Radius Health, Inc.
Form 10-Q
August 04, 2017
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2017
Or
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to .

Commission File Number 001-35726

Radius Health, Inc.
(Exact name of registrant as specified in its charter)

Delaware	80-0145732
(State or other jurisdiction of Incorporation or organization)	(IRS Employer Identification Number)

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

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

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 x No o

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

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 x Accelerated filer o

Non-accelerated filer o Smaller reporting company o

Emerging growth company o

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. o

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

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Number of shares of the registrant's Common Stock, $.0001 par value per share, outstanding as of July 31, 2017: 43,504,250 shares

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RADIUS HEALTH, INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2017

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Item 1. Condensed Consolidated Financial Statements

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

	June 30, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 135,110	$ 258,567
Restricted cash	47	47
Marketable securities	79,606	73,880
Trade receivables, net	1,211	—
Inventory	1,636	—
Prepaid expenses and other current assets	5,940	2,315
Total current assets	223,550	334,809
Property and equipment, net	6,738	4,922
Intangible assets	8,579	—
Other assets	558	551
Total assets	$ 239,425	$ 340,282
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,396	$ 6,128
Accrued expenses and other current liabilities	27,378	26,597
Total current liabilities	31,774	32,725
Other non-current liabilities	331	379
Total liabilities	$ 32,105	$ 33,104
Commitments and contingencies		
Stockholders' equity:		
Common stock, $.0001 par value; 200,000,000 shares authorized, 43,502,335 shares and 43,141,134 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	4	4
Additional paid-in-capital	960,736	935,671
Accumulated other comprehensive income	3	71
Accumulated deficit	(753,423)	(628,568)
Total stockholders' equity	207,320	307,178
Total liabilities and stockholders' equity	$ 239,425	$ 340,282

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
REVENUES:				
Product revenue, net	$980	$—	$980	$—
OPERATING EXPENSES:				
Cost of sales	105	—	105	—
Research and development	19,652	26,891	39,179	54,374
Selling, general and administrative	50,121	17,193	88,220	30,839
Loss from operations	(68,898)	(44,084)	(126,524)	(85,213)
OTHER (EXPENSE) INCOME:				
Other expense, net	(97)	(95)	(17)	(96)
Interest income	557	744	1,164	1,411
NET LOSS	$(68,438)	$(43,435)	$(125,377)	$(83,898)
OTHER COMPREHENSIVE LOSS:				
Unrealized (loss) gain from available-for-sale securities	(32)	(49)	(69)	183
COMPREHENSIVE LOSS	$(68,470)	$(43,484)	$(125,446)	$(83,715)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED (Note 10)	$(68,438)	$(43,435)	$(125,377)	$(83,898)
LOSS PER SHARE:				
Basic and diluted	$(1.58)	$(1.01)	$(2.90)	$(1.95)
WEIGHTED AVERAGE SHARES:				
Basic and diluted	43,410,053	43,042,883	43,300,243	43,027,903

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2017	2016
CASH FLOWS USED IN OPERATING ACTIVITIES:		
Net loss	$(125,377)	$(83,898)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	695	216
Amortization of premium (discount) on marketable securities, net	(75)	782
Stock-based compensation	20,533	10,632
Changes in operating assets and liabilities:		
Inventory	(1,636)	—
Trade receivables, net	(1,211)	—
Prepaid expenses and other current assets	(3,625)	1,772
Other long-term assets	(7)	(188)
Accounts payable	(1,732)	(3,201)
Accrued expenses and other current liabilities	(466)	1,248
Other non-current liabilities	(48)	—
Net cash used in operating activities	(112,949)	(72,637)
CASH FLOWS (USED IN) PROVIDED BY INVESTING ACTIVITIES:		
Purchases of property and equipment	(1,131)	(919)
Payments for capitalized milestones	(8,712)	—
Purchases of marketable securities	(111,983)	(225,497)
Sales and maturities of marketable securities	106,264	258,257
Net cash (used in) provided by investing activities	(15,562)	31,841
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	4,024	1,672
Proceeds from issuance of shares under employee stock purchase plan	1,030	—
Net cash provided by financing activities	5,054	1,672
NET DECREASE IN CASH AND CASH EQUIVALENTS	(123,457)	(39,124)
CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	258,567	159,678
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$135,110	$120,554
SUPPLEMENTAL DISCLOSURES:		
Cash paid for income taxes	$21	$—
Property and equipment purchases in accrued expenses at period end	$1,247	$345

See accompanying notes to unaudited condensed consolidated financial statements.

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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 therapeutics in the areas of osteoporosis, oncology and endocrine diseases. On April 28, 2017, the Company's first commercial product, TYMLOS™ for subcutaneous injection ("abaloparatide-SC"), was approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. The Company's European Marketing Authorisation Application ("MAA") for abaloparatide for subcutaneous injection, which, if approved, will be marketed in the European Union as Eladynos™, is under review by the Committee for Medicinal Products for Human Use of the EMA ("CHMP"). The Company's clinical pipeline includes an investigational abaloparatide transdermal patch ("abaloparatide-TD") for potential use in the treatment of women with postmenopausal osteoporosis and the investigational drug elacestrant (RAD1901) for potential use in the treatment of hormone-driven and/or hormone-resistant breast cancer, as well as for potential use in the treatment of vasomotor symptoms in postmenopausal women. Radius is also developing RAD140, a non-steroidal, selective androgen receptor modulator under investigation 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 June 30, 2017, the Company had an accumulated deficit of $753.4 million, and total cash, cash equivalents and marketable securities of $214.7 million.

Based upon its cash, cash equivalents and marketable securities balance as of June 30, 2017, the Company believes that, prior to the consideration of 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 not less than twelve months from the date of this filing. The Company expects to finance its commercial launch activities in the United States and development costs of its clinical product portfolio with its existing cash and cash equivalents and marketable securities, or through strategic financing opportunities that could include, but are not limited to, partnering or other collaboration agreements, future offerings of its equity, royalty-based financing arrangements, 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 planned commercialization activities or complete its planned preclinical studies and clinical trials and obtain approval of certain investigational product candidates from the FDA or foreign regulatory authorities.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation—The accompanying unaudited condensed consolidated financial statements and the related disclosures of the Company have been prepared in accordance with accounting principles generally accepted in the United States (“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 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 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 six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2017. Subsequent events have been evaluated up to the date of issuance of these financial statements. These interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes, which are contained in our Annual Report on Form 10-K for the year ended December 31, 2016 ("2016 Form 10-K"), filed with the Securities and Exchange Commission ("SEC") on February 24, 2017.

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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 2016 Form 10-K that require the Company to make estimates and assumptions include: research and development costs, stock-based compensation and fair value measures. There were no changes to significant accounting policies during the six months ended June 30, 2017, except for the adoption of two Accounting Standards Updates ("ASU") issued by the Financial Accounting Standards Board ("FASB"), as well as significant accounting policies over revenue, inventory, and intangibles, each of which is detailed below.

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

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

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

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

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

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

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If taxes should be collected from Customers relating to product sales and remitted to governmental authorities, they will be excluded from revenue. The Company expenses incremental costs of obtaining a contract when incurred, if the expected amortization period of the asset that the Company would have recognized is one year or less. However, no such costs were incurred during the three and six months ended June 30, 2017.

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

The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplated application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of June 30, 2017 and, therefore, the transaction price was not reduced further during the three months ended June 30, 2017. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances— The Company generally provides Customers with discounts which include incentive fees that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company compensates (through trade discounts and allowances) its Customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of products to the Customer and, therefore, these payments have been recorded as a reduction of revenue within the statement of operations and comprehensive loss through June 30, 2017, as well as a reduction to trade receivables, net on the condensed consolidated balance sheets.

Product Returns— Consistent with industry practice, the Company generally offers Customers a limited right of return for product that has been purchased from the Company based on the product's expiration date, which lapses upon shipment to a patient. The Company estimates the amount of its product sales that may be returned by its Customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as reductions to trade receivables, net on the condensed consolidated balance sheets. The Company currently estimates product return liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company has not received any returns to date and believes that returns of its products will be minimal.

Provider Chargebacks and Discounts— Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and trade receivables, net. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and the Company generally issues credits for such

amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, and chargebacks that Customers have claimed, but for which the Company has not yet issued a credit.

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

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product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

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

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

To date, the Company's only source of product revenue has been from the U.S. sales of TYMLOS, which it began shipping to Customers in May 2017. The following table summarizes activity in each of the product revenue allowance and reserve categories for the three months ended June 30, 2017 (in thousands):

	Chargebacks, Discounts, and Fees	Government and other rebates	Returns	Total
Beginning balance	$ —	$ —	$ —	$—
Provision related to sales in the current year	271	86	75	432
Credit and payments made	—	—	—	—
Ending balance	$ 271	$ 86	$ 75	$432

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.

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

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

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

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

The Company assesses its intangible assets for impairment if indicators are present or changes in circumstance suggest that impairment may exist. Events that could result in an impairment, or trigger an interim impairment assessment, include the receipt of additional clinical or nonclinical data regarding one of the Company's drug candidates or a potentially competitive drug candidate, changes in the clinical development program for a drug candidate, or new information regarding potential sales

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for the drug. If impairment indicators are present or changes in circumstance suggest that impairment may exist, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of each intangible asset to its carrying value on the condensed consolidated balance sheet. If the undiscounted cash flows used in the recoverability test are less than the carrying value, the Company would determine the fair value of the intangible asset and recognize an impairment loss if the carrying value of the intangible asset exceeds its fair value.

Accounting Standards Updates— In January 2016, the FASB issued ASU No. 2016-01, Financial Statements-Overall (Subtopics 825-10) ("ASU 2016-01"). ASU 2016-01 provides updated guidance on the recognition and measurement of financial assets and financial liabilities that will supersede most current guidance. ASU 2016-01 primarily affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. The amendments in ASU 2016-01 supersede the guidance to classify equity securities with readily determinable fair values into different categories and require equity securities to be measured at fair value with changes in the fair value recognized through net income. The amendments under ASU 2016-01 are effective, for public business entities, for periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The Company does not expect the adoption of ASU 2016-01 to have a material impact on its results of operations, financial position or cash flows.

In February 2016, the FASB issued ASU No. 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 supersedes the lease guidance under FASB Accounting Standards Codification ("ASC") Topic 840, Leases, resulting in the creation of FASB ASC Topic 842, Leases. ASU 2016-02 requires a lessee to recognize in the statement of financial position a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term for both finance and operating leases. ASU 2016-02 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. Early adoption is permitted. The Company is currently assessing the potential impact of adopting ASU 2016-02 on its financial statements and related disclosures.

In 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. Early adoption is permitted. The Company does not expect the adoption of ASU 2016-05 to have a material impact on its results of operations, financial position or cash flows.

