Radius Health, Inc.
Form 8-K
July 19, 2016

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# FORM 8-K

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**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 13, 2016**

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# RADIUS HEALTH, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **001-35726** | **80-0145732** |
|---|---|---|
| (State or other jurisdiction of incorporation or organization) | (Commission File Number) | (I.R.S. Employer Identification No.) |

**950 Winter Street**

**Waltham, MA 02451**

(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)

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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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**Item 1.01 Entry into a Material Definitive Agreement.**

On July 13, 2016, Radius Health, Inc. (the Company, we, and our ) entered into a Manufacturing Services Agreement (the Manufacturing Agreement ) with Lonza Sales Ltd ( Lonza ), effective as of June 28, 2016. Pursuant to the Manufacturing Agreement, Lonza has agreed to manufacture the commercial supply of the active pharmaceutical ingredient for abaloparatide (the API ), the Company s lead drug product candidate. The Company and Lonza previously entered into a Development and Manufacturing Services Agreement, dated October 16, 2007, as amended, under which Lonza provided the API for clinical development.

Under the Manufacturing Agreement, Lonza has agreed to manufacture the API pursuant to purchase orders and in accordance with the forecasts provided by the Company and the manufacturing specifications agreed upon between the Company and Lonza. The Company has agreed to purchase the API in batches at a price per gram in euros, subject to an annual increase by Lonza. The Company is also required to purchase a minimum number of batches annually. The Company may be obligated to pay certain fees upon cancellation of purchase orders, for additional storage of the API, or for failure to timely deliver to Lonza any materials that may be supplied by the Company.

The Manufacturing Agreement has an initial term of six years, beginning on June 28, 2016, and will automatically renew for successive three-year terms unless either party provides notice of non-renewal 24 months before the end of the then-current term. Lonza may terminate the Manufacturing Agreement for any reason upon 30-months notice. The Company may terminate the Manufacturing Agreement for any reason upon 24-months notice, if the Company fails to obtain regulatory marketing approval for abaloparatide upon 12-months notice to Lonza, or if abaloparatide is withdrawn from the market upon 12-months notice to Lonza. Either party may terminate the Manufacturing Agreement for breach of the agreement, subject to a period in which the breach may be cured, due to a party s bankruptcy, insolvency, or dissolution, or due to a force majeure event that continues for three months or more.

The Manufacturing Agreement also includes customary provisions relating to, among others, insurance and indemnification, delivery and acceptance procedures, intellectual property, warranties, and confidentiality. Each party s aggregate liability under the Manufacturing Agreement is limited to the greater of the total amount paid by the Company in the twelve months preceding the last claim or $2.0 million. This limit does not apply to liability arising from fraud, gross negligence, or intentional misconduct, a breach of confidentiality, indemnification by the Company for third-party claims or the Company s payment obligations.

*Forward-Looking Statements*

This Current Report on Form 8-K 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.

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 abaloparatide delivered via subcutaneous injection ( abaloparatide-SC ), and our inability to ensure that abaloparatide-SC will obtain regulatory approval or be successfully commercialized; 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; delays in enrollment of patients in our clinical trials, which could delay or prevent regulatory approvals; our reliance on third parties to formulate and manufacture our product candidates; failure to establish an effective

distribution process for abaloparatide-SC; our lack of experience selling, marketing and distributing products and our lack of internal capability to do so; and the effects of product liability lawsuits on

commercialization of our products. These and 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 25, 2016, 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 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.

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| Date: July 19, 2016 | By: | /s/ B. Nicholas Harvey<br>Name: B. Nicholas Harvey<br>Title: Chief Financial Officer |