

RADIUS HEALTH, INC.

FORM 8-K (Current report filing)

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Address	ATTN: CHIEF FINANCIAL OFFICER 950 WINTER STREET WALTHAM, MA, 02451
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 10, 2018

RADIUS HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-35726
(Commission
File Number)

80-0145732
(IRS Employer
Identification No.)

**950 Winter Street,
Waltham, MA**
(Address of principal executive offices)

02451
(Zip Code)

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

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition .

On May 10, 2018, Radius Health, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2018. A copy of the press release is attached hereto as Exhibit 99.1.

The information contained in this Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly provided by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 10, 2018.

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 hereunto duly authorized.

RADIUS HEALTH, INC.

Date: May 10, 2018

By: /s/ Jose Carmona
Name: Jose Carmona
Title: Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 10, 2018.



Radius Health Reports First Quarter 2018 Financial and Operating Results and Provides Business Update

First quarter 2018 TYMLOS® sales increase to \$14.5 million, a 90% increase over the fourth quarter of 2017

TYMLOS captured on average 13% of the U.S. anabolic osteoporosis market and 31% of new anabolic patient starts in the quarter

Radius targets TYMLOS capturing on average 19-21% of the U.S. anabolic osteoporosis market in 2018 and expects the U.S. anabolic market to grow by 5-7% versus 2017

Initiated Phase 3 Trial of abaloparatide-SC for the treatment of male osteoporosis

Significant progress in clinical pipeline with finalization of Phase 3 development pathways for elacestrant and abaloparatide-patch

Conference call scheduled for 8:00 AM ET today

WALTHAM, Mass., May 10, 2018 -- Radius Health, Inc. ("Radius" or the "Company") (Nasdaq: RDUS), today reported its financial results for the first quarter ended March 31, 2018 and provided a business update.

“The Company’s first quarter results highlight the strong performance of TYMLOS in the U.S. anabolic osteoporosis market, having captured one third of new patient starts with bone building anabolic therapy within less than a year of our commercial launch” said Jesper Hoeiland, President and Chief Executive Officer of Radius. “We remain focused on further increasing our market penetration and are committed to achieving leadership in the anabolic market with our differentiated and responsibly priced drug.”

“I’m also very pleased that we made significant progress in advancing our clinical pipeline. Having finalized our development pathways for elacestrant and abaloparatide-patch, we remain on track with our preparations to launch these global pivotal studies,” Mr. Hoeiland concluded.

TYMLOS® (abaloparatide) injection

- First quarter 2018 sales of TYMLOS in the U.S. were \$14.5 million, an increase of 90% from the fourth quarter of 2017. TYMLOS prescriptions reached 31% of new anabolic patient starts (based on New Patients to Brand, NBRx PMOT) and 13% of the total U.S. anabolic osteoporosis market (based on Patient Months on Therapy, TRx PMOT) in the first quarter of 2018.
- Less than a year after launch, TYMLOS has surpassed the level of U.S. commercial market access for the competing anabolic product, with 95% coverage in commercial plans. TYMLOS coverage in Medicare Part D plans has also increased to 43%. 263 million lives now have access to

TYMLOS representing 88% of the total insured US population.

- At the Academy of Managed Care Pharmacy (AMCP) Annual Meeting on April 25th, Radius presented two posters in support of the clinical and cost-effective value of treating earlier with TYMLOS to build bone followed by antiresorptive maintenance treatments. The findings demonstrate that sequential therapy of TYMLOS followed by generic alendronate was shown to improve outcomes at a lower total cost of care compared to teriparatide followed by generic alendronate for the treatment of US women at high risk for fracture. Further, sequential therapy with TYMLOS followed by generic alendronate was shown to improve outcomes at a lower total cost of care compared to starting with generic alendronate for women at high risk of fracture.
- There was a 103% increase in the total number of U.S. physicians prescribing TYMLOS in the first quarter of 2018 versus the previous quarter. TYMLOS' share of the total anabolic volume written by these physicians increased from 20% in the fourth quarter of 2017 to 38% in the first quarter of 2018. TYMLOS' share of new prescriptions written by these physicians increased from 32% in the fourth quarter of 2017 to 49% in the first quarter of 2018.
- The Company's Awareness Trial and Usage Survey in the first quarter of 2018 showed TYMLOS reaching 80% of aided awareness, and a high intention by physicians to treat with TYMLOS, surpassing the competing anabolic product in the market.
- Radius expects TYMLOS to capture on average 19-21% of the U.S. anabolic osteoporosis market in 2018 and that the U.S. anabolic market will continue its positive growth trajectory since TYMLOS was launched in May 2017, with an expected 5-7% volume increase.
- A 5.9% price increase for TYMLOS took effect on February 22, 2018.