In May 2017, the FASB issued ASU 2017-09, Compensation-Stock Compensation (Topic 718) Scope of Modification Accounting. ASU 2017-09 provides clarification on when modification accounting should be used for changes to the terms or conditions of a share-based payment award. The amendments in ASU 2017-09 are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2017, with early adoption permitted, applied prospectively to an award modified on or after the adoption date. This ASU does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The Company is currently assessing the impact that adopting this new accounting standard will have on its consolidated financial statements.

3. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	June 30, 2017	December 31, 2016
Commercial costs	$7,618	$ 4,038
Research costs - Nordic	—	1,228
Research costs - other	5,688	8,404
Payroll and employee benefits	9,888	9,338
Professional fees	4,063	3,494
Other current liabilities	121	95
Total accrued expenses and other current liabilities	$27,378	$ 26,597

4. Marketable Securities

Available-for-sale marketable securities and cash and cash equivalents as of June 30, 2017 and December 31, 2016 consist of the following (in thousands):

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	June 30, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and cash equivalents:				
Cash	$98,201	$ —	$ —	$98,201
Money market funds	30,573	—	—	30,573
Domestic corporate debt securities	6,336	—	—	6,336
Total	$135,110	$ —	$ —	$135,110
Marketable securities:				
Domestic corporate debt securities	$34,918	$ —	$ (9)	$34,909
Domestic corporate commercial paper	44,685	12	—	44,697
Total	$79,603	$ 12	$ (9)	$79,606

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

There were no debt securities that had been in an unrealized loss position for more than 12 months as of June 30, 2017 or December 31, 2016. There were 15 debt securities in an unrealized loss position for less than 12 months at June 30, 2017 and there were 13 debt securities that had been in an unrealized loss position for less than 12 months at December 31, 2016. The aggregate unrealized loss on these securities as of June 30, 2017 and December 31, 2016 was approximately $9 thousand and $6 thousand, respectively, and the fair value was $33.7 million and $35.7 million, respectively. 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 June 30, 2017.

As of June 30, 2017, marketable securities consisted of investments that mature within one year.

5. Fair Value Measurements

The Company determines the fair values 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.

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- 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 six months ended June 30, 2017 and 2016, respectively.

The following table summarizes the financial instruments measured at fair value on a recurring basis in the accompanying condensed consolidated balance sheets as of June 30, 2017 and December 31, 2016 (in thousands):

	As of June 30, 2017			
	Level 1	Level 2	Level 3	Total
Assets				
Cash and cash equivalents:				
Cash	$98,201	$—	$ —	$98,201
Money market funds (1)	30,573	—	—	30,573
Domestic corporate debt securities (2)	—	6,336	—	6,336
Total	$128,774	$6,336	$ —	$135,110
Marketable Securities				
Domestic corporate debt securities (2)	$—	$34,909	$ —	$34,909
Domestic corporate commercial paper (2)	—	44,697	—	44,697
Total	$—	$79,606	$ —	$79,606

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

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

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

6. License Agreements

Ipsen

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

co-promotion agreement for abaloparatide-SC) and France (where the Company's commercialization rights were subject to certain co-marketing and co-promotion rights

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exercisable by Ipsen, provided that certain conditions included in the License Agreement were met). The Company believes that Ipsen's co-marketing and co-promotion rights in France have permanently expired. Ipsen also granted the Company an exclusive right and license under the Ipsen compound technology and related patents to make and have made compounds or product in Japan. Ipsen further granted the Company an exclusive right and license under certain Ipsen formulation technology and related patents solely for purposes of enabling the Company to develop, manufacture and commercialize compounds and products covered by the compound technology license in all countries, except Japan and France (as discussed above).

In consideration for these rights, the Company made nonrefundable, non-creditable payments in the aggregate of $13.0 million to Ipsen, including payment in recognition of certain milestones having been achieved through June 30, 2017. The License Agreement provides for further payments upon the achievement of certain future regulatory and commercial milestones. Total additional milestone payments that could be payable under the agreement is €24.0 million (approximately $27.4 million). In connection with the FDA's approval of TYMLOS in April 2017, the Company paid Ipsen a milestone of €8.0 million (approximately $8.7 million) under the License Agreement, which the Company recorded as an intangible asset within the condensed consolidated balance sheet as of June 30, 2017 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 date of the last to expire of the abaloparatide patents licensed from or co-owned with Ipsen, barring any extension thereof, is expected to be March 26, 2028.

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

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

The Company is currently in arbitration proceedings with Ipsen in connection with the License Agreement. See "Legal Proceedings" for more information.

Eisai Co. Ltd.

In June 2006, the Company entered into a license agreement (the “Eisai Agreement”), with Eisai Co. Ltd. (“Eisai”). Under the Eisai Agreement, Eisai granted to the Company an exclusive right and license to research, develop, manufacture and commercialize elacestrant (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 Amendment, as amended, also provides for additional payments of up to $22.3 million, payable upon the achievement of certain clinical and regulatory milestones.

Under the Eisai Agreement, as amended, should a product covered by the licensed technology be commercialized, the Company will be obligated to pay to Eisai royalties in a variable mid-single digit range based on net sales of the product on a country-by-country basis. The royalty rate will be reduced, on a country-by-country basis, at such time as the last remaining valid claim in the licensed patents expires, lapses or is invalidated and the product is not covered by data protection clauses. In addition, the royalty rate will be reduced, on a country-by-country basis, if, in addition to

the conditions specified in the previous sentence, sales of lawful generic versions of such product account for more than a specified minimum percentage of the total sales of all products that contain the licensed compound during a calendar quarter. The latest licensed patent is expected to expire, barring any extension thereof, on August 18, 2026. The Eisai Agreement, as amended, also grants the Company the right to grant sublicenses with prior written approval from Eisai. If the Company sublicenses the licensed technology to a third party, the Company will be obligated to pay Eisai, in addition to the milestones referenced above, a fixed low double-digit percentage of certain fees received from such sublicensee and royalties in the low single digit range based on net sales of the sublicensee. The Eisai Agreement expires on a country-by-

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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.

7. Research Agreements

Abaloparatide-SC Phase 3 Extension Study

The Company contracted with Nordic Bioscience Clinical Development VII A/S ("Nordic") to conduct a Phase 3 clinical trial of abaloparatide-SC (the "Phase 3 Clinical Trial"). The Company also contracted with Nordic to perform an extension study to evaluate six months of standard-of-care osteoporosis management following the completion of the Phase 3 Clinical Trial (the "Extension Study"), and, upon completion of this initial six months, an additional period of 18 months of standard-of-care osteoporosis management (the “Second Extension”).

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

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

8. Stock-Based Compensation

Stock Options

A summary of stock option activity during the six months ended June 30, 2017 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, 2016	6,374	$ 31.60		
Granted	1,631	43.86		
Exercised	(318)	12.65		
Cancelled	(218)	35.37		
Expired	—	—		
Options outstanding at June 30, 2017	7,469	$ 34.98	7.46	$ 99,843
Options exercisable at June 30, 2017	3,525	$ 26.69	5.92	$ 75,462

The weighted-average grant-date fair value per share of options granted during the three and six months ended June 30, 2017 was $19.90 and $24.02, respectively. As of June 30, 2017, there was approximately $78.8 million of total unrecognized compensation expense related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.8 years.

Restricted Stock Units

The Company awards restricted stock units ("RSUs") to employees under its 2011 Equity Incentive Plan. Each RSU entitles the holder to receive one share of the Company's common stock when the RSU vests. The RSUs vest in four substantially equal installments on each of the first four anniversaries of the vesting commencement date, subject to the employee's continued employment with, or service to, the Company on such vesting date. Compensation expense is recognized on a straight-line basis. In February 2017, the Company awarded 84,950 restricted stock units ("RSUs") to employees at an average grant date fair value of $45.65 per RSU.

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A summary of RSU activity during the six months ended June 30, 2017 is as follows (in thousands, except for per share amounts):

	RSUs	Weighted-Average Grant Date Fair Value (in dollars per share)
RSUs Outstanding at December 31, 2016	57	$ 33.03
Granted	85	45.65
Vested	(14)	33.03
Forfeited	(11)	42.09
RSUs Outstanding at June 30, 2017	117	$ 41.41

As of June 30, 2017, there was approximately $4.6 million of total unrecognized compensation expense related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 3.3 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 June 30, 2017, the Company had recorded a liability of $1.2 million related to its ESPP obligations. In accordance with the terms of our employee stock purchase plan, the Company recorded stock-based compensation expense of $0.3 million and $0.6 million for the three and six-month periods ended June 30, 2017, respectively.

9. Income Taxes

The Company did not record a federal or state income tax provision or benefit for the six months ended June 30, 2017 and 2016 due to the expected loss before income taxes to be incurred for the years ended December 31, 2017 and 2016, as well as the Company’s continued maintenance of a full valuation allowance against its net deferred tax assets. In December 2016, the Company migrated certain of its intellectual property to a foreign holding company operating in Bermuda. During 2017, the Company implemented additional steps relating to this internal strategy including executing transfer-pricing and cost share arrangements.

10. Net Loss Per Share

Basic and diluted net loss per share is calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Numerator:				
Net loss	$(68,438)	$(43,435)	$(125,377)	$(83,898)
Denominator:				
Weighted-average number of common shares used in loss per share - basic and diluted	43,410,053	43,042,883	43,300,243	43,027,903
Loss per share - basic and diluted	$(1.58)	$(1.01)	$(2.90)	$(1.95)

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 six months ended June 30, 2017 and 2016, 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.

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	Three and Six Months Ended June 30,	
	2017	2016
Options to purchase common stock	7,468,544	6,079,346
Warrants	605,415	631,587
Restricted stock units	117,253	58,500

11. Commitments and Contingencies

Litigation - The Company may be subject to legal proceedings and claims which arise in the ordinary course of its business. In the Company's opinion, the ultimate resolution of these matters is not expected to have a material effect on its consolidated financial statements. The Company records a liability in its consolidated financial statements for these matters when a loss is known or considered probable and the amount can be reasonably estimated. The Company reviews these estimates each accounting period as additional information is known and adjusts the loss provision when appropriate. If a matter is both probable to result in a liability and the amounts of loss can be reasonably estimated, the Company estimates and discloses the possible loss or range of loss to the extent necessary to make the consolidated financial statements not misleading. If the loss is not probable or cannot be reasonably estimated, a liability is not recorded in its consolidated financial statements.

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

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

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

On July 31, 2017, Ipsen submitted its Statement of Claim to the Arbitral Tribunal. The arbitration proceeding is continuing and a hearing on the merits is anticipated to be held in December 2017. Given that this matter is at a preliminary stage, the Company cannot predict or assess the likely outcome of these proceedings.

