

Radius Health, Inc.
Form 8-K
July 27, 2018

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 | 001-35726 | 80-0145732 |
| (State or other jurisdiction | (Commission | (IRS Employer |
| of incorporation) | File Number) | 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)

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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 | <u>Radius Health, Inc. Press Release dated July 24, 2018</u> |

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