

RADIUS HEALTH, INC.

FORM 8-K (Current report filing)

Filed 02/23/17 for the Period Ending 02/23/17

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): February 23, 2017

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))
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Item 2.02 Results of Operations and Financial Condition.

On February 23, 2017, Radius Health, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2016. 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

Exhibit 99.1 shall be deemed to be furnished, and not filed:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 23, 2017.

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.

Dated: February 23, 2017

By: /s/ B. Nicholas Harvey
Name: B. Nicholas Harvey
Title: Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 23, 2017.



Radius Health Reports Fourth Quarter and Full Year 2016 Financial and Operating Results

US FDA PDUFA for abaloparatide-SC is March 30, 2017

Build out of Commercial Organization to be completed in 1Q 2017

24-month ACTIVEExtend trial has concluded, Radius to report top-line results in 2Q 2017

Waltham, Massachusetts – February 23, 2017 (GLOBE NEWSWIRE): Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq:RDUS), a science-driven biopharmaceutical company that is committed to developing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases, reported its financial results for the fourth quarter and full year ended December 31, 2016, and provided a business update. As of December 31, 2016, Radius had \$332.4 million in cash, cash equivalents and marketable securities.

“We continue to work closely with the U.S. Food and Drug Administration as we move towards the March 30, 2017 PDUFA for abaloparatide-SC for postmenopausal osteoporosis. Our highly experienced leadership is completing the build out of our commercial organization with seasoned talent who have demonstrated success across sales, marketing, reimbursement and distribution and are fully prepared to support a successful launch, pending favorable regulatory review,” said Robert Ward, President and Chief Executive Officer of Radius. “2017 will be a major inflection point for Radius, as we evolve towards a commercial company. We are confident that we are prepared for this change and have the talent, experience and resources required to deliver sustainable high performance.”

Pipeline Updates

Abaloparatide-SC

Radius’ new drug application (NDA) in the United States for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis was accepted for filing by the FDA and granted a Prescription Drug User Fee Act (PDUFA) date of March 30, 2017. Radius’ marketing authorisation application (MAA) to the European Medicines Agency (EMA), is currently undergoing regulatory review, and we anticipate receiving an opinion from the Committee for Medicinal Products for Human Use (CHMP) in 2017.

On February 1, 2017, results from the first six months of the recently completed 24- month ACTIVEExtend trial were published in the Mayo Clinic Proceedings “*Eighteen Months of Treatment With Subcutaneous Abaloparatide Followed by 6 Months of Treatment With Alendronate in Postmenopausal Women With Osteoporosis: Results of the ACTIVEExtend Trial*”. The 24-month ACTIVEExtend clinical trial has completed and Radius will report the top line results in the second quarter of 2017.

Abaloparatide-SC as a treatment for postmenopausal women with osteoporosis is an investigational product and its safety and efficacy have not been established.

Abaloparatide-TD

Last September, at the annual meeting of the American Association for Bone Mineral Research (ASBMR), we presented the positive results from a human replicative clinical evaluation of an optimized abaloparatide transdermal patch. These results established an important demonstration of how we have changed the pharmacokinetic profile in our program to develop a bioequivalent transdermal patch. Currently, we are focused on completing the manufacturing, scale-up, and other required activities needed to initiate a pivotal study to evaluate bioequivalence to abaloparatide-SC. We believe that the transdermal patch program has the potential to allow physicians who treat osteoporosis, but rarely use injectable drugs, an opportunity to expand their practices to include the use of anabolic therapy.

RAD1901

On December 8, 2016, at the San Antonio Breast Cancer symposium we reported on the encouraging results of our ongoing Phase 1 studies of RAD1901 in advanced breast cancer. We were pleased with the clear demonstration of activity at the 400 mg dose in this heavily pretreated patient population. We plan to engage with regulatory agencies to gain alignment on defining the next steps for the program in the first half of 2017, which would include the design of a Phase 2 trial. Also in the first half of this year, we plan to report results from our completed Phase 2b trial in vasomotor symptoms.

RAD140

In December 2016, we submitted an investigational new drug application, or IND, to the FDA for RAD140, a selective androgen receptor modulator discovered in-house at Radius. We expect to initiate a first-in-human Phase 1 clinical trial in women with hormone receptor positive breast cancer in 2017.

