
**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): July 24, 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 8.01 Other Events.

On March 22, 2018, the Committee for Medicinal Products for Human Use (“CHMP”), the scientific committee of the European Medicines Agency, adopted a negative opinion on the marketing authorization application (“MAA”) submitted by Radius Health, Inc. (the “Company”) for abaloparatide-SC for the treatment of osteoporosis in postmenopausal women at increased risk for fracture. In April 2018, the Company submitted a request for re-examination of the CHMP’s opinion.

On July 24, 2018, the Company announced that, following a re-examination procedure, the CHMP had communicated a negative trend vote for the MAA. On July 27, 2018, the CHMP communicated that it maintained its negative opinion on the MAA at its formal final vote.

A copy of the press release issued by the Company on July 24, 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 July 24, 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: July 27, 2018

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



Radius Health Provides Update on Appeal of CHMP Opinion for Abaloparatide-SC

WALTHAM, Mass., July 24, 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 following a re-examination procedure, the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), has communicated a negative trend vote for the Company's marketing authorization application (MAA) for abaloparatide-SC for the treatment of osteoporosis in postmenopausal women at increased risk for fracture. A negative trend vote means that it is likely that the CHMP will maintain its negative opinion for the MAA at its formal final vote, which it has indicated will occur prior to the end of its meeting this week.

"We are disappointed with this assessment on behalf of the estimated 22 million women in Europe who are diagnosed with osteoporosis. No new anabolic bone-building agent has been approved in Europe for the treatment of this debilitating disease in almost 10 years," said Jesper Høiland, President and Chief Executive Officer of Radius Health. "We remain confident in abaloparatide-SC and 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 Limited, 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 10,000 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-receptor 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 a final CHMP vote on our MAA; our expectations regarding commercialization of TYMLOS in the U.S.; our efforts to make abaloparatide available in other markets and our entry into potential collaborations related thereto; 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.

Investor & Media Relations Contact:

Elhan Webb, CFA

Email: ewebb@radiuspharm.com

Phone: 617-551-4011