RADIUS HEALTH, INC.

FORM 8-K
(Current report filing)

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Address	ATTN: CHIEF FINANCIAL OFFICER 950 WINTER STREET WALTHAM, MA 02451
Telephone	617-551-4000
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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): July 13, 2017

RADIUS HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35726**	**80-0145732**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer 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)

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.

On July 13, 2017, Radius Health, Inc. ("Radius") entered into a License and Development Agreement (the "Agreement") with Teijin Limited ("Teijin") for abaloparatide for subcutaneous injection ("abaloparatide-SC") in Japan. Teijin is developing abaloparatide-SC in Japan under an agreement with Ipsen Pharma S.A.S. and has initiated a phase 3 trial in Japanese patients with osteoporosis. Radius and Teijin Pharma Limited (a subsidiary of Teijin) previously entered into a Safety Agreement, dated November 30, 2007, which provides for the exchange of safety information related to abaloparatide-SC to enable safety reporting to global health agencies.

Pursuant to the Agreement, Radius granted Teijin (i) an exclusive license under certain of Radius' intellectual property to develop and commercialize abaloparatide-SC in Japan, (ii) a non-exclusive license under certain of Radius' intellectual property to manufacture abaloparatide-SC for commercial supply in Japan, and (iii) a right of reference to certain of Radius' regulatory data related to abaloparatide-SC for purposes of developing, manufacturing and commercializing abaloparatide-SC in Japan. In consideration for these rights, Teijin is obligated to pay Radius an upfront payment, to make payments to Radius upon the achievement of certain regulatory and sales milestones, and to pay Radius a royalty based on net sales of abaloparatide-SC in Japan during the royalty term. In addition, Radius has an option to negotiate a co-promotion agreement with Teijin for abaloparatide-SC in Japan.

Teijin granted Radius (i) an exclusive license under certain of Teijin's intellectual property to develop, manufacture and commercialize abaloparatide-SC outside Japan and (ii) a right of reference to certain of Teijin's regulatory data related to abaloparatide-SC for purposes of developing, manufacturing and commercializing abaloparatide-SC outside Japan. Radius maintains full global rights to its development program for abaloparatide-transdermal, which is not part of the Agreement. Pursuant to the Agreement, the parties may further collaborate on new indications for abaloparatide-SC.

Unless earlier terminated, the Agreement expires on the later of the (i) date on which the use, sale or importation of abaloparatide-SC is no longer covered by a valid claim under the Radius patent rights licensed to Teijin in Japan, (ii) expiration of marketing or data exclusivity for abaloparatide-SC in Japan, or (iii) 10 th anniversary of the first commercial sale of abaloparatide-SC in Japan. Either party may terminate the Agreement for an uncured material breach or default or a bankruptcy event of the other party. Teijin may terminate the Agreement, with prior notice to Radius, if Teijin reasonably believes that abaloparatide-SC cannot reasonably be developed or commercialized or it cannot continue to commercialize abaloparatide-SC due to reasons of safety, efficacy, pharmaeconomics, economic hardship and/or marketability, and Teijin permanently abandons the development and commercialization of abaloparatide-SC.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, a copy of which Radius intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending September 30, 2017. A copy of the press release announcing the Agreement is attached hereto as Exhibit 99.1 and is being furnished and 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 Exchange Act or the Securities Act of 1933, as amended, except as expressly provided by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated July 13, 2017.

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 13, 2017

By: /s/ Brent Hatzis-Schoch
Name: Brent Hatzis-Schoch
Title: General Counsel

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated July 13, 2017.