Building A Commercial Organization For Sustainable Growth

In our evolution towards becoming a fully integrated biopharmaceutical company, our accomplished senior leadership is completing the build out of our commercial, medical and compliance organizations to support the potential commercialization of abaloparatide-SC in the United States, pending favorable regulatory review. Our sales leaders have already hired over 90% of our clinical sales specialists with a focus on identifying the most experienced team possible. The result is a sales team with substantial osteoporosis, injectable and women's health experience, and the majority have had prior launch experience, which matches the depth of experience across our Medical Science Liaison team.

If approved, we intend to distribute abaloparatide-SC in the United States through a network of distributors and specialty pharmacies. Under this distribution model, both the distributors and specialty pharmacies would take physical delivery of product and the specialty pharmacies would dispense the product directly to patients.

Under the leadership of our Chief Compliance Officer, we are continuing to strengthen our compliance program in support of launch of abaloparatide-SC as part of our commitment to a strong culture of compliance and good corporate governance.

Radius Expects the Following Upcoming Milestones

- Abaloparatide-SC
 - FDA PDUFA date of March 30, 2017
 - Receive a CHMP opinion regarding the EMA's review of the abaloparatide-SC MAA in 2017
 - Enter into a partnership for the potential commercialization of abaloparatide-SC prior to commercial launch
 - Report top-line results from the recently completed 24-month ACTIVEExtend clinical trial in the second quarter of 2017
- RAD1901
 - Complete ongoing Phase 1 breast cancer clinical trials
 - Engage with regulatory authorities in 1H 2017 to gain alignment on defining next steps for the program, which would include the design of a Phase 2 breast cancer trial
 - In 1H 2017, complete, and report results from, our ongoing Phase 2b vasomotor trial

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- RAD140
 - Initiate a first-in-human Phase 1 study in 2017 in women with hormone receptor positive breast cancer

Radius Expects To Make Presentations at the Following Upcoming Conferences

- On March 6, 2017, Radius President and CEO, Robert Ward will make a presentation and will host one-on-ones at the Cowen Conference in Boston
- On March 24-25, 2017, at the 2017 World Congress of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (WCO-IOF-ESCEO), 4 scientific presentations will be made on abaloparatide titled:
 - *“Effects of abaloparatide-SC on bone mineral density and risk of fracture in postmenopausal women aged 80 years or older with osteoporosis”*
 - *“Abaloparatide-SC decreases vertebral, nonvertebral, major osteoporotic, and wrist fractures in a subset of postmenopausal women at high risk of fracture by FRAX score”*
 - *“Abaloparatide-SC for postmenopausal osteoporosis: analysis of the number needed to treat compared with teriparatide”*
 - *“Abaloparatide-SC significantly reduces vertebral and nonvertebral fractures and increases bone mineral density regardless of baseline risk: results from the ACTIVE phase 3 clinical trial”*

Fourth Quarter 2016 Financial Results

For the three months ended December 31, 2016, Radius reported a net loss of \$52.7 million, or \$1.22 per share, as compared to a net loss of \$33.2 million, or \$0.77 per share, for the three months ended December 31, 2015. The increase in net loss for the three months ended December 31, 2016 as compared to the three months ended December 31, 2015 was primarily due to an increase in research and development and general and administrative expenses, partially offset by a decrease in loss on retirement of note payable, a decrease in interest expense and an increase in interest income.

Research and development expenses for the three months ended December 31, 2016 were \$25.6 million, compared to \$22.2 million for the same period in 2015. This

increase was primarily driven by higher research and development costs associated with the development of RAD1901 to support a Phase 1 study in metastatic breast cancer that commenced in late 2014 and a Phase 2b study in postmenopausal vasomotor symptoms that commenced in December 2015. This increase was also a result of an increase in compensation expense, including stock-based compensation, due to an increase in headcount from December 31, 2015 to December 31, 2016.

General and administrative expenses for the three months ended December 31, 2016 were \$27.5 million, compared to \$11.6 million for the same period in 2015. This increase was primarily attributable to an increase in professional support costs, including the costs associated with increasing headcount and preparing for the potential commercialization of abaloparatide-SC, subject to a favorable regulatory review.

This increase was also driven by an increase in compensation expense, including stock-based compensation, due to an increase in headcount from December 31, 2015 to December 31, 2016.

Full Year 2016 Financial Results

For the twelve months ended December 31, 2016, Radius reported a net loss of \$182.8 million, or \$4.24 per share, as compared to a net loss of \$101.5 million, or \$2.56 per share, for the twelve months ended December 31, 2015. The increase in net loss for 2016 was primarily due to an increase in research and development expenses and general and administrative expenses, partially offset by a decrease in loss on retirement of note payable, a decrease in interest expense and an increase in interest income.