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 (the “Device”) customized for subcutaneous injection of 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 agreed to make milestone payments for Ypsomed’s capital developments regarding the initiation of the commercial supply of the Device and to pay a one-time capacity fee. All costs and payments under the agreement are delineated in Swiss Francs. The agreement has an initial term of three years from the earlier of the date of delivery of the first commercial Devices for regulatory approval and June 1, 2017, after which it automatically renews for two-year terms until terminated. The Company agreed to purchase the Device subject to certain minimum annual

quantity requirements under the agreement. During the initial term of the agreement, the Company estimates that it will be obligated to make total minimum payments to Ypsomed of approximately CHF 3.9 million ($4.0 million) in the aggregate, including the milestone payments and one-time capacity fee.

In June 2016, the Company entered into a commercial supply agreement with Vetter Pharma International, GmbH ("Vetter"), pursuant to which Vetter agreed to formulate the finished TYMLOS drug product containing the active pharmaceutical ingredient ("API") of TYMLOS, to fill cartridges with the drug product, to assemble the pen delivery device, and to package and label 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

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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 provides notice of non-renewal two years before the end of the then current term. There are no minimum purchase requirements under the terms of this contract.

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 TYMLOS. The Company agreed to purchase the API in batches at a price per gram in euros, subject to an annual increase by PPL. The Company also agreed to purchase a minimum number of batches annually. The agreement has an initial term of six years, after which, it automatically renews for three-year terms unless either party provides notice of non-renewal 24 months before the end of the then-current term.

12. Inventory

Inventory consists of the following at June 30, 2017 (in thousands):

	June 30, 2017	December 31, 2016
Raw materials	$ 1,612	$ —
Work in process	—	—
Finished goods	24	—
Total inventories	$ 1,636	$ —

Inventory acquired prior to receipt of the marketing approval for TYMLOS 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.

13. Intangible Assets

The following table presents intangible assets as of June 30, 2017 (in thousands):

	June 30, 2017	Estimated useful life
Acquired and in-licensed rights	$ 8,712	11 Years
Less: accumulated amortization	(133)	
Total intangible asset, net	$ 8,579	

The increase in acquired and in-licensed rights as of June 30, 2017 was due to the milestone of €8.0 million (approximately $8.7 million) paid to Ipsen, which was triggered by the FDA approval of TYMLOS on April 28, 2017. The Company recorded approximately $0.1 million in amortization expense related to intangible assets, using the straight-line methodology, during the three months ended June 30, 2017. Estimated future amortization expense for intangible assets as of June 30, 2017 is approximately $0.4 million for the remainder of 2017, and approximately $0.8 million per year thereafter.

14. Subsequent Events

On July 13, 2017, the Company entered into a license and development agreement with Teijin Limited (“Teijin”) for abaloparatide-SC in Japan. Pursuant to the agreement, the Company granted Teijin (i) an exclusive license under certain of the Company’s intellectual property to develop and commercialize abaloparatide-SC in Japan, (ii) a non-exclusive license under certain of the Company’s intellectual property to manufacture abaloparatide-SC for commercial supply in Japan, and (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. Teijin is developing abaloparatide-SC in Japan under an agreement with Ipsen and has initiated a phase 3 trial in Japanese patients with osteoporosis. In consideration for these rights, the Company will receive up to an aggregate of $50 million, including an upfront payment and payments upon the achievement of certain regulatory and sales milestones, and a fixed low double-digit royalty based on net sales of abaloparatide-SC in Japan during the royalty term. In addition, the Company has an option to negotiate for a co-promotion agreement with Teijin for abaloparatide-SC in Japan. Teijin is responsible for all costs related to the development, manufacture and commercialization of abaloparatide-SC in Japan.

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

The outcome of the events described in these forward-looking statements is subject to known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from the results anticipated by these forward-looking statements. These important factors include our financial performance, the uncertainties inherent in the launch of any new pharmaceutical product or the 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 Item 1A of this Quarterly Report on Form 10-Q. 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 therapeutics in the areas of osteoporosis, oncology and endocrine diseases. On April 28, 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. We commenced U.S. commercial sales of TYMLOS during the

second quarter of 2017. In May 2017, we announced positive top-line results from our completed 24-month ACTIVExtend clinical trial for TYMLOS, which met all of its primary and secondary endpoints. In July 2017, we entered into a license and development agreement with Teijin Limited ("Teijin") for abaloparatide for subcutaneous injection ("abaloparatide-SC") in Japan. Under this agreement, we will receive an upfront payment, 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

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negotiate for a co-promotion agreement with Teijin for abaloparatide-SC in Japan. Our European Marketing Authorisation Application (“MAA”) for abaloparatide-SC which, if approved, will be marketed in the European Union as Eladynos™, is under review by the Committee for Medicinal Products for Human Use (“CHMP”) of the European Medicines Agency (“EMA”) and we expect an opinion from the CHMP regarding the MAA for Eladynos prior to the end of 2017.

Our clinical pipeline includes an abaloparatide transdermal patch, or abaloparatide-TD, for potential use in the treatment of women with postmenopausal osteoporosis. We are focused on completing the manufacturing scale-up, production, and other activities required for the initiation of a pivotal bioequivalence study for abaloparatide-TD. In addition, we are evaluating our investigational product candidate, elacestrant (RAD1901), a selective estrogen receptor down-regulator/degrader, for potential use in the treatment of hormone-driven and/or hormone-resistant breast cancer, as well as for potential use in the treatment of vasomotor symptoms in postmenopausal women. We recently completed enrollment in both of our ongoing Phase 1 studies of elacestrant in advanced metastatic breast cancer. In June 2017, we discussed the data from these ongoing Phase 1 studies with the FDA to gain alignment on defining the next steps for our elacestrant breast cancer program, including the design of a Phase 2 trial. Following this discussion, the FDA agreed that a single-arm monotherapy Phase 2 study of under 200 patients is appropriate and provided additional feedback on the proposed clinical protocol, including confirmation that the primary endpoint will be objective response rate (“ORR”), coupled with durability of response (“DOR”). The FDA indicated that, depending on the study results, which must demonstrate superiority to then available therapies, the single-arm Phase 2 trial could be considered a pivotal study for accelerated approval as long as we have commenced a confirmatory study by the time of our NDA submission. We will provide further study details when the Phase 2 study is started and will continue to pursue additional pathways to accelerated approval. We expect to complete and report results from our elacestrant Phase 2b vasomotor trial in the second half of 2017.

We are also developing our internally developed investigational product candidate, RAD140, a non-steroidal selective androgen receptor modulator ("SARM") for potential use in the treatment of breast cancer. In December 2016, we submitted an investigational new drug application ("IND") to the FDA and expect to initiate a first-in-human Phase 1 study of RAD140 in women with hormone receptor positive breast cancer in the second half 2017.

Abaloparatide

On April 28, 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-TD.

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 the second quarter of 2017. We are commercializing TYMLOS in the United States through our commercial organization. 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. In December 2014, we announced positive 18-month top-line data from our Phase 3 ACTIVE clinical trial. These results were published in the Journal of the American Medical Association ("JAMA") in August 2016. In June 2015, we announced the positive top-line data from the first six months of the ACTIVExtend clinical trial of TYMLOS and the 25-month combined fracture data from the ACTIVE and ACTIVExtend clinical trials. These data were published in the Mayo Clinic Proceedings in February 2017.

The combined 25-month fracture data from our Phase 3 clinical trial program for TYMLOS formed the basis of our regulatory submissions in the United States and Europe. In November 2015, we submitted an MAA for Eladynos to the EMA, which was validated and is currently undergoing active regulatory assessment by the CHMP. In July 2017, the CHMP issued a second Day-180 List of Outstanding Issues and requested additional data analyses related to the safety and efficacy of abaloparatide-SC in the process of their ongoing regulatory review. We expect that the CHMP may adopt an opinion regarding our MAA for Eladynos prior to the end of 2017. Assuming regulatory success, we intend to enter into one or more collaborations for the commercialization of Eladynos outside of the United States

prior to commercial launch in the European Union.

In May 2017, we announced positive top-line results from the completed 24-month ACTIVExtend clinical trial of TYMLOS, which met all of its primary and secondary endpoints. In ACTIVExtend, patients who had completed 18 months of TYMLOS (abaloparatide) injections or placebo in the ACTIVE Phase 3 trial were transitioned to receive 24 additional months of open-label alendronate. For the subset of ACTIVE trial patients (n=1139) that enrolled in the ACTIVExtend trial, the previous TYMLOS-treated patients had a significant 84% relative risk reduction ($p<0.0001$) in the incidence of new vertebral fractures compared with women 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

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osteoporotic fractures (p=0.011) compared with women 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 women 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 women who received placebo followed by alendronate. The adverse events reported during the alendronate treatment period were similar between the previous TYMLOS-treated patients and the previous placebo group. The incidences of cardiovascular adverse events including serious adverse events were similar between groups. There have been no cases of osteonecrosis of the jaw or atypical femoral fracture in the entire TYMLOS development program. The results from the completed ACTIVExtend trial will be presented at an upcoming scientific meeting in the third quarter of 2017 and we plan to submit a supplemental new drug application in connection with this data to the FDA prior to the end of 2017. In July 2017, we entered into a license and development agreement with Teijin for abaloparatide-SC in Japan. Pursuant to the agreement, we will receive an upfront payment, 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.

Abaloparatide-TD

We are also developing abaloparatide-transdermal, which we refer to as abaloparatide-TD, 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-TD technology. We are developing abaloparatide-TD toward future global regulatory submissions to build upon the potential success of TYMLOS. We commenced a human replicative clinical evaluation of the optimized abaloparatide-TD patch in December 2015, with the goal of achieving comparability to TYMLOS. In September 2016, we presented results from this evaluation, which showed that the pharmacokinetic profile of an optimized abaloparatide-TD patch with respect to Tmax, T1/2, and AUC was successfully modified so as to improve comparability to TYMLOS. The results of this clinical evaluation will inform the design of a pivotal bioequivalence study that will be initiated following completion of activities related to manufacturing scale-up, production, and other activities required for the initiation of that study.

Commercial, Medical and Compliance Organizations

We intend to commercialize TYMLOS on our own in the United States through our field-based sales organization of more than 200 regional sales managers and clinical sales specialists who are experienced in launching specialty pharmaceutical products, including many with osteoporosis sales experience.

After receiving regulatory approval of TYMLOS in the United States in April 2017 for the treatment of postmenopausal women at high risk of osteoporotic fracture, we have focused commercial efforts on increasing access to, and utilization of, TYMLOS. We have a full-spectrum commercialization team that includes experienced professionals in marketing, communications, professional education, patient education, reimbursement and market access, trade, distribution and call centers, commercial operations, commercial analytics, market research, and forecasting.

We also have a distribution network of well-established distributors and specialty pharmacies for TYMLOS in the United States. Under our distribution model, both the distributors and specialty pharmacies take physical delivery of TYMLOS and the specialty pharmacies dispense TYMLOS directly to patients.

Our medical organization is comprised of 40 professionals, many field-based, with clinical and scientific experience within academic medical centers, clinical medical practice, research institutions, and industry. Our team is organized by key functions, including medical affairs, pharmacovigilance, medical information, publications, and health economics outcomes research.

