RADIUS HEALTH, INC.

FORM 8-K
(Current report filing)

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Address	ATTN: CHIEF FINANCIAL OFFICER 950 WINTER STREET WALTHAM, MA 02451
Telephone	617-551-4000
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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): July 21, 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))

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 July 21, 2017, Radius Health, Inc. issued a press release announcing that on July 21, 2017 the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), issued a second Day-180 List of Outstanding Issues and requested additional data analyses related to the safety and efficacy of abaloparatide for subcutaneous injection in the process of their ongoing regulatory review. 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 July 21, 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: July 21, 2017

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated July 21, 2017.

Radius Health Announces that the Committee for Medicinal Products for Human Use (CHMP) Has Issued a Second Day-180 List of Outstanding Issues in its Regulatory Review of Eladynos™ (Abaloparatide-SC), a Bone Building Agent for the Treatment of Postmenopausal Women with Osteoporosis at High Risk for Fracture

Radius Health anticipates an opinion from the CHMP regarding the MAA for Eladynos (abaloparatide-SC) before year-end

WALTHAM, Mass., July 21, 2017, Radius Health, Inc. (Nasdaq:RDUS), a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases, today announced that on July 21, 2017 the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA), issued a second Day-180 List of Outstanding Issues and requested additional data analyses related to the safety and efficacy of abaloparatide-SC in the process of their ongoing regulatory review. Radius expects the CHMP to issue an opinion regarding the MAA for abaloparatide-SC prior to the end of 2017.

“There is a significant unmet medical need among postmenopausal women with osteoporosis at high risk of a fracture,” said Jesper Høiland, President and Chief Executive Officer of Radius Health, “and we look forward to working with the CHMP to address the additional questions raised in the review.”

If approved, abaloparatide-SC will be marketed in the European Union as Eladynos and would be the first new anabolic approved in Europe in 14 years. Abaloparatide-SC 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 and is marketed in the U.S. as *TYMLOS*™.

About *TYMLOS* (abaloparatide)

TYMLOS (abaloparatide) was approved by the U.S. Food and Drug Administration for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In the European Union abaloparatide-SC is an investigational agent and has not been approved.

Radius also is developing abaloparatide-transdermal (abaloparatide-TD) based on 3M's paten ted Microstructured Transdermal System technology for potential use as a treatment for postmenopausal women with osteoporosis.

IMPORTANT SAFETY INFORMATION FROM THE U.S. PRESCRIBING INFORMATION

WARNING: RISK OF OSTEOSARCOMA

- **Abaloparatide caused a dose-dependent increase in the incidence of osteosarcoma (a malignant bone tumor) in male and female rats. The effect was observed at systemic exposures to abaloparatide ranging from 4 to 28 times the exposure in humans receiving the 80 mcg dose. It is unknown if TYMLOS will cause osteosarcoma in humans.**
- **The use of TYMLOS is not recommended in patients at increased risk of osteosarcoma including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton.**
- **Cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.**

Orthostatic Hypotension: Orthostatic hypotension may occur with TYMLOS, typically within 4 hours of injection. Associated symptoms may include dizziness, palpitations, tachycardia or nausea, and may resolve by having the patient lie down. For the first several doses, TYMLOS should be administered where the patient can sit or lie down if necessary.

Hypercalcemia: TYMLOS may cause hypercalcemia. TYMLOS is not recommended in patients with pre-existing hypercalcemia or in patients who have an underlying hypercalcemic disorder, such as primary hyperparathyroidism, because of the possibility of exacerbating hypercalcemia.

Hypercalciuria and Urolithiasis: TYMLOS may cause hypercalciuria. It is unknown whether TYMLOS may exacerbate urolithiasis in patients with active or a history of urolithiasis. If active urolithiasis or pre-existing hypercalciuria is suspected, measurement of urinary calcium excretion should be considered.

Adverse Reactions: The most common adverse reactions (incidence ≥2%) are hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain and vertigo.

INDICATIONS AND USAGE

TYMLOS is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fr acture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, TYMLOS reduces the risk of vertebral fractures and nonvertebral fractures.

Limitations of Use
Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

For complete TYMLOS prescribing information, including Boxed Warning, please visit www.tymlos.com

About Osteoporosis

Osteoporosis is a silent disease, often displaying no signs or symptoms until a fracture occurs, leaving the majority of patients undiagnosed and untreated, representing a high unmet medical need. Osteoporotic fractures create a significant healthcare burden. An estimated two million osteoporotic fractures occur annually in the United States, and this number is projected to grow to three million by 2025.

The National Osteoporosis Foundation (NOF) has estimated that eight million women already have osteoporosis, and another approximately 44 million may have low bone mass placing them at increased risk for osteoporosis.

The annual incidence of osteoporotic fractures is higher than that of stroke, heart attack and breast cancer combined; osteoporotic fractures also account for more hospitalizations and associated costs than cardiovascular disease and breast cancer.

About Radius

Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases. 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 in April 2017. Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis is under regulatory review in Europe. The Radius clinical pipeline includes an investigational abaloparatide transdermal patch for potential use in postmenopausal women with osteoporosis and the investigational drug elacestrant (RAD1901) for potential use in hormone-driven and/or hormone-resistant breast cancer, and vasomotor symptoms in postmenopausal women. Radius' RAD140, a non-steroidal, selective androgen receptor modulator

(SARM), is 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: the progress of Eladynos (abaloparatide-SC) in the regulatory process with the EMA, including the expected timing of an opinion from the CHMP regarding our MAA for Eladynos; expectations regarding the significance of clinical trial data for abaloparatide-SC; the potential medical benefit of treatment with TYMLOS for postmenopausal women with osteoporosis; the incidence of osteoporotic fractures and the health burden associated with osteoporosis; and the potential clinical uses and therapeutic and other benefits of our product candidates, including abaloparatide-TD, 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: our dependence on the success of TYMLOS; risks related to competitive products; the risk that the results of clinical trials of TYMLOS will not meet ex-U.S. regulatory requirements for approval or that ex-U.S. regulatory authorities may require additional data or further studies, including our inability to ensure that abaloparatide-SC will obtain regulatory approval in Europe on the timing we expect or at all; risks related to our ability to successfully commercialize TYMLOS, including the failure to achieve market acceptance of TYMLOS in the U.S. or in any market where it may be approved; the availability of coverage and risks related to pricing and reimbursement for TYMLOS; risks related to manufacturing and supply; risks related to intellectual property; risks related to establishing and maintaining an effective process for distribution of TYMLOS; and the 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 in our other reports filed with the SEC, that 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 Relations Contact :
Barbara Ryan
Email: bryan@radiuspharm.com
Phone: 203-274-2825