Pipeline Highlights

Abaloparatide -Transdermal Patch (abaloparatide-patch)

- In Q1 2018, Radius finalized a development pathway for abaloparatide-patch after regulatory alignment with the FDA and entered into a scale-up and commercial supply agreement with 3M Company (3M).
- The Company is on track with its ongoing efforts with partner 3M to increase manufacturing capacity to support the pivotal study and for clinical and non-clinical studies that will be included in a future New Drug Application (NDA) submission. The Phase 3 study of abaloparatide-patch is planned to start in mid-2019.

Abaloparatide - Subcutaneous (SC)

- **European MAA**
In March 2018, Radius announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency adopted a negative opinion on the Company's marketing authorization application (MAA) for abaloparatide-SC for the treatment of

osteoporosis in postmenopausal women at increased risk for fracture. In April 2018, Radius submitted a re request for re-examination of the CHMP's opinion.

- **Male Osteoporosis Trial**

In March 2018 Radius initiated the Phase 3 ATOM (Abaloparatide Treatment for Osteoporosis in Males) study of abaloparatide-SC for the treatment of osteoporosis in men, which, if successful, will form the basis of a supplemental NDA seeking to expand TYMLOS' label. The study is a randomized, double-blind, placebo-controlled trial that will enroll approximately 225 men with osteoporosis at high risk of fracture. The study will include a primary endpoint of change in lumbar spine bone mineral density ("BMD") at 12 months versus placebo, and specialized high-resolution imaging of bone structure in a subset of the study participants.

Male osteoporosis is estimated to account for approximately 10% of the total treated osteoporotic patient population.

Elacestrant (RAD1901)

- Based on EMA and FDA feedback, Radius announced in March 2018 that it will conduct a single, randomized, comparator controlled Phase 3 trial of elacestrant as a third-line monotherapy in approximately 300 patients with ER positive/HER2 negative advanced/metastatic breast cancer. Depending on the results, this study is expected to support applications for global marketing approvals for elacestrant. Patients in the study would be randomized to receive either elacestrant or an investigator's choice of an approved hormonal agent and the primary endpoint of the study will be progression-free survival (PFS). Start-up activities for the randomized study are well underway and Radius will provide further study details when the Phase 3 trial is initiated, which the Company expects will be in the second half of 2018.

RAD140

- Patient enrollment is ongoing in the Phase 1 study evaluating the safety and maximum tolerated dose of RAD140, a nonsteroidal selective androgen receptor modulator (SARM), in patients with hormone receptor-positive, locally advanced or metastatic breast cancer. The Company expects to provide an update on the RAD140 development program by the end of 2018.

Operational Activities

- In March 2018, the Company consolidated operations in its headquarters in Waltham, Massachusetts and office in Wayne, Pennsylvania. As part of this consolidation, Radius' Parsippany, New Jersey office will be closed.

Anticipated Upcoming Milestones

- Elacestrant
 - Initiate a Phase 3 clinical trial as third-line monotherapy in advanced/metastatic ER-positive/HER2-negative breast cancer patients in the second half of 2018
 - Collaboration agreement for elacestrant combination therapy
- RAD140

- Continue enrollment in the Phase 1 study and provide a program update by the end of 2018
- Abaloparatide
 - Initiate clinical bone histomorphometry study in the first half of 2018
 - Publication of ACTIVEExtend Phase 3 data
 - Enter into a partnership for the potential commercialization of abaloparatide-SC outside the US and Japan

Expected Radius Presentations at Upcoming Conferences in 2Q 2018

- On May 15-17, the Company will present and host one-on-one meetings at the Bank of America Merrill Lynch Healthcare Conference in Las Vegas, Nevada.
- On June 12-14, the Company will present and host one-on-one meetings at the Goldman Sachs Global Healthcare Conference in Palos Verdes, California.

First Quarter 2018 Financial Results

For the three months ended March 31, 2018, Radius reported a net loss of \$61.6 million, or \$1.37 per share, compared to a net loss of \$56.9 million, or \$1.32 per share, for the three months ended March 31, 2017.

For the three months ended March 31, 2018, Radius reported TYMLOS net product revenues of \$14.5 million compared to zero TYMLOS revenue in the three months ended March 31, 2017.