Under the leadership of our Chief Compliance Officer, we have implemented a compliance program in support of a strong culture of compliance and good corporate governance. Our leadership, managers and staff have devoted substantial amounts of time to compliance initiatives, including establishing and maintaining effective disclosure and financial controls and corporate governance practices, as required by the Sarbanes-Oxley Act of 2002, as amended,

and rules subsequently implemented by the Securities and Exchange Commission ("SEC") and NASDAQ.

Elacestrant (RAD1901)

Elacestrant (RAD1901) is a selective estrogen receptor down-regulator/degrader ("SERD"), that has potential for use as a daily oral non-steroidal treatment for hormone-driven and/or hormone-resistant, breast cancer. We hold worldwide commercialization rights to elacestrant. Elacestrant is currently being investigated in postmenopausal women with advanced estrogen receptor positive, or ER-positive, HER2-negative breast cancer, the most common form 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

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for the treatment of breast cancer. In April 2017, we presented new preclinical data on the impact of elacestrant in preclinical models of endocrine sensitive/resistant breast cancer.

Phase 1 - Dose-Escalation 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 recently completed patient enrollment in our Phase 1 dose-escalation and expansion study.

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

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

Phase 1 - FES-PET Study

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

In December 2016, we reported positive results from the ongoing 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. The most commonly reported adverse events reported to date in this study have been grade 1 and 2 nausea and dyspepsia. We enrolled 5 additional patients in the 400-mg daily oral cohort, followed by 8 patients in the 200-mg daily oral cohort.

Phase 1 - Recent Progress

To date, no dose limiting toxicities have been reported in the elacestrant program. We recently completed patient enrollment in both of our ongoing elacestrant Phase 1 breast cancer trials. In June 2017, we discussed the data from the ongoing Phase 1 studies with the FDA to gain alignment on defining the next steps for our elacestrant breast cancer program, including the design of a Phase 2 trial. Following this discussion, the FDA agreed that a single-arm monotherapy Phase 2 study of under 200 patients is appropriate and provided additional feedback on the proposed clinical protocol, including confirmation that the primary endpoint will be ORR, coupled with DOR. The FDA indicated that, depending on the study results, which must demonstrate superiority to then available therapies, the single-arm Phase 2 trial could be considered a pivotal study for accelerated approval as long as we have commenced a confirmatory study by the time of our NDA submission. We will provide further study details when the Phase 2 study is started and will continue to pursue additional pathways to accelerated approval.

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.
Collaborations

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In July 2016, we entered into a preclinical collaboration with Takeda Pharmaceutical Company Limited to evaluate the combination of our investigational drug 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.

In January 2016, we entered into a worldwide clinical collaboration with Novartis Pharmaceuticals to evaluate the safety and efficacy of combining our investigational drug elacestrant, with Novartis' investigational agent LEE011 (ribociclib), a CDK 4/6 inhibitor, and BYL719 (alpelisib), an investigational phosphoinositide 3-kinase inhibitor. We expect the results from these studies will be presented at an upcoming scientific meeting.

Phase 2b - Vasomotor Symptoms Study

Elacestrant is also being evaluated at low doses as an estrogen receptor ligand for the potential relief of the frequency and severity of moderate to severe hot flashes in postmenopausal women with vasomotor symptoms. We expect to report results from our Phase 2b clinical study of elacestrant for the potential treatment of postmenopausal vasomotor symptoms in the second half of 2017.

RAD140

RAD140 is a nonsteroidal selective androgen receptor modulator, or 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, which resulted from an internal discovery program.

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. In April 2017, we presented these RAD140 preclinical results at a major scientific congress. We submitted an IND to the FDA for RAD140 in December 2016 and plan to initiate a first-in-human Phase 1 study of RAD140 in women with hormone receptor positive breast cancer in 2017.

Financial Overview

Product Revenue

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

Research and Development Expenses

Research and development expenses consist primarily of clinical testing costs 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) historically has represented the largest portion of our research and development expenses for our development programs. We began tracking program expenses for TYMLOS (abaloparatide) in 2005, and program expenses from inception to June 30, 2017 were approximately $213.2 million. We began tracking program expenses for abaloparatide-TD in 2007, and program expenses from inception to June 30, 2017 were approximately $40.1 million. We began tracking program expenses for elacestrant (RAD1901) in 2006, and program expenses from inception to June 30, 2017 were approximately $58.4 million. We began tracking program expenses for RAD140 in 2008, and program expenses from inception to June 30, 2017 were approximately $10.3 million. These expenses relate primarily to external costs associated with manufacturing, preclinical studies and clinical trial costs.

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

The following table sets forth our research and development expenses that are directly attributable to the programs listed below for the three and six months ended June 30, 2017 and 2016 (in thousands):

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Abaloparatide-SC*	$1,297	$6,612	$297	$12,389
Abaloparatide-TD	327	1,544	1,032	3,690
Elacestrant (RAD1901)	29	5,142	2,907	13,259
RAD140	(37)	770	1,321	1,127

*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

Selling, general and administrative expenses consist primarily of salaries and related expenses for pre-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 the statement of operations and comprehensive loss (i.e., research and development or general and administrative expenses).

Interest Income and Other Income

Interest income reflects interest earned on our cash, cash equivalents and marketable securities. Other income for the first half of 2017 reflects a portion of the Massachusetts Life Science Center awards recognized as income for certain taxes paid.

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 ("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, which we discussed in our Annual Report on Form 10-K for the year ended December 31, 2016. 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 six months ended June 30, 2017. There were no changes to significant accounting policies during the six months ended June 30, 2017, except for the adoption of two Accounting Standards Updates issued by the Financial Accounting Standards Board, as well as significant accounting policies over revenue, inventory, and intangibles, each of which is detailed below, except intangibles, which is not considered a critical accounting policy and estimate by management.

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

Historically, the Company recognized stock-based compensation net of estimated forfeitures over the vesting period of the respective grant. Effective January 1, 2017, the Company adopted ASU 2016-09 and changed its accounting policy to recognize forfeitures as they occur. The new forfeiture policy election was adopted using a modified retrospective approach with a cumulative effect adjustment of approximately $0.5 million to retained earnings as of January 1, 2017. In addition, the Company recognized $6.1 million of accumulated excess tax benefits as deferred tax assets that under the previous guidance could not be recognized until the benefits were realized through a reduction in cash taxes paid. This part of the guidance was

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applied using a modified retrospective method with a cumulative-effect adjustment to the accumulated deficit for the excess tax benefits not previously recognized. However, given the full valuation allowance placed on the additional $6.1 million of deferred tax assets, the recognition upon adoption had no impact to our accumulated deficit as of January 1, 2016. The adoption of ASU 2016-09 effective January 1, 2017 had no other material impacts on the Company's results of operations, financial position or cash flows.

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

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

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

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

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

Results of Operations

Three Months Ended June 30, 2017 and 2016 (in thousands, except percentages)

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	Three Months Ended June 30,		Change	
	2017	2016	$	%
Revenues:				
Product revenue, net	$980	$—	$980	100 %
Operating expenses:				
Cost of sales	105	—	105	100 %
Research and development	19,652	26,891	(7,239)	(27)%
Selling, general and administrative	50,121	17,193	32,928	192 %
Loss from operations	(68,898)	(44,084)	24,814	56 %
Other (expense) income:				
Other expense, net	(97)	(95)	2	2 %
Interest income	557	744	(187)	(25)%
Net loss	$(68,438)	$(43,435)	$25,003	58 %

Product revenue— We began commercially selling TYMLOS within the United States in May 2017, following receipt of the FDA's approval to do so on April 28, 2017. For the three months ended June 30, 2017 we recorded approximately $1.0 million of net product revenue. For further discussion regarding our revenue recognition policy, see 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.

Cost of sales— Cost of sales of $0.1 million for the three months ended June 30, 2017, consisted of costs associated with the manufacturing of TYMLOS, royalties owed to our licensor for such sales, and certain period costs. 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 June 30, 2017 were expensed prior to the April 2017 FDA approval and, therefore, are not included in cost of sales during this period. We expect cost of sales to increase in relation to product revenues as we deplete these inventories.

Research and development expenses— For the three months ended June 30, 2017, research and development expense was $19.7 million compared to $26.9 million for the six months ended June 30, 2016, a decrease of $7.2 million, or 27%. This decrease was primarily driven by a $5.3 million decrease in regulatory and professional fees associated with abaloparatide-SC regulatory applications, a $5.1 million decrease in RAD1901 project costs, and a $1.2 million decrease in development costs associated with the abaloparatide-TD program. This decrease was partially offset by a $4.5 million increase in compensation expense, including stock-based compensation, due to an increase in headcount from 86 research and development employees as of June 30, 2016 to 109 research and development employees as of June 30, 2017.

Selling, general and administrative expenses— For the three months ended June 30, 2017, selling, general and administrative expense was $50.1 million compared to $17.2 million for the three months ended June 30, 2016, an increase of $32.9 million, or 192%. This increase was primarily the result of an increase of approximately $9.5 million in professional fees and support costs during the three months ended June 30, 2017, including the costs associated with increasing headcount and preparing for the commercialization of TYMLOS in the United States. This increase was also driven by a $19.6 million increase in compensation expense, including stock-based compensation, due to an increase in headcount from 62 general and administrative employees as of June 30, 2016 to 119 selling, general and administrative employees and 253 sales related personnel as of June 30, 2017.

Interest income—For the three months ended June 30, 2017, interest income was approximately $0.6 million compared to $0.7 million for the three months ended June 30, 2016, a decrease of $0.2 million, or 25%. This decrease was primarily due to the combined effects of a decrease in the balance of our investments coupled with an increase in the rate of return on investments in the three months ended June 30, 2017 as compared to those of the three months ended June 30, 2016.

Six Months Ended June 30, 2017 and 2016 (in thousands, except percentages)

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	Six Months Ended June 30,		Change	
	2017	2016	$	%
Revenues:				
Product revenue, net	$980	$—	$980	100 %
Operating expenses:				
Cost of sales	105	$—	105	100 %
Research and development	39,179	54,374	(15,195)	(28)%
Selling, general and administrative	88,220	30,839	57,381	186 %
Loss from operations	(126,524)	(85,213)	41,311	48 %
Other (expense) income:				
Other expense, net	(17)	(96)	(79)	(82)%
Interest income (expense), net	1,164	1,411	(247)	(18)%
Net loss	$(125,377)	$(83,898)	$41,479	49 %

Product revenue— We began commercially selling TYMLOS within the United States in May 2017, following receipt of the FDA's approval to do so on April 28, 2017. For the six months ended June 30, 2017 we recorded approximately $1.0 million of net product revenue. For further discussion regarding our revenue recognition policy, see 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.

