

Radius Health, Inc.
Form 8-K
March 02, 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): February 27, 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 1.01 Entry into a Material Definitive Agreement.

Commercial Supply Agreement

On February 27, 2018 (the “Effective Date”), Radius Health, Inc. (“Radius”) entered into a Scale-Up and Commercial Supply Agreement (the “Supply Agreement”) with 3M Company (“3M Company”) and 3M Innovative Properties Company (“3M IPC” and collectively with 3M Company, “3M”). Pursuant to the Supply Agreement, 3M agreed to exclusively manufacture Phase 3 and global commercial supplies of an abaloparatide-coated transdermal patch product (“Product”) and associated applicator devices (“Applicator”) for Radius. Radius and 3M previously entered into a Development and Clinical Supplies Agreement (the “Development Agreement”), dated June 19, 2009, as amended, pursuant to which Product and Applicator were developed.

Under the Supply Agreement, 3M will manufacture Product and Applicator for Radius according to agreed-upon specifications in sufficient quantities to meet Radius’ projected supply requirements. 3M will manufacture commercial supplies of Product at unit prices that decrease with an increase in the quantity ordered. Radius will pay 3M a mid-to-low single digit royalty on worldwide net sales of Product and reimburse 3M for certain capital expenditures incurred to establish commercial supply of Product. Radius is responsible for providing, at its expense, supplies of its proprietary drug substance, abaloparatide, to be used in manufacturing Product. During the term of the Supply Agreement, 3M and Radius have agreed to work exclusively with each other with respect to the delivery of abaloparatide, parathyroid hormone (“PTH”), and/or PTH related proteins via active transdermal, intradermal, or microneedle technology.

The initial term of the Supply Agreement began on the Effective Date and will continue for five years after the first commercial sale of Product. The Supply Agreement then automatically renews for successive three-year terms, unless earlier terminated pursuant to its terms, or upon either party’s notice of termination to the other 24 months prior to the end of the then-current term. The Supply Agreement may be terminated by either party upon an uncured material breach of its terms by the other party, or due to the other party’s bankruptcy, insolvency, or dissolution. Radius may terminate the Supply Agreement upon the occurrence of certain events, including for certain clinical, technical, or commercial reasons impacting Product, if Radius is unable to obtain U.S. regulatory approval for Product within a certain time period, or if Radius ceases development or commercialization of Product. 3M may terminate the Supply Agreement upon the occurrence of certain events, including if there are certain safety issues related to Product, if Radius is unable to obtain U.S. regulatory approval for Product within a certain time period, or if Radius fails to order Product for a certain period of time after commercial launch of the Product in the U.S. Upon certain events of termination, 3M is required to transfer the manufacturing processes for Product and Applicator to Radius or a mutually agreeable third party and continue supplying Product and Applicator for a period of time pursuant to Radius’ projected supply requirements.

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. The foregoing description of the Supply Agreement does not purport to be complete and is qualified in its entirety by reference to the Supply Agreement, a copy of which Radius intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending March 31, 2018.

Amendment to Development Agreement

On February 27, 2018, Radius entered into a Sixth Amendment (the “Amendment”) to the Development Agreement. Pursuant to the Amendment, the parties agreed to extend the initial term of the Development Agreement until June 19, 2019. The Development Agreement then automatically renews for additional one-year terms, unless earlier terminated pursuant to its terms, or until the earliest of (i) the expiration or termination of the Supply Agreement, (ii) the mutual written agreement of the parties, or (iii) prior written notice by either party to the other party at least ninety days prior

to the end of the then-current term of the Development Agreement that such party declines to extend the term.

The Amendment also amends and restates the intellectual property provisions of the Development Agreement to be consistent with the intellectual property provisions of the Supply Agreement.

The foregoing description of the Amendment does not purport to be complete and is qualified in its entirety by reference to the Amendment, a copy of which Radius intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending March 31, 2018.

Item 5.03 Amendments to Articles of Incorporation or Bylaws; Change in Fiscal Year.

Effective February 27, 2018, the Board of Directors of Radius amended Article II, Section 2.11 of Radius' Amended and Restated Bylaws (the "Bylaws") to change the voting standard in uncontested elections of directors from a plurality voting standard to a majority voting standard. The Bylaws previously provided for a plurality voting standard in both contested and uncontested elections of directors. Following the amendment, plurality voting will continue to be the voting standard in contested elections, which occurs where the number of director nominees exceeds the number of directors to be elected.

The foregoing description of the amendments to the Bylaws does not purport to be complete and is qualified in its entirety by reference to the full text of the Bylaws, filed as Exhibit 3.1 to this Current Report on Form 8-K, and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
3.1	<u>Amended and Restated By-Laws.</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: March 2, 2018 By: /s/ Brent Hatzis-Schoch
Name: Brent Hatzis-Schoch
Title: General Counsel

EXHIBIT INDEX

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