Research and development expenses for the twelve months ended December 31, 2016 were \$107.4 million, compared to \$68.3 million for 2015. The increase was primarily attributable to increased compensation expense, including an increase of \$3.3 million of non-cash stock-based compensation expense, due to growth in headcount from 48 research and development employees as of December 31, 2015, to 107 research and development employees as of December 31, 2016. This increase was also driven by higher contract service costs associated with the development of our investigational product candidate RAD1901 as a result of the increased clinical and manufacturing activities in 2016, as compared to 2015. These increases were partially offset by a decrease in the total professional contract service costs associated with the development of abaloparatide-SC as more subjects completed study protocol activities associated with the 24-month ACTIVEExtend clinical trial in 2016, as compared to 2015.

General and administrative expenses for the twelve months ended December 31, 2016 were \$77.5 million, compared to \$30.8 million for 2015. This increase was primarily due to increased professional support costs of approximately \$19.4 million, including costs associated with preparing for the potential commercialization of abaloparatide-SC, subject to a favorable regulatory review, as compared to 2015. This increase was also driven by increased compensation expense, including an increase of \$8.0 million of non-cash stock-based compensation expense, due to growth in headcount from 27 general and administrative employees as of December 31, 2015, to 130 general and administrative employees as of December 31, 2016.

For the twelve months ended December 31, 2016, the decrease in loss on retirement of note payable was \$1.6 million and other expenses increased by \$0.3 million. These amounts were partially offset by the increase in interest income from investments of \$1.4 million and a decrease in interest expense of \$1.9 million.

As of December 31, 2016, Radius had \$332.4 million in cash, cash equivalents and marketable securities. Based upon Radius' cash, cash equivalents and marketable securities balance, Radius believes that, prior to the consideration of revenue from the potential future sales, subject to favorable regulatory review, of any of its investigational products, it has sufficient capital to fund its development plans, U.S. commercial scale-up and other operational activities for not less than twelve months from the date of this press release and into 2018.

Conference Call and Webcast

In connection with the earnings release, Radius will host a conference call and live audio webcast at 4:30 p.m. ET on Thursday, February 23, 2017 to discuss the financial results, and give an update on the Company's progress.

Conference Call Information:

Date: Thursday, February 23, 2017

Time: 4:30 p.m. ET

Domestic Dial-in Number: 1-877-705-6003

International Dial-in Number: 1-201-493-6725

Live webcast: <http://public.viavid.com/index.php?id=122846>

For those unable to participate in the conference call or live webcast, a replay will be available until March 9, 2017 at 11:59 p.m. ET. To access the replay, dial domestic 1-844-512-2921, international 1-412-317-6671. The replay passcode is 13654552.

A live audio webcast of the call will also be available on the Investors section of the Company's website, www.radiuspharm.com. A webcast replay will be available for two weeks on the Radius website, www.radiuspharm.com.

About Radius

Radius is a science-driven biopharmaceutical company that is committed to developing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases. Radius' lead product candidate, the investigational drug abaloparatide for subcutaneous injection, has completed Phase 3 development for potential use in the reduction of fracture risk in postmenopausal women with osteoporosis. Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis is under regulatory review in Europe and a New Drug Application (NDA) has been accepted for filing by the FDA with a PDUFA date of March 30, 2017. The Radius clinical pipeline also includes an investigational abaloparatide transdermal patch for potential use in osteoporosis and the investigational drug RAD1901 for potential use in hormone-driven and/or hormone-resistant breast cancer, and vasomotor symptoms in postmenopausal women. Radius' pipeline also includes RAD140, a non-steroidal, selective androgen receptor modulator (SARM) under investigation for potential use in breast cancer. For more information, please visit www.radiuspharm.com

About Abaloparatide

Abaloparatide is an investigational therapy for the potential treatment of women with postmenopausal osteoporosis who are at an increased risk for a fracture. Abaloparatide is a novel synthetic peptide that engages the parathyroid hormone receptor (PTH1 receptor) and was selected for clinical development based on its potential for favorable bone building activity.