Cost of sales— Cost of sales of $0.1 million for the six months ended June 30, 2017, consisted of costs associated with the manufacturing of TYMLOS, royalties owed to our licensor for such sales, and certain period costs. 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 six months ended June 30, 2017 were expensed prior to the April 2017 FDA approval and, therefore, are not included in cost of sales during this period. We expect cost of sales to increase in relation to product revenues as we deplete these inventories.

Research and development expenses— For the six months ended June 30, 2017, research and development expense was $39.2 million compared to $54.4 million for the six months ended June 30, 2016, a decrease of $15.2 million, or 28%. This decrease was primarily driven by a $12.1 million decrease in abaloparatide-SC project costs, a $10.4 million decrease in RAD1901 project costs, and a $2.7 million decrease in development costs associated with abaloparatide-TD. This decrease was partially offset by a $9.1 million increase in compensation expense, including stock-based compensation, due to an increase in headcount from 86 research and development employees as of June 30, 2016 to 109 research and development employees as of June 30, 2017.

Selling, general and administrative expenses— For the six months ended June 30, 2017, selling, general and administrative expense was $88.2 million compared to $30.8 million for the six months ended June 30, 2016, an increase of $57.4 million, or 186%. This increase was primarily the result of an increase of approximately $17.9 million in professional fees and support costs during the six months ended June 30, 2017, including the costs associated with increasing headcount and preparing for the commercialization of TYMLOS in the United States. This increase was also driven by a $34.2 million increase in compensation expense, including stock-based compensation, due to an increase in headcount from 62 general and administrative employees as of June 30, 2016 to 119 selling, general and administrative employees and 253 sales related personnel as of June 30, 2017.

Interest income—For the six months ended June 30, 2017, interest income was approximately $1.2 million compared to $1.4 million for the six months ended June 30, 2016, a decrease of $0.2 million, or 18%. This decrease was primarily due to the combined effects of a decrease in the balance of our investments coupled with an increase in the rate of return on investments in the six months ended June 30, 2017 as compared to those of the six months ended June 30, 2016.

Liquidity and Capital Resources

From inception to June 30, 2017, we have incurred an accumulated deficit of $753.4 million, primarily as a result of expenses incurred through a combination of research and development activities related to our various product candidates and expenses supporting those activities. Our total cash, cash equivalents and short-term marketable

securities balance as of June 30, 2017 was $214.7 million. We have financed our operations since inception primarily through the public offerings of our common stock, private sales of preferred stock, and borrowings under credit facilities and, following our commercial launch of TYMLOS in the United States, we have just begun financing a portion of our operations with product revenue.

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Based upon our cash, cash equivalents and marketable securities balance, we believe that, prior to the consideration of proceeds from partnering and/or collaboration activities, we have sufficient capital to fund our development plans, U.S. commercial and other operational activities for not less than twelve months from the date of this filing. We expect to finance the future U.S. commercial activities and development costs of our clinical product portfolio with our existing cash, cash equivalents and marketable securities, or through strategic financing opportunities, that could include, but are not limited to partnering or other collaboration agreements, future offerings of equity, royalty-based financing arrangements, or the incurrence of debt or other alternative financing arrangements. However, there is no guarantee that any of these financing opportunities will be available to us on favorable terms, and some could be dilutive to existing stockholders. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development and commercialization activities, the results of our clinical trials, and the review and potential approval of our products by the FDA and the EMA. The successful development of our investigational product candidates is subject to numerous risks and uncertainties associated with developing drugs, which could have a significant impact on the cost and timing associated with the development of our product candidates. If we fail to obtain additional future capital, we may be unable to complete our planned preclinical and clinical trials and obtain approval of any investigational product candidates from the FDA and foreign regulatory authorities.

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 under Item 1A.

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

	Six Months Ended June 30,		Change	
	2017	2016	$	%
Net cash (used in) provided by:				
Operating activities	$(112,949)	$(72,637)	$(40,312)	(55)%
Investing activities	(15,562)	31,841	(47,403)	(149)%
Financing activities	5,054	1,672	3,382	202%
Net decrease in cash and cash equivalents	$(123,457)	$(39,124)	(84,333)	(216)%

Cash Flows from Operating Activities

Net cash used in operating activities during the six months ended June 30, 2017 was $112.9 million, which was primarily the result of a net loss of $125.4 million, partially offset by $21.2 million of net non-cash adjustments to reconcile net loss to net cash used in operations and net changes in working capital of $7.4 million. The $125.4 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 $21.2 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of $20.5 million and depreciation of $0.7 million.

Net cash used in operating activities during the six months ended June 30, 2016 was $72.6 million, which was primarily the result of a net loss of $83.9 million, partially offset by $11.6 million of net non-cash adjustments to reconcile net loss to net cash used in operations and net changes in working capital of $0.4 million. The $83.9 million net loss was primarily due to abaloparatide-SC program development expenses, including clinical and manufacturing costs, along with employee compensation and consulting costs incurred to support regulatory submissions and preparation for the commercial launch of TYMLOS in the United States. The $11.6 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock-based compensation expense of $10.6 million, amortization of premiums on marketable securities of $0.8 million and depreciation of $0.2 million.

Cash Flows from Investing Activities

Net cash used in investing activities during the six months ended June 30, 2017 was $15.6 million, which was primarily the result of $112.0 million of purchases of marketable securities and $8.7 million payments for capitalized milestones. These activities were partially offset by $106.3 million of net proceeds received from the sale or maturity of marketable securities.

Net cash provided by investing activities during the six months ended June 30, 2016 was $31.8 million, which was primarily the result of $258.3 million of net proceeds received from the sale or maturity of marketable securities partially offset by $225.5 million of purchases of marketable securities.

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Our investing cash flows will be impacted by the timing of purchases and sales of 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 six months ended June 30, 2017 was $5.1 million, which primarily consisted of $4.0 million of proceeds received from exercises of stock options and $1.0 million received upon issuance of common stock under the Radius Health, Inc. 2016 Employee Stock Purchase Plan.

Net cash provided by financing activities during the six months ended June 30, 2016 consisted of $1.7 million of proceeds received from the exercise of stock options.

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 ("Device"), customized for subcutaneous injection of 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 agreed to make milestone payments for Ypsomed's capital developments in connection with the initiation of the commercial supply of the Device and to pay a one-time capacity fee. All costs and payments under the agreement are delineated in Swiss Francs. The agreement has an initial term of three years from the earlier of the date of delivery of the first commercial Devices for regulatory approval and June 1, 2017, after which, it automatically renews for two-year terms until terminated. During the initial term of the agreement, we estimate that we will be obligated to make total minimum payments to Ypsomed of approximately CHF 3.9 million ($4.0 million) in the aggregate, including the milestone payments and one-time capacity fee.

In June 2016, we entered into a commercial supply agreement with Vetter Pharma International, GmbH ("Vetter"), pursuant to which Vetter agreed to formulate the finished TYMLOS drug product containing the active pharmaceutical ingredient ("API"), of TYMLOS, to fill cartridges with the drug product, to assemble the pen delivery device, and to package and label the pen for commercial distribution. We agreed to purchase the cartridges and pens in specified batch sizes at a price per unit. For labeling and packaging services, we agreed to pay a per unit price dependent upon the number of pens loaded with cartridges that are labeled and packaged. These prices are subject to an annual price adjustment. The 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 provides notice of non-renewal two years before the end of the then-current term. There are no minimum purchase requirements under the terms of this contract.

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 TYMLOS. We agreed to purchase the API in batches at a price per gram in euros, subject to an annual increase by PPL. We also agreed to purchase a minimum number of batches annually. The agreement has an initial term of a six years, after which, it automatically renews for three-year terms unless either party provides notice of non-renewal 24 months before the end of the then-current term.

Research and Development Agreements

Abaloparatide-SC Phase 3 Clinical Trial

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

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

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

all obligations due to Nordic in relation to the Extension Study have been paid.

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License Agreement Obligations

TYMLOS (abaloparatide)

In September 2005, we entered into a license agreement with Ipsen, as amended, or the License Agreement, under which we exclusively licensed certain Ipsen compound technology and related patents covering abaloparatide to research, develop, manufacture and commercialize certain compounds and related products in all countries, except Japan (where we have an option to negotiate a co-promotion agreement for abaloparatide-SC with Teijin) and France (where our commercialization rights were subject to certain co-marketing and co-promotion rights exercisable by Ipsen, provided that certain conditions included in the License Agreement were met). We believe that Ipsen's co-marketing and co-promotion rights in France have permanently expired. Ipsen also granted us an exclusive right and license under the Ipsen compound technology and related patents to make and have made compounds or product in Japan. Ipsen further granted us an exclusive right and license under certain Ipsen formulation technology and related patents solely for purposes of enabling us to develop, manufacture and commercialize compounds and products covered by the compound technology license in all countries, except Japan and France (as discussed above). In consideration for the rights to abaloparatide and in recognition of certain milestones having been met to date, we have paid to Ipsen an aggregate amount of $13.0 million. The License Agreement further requires us to make payments upon the achievement of certain future regulatory and commercial milestones. Total additional milestone payments that could be payable under the agreement are €24.0 million (approximately $27.4 million). In connection with the FDA's approval of TYMLOS in April 2017, we are obligated to pay Ipsen a milestone of €8.0 million (approximately $8.7 million) under the License Agreement, which we will record as an intangible asset and amortize over the remaining term of the License Agreement or the expected product life-cycle of TYMLOS, 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 are currently in arbitration proceedings with Ipsen in connection with the License Agreement. See “Legal Proceedings” for more information.

Elacestrant (RAD1901)

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 Amendment, as

amended, also provides for additional payments of up to $22.3 million, payable upon the achievement of certain future clinical and regulatory milestones.

Under the Eisai Agreement, as amended, should a product covered by the licensed technology be commercialized, we will be obligated to pay to Eisai royalties in a variable mid-single digit range based on net sales of the product on a country-by-country basis. The royalty rate will be reduced, on a country-by-country basis, at such time as the last remaining valid claim in the

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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.

Net Operating Loss Carryforwards

As of December 31, 2016, we had federal and state net operating loss carryforwards of approximately $526.7 million and $385.3 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 statement of operations.

Off-Balance Sheet Arrangements

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

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.

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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 June 30, 2017, we had cash, cash equivalents and short-term marketable securities of $214.7 million, consisting of cash, money market funds, domestic corporate debt securities, domestic corporate commercial paper, and asset-backed securities. This exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable securities. 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 June 30, 2017, we do not have any hard-to-value investment securities or securities for which a market is not readily available or active.

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

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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 June 30, 2017.

Changes in Internal Control over Financial Reporting

During the quarter ended June 30, 2017, we began generating revenue from the sale of TYMLOS in the United States. We consider the accounting for our net product revenue to be material to the results of operations for the three months ended June 30, 2017, and believe that the additional internal controls and procedures relating to the accounting for net product revenues, as well as adoption of Topic 606 in connection therewith, and related commercial inventory, have a material effect on our internal control over financial reporting. During the quarter ended June 30, 2017, there were no further changes in our internal controls over financial reporting. See Note 2, "Basis of Presentation and Significant Accounting Policies" to our unaudited condensed consolidated financial statements contained in this Quarterly Report on Form 10-Q for further details.

