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): March 10, 2017

RADIUS HEALTH, INC.
(Exact name of registrant as specified in its charter)

Delaware	001-35726	80-0145732
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

950 Winter Street, Waltham, MA	02451
(Address of principal executive offices)	(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))

Item 8.01 Other Events .

On March 10, 2017, Radius Health, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has extended the Prescription Drug User Fee Act date for the Company's New Drug Application ("NDA") for abaloparatide-SC by three months to June 30, 2017 to allow time to review information submitted by the Company in response to information requests from the FDA . The Company's submission of the additional information has been determined by the FDA to constitute a Major Amendment to the NDA. A copy of the press release is filed as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated March 10, 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.

Date: March 10, 2017

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated March 10, 2017.

Mar 10, 2017

Radius Health Receives Notification of PDUFA Extension for Abaloparatide-SC

PDUFA goal date extended by standard extension period of three months to June 30, 2017

WALTHAM, Massachusetts – March 10, 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, today announced that the U.S. Food and Drug Administration (FDA) will require additional time to complete its review of the New Drug Application (NDA) for Abaloparatide-SC. In a notice received from the FDA last evening, the Prescription Drug User Fee Act (PDUFA) date for Abaloparatide-SC has been extended to June 30, 2017.

The FDA extended the action date to allow time to review information submitted by Radius Health in response to the FDA’s Information Requests. The FDA stated that the PDUFA goal date has been extended by three months to allow for a full review of the submission. In the letter, the FDA has not requested any additional information from the Company.

“ Our primary goal is to bring treatment to patients with postmenopausal osteoporosis as quickly as possible. We appreciate the efforts of the FDA to conduct a complete review of all of the data supporting our NDA and we remain committed to working closely with them throughout the remainder of the regulatory process .” said Robert Ward, President and Chief Executive Officer of Radius Health.

Radius will host a conference call at 9:15 AM. ET on Friday, March 10, 2017 to discuss the FDA Notification.

Conference Call Information:
Date: Friday, March 10, 2017

Time: 9:00 a.m. ET
Domestic Dial-in Number: 1-877-705-6003
International Dial-in Number: 1-201-493-6725

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 June 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' preclinical pipeline includes RAD140, a non-steroidal, selective androgen receptor modulator (SARM) under investigation for potential use in 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 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 June 30, 2017 . Radius also is developing abaloparatide-transdermal (abaloparatide-TD) based on 3M's patented Microstructured Transdermal System technology for potential use as a treatment for osteoporosis.

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 status and progress of abaloparatide-SC in the regulatory process with the FDA and the timing of potential regulatory actions, and the potential clinical uses for 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; and the risk of litigation regarding our intellectual property rights. These and other important factors discussed under the caption "Risk Factors" in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on February 24, 2017, and our other reports filed 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.

Radius Health

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