Radius Health, Inc.
Form 8-K
June 02, 2016

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 31, 2016**

RADIUS HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35726**	**80-0145732**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

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

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

N/A
(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01. Regulation FD.

On May 31, 2016, Radius Health, Inc. (the Company or Radius) issued a press release in connection with the announcement discussed in Item 8.01 below. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Form 8-K (including Exhibit 99.1) 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 Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 8.01. Other Events.

On May 31, 2016, Radius announced that its New Drug Application (NDA) for abaloparatide SC has been accepted for filing by the U.S. Food and Drug Administration (FDA).

The NDA is supported by data from the entire abaloparatide-SC development program, including the results from the 18-month Phase 3 ACTIVE trial in 2,463 postmenopausal women with osteoporosis and the first six months of the ACTIVExtend trial in 1,139 of the ACTIVE trial participants. Positive results for abaloparatide-SC treatment groups from the ACTIVE and ACTIVExtend trials have met the primary and secondary endpoints necessary for submission of the NDA, including the primary endpoint of reduction of vertebral fractures as well as key endpoints of reduction of nonvertebral, clinical, and major osteoporotic fractures. In these and the other trials submitted in the NDA, abaloparatide-SC administered at a dose of 80 mcg daily was generally safe and well tolerated in postmenopausal women with osteoporosis.

As previously disclosed, Radius submitted a Centralised Marketing Authorisation Application (MAA) for abaloparatide-SC in the European Union on November 17, 2015, which was validated by the European Medicines Agency (EMA) in December 2015, and is currently undergoing regulatory assessment by the Committee for Medicinal Products for Human Use of the EMA (CHMP). The EMA has granted Radius an additional 3-month extension to the procedural timetable for response in the ongoing MAA assessment. As a result of this extension to the procedural timetable, the Company now anticipates that the CHMP may adopt an Opinion regarding the MAA in late 2016 or in 2017.

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

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the expected timing of the CHMP s Opinion regarding the MAA.

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: the risk that the CHMP review of the MAA will take longer than our current expectations; our limited operating history; 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 having most of our products in early stage 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 delays in enrollment of patients in our clinical trials, which could delay or prevent regulatory approvals. 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 25, 2016, 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 Current Report. Any such forward-looking statements represent management s estimates as of the date of this Current Report. 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 report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

Exhibit No.	**Description**
99.1	Press Release issued on May 31, 2016

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: June 1, 2016	By:	/s/ B. Nicholas Harvey Name: B. Nicholas Harvey Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued on May 31, 2016