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PART II— OTHER INFORMATION

Item 1. Legal Proceedings.

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

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

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

On July 31, 2017, Ipsen submitted its Statement of Claim to the Arbitral Tribunal. The arbitration proceeding is continuing and a hearing on the merits is anticipated to be held in December 2017. Given that this matter is at a preliminary stage, we cannot predict or assess the likely outcome of these proceedings.

Item 1A. Risk Factors.

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

Risks Related to Our Financial Position and Need for Capital

We are not currently profitable and may never become profitable.

We had net losses of $182.8 million, $101.5 million, and $62.5 million for the years ended December 31, 2016, 2015, and 2014, respectively. As of June 30, 2017, we had an accumulated deficit of $753.4 million. Until we succeed in commercializing TYMLOS, we expect to incur substantial losses and may never achieve or maintain profitability. We also expect to continue to incur significant operating and capital expenditures and anticipate that our expenses will increase substantially as we:

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

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

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

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

Based upon our cash, cash equivalents and marketable securities balance as of June 30, 2017, we believe that, prior to the consideration of proceeds from partnering and/or collaboration activities, we have sufficient capital to fund our development plans, U.S. commercial and other operational activities for not less than twelve months from the date of this filing. We have based this estimate on assumptions that may prove to be wrong, and we could use up our available capital resources sooner than we currently expect. If we fail to obtain additional capital, we may be forced to reduce or forego sales and marketing efforts for TYMLOS or unable to complete our planned preclinical and clinical trials and obtain approval of product candidates from the FDA and foreign regulatory authorities. In addition, we could be forced to discontinue product development or forego attractive business opportunities or discontinue our operations entirely. Any additional sources of financing may not be available or may not be available on favorable terms and will likely involve the issuance of additional equity securities, which will have a dilutive effect on stockholders. Our future capital requirements will depend on many factors, including the scope and progress made in our research and development activities and our clinical studies and the expenses associated with our commercialization efforts for TYMLOS.

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

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

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

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

- conducting sales and marketing activities for products if and when approved;
- continuing to undertake preclinical development and clinical trials;

- participating in regulatory approval processes; and
- formulating and manufacturing products.

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

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

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

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

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

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

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

We are subject to foreign currency risk.

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

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

We are currently involved in a pending arbitration proceeding. In November 2016, we received notice that in October 2016, Ipsen Pharma SAS, or Ipsen, had initiated arbitration proceedings against us in the International Chamber of Commerce’s International Court of Arbitration. Ipsen’s Request for Arbitration alleges that we breached various provisions of the License Agreement concerning abaloparatide, including with regard to Ipsen's right to co-promote abaloparatide in France and a license from us with respect to Japan. Ipsen seeks declaratory relief, compliance with the License Agreement, damages, costs and fees as a result of the purported breaches, and alleges the monetary value of these claims is approximately €50 million. In January 2017, we submitted an Answer denying Ipsen’s claims and alleging counterclaims against Ipsen for breach of the License Agreement and other declaratory judgment. We asserted, among other things, that Ipsen's claimed rights to co-promote abaloparatide in France and to a license from us with respect to Japan have permanently expired, and that Ipsen has breached the License Agreement by, among other things, allowing certain patents to expire and by purporting to license to a third-party certain manufacturing and

other rights that we contend Ipsen exclusively licensed to us. In February 2017, Ipsen submitted a Reply denying our counterclaims and alleging that we are precluded from asserting them. Following a preliminary hearing before the Arbitral Tribunal to determine certain jurisdictional and contractual defenses asserted by Ipsen in its Reply, on July 17, 2017, the Arbitral Tribunal issued a decision finding it has jurisdiction to decide our counterclaims and that our counterclaims are not contractually barred. On July 31, 2017, Ipsen submitted its Statement of Claim to the Arbitral Tribunal. The arbitration proceeding is continuing and a hearing on the merits is anticipated to be held in December 2017. We are seeking dismissal of Ipsen's claims, as well as declaratory relief, compliance with the License Agreement, and other damages,

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costs and fees to be determined by the Arbitral Tribunal. However, if such defense is unsuccessful, and Ipsen prevails on any of its claims, such an adverse determination could have a material adverse effect on our business, operating results, financial condition and liquidity.

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

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

Risks Related to the Commercialization and Development of Our Product Candidates

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

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

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

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- our ability to maintain, enforce and defend third-party challenges to our intellectual property rights in and to TYMLOS.

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

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

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

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

In addition, the FDA or foreign regulatory authorities may change their approval policies or adopt new regulations. We cannot assure you that we will receive the approvals necessary to commercialize any additional product candidates, including any product candidates we are currently developing or may acquire or develop in the future. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its indicated use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires

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substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for proposed uses.

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

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

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

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

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

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

In November 2015, we submitted a marketing authorization application for Eladynos (abaloparatide-SC) to the EMA. The MAA was validated and is currently undergoing active regulatory assessment by the Committee for Medicinal Products for Human Use, or CHMP, the scientific committee of the EMA. In July 2017, the CHMP issued a second Day-180 List of Outstanding Issues, including two major objections, and requested additional data analyses related to the safety and efficacy of Eladynos as part of its ongoing regulatory review. The major objections relate to our inclusion of data from two clinical trial sites that, based upon EMA inspection findings, are not considered to comply with good clinical practice (“GCP”) requirements. If these data are excluded, the statistical power of submitted clinical trial data is reduced, impacting statistical significance and the overall benefit-risk assessment. We will provide the requested additional data analyses and discuss with the CHMP potential pathways for the approval of abaloparatide-SC.

While we believe we have adequate data to demonstrate the safety and efficacy of Eladynos, the EMA reviewers may not be satisfied with our responses or may require additional information, which we may not be able to provide in a timely manner or at all. If we are unable to demonstrate the safety and efficacy of Eladynos to the satisfaction of the EMA, we may not receive marketing authorization for Eladynos in Europe, or if we need additional time to satisfy the EMA of Eladynos’ safety and efficacy, approval for marketing authorization in Europe could be delayed.

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

Our product development programs and the commercialization of TYMLOS or any of our product candidates will require substantial cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product

candidates. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements.

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

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

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

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

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

In addition, we, the FDA, or other equivalent regulatory authorities and ethics committees with jurisdiction over our studies may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA or foreign regulatory authorities find deficiencies in our regulatory submissions or the conduct of these trials. Therefore, we cannot predict with any certainty the schedule for existing or future clinical trials. Any such unexpected expenses or delays in our clinical trials could increase our need for additional capital, which may not be available on favorable terms or at all.

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

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

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

Even if our clinical trials are completed as planned, we cannot be certain that the results will support regulatory approval of our product candidates. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for proposed uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials

will delay the submission of our NDAs to the FDA or equivalent application to foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates and

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generate product revenues. In addition, our clinical trials to date (other than the ACTIVE Phase 3 Clinical Trial for abaloparatide-SC) have involved small patient populations. Because of the small sample sizes, the results of these clinical trials may not be indicative of future results.

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

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

In general, the FDA requires two pivotal trials to support approval of an NDA, but in certain circumstances, will approve an NDA based on only one pivotal trial and on an accelerated basis. The FDA indicated that, depending on the study results, a single-arm Phase 2 trial of elacestrant could be considered a pivotal study sufficient for us to request accelerated approval. The FDA said that, in order for this single-arm Phase 2 trial of elacestrant to be sufficient, elacestrant would, among other things, need to demonstrate superiority to then available therapies and we must have commenced a confirmatory study by the time of our NDA submission. As a result of these and other additional requirements, the FDA may require that we conduct additional trials beyond the currently contemplated single-arm Phase 2 trial before we can submit an NDA for elacestrant even if such trial is successful.

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

Undesirable side effects caused by our product candidates could cause us, regulatory authorities, and/or ethics committees to interrupt, delay or halt clinical trials and could result in a more restrictive label or cause the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval, if ever. If our product candidates result in undesirable side effects or have characteristics that are unexpected, we may need to abandon their development. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

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

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

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

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

TYMLOS and any other product candidate for which we obtain marketing approval, along with the manufacturing processes, distribution processes, post-approval clinical data, labeling, advertising and promotional activities for such product, are subject to continuing requirements of and review by the FDA and foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control, quality assurance and corresponding maintenance of

records and documents, and requirements regarding the distribution of drug products, including drug samples to physicians and recordkeeping. Marketing approval of TYMLOS and any other product candidate for which we obtain marketing approval are subject to limitations on the

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indicated uses for which it may be marketed or to the conditions of approval, and contain requirements for costly post-marketing testing and surveillance to monitor the safety and/or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and, if we market TYMLOS or any of our other products which may be approved for other than their approved indications, we may be subject to enforcement action for off-label marketing.

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

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

In addition, the FDA's policies may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

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

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

- perceptions by members of the healthcare community, including physicians and key opinion leaders, about the safety and effectiveness of our drug;
- the approved indicated uses for our product;
- cost-effectiveness of our product relative to competing products;
- availability of coverage and reimbursement for our product from government or other healthcare payors; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

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

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revisions to approved labeling which could limit the indications or patient population for a product or could even lead to the withdrawal of a product from the market. Because we expect sales of TYMLOS to generate substantially all of our product revenues for the foreseeable future, its failure to gain market acceptance or, once gained, a decrease in market acceptance would harm our business and would require us to seek additional financing.

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

Our ability to successfully commercialize TYMLOS or any of our other product candidates if approved, alone or with collaborators, will depend in large part on the extent to which coverage and reimbursement will be available post-approval from:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payors.

In the United States and internationally, sales of products that we market in the future, and our ability to generate revenues on such sales, are dependent, in significant part, on the availability and level of coverage and reimbursement from third-party payors such as state and federal governments, managed care providers and private insurance plans. Private insurers, such as health maintenance organizations and managed care providers, have implemented cost cutting and reimbursement initiatives and likely will continue to do so in the future. These include establishing formularies that govern the drugs and biologics that will be offered and also the out-of-pocket obligations of member patients for such products. In addition, particularly in the United States and increasingly in other countries, we may be required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities. It is possible that future legislation in the United States and other jurisdictions could be enacted which could potentially impact the reimbursement rates for the products we are developing and may develop in the future and also could further impact the levels of discounts and rebates paid to federal and state government entities. Any legislation that impacts these areas, including the ongoing consideration of the repeal and replacement of the ACA and other legislation focused on drug pricing, could impact, in a significant way, our ability to generate revenues from sales of products that we bring to market, including TYMLOS and any other product candidates that may receive marketing approval.

