

Radius Health, Inc.
Form 8-K
November 17, 2015

**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): **November 17, 2015**

RADIUS HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-35726
(Commission
File Number)

80-0145732
(I.R.S. Employer
Identification No.)

**950 Winter Street
Waltham, MA 02451**

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(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:

- 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))
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Item 7.01 Regulation FD Disclosure

On November 17, 2015, Radius Health, Inc. (the Company) announced that it had submitted a Marketing Authorization Application in Europe for abaloparatide-SC. The Company also announced that it now plans to submit a New Drug Application to the United States Food and Drug Administration for abaloparatide-SC by the end of the first quarter of 2016. A copy of the press release discussing this announcement is furnished as Exhibit 99.1 to this current report on Form 8-K (the Current Report).

The information in Item 7.01 of this Current Report (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 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 November 17, 2015 |

Forward-Looking Statements

This Current Report 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 statements regarding the expected timing of regulatory submissions for abaloparatide-SC.

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 have no product revenues; our need for additional funding, which may not be available; we are not currently profitable and may never become profitable; risks related to raising additional capital; our limited operating history; quarterly fluctuation in our financial results; failure of the financial institutions in which we hold our cash and cash equivalents; market, interest, and credit risk; our dependence on the success of abaloparatide-SC, and our inability to ensure that abaloparatide-SC will obtain regulatory approval or be successfully commercialized; 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

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candidates; product candidates for which we obtain marketing approval, if any, could be subject to restrictions or withdrawal from the market and we may be subject to penalties; failure to achieve market acceptance of our product candidates; risks related to the use of our limited resources on particular product candidates and not others; delays in enrollment of patients in our clinical trials, which could delay or prevent regulatory approvals; the dependence of our drug development program upon third-parties who are outside of our control; the risk that a regulatory or government official will determine that third-parties with a financial interest in the outcome of the Phase 3 study of abaloparatide-SC affected the reliability of the data from the study; our reliance on third parties to formulate and manufacture our product candidates; failure to establish additional collaborations; our lack of experience selling, marketing and distributing products and our lack of internal capability to do so; failure to compete successfully against other drug companies; developments by competitors may render our products

or technologies obsolete or non-competitive; risks related to the fact that our drugs may sell for inadequate prices or patients may be unable to obtain adequate reimbursement; the effects of product liability lawsuits on commercialization of our products; failure to comply with obligations of our intellectual property licenses; failure to protect our intellectual property or failure to secure necessary intellectual property related to abaloparatide-SC, abaloparatide-TD, RAD1901 and/or RAD140; our or our licensors' inability to obtain and maintain patent protection for technology and products; risks related to our compliance with patent application and maintenance requirements; failure to protect the confidentiality of our trade secrets; risks related to our infringement of third parties' rights; or the costs of defending against infringement by third parties; claims of wrongful disclosure or use of trade secrets by employees' former employers; risks associated with intellectual property litigation, including expending substantial resources and distracting personnel from their normal responsibilities; risks associated with healthcare reform; our failure to comply with healthcare laws and regulations; our exposure to claims associated with the use of hazardous materials and chemicals; as we become involved in drug commercialization, risk related to our inability to successfully manage our growth and expanded operations; risks relating to business combinations and acquisitions; our reliance on key executive officers and advisors; our inability to hire additional qualified personnel; volatility in the price of our common stock; capital appreciation is the only source of gain for our common stock; risks related to increased the costs and compliance initiatives associated with operating as a public company; our directors, executive officers and principal stockholders have substantial influence over us and could delay or prevent a change in control; future sales and issuances of our common stock could depress the price of our common stock; risks related to securities or industry analysts ceasing to publish research about us or publishing inaccurate or unfavorable information about us, which could cause the price of our common stock to decline; provisions in our charter documents and Delaware law that could discourage takeover attempts; and our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or SEC, on November 5, 2015, 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 Current Report.

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: November 17, 2015

By:

/s/ B. Nicholas Harvey
Name: B. Nicholas Harvey
Title: Chief Financial Officer

EXHIBIT INDEX

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