIT INDEX

Unless otherwise indicated, all references to previously filed Exhibits refer to the Company's filings with the Securities and Exchange Commission ("SEC"), under File No. 001-35726.

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed/ Furnished Herewith
		Form	File No.	Filing Exhibit Date	
<u>3.1</u>	Restated Certificate of Incorporation	8-K	3.1	6/13/2014	
<u>3.2</u>	Amended and Restated By-Laws	8-K	3.1	3/2/2018	
<u>10.1</u> <sup>^</sup>	Separation Agreement and General Release of Claims, dated September 19, 2018, between the Company and Gary Hattersley				*
<u>10.2</u> <sup>^</sup>	Consulting Agreement, dated September 19, 2018, between the Company and Gary Hattersley				*
<u>31.1</u>	Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)/15d-14(a)				*
<u>31.2</u>	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)/15d-14(a)				*
<u>32.1</u>	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				**
101.INS	XBRL Instance Document				*
101.SCH	XBRL Taxonomy Extension Schema Document				*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				*

\* Filed herewith.

\*\* Furnished herewith.

<sup>^</sup> Management contracts and compensatory plans.

SIGNATURES

45

---

Table of Contents

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

RADIUS HEALTH, INC.

By: /s/ Jesper Hoeiland  
Jesper Hoeiland  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: November 1, 2018

By: /s/ Jose Carmona  
Jose Carmona  
Chief Financial Officer  
(Principal Accounting and Financial Officer)

Date: November 1, 2018