Radius Health, Inc. Form 8-K June 29, 2016

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): June 23, 2016

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

(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:

- 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 June 23, 2016, Radius Health, Inc. (the Company, we, and our) entered into a Supply Agreement (the Supply Agreement) with Ypsomed A (Ypsomed), effective as of September 30, 2015. Pursuant to the Supply Agreement, Ypsomed will supply a disposable pen injection device customized for injection of abaloparatide, the Company s drug product candidate (the Device), to be used in the commercial distribution of abaloparatide. The Company and Ypsomed previously entered into a Development and Clinical Supply Agreement, effective July 1, 2014, under which Ypsomed and the Company developed the Device for the Company s abaloparatide cartridges.

Under the Supply Agreement, Ypsomed will manufacture the Device according to specifications agreed upon between Ypsomed and the Company and will supply the Device to meet the supply requirements projected by the Company. The Company has agreed to purchase the Device at prices per Device that decrease with an increase in quantity supplied, subject to adjustment based on actual supply amounts. The Company is required to purchase a minimum number of Devices during the initial term of the Supply Agreement, and minimum purchase amounts in subsequent terms will be determined by mutual agreement or, in the absence of mutual agreement, will be an amount no less than the minimum annual average quantity purchased during the initial term. In addition, the Company has agreed to make milestone payments for Ypsomed's capital developments in connection with the initialization of the commercial supply of the Device and to pay a one-time capacity fee. All costs and payments under the Supply Agreement are delineated in Swiss Francs. During the initial term of the Supply Agreement, the Company estimates that it will be obligated to make total minimum payments to Ypsomed of approximately CHF 3,850,000 (\$ 3,921,000) in the aggregate, including the milestone payments and one-time capacity fee.

The Supply Agreement has an initial term that began on September 30, 2015 and will continue for three years after the earlier of (i) the date on which the first commercial batch of Devices is delivered after regulatory approval or (ii) June 1, 2017. The Supply Agreement will then automatically renew for two-year terms until terminated. Ypsomed or the Company may terminate the Supply Agreement at any time by providing notice to the other party 18 months prior to the end of the then-current term. The Supply Agreement may also be terminated by either party upon material breach of the Supply Agreement, due to a party s bankruptcy, insolvency, or dissolution, or due to a change of control of either party under certain circumstances. The Company may terminate the Supply Agreement in the event that it is unable to obtain regulatory or other approval for the manufacture and sale of abaloparatide or such approval is revoked.

During the term of the Supply Agreement, Ypsomed has agreed to supply the Device exclusively to the Company in the United States, the European Union, and Switzerland, with additional countries that may be added upon mutual agreement.

The Supply Agreement also includes customary provisions relating to, among others, delivery, inspection procedures, warranties, quality management, regulatory and other approvals, patient complaints, intellectual property rights, indemnification, and confidentiality.

Conversions to U.S. dollars in this Current Report on Form 8-K are based on the exchange rate as of June 28, 2016 and are for informational purposes only.

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, including without limitation statements regarding the estimated amounts to be paid under the Supply Agreement.

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-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.

Date: June 29, 2016 By: /s/ B. Nicholas Harvey

Name: B. Nicholas Harvey
Title: Chief Financial Officer

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