Abaloparatide has completed Phase 3 development for potential use as a daily self-administered injection (abaloparatide-SC). In the fourth quarter of 2015, Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of patients with postmenopausal osteoporosis was validated and is currently undergoing regulatory review by the European Medicines Agency (EMA). Radius submitted a New Drug Application (NDA) for abaloparatide-SC to the US Food and Drug Administration (FDA) at the end of the first quarter of 2016, which has been accepted for filing with a PDUFA date of March 30, 2017. Radius also is developing an investigational

abaloparatide-transdermal patch (abaloparatide-TD) based on 3M's patented Microstructured Transdermal System technology for potential use as a treatment for osteoporosis.

About RAD1901

RAD1901 is a selective estrogen receptor down-regulator/degrader (SERD), which at high doses is being evaluated for potential use as an oral non-steroidal treatment for hormone-driven, or hormone-resistant, breast cancer. RAD1901 is currently being investigated for potential use in postmenopausal women with estrogen receptor positive (ER+), HER2-negative advanced 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.

RAD1901 also is being evaluated in a Phase 2b study at low doses for potential relief of the frequency and severity of moderate to severe hot flashes in postmenopausal women with vasomotor symptoms. Additional information on the clinical trial program of RAD1901 is available on www.clinicaltrials.gov.

RAD140

RAD140 is a nonsteroidal selective androgen receptor modulator. The androgen receptor (AR) is highly expressed in many estrogen receptor (ER)-positive, ER-negative, and triple-negative receptor 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, which is highly expressed in many breast cancers.

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 the progress of abaloparatide-SC in the regulatory process with the FDA and the EMA and the expected timing of potential regulatory actions, the expected timing of potential collaboration agreements, our plans for commercialization of abaloparatide-SC, the progress in the development of our product candidates, including abaloparatide-SC,

abaloparatide-TD, RAD1901 and RAD140, each of the statements under the heading “Radius Expects The Following Upcoming Milestones,” upcoming events and presentations, 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-SC, abaloparatide-TD, RAD1901 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 have no product revenues and may 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 abaloparatide-SC, and our inability to ensure that abaloparatide-SC will obtain regulatory approval or be successfully commercialized; 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; risk related to manufacturing and supply; 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 most recent Annual Report on Form 10-K 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.

Consolidated Balance Sheets
(Amounts in thousands, except share and per share amounts)

	December 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 258,567	\$ 159,678
Restricted cash	47	—
Marketable securities	73,880	313,661
Prepaid expenses and other current assets	2,315	6,969
Total current assets	334,809	480,308
Property and equipment, net	4,922	1,897
Other assets	551	260
Total assets	\$ 340,282	\$ 482,465
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,128	\$ 6,228
Accrued expenses and other current liabilities	26,597	14,952
Total current liabilities	32,725	21,180
Other non-current liabilities	379	—
Total liabilities	\$ 33,104	\$ 21,180
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.0001 par value; 200,000,000 shares authorized, 43,141,134 shares and 42,984,243 shares issued and outstanding at December 31, 2016 and 2015, respectively	\$ 4	\$ 4
Additional paid-in-capital	935,671	907,040
Accumulated other comprehensive income	71	5
Accumulated deficit	(628,568)	(445,764)
Total stockholders' equity	307,178	461,285
Total liabilities and stockholders' equity	\$ 340,282	\$ 482,465

Consolidated Statement of Operations and Comprehensive Loss

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
OPERATING EXPENSES:				
Research and development	\$ 25,579	\$ 22,226	\$ 107,406	\$ 68,280
General and administrative	27,463	11,585	77,542	30,797
Loss from operations	(53,042)	(33,811)	(184,948)	(99,077)
OTHER INCOME (EXPENSE):				
Other income (expense), net	(119)	92	(293)	(35)
Loss on retirement of note payable	—	—	—	(1,572)
Interest income	441	479	2,437	1,043
Interest expense	—	—	—	(1,885)
NET LOSS	\$ (52,720)	\$ (33,240)	\$ (182,804)	\$ (101,526)
OTHER COMPREHENSIVE INCOME, NET OF TAX:				
Unrealized gain (loss) from marketable securities	19	(94)	66	26
COMPREHENSIVE LOSS	\$ (52,701)	\$ (33,334)	\$ (182,738)	\$ (101,500)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:	\$ (52,720)	\$ (33,240)	\$ (182,804)	\$ (101,526)
LOSS PER SHARE:				
Basic and diluted	\$ (1.22)	\$ (0.77)	\$ (4.24)	\$ (2.56)
WEIGHTED AVERAGE SHARES:				
Basic and diluted	43,122,210	42,924,137	43,067,952	39,643,099

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