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

Future legislation, including the current versions being considered at the federal and state level in the United States and at the national level in EU Member States, or regulatory actions implementing recent or future legislation may

have a significant effect on our business. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for TYMLOS or our other product candidates, once approved, market acceptance of our products could be reduced. In addition, negotiating prices with government authorities under current and proposed legislation can delay the commercialization of our product candidates.

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

candidates.

We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to internally formulate or manufacture TYMLOS or our other product candidates in the quantities needed to meet commercial demand for TYMLOS, or to internally conduct our research and development activities and clinical trials for our other product candidates. Therefore, we rely on, and expect to continue relying on for the foreseeable future, a limited number of third parties to manufacture and supply materials (including raw materials and subunits), drug substance, or API, and drug product, as well as to perform additional steps in the manufacturing process, such

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as filling, labeling, and storage of TYMLOS and our other product candidates. There are a limited number of third parties with facilities and capabilities suited for the manufacturing process of TYMLOS and our other product candidates, which creates a heightened risk that we may not be able to obtain materials and APIs in the quantity and purity that we require. In addition, the process for adding new manufacturing capacity can be lengthy and could cause delays in our development efforts. Any interruption of the development or operation of those facilities due to, among other reasons, events such as order delays for equipment or materials, equipment malfunction, quality control and quality assurance issues, regulatory delays and possible negative effects of such delays on supply chains and expected timelines for product availability, production yield issues, shortages of qualified personnel, discontinuation of a facility or business or failure or damage to a facility by natural disasters such as earthquake or fire, could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available TYMLOS, our other product candidates or materials.

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

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

We depend on a number of single source contract manufacturers to supply key components of abaloparatide. For example, we depend on PPL, which has agreed to produce supplies of abaloparatide API to support the abaloparatide-SC and abaloparatide-TD clinical studies and the commercial supplies of TYMLOS. We also depend on Vetter and Ypsomed for the production of finished drug product clinical and commercial supplies of TYMLOS and we depend on 3M for the production of abaloparatide-TD. If our relationship with any of these contract manufacturers is terminated, or if they are unable to produce abaloparatide or related components in required quantities, on a timely basis or at all, and/or in compliance with the terms of our agreements, our business and financial condition would be materially harmed. Because the manufacturing process for abaloparatide-TD requires the use of 3M's proprietary technology, 3M is our sole source for finished clinical trial supplies of abaloparatide-TD. To date, we have not entered into a commercial supply agreement with 3M. If we are not able to negotiate commercial supply terms with 3M, as we depend on 3M for production of abaloparatide-TD, we would be unable to commercialize this product if it were to be approved. Or, if we are forced to accept unfavorable terms for our future relationship with 3M, our business and financial condition would be materially harmed. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms, or at all, because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs or related components in the volume and of the quality required to meet our clinical needs and commercial needs.
- Our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products.

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- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other government regulations and corresponding foreign standards, and failure to comply with cGMP or corresponding foreign standards can result in compliance actions that may limit a manufacturer's production or prohibit a manufacturer from producing some or all products at a facility and/or importing it into the United States or a foreign country. We do not have control over third-party manufacturers' compliance with these regulations and standards.
- If any third-party manufacturer makes improvements in the manufacturing process for our products, any such improvement(s) could be subject to FDA review and prior approval, and we may not own, or may have to share, the intellectual property rights to the innovation.

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

If we fail to establish and maintain an effective distribution process utilizing cold chain logistics for TYMLOS, our business may be adversely affected.

We are continuing to build the infrastructure necessary for distributing TYMLOS to patients. We contracted with a third-party logistics company to warehouse TYMLOS and distribute it to specialty pharmacies and wholesale distributors who will supply it to the market. TYMLOS is required to be maintained at a controlled refrigerated temperature throughout the distribution chain. This distribution chain requires significant coordination among our manufacturing, supply-chain and finance teams, as well as commercial departments, including market access, sales, and marketing. In addition, failure to secure and maintain contracts with appropriate pharmacy providers and/or wholesale distributors could negatively impact the distribution of TYMLOS, and failure to coordinate financial systems could negatively impact our ability to accurately report product revenue. If we are unable to effectively establish and manage the distribution process, the commercial launch and sales of TYMLOS will be delayed or severely compromised and our results of operations will be harmed.

Risks Related to Marketing and Sale of Our Products

We have only recently completed the hiring and deployment of our commercial and medical affairs organizations and have just recently commenced selling, marketing and distributing TYMLOS. If we are unable to maintain these capabilities on our own or through partnerships or collaborations, we may not be able to successfully commercialize TYMLOS or any future product candidates or generate product revenue.

We recently completed the hiring and deployment of our commercial and medical affairs capabilities and we have only recently commenced commercializing a pharmaceutical product. We recently established a sales force to market and sell TYMLOS in the United States to specialists and also intend to pursue collaborative arrangements to market and sell abaloparatide-SC outside of the United States. Therefore, our future success depends, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborators' strategic interest in the products under development and such collaborators' ability to successfully market and sell any such products.

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

- identify, recruit, hire, train, incentivize and retain a significant number of commercial and medical affairs personnel, including a specialty sales force with appropriate technical expertise;
- train our sales representatives, who will have no prior experience with our company or TYMLOS, to deliver clear and compelling messages within the scope of the approved labeling and in accordance with other applicable FDA requirements regarding TYMLOS and to be credible and persuasive in educating physicians on the appropriate situations to consider prescribing it as set forth in the approved labeling;
- ensure our commercial customer-facing team, including sales, market access, and field logistics professionals, effectively build relationships with their respective customers;
- manage a geographically dispersed national commercial customer-facing organization; and
- manage our significant projected growth and the integration of new personnel.

Building and maintaining our commercial and medical affairs capabilities may be more expensive and time consuming than we anticipate, requiring us to divert resources from other intended purposes or preventing us from

building these capabilities to the desired levels. Any failure or delay in building and maintaining these capabilities on our own or through

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partnerships or collaborations will adversely impact the successful commercialization of TYMLOS, or any future product candidate. If we establish a partnership or collaboration for purposes of commercializing abaloparatide-SC, or any future product candidate, the launch of that product candidate would need to be established in conjunction with our partner, which could result in a change in timing of the commercial launch.

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

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

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

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

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

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

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our product TYMLOS, and product candidates abaloparatide-TD, elacestrant and RAD140, if approved, will compete against existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the United States and abroad. In addition, companies doing business in different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals, and greater manufacturing and marketing

capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures or other collaborations, and therefore, we may not be able to hire or retain qualified personnel to run all facets of our business. These risks could render our products or technologies obsolete or non-competitive.

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

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

Risks Related to Our Intellectual Property

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

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

In November 2016, we received notice that in October 2016, Ipsen initiated arbitration proceedings against us in the International Chamber of Commerce’s International Court of Arbitration. Ipsen’s Request for Arbitration alleges that we breached various provisions of the License Agreement concerning abaloparatide, including with regard to Ipsen's right to co-promote abaloparatide in France and a license from us with respect to Japan. Ipsen seeks declaratory relief, compliance with the License Agreement, damages, costs and fees as a result of the purported breaches, and alleges the monetary value of these claims is approximately €50 million. In January 2017, we submitted an Answer denying Ipsen’s claims and alleging counterclaims against Ipsen for breach of the License Agreement and other declaratory judgment. We asserted, among other things, that Ipsen's claimed rights to co-promote abaloparatide in France and to a license from us with respect to Japan have permanently expired, and that Ipsen has breached the License Agreement by, among other things, allowing certain patents to expire and by purporting to license to a third-party certain manufacturing and other rights that we contend Ipsen exclusively licensed to us. In February 2017, Ipsen submitted a Reply denying our counterclaims and alleging that we are precluded from asserting them. Following a preliminary hearing before the Arbitral Tribunal to determine certain jurisdictional and contractual defenses asserted by Ipsen in its Reply, on July 17, 2017, the Arbitral Tribunal issued a decision finding it has jurisdiction to decide our counterclaims and that our counterclaims are not contractually barred. On July 31, 2017, Ipsen submitted its Statement of Claim to the Arbitral Tribunal. We are seeking dismissal of Ipsen’s claims, as well as declaratory relief, compliance with the License Agreement, and other damages, costs and fees to be determined by the Arbitral Tribunal. The arbitration proceeding is continuing and a hearing on the merits is anticipated to be held in December 2017. Given that this matter is at a preliminary stage, we cannot predict or assess the likely outcome of these proceedings.

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

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

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

proceeding with Ipsen regarding these Ipsen rights and related terms of our license agreement.

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

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Patent No. 2957278) has been issued in Europe. This patent also has an expiration date of October 3, 2027, absent any issued supplementary protection certificates, or SPCs.

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

We and 3M are co-assignees to several foreign and corresponding U.S. patent applications with the earliest priority date of April 22, 2011, which cover various aspects of abaloparatide for microneedle application. Any issued patents resulting from these applications will expire in 2032. However, pending patent applications in the United States and elsewhere may not issue since the interpretation of the legal requirements of patentability in view of claimed inventions are not always predictable. Additional intellectual property covering abaloparatide-TD technology exists in the form of proprietary information protected as trade secrets. These can be accidentally disclosed to, independently derived by or misappropriated by competitors, possibly reducing or eliminating the exclusivity advantages of this form of intellectual property, thereby allowing those competitors more rapid entry into the marketplace with a competitive product, which reduces our advantage with abaloparatide-TD. In addition, trade secrets may in some instances become publicly available through required disclosures in regulatory files. Alternatively, competitors may sometimes reverse engineer a product once it becomes available on the market. Even where a competitor does not use an identical technology for the delivery of abaloparatide, it is possible that they could achieve an equivalent or even superior result using another technology. Such occurrences could lead to either one or more alternative competitor products becoming available on the market and/or one or more generic competitor products on the market gaining market share and causing a corresponding decrease in market share and/or price for abaloparatide-TD even if it were to be successfully developed and approved by the FDA.

Patents covering elacestrant as a composition of matter, as well as the use of elacestrant for the treatment of estrogen-dependent breast cancer, have been issued in the United States, Canada, Australia, Japan and Europe, and are pending in India. The elacestrant composition of matter patents in the United States expire in 2023 and may be adjusted to 2026 (not including any Hatch-Waxman patent term extension). One patent has been issued in the United States (U.S. Patent No. 8,933,130) for treating vasomotor disturbances or hot flashes on January 13, 2015 (statutory term expires on June 22, 2027, and may be adjusted to October 19, 2031 with 1,580 days of patent term adjustment due to delays in patent prosecution by the USPTO). Another patent relating to methods of treating vasomotor symptoms and clinical dosage strengths using elacestrant has been issued in the United States (U.S. Patent No. 9,555,014). This patent has a normal expiry of May 12, 2031, not including any Hatch-Waxman patent term extension. Additional patent applications relating to methods of treating vasomotor symptoms and clinical dosage strengths using elacestrant have been issued in Canada, Europe, and Mexico. Pending patent applications may not issue since the interpretation of the legal requirements of patentability in view of any claimed invention before a patent office are not always predictable. As a result, we could encounter challenges or difficulties in building, maintaining and/or defending our intellectual property both in the United States and abroad.

