

Radius Health, Inc.
Form 10-Q
August 07, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2018

Or

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

For the transition period from to .

Commission File Number 001-35726

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐

Non-accelerated filer ☐ Smaller reporting company ☐

Emerging growth company ☐

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

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

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Number of shares of the registrant's Common Stock, \$.0001 par value per share, outstanding as of August 6, 2018:
45,476,455 shares

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Item 1. Condensed Consolidated Financial Statements

Radius Health, Inc.

Condensed Consolidated Balance Sheets

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

	June 30, 2018 (unaudited)	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 51,441	\$ 118,564
Restricted cash	555	55
Marketable securities	179,730	134,714
Accounts receivable, net	10,957	4,441
Inventory	6,220	4,366
Prepaid expenses	6,527	5,175
Other current assets	1,467	2,191
Total current assets	256,897	269,506
Investments	86,763	176,978
Property and equipment, net	5,210	6,195
Intangible assets	7,781	8,180
Other assets	633	799
Total assets	\$ 357,284	\$ 461,658
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,532	\$ 3,915
Accrued expenses and other current liabilities	45,177	49,512
Total current liabilities	47,709	53,427
Other non-current liabilities	142	189
Notes payable	172,674	166,006
Total liabilities	\$ 220,525	\$ 219,622
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.0001 par value; 200,000,000 shares authorized, 45,476,455 shares and 44,616,586 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	5	4
Additional paid-in-capital	1,150,765	1,124,630
Accumulated other comprehensive loss	(1,290)	(314)
Accumulated deficit	(1,012,721)	(882,284)
Total stockholders' equity	136,759	242,036
Total liabilities and stockholders' equity	\$ 357,284	\$ 461,658

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,	
	2018	2017	2018	2017
REVENUES:				
Product revenue, net	\$22,629	\$ 980	\$37,176	\$ 980
OPERATING EXPENSES:				
Cost of sales - product	1,603	105	2,691	105
Cost of sales - intangible amortization	200	—	399	—
Research and development	26,324	19,652	49,175	39,179
Selling, general and administrative	48,579	50,121	96,605	88,220
Other operating expenses	10,801	—	10,801	—
Loss from operations	(64,878)	(68,898)	(122,495)	(126,524)
OTHER (EXPENSE) INCOME:				
Other income (expense)	171	(97)	66	(17)
Interest expense	(5,683)	—	(11,248)	—
Interest income	1,508	557	3,240	1,164
NET LOSS	\$(68,882)	\$(68,438)	\$(130,437)	\$(125,377)
OTHER COMPREHENSIVE LOSS:				
Unrealized gain (loss) from available-for-sale debt securities	192	(32)	(976)	(69)
COMPREHENSIVE LOSS	\$(68,690)	\$(68,470)	\$(131,413)	\$(125,446)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED (Note 11)	\$(68,882)	\$(68,438)	\$(130,437)	\$(125,377)
LOSS PER SHARE:				
Basic and diluted	\$(1.52)	\$(1.58)	\$(2.89)	\$(2.90)
WEIGHTED AVERAGE SHARES:				
Basic and diluted	45,430,678	43,410,053	45,185,588	43,300,243

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,	
	2018	2017
CASH FLOWS USED IN OPERATING ACTIVITIES:		
Net loss	\$(130,437)	\$(125,377)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,341	695
Amortization of discount on marketable securities, net	(278)	(75)
Amortization of debt discount and debt issuance costs	6,668	—
Stock-based compensation	15,569	20,533
Changes in operating assets and liabilities:		
Inventory	(1,854)	(1,636)
Accounts receivable, net	(6,516)	(1,211)
Prepaid expenses	(1,352)	(3,738)
Other current assets	724	113
Other long-term assets	166	(7)
Accounts payable	(1,383)	(1,732)
Accrued expenses and other current liabilities	(4,221)	(466)
Other non-current liabilities	(47)	(48)
Net cash used in operating activities	(121,620)	(112,949)
CASH FLOWS PROVIDED BY (USED IN) INVESTING ACTIVITIES:		
Purchases of property and equipment	(71)	(1,131)
Payments for capitalized milestones	—	(8,712)
Purchases of marketable securities	(499)	(111,983)
Sales and maturities of marketable securities	45,000	106,264
Net cash provided by (used in) investing activities	44,430	(15,562)
CASH FLOWS PROVIDED BY FINANCING ACTIVITIES:		
Proceeds from exercise of stock options and warrant exercises	8,826	4,024
Proceeds from issuance of shares under employee stock purchase plan	1,741	1,030
Net cash provided by financing activities	10,567	5,054
NET DECREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(66,623)	(123,457)
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT BEGINNING OF YEAR	118,619	258,614
CASH, CASH EQUIVALENTS, AND RESTRICTED CASH AT END OF PERIOD	\$51,996	\$135,157
SUPPLEMENTAL DISCLOSURES:		
Cash paid for income taxes	\$22	\$21
Property and equipment purchases in accrued expenses at period end	\$114	\$1,247

