RADIUS HEALTH, INC.

FORM 8-K
(Current report filing)

Filed 03/23/18 for the Period Ending 03/22/18

Address	ATTN: CHIEF FINANCIAL OFFICER 950 WINTER STREET WALTHAM, MA, 02451
Telephone	617-551-4000
CIK	0001428522
Symbol	RDUS
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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 22, 2018

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))

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 8.01 Other Events .

On March 22, 2018, the Committee for Medicinal Products for Human Use, the scientific committee of the European Medicines Agency, adopted a negative opinion on the marketing authorization application submitted by Radius Health, Inc. (the "Company") for abaloparatide-SC for the treatment of osteoporosis in postmenopausal women at increased risk for fracture. A copy of the press release issued by the Company on March 22, 2018 in connection with this event is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Radius Health, Inc. Press Release dated March 22, 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: March 23, 2018

By: /s/ Brent Hatzis-Schoch
Name: Brent Hatzis-Schoch
Title: General Counsel

Radius Health Provides Update on CHMP Opinion for Abaloparatide-SC

WALTHAM, Mass., March 22, 2018 – Radius Health, Inc. (Nasdaq: RDUS), a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics in the areas of osteoporosis and oncology, today announced that after an oral explanation the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), has communicated a negative trend vote on the benefit-risk balance for the Company's marketing authorization application (MAA) for abaloparatide-SC for the treatment of osteoporosis in postmenopausal women at increased risk for fracture. The EMA has informed the Company that the CHMP will therefore adopt a negative opinion on the MAA today, Thursday, March 22, 2018. The Company expects that the EMA will provide further information related to its decision on its website at www.ema.europa.eu/ema . Radius intends to appeal and immediately seek a re-examination of the CHMP opinion.

"While we are disappointed with the CHMP's assessment, we are confident in abaloparatide-SC and our clinical trial data supporting the MAA, which was also the basis for FDA approval of the product in the U.S.," said Jespe r Høiland, President and Chief Executive Officer of Radius Health. "We remain focused on the commercialization of TYMLOS™ in the U.S., the largest market in revenues for anabolics globally, and continue our efforts to make abaloparatide-SC available in Japan through our collaboration with Teijin, as well as in other markets through partnership agreements."

TYMLOS (abaloparatide) injection was approved by the U.S. Food and Drug Administration in April 2017, for the treatment of postmenopausal women with osteoporosis at high risk for fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. Since then, over 5,000 patients have been treated with TYMLOS in the U.S.

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-rec eptor positive breast cancer. For more information, please visit www.radiuspharm.com .

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 expectation that the CHMP will issue a negative opinion on our MAA for abaloparatide-SC and our intention to appeal and seek re-examination of the CHMP's opinion; our efforts to make abaloparatide available in other markets; 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 period 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 forwar d-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.

Investor & Media Relations Contact:

Elhan Webb, CFA
Email: ewebb@radiuspharm.com
Phone: 617-551-4011