Research and development expense for the three months ended March 31, 2018, was \$22.9 million compared to \$19.5 million for the three months ended March 31, 2017, an increase of \$3.4 million, or 17%. This increase was primarily driven by a \$2.5 million increase in abaloparatide-SC project costs, a \$0.6 million increase in elacestrant project costs, a \$0.3 million increase in RAD140 project costs, and a \$0.1 million increase in abaloparatide-patch project costs. These increases were partially offset by a \$0.9 million decrease in vasomotor project related spending. Additionally, there was an increase in headcount from 111 research and development employees as of March 31, 2017 to 131 research and development employees as of March 31, 2018.

For the three months ended March 31, 2018, selling, general and administrative expense was \$48.0 million compared to \$38.1 million for the three months ended March 31, 2017, an increase of \$9.9 million, or 26%. This increase was primarily the result of a \$6.6 million and \$2.3 million increase in compensation and travel related expenses, respectively, due to an increase in headcount from 363 selling, general and administrative employees as of March 31, 2017 to 405 selling, general and administrative employees as of March 31, 2018.

As of March 31, 2018, Radius had \$367.3 million in cash, cash equivalents and marketable securities. Based upon the Company's cash, cash equivalents and marketable securities balance as of March 31, 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 and other operational activities for not less than twelve months from the date of this press release.

Condensed Consolidated Balance Sheets

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

	March 31, 2018	December 31, 2017
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 56,088	\$ 118,564
Restricted cash	55	5
Marketable securities	179,453	134,714
Accounts receivables, net	8,048	4,444
Inventory	5,438	4,360
Prepaid expenses	6,429	5,174
Other current assets	2,241	2,194
Total current assets	<u>257,752</u>	<u>269,504</u>
Investments	131,750	176,974
Property and equipment, net	5,762	6,194
Intangible assets	7,981	8,184
Other assets	756	794
Total assets	<u>\$ 404,001</u>	<u>\$ 461,654</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,525	\$ 3,914
Accrued expenses and other current liabilities	34,849	49,514
Total current liabilities	<u>39,374</u>	<u>53,428</u>
Other non-current liabilities	165	184
Note payable	169,284	166,004
Total liabilities	<u>208,823</u>	<u>219,624</u>
Stockholders' equity:		
Common stock, \$.0001 par value; 200,000,000 shares authorized, 45,214,387 shares and 44,616,586 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	5	4
Additional paid-in-capital	1,140,495	1,124,634
Accumulated other comprehensive loss	(1,483)	(314)
Accumulated deficit	(943,839)	(882,284)
Total stockholders' equity	<u>195,178</u>	<u>242,034</u>
Total liabilities and stockholders' equity	<u>\$ 404,001</u>	<u>\$ 461,654</u>

Condensed Consolidated Statement of Operations and Comprehensive Loss
(Unaudited amounts in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2018	2017
REVENUES:		
Product revenue, net	\$ 14,547	\$ -
OPERATING EXPENSES:		
Cost of sales - product	1,088	-
Cost of sales - intangible amortization	200	-
Research and development	22,851	19,527
Selling, general, and administrative	48,025	38,099
Loss from operations	(57,617)	(57,626)
OTHER (EXPENSE) INCOME:		
Other (expense) income, net	(104)	80
Interest expense	(5,566)	-
Interest income	1,732	607
NET LOSS	\$ (61,555)	\$ (56,939)
OTHER COMPREHENSIVE LOSS:		
Unrealized loss from available-for-sale debt securities	(1,169)	(37)
COMPREHENSIVE LOSS	\$ (62,724)	\$ (56,976)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:	\$ (61,555)	\$ (56,939)
LOSS PER SHARE:		
Basic and diluted	\$ (1.37)	\$ (1.32)
WEIGHTED AVERAGE SHARES:		
Basic and diluted	44,937,776	43,185,952

Webcast and Conference Call

In connection with today's reporting of First Quarter Financial Results, Radius will host a conference call and live audio webcast at 8:00 a.m. ET today, May 10, 2018, to discuss the commercial outlook for TYMLOS, review the financial results and provide a Company update.

Conference Call Information:

Date: Thursday, May 10, 2018

Time: 8:00 a.m. ET

Domestic Dial-in Number: (866) 323-7965

International Dial-in Number: (346) 406-0961

Conference ID: 6964878

Live webcast: <https://edge.media-server.com/m6/p/y98kugt8>

For those unable to participate in the conference call or webcast, a replay will be available from May 10, 2018 at 7:30 p.m. ET until May 17, 2018 at 6:30 p.m. ET. To access the replay, dial (855) 859-2056 for U.S. or (404) 537-3406 for International. The replay pin number is 6964878.