Patent applications covering RAD140 and other selective androgen receptor modulator compounds have been granted in the United States, Europe, Canada, Mexico, Japan and Australia, and are pending in Brazil and India. The RAD140 composition of matter patents expire in 2029 in the United States (not including any Hatch-Waxman patent term extension) and additional countries if and when they issue.

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

We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to patents issued or licensed to us, including interference proceedings before the USPTO. Third parties also may assert infringement claims against us. If we are found to infringe a third-party's intellectual property rights, we could be required to obtain a license from such third-party to continue developing and marketing

our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. For example, we are aware of a patent issued in the United States claiming the use of elacestrant for an indication we are not pursuing and a patent application filed with the USPTO that could be relevant to the use of elacestrant to treat indications for which we are developing elacestrant. If a patent issues from this patent application with claims covering the use of elacestrant to treat

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indications for which we are developing elacestrant, we may need to license the patent in order to commercialize elacestrant specifically for the treatment of such indications even if elacestrant were successfully developed and approved. We cannot assure you that we will be able to secure a license on reasonable terms, if at all. If we need a license of such patent in order to commercialize elacestrant and are unable to secure one on reasonable terms, our business would be materially harmed.

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

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued that protect our technology or products or that effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Assuming the other requirements for patentability are met, in the United States, prior to March 16, 2013, the first to make the claimed invention was entitled to the patent, or a "first-to-invent" system, while outside the United States, the first to file a patent application is entitled to the patent, or a "first-to-file" system. With the implementation of the Leahy-Smith America Invents Act, the United States now has a first-to-file system for patent applications filed on or after March 16, 2013. We may become involved in opposition, interference or derivation proceedings challenging our patent rights or the patent rights of others. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned and licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. An adverse determination in any such proceeding could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

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

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will come due for payment periodically throughout the lifecycle of patent applications and issued patents. In order to help ensure that we comply with any required fee payment, documentary and/or procedural requirements as they might relate to any patents for which we are an assignee or co-assignee, we employ competent legal help and related professionals as needed to comply with those requirements. Our outside patent counsel uses CPA Global for patent annuity payments. We depend on Eisai to comply with any required fee payment, documentary and/or procedural requirements as they might relate to any patents we have licensed from them. Failure to meet a required fee payment, document production or procedural

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requirement can result in the abandonment of a pending patent application or the lapse of an issued patent. In some instances, the defect can be cured through late compliance but there are situations where the failure to meet the required event cannot be cured. Any failures could compromise the intellectual property protection around our preclinical or clinical candidates and possibly weaken or eliminate our ability to protect our eventual market share for that product.

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

In addition to our patented technology and products, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to our trade secrets, such as our corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach the agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for any breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by a competitor, our competitive position would be harmed.

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

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

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

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

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

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

Some of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in

defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

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

Risks Related to Legislation and Administrative Actions

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

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

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

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

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

- the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of various electronic healthcare transactions and protects the security and privacy of protected health information;
- the federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; in addition, the government may assert that a claim including items or services resulting

from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

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- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation;
- the federal Physician Payment Sunshine Act, or the Sunshine Act, requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. Manufacturers are required to submit reports to the government by the 90th day of each calendar year; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

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

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

In June 2016, the U.K. affirmatively voted in a non-binding referendum advising for the exit of the U.K. from the European Union, commonly referred to as “Brexit”. In March 2017, the U.K. government formally notified the European Council of its intention to leave the EU after it triggered Article 50 of the Lisbon Treaty to begin the two-year negotiation process establishing the future terms of the U.K.’s relationship with the European Union, including the terms of trade between the U.K. and the European Union. The effects of Brexit will depend on any agreements the U.K. makes to retain access to European Union markets either during a transitional period or more permanently. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which European Union laws to replace or replicate and could have a material impact on its economy and the future growth of its various industries.

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

significantly reduce global market liquidity. Any of these effects of Brexit, among others, could adversely affect our business, financial condition, operating results and cash flows.

Risks Related to Employee Matters and Managing Growth

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

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

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

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

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

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

Our success will depend upon the expansion of our operations and the effective management of our growth, and if we are unable to manage this growth effectively, our business will be harmed. We have recently expanded, and will continue to expand, our development, regulatory, manufacturing, quality, distribution, sales and marketing capabilities. As part of this expansion, we expect we will need to manage additional relationships with various collaborators, suppliers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our operational, financial and management controls, reporting systems and procedures. For example, some jurisdictions, such as the District of Columbia, have imposed licensing requirements for sales representatives. In addition, the District of Columbia and the Commonwealth of Massachusetts, as well as the federal government by way of the Sunshine Act, have established reporting requirements that would require public reporting of compensation and other "transfers of value" paid to health care professionals and teaching hospitals, as well as ownership and investment interests held by such professionals and their immediate family members. Because the reporting requirements vary in each jurisdiction, compliance will be complex and expensive and may create barriers to entering the commercialization phase. The need to build new systems as part of our growth could place a strain on our administrative and operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Such requirements may also impact our opportunities to collaborate with physicians at academic research centers as new restrictions on academic-industry relationships are put in place. In the past, collaborations between academia and industry have led to important new innovations, but the new laws may have an effect on these activities. While we cannot predict whether any legislative or regulatory changes will have negative or positive effects, they could have a material adverse effect on our business, financial condition and potential profitability.

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

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

our commercialization capabilities include:

- an inability to retain an adequate number of effective commercial personnel;
- our ability to train sales personnel, who may have limited experience with our company or TYMLOS, to deliver a consistent and compliant message regarding TYMLOS that will be compelling to physicians who may prescribe TYMLOS;

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- an inability to equip sales personnel with effective materials, including medical and sales literature to help them educate physicians and our healthcare providers regarding TYMLOS and its proper administration;
- unforeseen costs and expenses associated with maintaining and further developing an independent sales and marketing organization.

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

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

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

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

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

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

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

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

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

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

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

Risks Relating to Our Securities

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

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

- actions or delays by the FDA, EMA or other foreign regulatory authority in respect of any NDA, MAA or other application we may submit for any of our product candidates, including our MAA for Eladynos;
- results of clinical trials of our product candidates or those of our competitors;
- our operating performance and the operating performance of similar companies;
- the success of competitive products;
- the overall performance of the equity markets;
- the number of shares of our common stock publicly owned and available for trading;
- threatened or actual litigation;
- changes in laws or regulations relating to our products, including changes in the structure of healthcare payment systems;
- any major change in our board of directors or management;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- large volumes of sales or other transfers of our shares of common stock by existing stockholders;
- general political, economic and market conditions; and
- the other factors described in this "Risk Factors" section.

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

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

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

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

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, and are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. If we are unable to maintain effective internal controls, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a publicly traded company or comply with the requirements of the SEC or Section 404. This could result in a restatement of our consolidated financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common shares, or investigation by regulatory authorities. Any such action or other

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negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain.

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

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

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

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

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

Pursuant to our equity incentive plans, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. We have reserved 9,860,000 shares of our common stock for issuance under our equity incentive plans as of December 31, 2016, which includes 2,960,000 shares of common stock issuable upon the exercise of options outstanding as of December 31, 2016, 25,000 shares of common stock issuable upon the vesting of performance stock units, and approximately 57,000 restricted stock units, each of which will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. In addition, as of December 31, 2016, warrants to purchase 0 shares of our common stock were outstanding. Pursuant to our employee stock purchase plan, eligible employees may participate in an employee stock purchase plan sponsored by us. The current plan allows for the issuance of 1,290,954 shares of common stock to eligible employees. As of December 31, 2016, there were 1,290,594 shares available for future sale to employees under this plan. Shares of our common stock issued upon exercise of these warrants may be sold in the public market, subject to prior registration or under an exemption from registration.

If securities or industry analysts cease to publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

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

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

Each of our executive officers is party to an employment agreement, and each of our other employees is party to an agreement or participates in a plan that provides change in control severance benefits including cash payments for severance and other benefits and acceleration of vesting of stock options and other equity awards in the event of a termination of employment in connection with a change in control of us. The payment of these severance benefits

could harm our financial condition and results. The accelerated vesting of options and equity awards could result in dilution to our existing stockholders and harm the market price of our common stock.

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

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

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

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

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

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

As of December 31, 2016, we had $526.7 million of federal and $385.3 million of state net operating loss carryforwards available to offset future taxable income. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have completed studies through December 31, 2015, to determine whether any ownership change has occurred since our formation and have determined that transactions have resulted in two ownership changes, as defined under Section 382. There could be additional ownership changes in the future that could further limit the amount of net operating loss and tax credit carryforwards that we can utilize.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

A list of exhibits is set forth on the Exhibit Index immediately following the signature page of this Quarterly Report on Form 10-Q, and is incorporated herein by reference.

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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 Høiland
Jesper Høiland

President and Chief Executive Officer
(Principal Executive Officer)

Date: August 3, 2017

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

Date: August 3, 2017

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EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation, filed on June 11, 2014	8-K	001-35726	3.1	6/13/2014	
3.2	Amended and Restated By-Laws	8-K	001-35726	3.2	6/13/2014	
10.1	Lease, dated June 28, 2017, between the Company and KBSIII Crosspoint at Valley Forge Trust					*
10.2	Sublease, dated March 11, 2016, between the Company and Rovi Corporation					*
10.3	First Amendment to Sublease, dated July 7, 2017, between the Company and Rovi Corporation					*
10.4	Radius Health, Inc. Form of Inducement Stock Option Agreement	S-8	333-215552	99.1	1/13/2017	
10.5	Employment Letter Agreement, dated May 9, 2017, between the Company and Jose Carmona	8-K	001-35726	10.1	5/15/2017	
10.6	Employment Inducement Stock Option Agreement, dated May 15, 2017, between the Company and Jose Carmona	8-K	001-35726	10.2	5/15/2017	
10.7	Separation Agreement and General Release of Claims, dated May 15, 2017, between the Company and B. Nicholas Harvey	8-K	001-35726	10.3	5/15/2017	
10.8	Consulting Agreement, dated May 17, 2017, between the Company and B. Nicholas Harvey	8-K	001-35726	10.4	5/15/2017	
10.9	Employment Agreement, dated June 23, 2017, between the Company and Jesper Høiland	8-K	001-35726	10.1	7/17/2017	
10.10	Employment Inducement Stock Option Agreement, dated July 17, 2017, between the Company and Jesper Høiland	8-K	001-35726	10.2	7/17/2017	

10.11	Agreement and General Release, dated July 16, 2017, between the Company and Robert Ward	8-K	001-35726	10.3	7/17/2017	
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rule 13a-14(a)/15d-14(a)					*
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rule 13a-14(a)/15d-14(a)					*
32.1	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					*

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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.