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 endocrine therapeutics in the areas of osteoporosis and oncology. In April 2017, the Company's first commercial product, TYMLOS® (abaloparatide) injection, was approved by the U.S. Food and Drug Administration (“FDA”) for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In April 2018, the Company submitted a request for re-examination of the negative opinion adopted by the Committee for Medicinal Products for Human Use (“CHMP”) of the European Medicines Agency (“EMA”) on the Company’s European Marketing Authorisation Application (“MAA”) for abaloparatide for subcutaneous administration (“abaloparatide-SC”) and in July 2018, following a re-examination procedure, the CHMP maintained its negative opinion. The Company's clinical pipeline includes an investigational abaloparatide transdermal patch (“abaloparatide-patch”) for potential use in the treatment of postmenopausal women with osteoporosis; the investigational drug elacestrant (RAD1901), a selective estrogen receptor degrader for potential use in the treatment of hormone-receptor positive breast cancer; and the investigational drug RAD140, a non-steroidal, selective androgen receptor modulator for potential use in the treatment of hormone-receptor positive breast cancer. The Company is subject to the risks associated with biopharmaceutical companies with a limited operating history, including dependence on key individuals, a developing business model, the necessity of securing regulatory approvals to market its investigational product candidates, market acceptance and the successful commercialization of TYMLOS, or any of the Company’s investigational product candidates following receipt of regulatory approval, competition for TYMLOS or any of the Company's investigational product candidates following receipt of regulatory approval, and the continued ability to obtain adequate financing to fund the Company’s future operations. The Company has incurred losses and expects to continue to incur additional losses for the foreseeable future. As of June 30, 2018, the Company had an accumulated deficit of \$1,012.7 million, and total cash, cash equivalents, restricted cash, marketable securities, and investments of \$318.5 million.

Based upon its cash, cash equivalents, marketable securities, and investments balance as of June 30, 2018, 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 activities in the United States and development costs of its clinical product portfolio with its existing cash and cash equivalents, marketable securities and investments, as well as future product sales or through strategic financing opportunities that could include, but are not limited to, partnering or other collaboration agreements, future offerings of its equity, royalty based financing arrangements, or the incurrence of debt or other alternative financing arrangements which may include a combination of the foregoing. However, there is no guarantee that any of these strategic or financing opportunities will be executed or executed on favorable terms, and some could be dilutive to existing stockholders. If the Company fails to obtain additional capital, it may be unable to conduct its planned commercialization activities or complete its planned preclinical studies and clinical trials and obtain approval of certain of its investigational product candidates from the FDA or foreign regulatory authorities.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation—The accompanying unaudited condensed consolidated financial statements and the related disclosures of the Company have been prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”) for interim financial reporting and as required by Regulation S-X, Rule 10-01.

Accordingly, they do not include all the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments (including those which are normal and recurring) considered necessary for a fair presentation of the interim financial information have been included.

When preparing financial statements in conformity with U.S. GAAP, the Company must make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the financial statements. Actual results could differ from those estimates. Additionally, operating results for the six months ended June 30, 2018 are not necessarily indicative of the results that may be expected for any other interim period or for the fiscal year ending December 31, 2018. Subsequent events have been evaluated up to the date of issuance of these financial statements. These interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial

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statements and notes, which are contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 ("2017 Form 10-K"), filed with the Securities and Exchange Commission ("SEC") on March 1, 2018. Certain prior period amounts have been reclassified to conform to the current period presentation.

Significant Accounting Policies—The significant accounting policies identified in the Company's 2017 Form 10-K that require the Company to make estimates and assumptions include: revenue recognition, inventory obsolescence, long-lived assets and intangible assets, accounting for stock-based compensation, contingencies, tax valuation reserves, fair value measures, and accrued expenses. There were no changes to significant accounting policies during the six months ended June 30, 2018, except for the adoption of three Accounting Standards Updates ("ASU") issued by the Financial Accounting Standards Board ("FASB"), which are detailed below.

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

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

	As of June 30, 2018	As of June 30, 2017
Cash and cash equivalents	\$51,441	\$135,110
Restricted cash	555	47
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	\$51,996	\$135,157

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

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

Accounting Standards Updates, Recently Issued—In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting ("ASU 2018-07"). ASU 2018-07 amends the FASB Accounting Standards Codification ("ASC") to expand the scope of FASB ASC Topic 718, Compensation-Stock Compensation, to include accounting for share-based payment transactions for acquiring goods and services from non-employees. The amendments in ASU 2018-07 are effective for all entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2018. Early adoption is permitted. The Company is currently assessing the potential impact of adopting ASU 2018-07 on its financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, Leases ("ASU 2016-02"). ASU 2016-02 supersedes the lease guidance under FASB ASC Topic 840, Leases, resulting in the creation of FASB ASC Topic 842, Leases. ASU 2016-02 requires a lessee to recognize in the statement of financial position a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term for both finance and operating

leases. 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.

3. Marketable Securities

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

	June 30, 2018		
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses
			Fair Value
Cash and cash equivalents:			
Cash	\$19,018	\$—	\$19,018
Money market funds	32,423	—	32,423
Total	\$51,441	\$—	\$51,441

Marketable securities:

Domestic corporate debt securities