Exhibit 99.1

Radius Health Announces License and Development Agreement for Abaloparatide-SC with Teijin Limited in Japan

- *Teijin granted a right of reference to Radius regulatory data and use of Radius Intellectual Property for development, manufacture and commercialization of abaloparatide-SC for Japan, the largest market globally for bone anabolics.*
- *Radius to receive upfront and milestone payments, royalties, and an option for co-promotion.*

Waltham, Massachusetts – July 13, 2017 (GLOBE NEWSWIRE): Radius Health, Inc. ("Radius") (Nasdaq:RDUS), a fully integrated science-driven biopharmaceutical company that is committed to developing and commercializing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases, announced today that it has entered into a license and development agreement with Teijin Limited in Japan for abaloparatide-SC. Teijin is developing abaloparatide-SC in Japan under an agreement with Ipsen Pharma S.A.S. and has initiated a phase 3 trial in Japanese patients with osteoporosis.

The collaboration agreement provides Teijin with the right to manufacture abaloparatide-SC for commercial supply in Japan, as well as the right to reference Radius' NDA and MAA and regulatory data to support its marketing application in Japan and to use Radius intellectual property, and provides Radius with an option to negotiate a co-promotion agreement for abaloparatide-SC in Japan. Radius will also receive upfront and milestone payments and royalties for the rights granted to Teijin. Teijin is conducting and funding its Japanese phase 3 development program and the parties may further collaborate in the future in new indications for the product. Radius maintains full global rights to its development program for abaloparatide-transdermal (abaloparatide-TD), which is not part of the agreement with Teijin.

"We are extremely pleased to partner with Teijin as they seek to complete their Phase 3 development of abaloparatide-SC and pursue regulatory approval in Japan," said Robert

E. Ward, President and CEO of Radius Health. “As Japan represents the largest anabolic market in the world, our partnership with Teijin is an important step in expanding the value of the abaloparatide franchise globally.”

About Radius

Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases. Radius' lead product, TYMLOS (abaloparatide) injection, was approved by the U.S. Food and Drug Administration for the treatment of postmenopausal women with osteoporosis at high risk for fracture. Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis is under regulatory review in Europe. The Radius clinical pipeline includes an investigational abaloparatide transdermal patch for potential use in osteoporosis and the investigational drug elacestrant (RAD1901) for potential use in hormone-driven and/or hormone-resistant breast cancer, and vasomotor symptoms in postmenopausal women. Radius' RAD140, a non-steroidal, selective androgen receptor modulator (SARM), is under investigation for potential use in hormone receptor positive breast cancer. For more information, please visit www.radiuspharm.com.

About *TYMLOS* (abaloparatide)

TYMLOS (abaloparatide) was approved by the U.S. Food and Drug Administration for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of women with postmenopausal osteoporosis was validated and is currently undergoing regulatory review by the European Medicines Agency (EMA).

Radius also is developing abaloparatide-transdermal (abaloparatide-TD) based on 3M's patented Microstructu red Transdermal System technology for potential use as a treatment for postmenopausal women with osteoporosis.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the potential for Radius and Teijin to further collaborate in new indications for abaloparatide-SC; progress toward expanding the value of the abaloparatide franchise globally; the size of the Japanese market for bone anabolics; and the potential clinical uses for abaloparatide-TD, elacestrant (RAD1901) and RAD140.

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 only recently started to commercialize TYMLOS in the U.S. and may need to raise additional funding, which may not be available; risks related to raising additional capital; our limited operating history; quarterly fluctuation in our financial results; our dependence on the success of TYMLOS, and our inability to ensure that TYMLOS will obtain regulatory approval outside the U.S., including in Japan, or be successfully commercialized in any market in which it is approved, including as a result of risk related to coverage, pricing and reimbursement; risks related to competitive products, any collaboration agreements failing to be successful; risks related to clinical trials, including our reliance on third parties to conduct key portions of our 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 candidates, including during the development of

abaloparatide-SC by Teijin in Japan, or during commercialization, if app roved; risk related to manufacturing, supply and distribution; and the risk of litigation or other challenges regarding our intellectual property rights. These and other important risks and uncertainties discussed in our filings with the Securities and Exc hange Commission, or SEC, including under the caption “Risk Factors” in our most recent Annual Report on Form 10-K and subsequent filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements m ade in this press release. Any such forward-looking statements represent management’s estimates as of the date of this press release. 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 press release.

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