Radius Health, Inc.
Form 8-K
July 05, 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 28, 2016**

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)

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))

Item 1.01 Entry into a Material Definitive Agreement.

On June 28, 2016, Radius Health, Inc. (the Company) entered into a Commercial Supply Agreement (the Supply Agreement) with Vetter Pharma International, GmbH (Vetter), effective as of January 1, 2016. Pursuant to the Supply Agreement, Vetter, through Vetter Pharma-Fertigung GmbH & Co. KG, has agreed to formulate the drug product containing the active pharmaceutical ingredient (API) of abaloparatide to be delivered via subcutaneous injection (abaloparatide-SC), the Company s lead drug product candidate, to fill cartridges with the drug product (the Cartridges) and assemble the pen delivery device (the Pen), and to package the Pen for commercial distribution. The Company and Vetter previously entered into a Development and Manufacturing Services Agreement, effective December 26, 2013, under which Vetter performed development and manufacturing services related to the clinical development of abaloparatide-SC.

Under the Supply Agreement, Vetter will perform its services according to purchase orders and at the standards agreed upon between Vetter and the Company. The Company has agreed to purchase the Cartridges and the Pen in specified batch sizes at a price per unit. For labeling and packaging services, the Company has agreed to pay a per unit price dependent upon the number of Pens loaded with Cartridges that are labeled and packaged (the Finished Products). These prices are subject to an annual price adjustment. The Company may initially sell and distribute the Finished Products only in the United States, Canada, Australia, New Zealand, the European Union, and Switzerland. Additional countries will be added upon agreement between the Company and Vetter, who will work together to meet regulatory and other requirements for those countries.

The Company will provide Vetter with forecasts of demand on a quarterly basis. If actual demand is less than forecasted demand, then the Company may, depending on the timing and amount of the reduced demand, be obligated to pay Vetter for a portion of lost net revenue, subject to Vetter using commercially reasonable efforts to offset the loss. In addition, if the Company cancels a purchase order or postpones manufacturing, or if the materials to be supplied by the Company are not timely available prior to the start of manufacture, the Company may be obligated to pay Vetter for most of the per unit price of cancelled Cartridges or packaging in order to compensate Vetter for unused manufacturing capacity, subject to Vetter using commercially reasonable efforts to use the manufacturing capacity for another customer.

Certain of Vetter s payment obligations under the Supply Agreement are subject to an annual cap equal to the lesser of a mid-teens percentage of the net amounts paid by the Company and a fixed mid-six digit amount in Euros (the Annual Cap). The Annual Cap applies to: (i) reimbursement amounts due to Vetter s failure to meet the target API level in the Cartridges; (ii) reimbursement amounts due to the damage, loss, or theft of material provided by the Company caused by Vetter s gross negligence; (iii) the cost of material supplied by the Company for replacement manufacturing by Vetter in connection with a defective product caused by Vetter s gross negligence; and (iv) costs and expenses in connection with a recall due to Vetter s gross negligence up to an amount of 50,000 (approximately $55,000) per recall.

The Supply Agreement has an initial term that began on January 1, 2016 and will continue for five years thereafter. The Supply Agreement will then automatically renew for two-year terms unless either party notifies the other party two years before the end of the then-current term that it does not intend to renew. Vetter may terminate the Supply Agreement effective upon written notice to the Company if (i) the Company fails to maintain the insurance required under the Supply Agreement, subject to a period in which the Company may cure this failure or (ii) the Company is found to be in breach of provisions regarding ethical business practices, laws, and regulations. The Company may terminate the Supply Agreement effective upon written notice to Vetter if (i) Vetter fails to obtain or maintain any material governmental licenses or approvals, subject to a period in which Vetter may cure this failure, (ii) if the Company has a good faith reason to believe that Vetter has breached provisions regarding ethical business practices, laws, and regulations or (iii) the Company fails to obtain marketing authorization for the Finished Product. Either party may terminate the Supply Agreement due to: (i) the other party s bankruptcy or insolvency, (ii) a party s failure to cure a breach of the Supply Agreement after being notified of such breach, (iii) a continuing force majeure event, or (iv) a failure to reach mutual agreement on a change in the scope of work or services that Vetter reasonably believes it cannot perform because the change is in violation of applicable law.

The Supply Agreement contains customary indemnification provisions with certain limitations. Vetter s

indemnification obligation for its infringement of a third party s intellectual property is limited to a mid-six digit amount in Euros per year for costs, and the Company is obligated to indemnify Vetter for costs due to a product liability claim caused by Vetter s negligence or gross negligence to the extent such costs are more than 5,000,000 (approximately $5,500,000) per year. In addition, the total annual aggregate liability for Vetter under the Supply Agreement is limited to 5,000,000 (approximately $5,500,000) per year with exceptions for certain circumstances, including Vetter s willful misconduct. The Company is also obligated to self-insure or maintain product liability insurance of at least $40,000,000 per year.

The Supply Agreement includes customary provisions relating to, among others, procedures for defective products, delivery, inspection and acceptance procedures, manufacturing facilities, regulatory matters, intellectual property rights, and confidentiality.

Conversions to U.S. dollars in this Current Report on Form 8-K are based on the exchange rate as of July 1, 2016 and are for informational purposes only.

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 5, 2016	By:	/s/ B. Nicholas Harvey Name: B. Nicholas Harvey Title: Chief Financial Officer