A live audio webcast of the call can be accessed from the Investors section of the Company's website, www.radiuspharm.com, where a webcast replay will be also available for 14 days. The full text of the announcement and financial results will also be available on the Company's website.

About Radius

Radius 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. Radius' lead product, TYMLOS (abaloparatide) injection, was approved by the U.S. Food and Drug Administration for the treatment of postmenopausal women with osteoporosis at high risk for fracture. The Radius clinical pipeline includes an investigational abaloparatide patch for potential use in osteoporosis; the investigational drug elacestrant (RAD1901) for potential use in hormone-receptor positive breast cancer; and the investigational drug RAD140, a non-steroidal, selective androgen receptor modulator (SARM) under investigation for potential use in hormone-receptor positive breast cancer. For more information, please visit www.radiuspharm.com.

About TYMLOS (abaloparatide) injection

TYMLOS (abaloparatide) injection was approved by the U.S. Food and Drug Administration 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. Radius also is developing abaloparatide-patch based on 3M Company's patented Microstructured Transdermal System technology for potential use as a treatment for postmenopausal women with osteoporosis.

About ACTIVE and ACTIVEExtend

The Phase 3 ACTIVE (Abaloparatide Comparator Trial In Vertebral Endpoints) trial was a randomized, double-blind, placebo-controlled, comparative, multicenter, 18 month international study in 2,463 postmenopausal women with osteoporosis designed to evaluate the efficacy and safety of abaloparatide-SC 80 mcg to reduce the risk of vertebral and nonvertebral fractures. The results of ACTIVE were published in the Journal of the American Medical Association in August of 2016. ACTIVEExtend, an extension of ACTIVE, enrolled patients who had completed 18 months of abaloparatide-SC or placebo in ACTIVE to receive up to 24 additional months of open-label alendronate. The results of the first six months of ACTIVEExtend were published in the Mayo Clinic Proceedings in February of 2017.

About Elacestrant (RAD1901)

Elacestrant is a selective estrogen receptor degrader (SERD), which is being evaluated for potential use as a once daily oral treatment for hormone-receptor positive breast cancer. Elacestrant is currently being investigated for potential use in women with advanced estrogen receptor 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 for the treatment of breast cancer.

About RAD140

RAD140 is a non-steroidal selective androgen receptor modulator (SARM). The androgen receptor (AR) is frequently expressed in many estrogen receptor (ER)-positive, ER-negative, and triple-negative breast cancers. Because of its receptor and tissue selectivity, potent activity, oral bioavailability, and long half-life, RAD140 could have clinical potential in the treatment of breast cancer. RAD140 resulted from an internal drug discovery program focused on the androgen receptor pathway and exhibits a differentiated mechanism of action compared to ER-targeted therapy.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding our expectations regarding commercialization of TYMLOS in the U.S., including regarding capturing a share of the U.S. anabolic osteoporosis market and regarding growth of the anabolic market; our European MAA for abaloparatide-SC; our expectations regarding our regulatory submissions and the timing of clinical trial initiations; our entry into potential collaborations, including the timing thereof; the progress in the development of our product candidates, including abaloparatide-patch, elacestrant (RAD1901) and RAD140; each of the statements under the headings "Anticipated Upcoming Milestones, and "Expected Radius Presentations at Upcoming Conferences in 1H 2018;" the sufficiency of our cash, cash equivalents and marketable securities, and the potential clinical uses and therapeutic and other benefits of our product candidates, including abaloparatide-patch, elacestrant and RAD140.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: we expect to need to raise additional funding, which may not be available; risks related to raising additional capital; our limited operating history; quarterly fluctuation in our financial results; our dependence on the success of TYMLOS, and our inability to ensure that TYMLOS will obtain regulatory approval outside the U.S. or be successfully commercialized in any market in which it is approved, including as a result of risk related to coverage, pricing and reimbursement; risks related to competitive products and any collaboration agreements failing to be successful; risks related to clinical trials, including our reliance on third parties to conduct key portions of our clinical trials and uncertainty that results will support our product candidate claims; the risk that adverse side effects will be identified during the development of our product candidates or during commercialization, if approved; risks related to manufacturing, supply and distribution; and the risk of litigation or other challenges regarding our intellectual property rights. These and other important risks and uncertainties discussed in our filings with the Securities and Exchange Commission, or SEC, including under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ending December 31, 2017 and subsequent filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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