Radius Health, Inc.
Form 8-K
October 01, 2014

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): **October 1, 2014**

RADIUS HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35952**	**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:

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 8.01. Other Events.

Radius Health, Inc. (the Company, we or us) recently updated its business information as follows:

RAD1901

In June 2014, the Company initiated the Phase 1 maximum tolerated dose (MTD) study in healthy volunteers of its investigational drug, RAD1901, a selective estrogen receptor degrader (SERD) being developed for potential use in the treatment of metastatic breast cancer, including breast cancer brain metastases. The study is designed to evaluate the tolerability, safety and pharmacokinetics of RAD1901, and also to use 18F-fluroestradiol positron emission tomography (FES-PET) imaging to provide a pharmacodynamic assessment of estrogen receptor turnover following administration of RAD1901. Levels of RAD1901 in cerebrospinal fluid samples taken from study subjects will be measured to confirm that RAD1901 has crossed the blood-brain barrier. On August 28, 2014, the Company announced that the FES-PET imaging from the MTD study of RAD1901 demonstrated potent SERD activity based on initial study results. The Company reported, based on FES-PET imaging, that a well-tolerated dose of RAD1901 strongly suppressed positive baseline estrogen receptor imaging sites in the first healthy volunteer in the FES-PET imaging cohort of the study. As of September 30, 2014, 40 subjects have completed dose escalation in the ongoing MTD study, and FES-PET imaging has been completed in a total of six subjects across two different doses. Each of the six subjects demonstrated, based on FES-PET imaging, suppression of the FES-PET signal to background levels after six days of dosing. The Company expects to report additional results from the MTD study of RAD1901 and to initiate a Phase 1b clinical study of RAD1901 for metastatic breast cancer in late 2014, and expects to submit available results for presentation at the American Society of Clinical Oncology conference in 2015.

We believe that, in 2012, the worldwide market for Faslodex, the only SERD approved by the FDA for the treatment of hormone-receptor positive metastatic breast cancer, was $654 million. The Company plans to expand the development program for RAD1901 to other estrogen receptor positive tumors and to continue to develop RAD1901 in low doses for potential use in the treatment of vasomotor symptoms.

Intellectual Property

The Company acquired and maintains exclusive worldwide rights, excluding Japan, to certain patents, data and technical information related to abaloparatide through a license agreement with an affiliate of Ipsen Pharma SAS (Ipsen). The composition of matter of abaloparatide is claimed in the United States (U.S. Patent No. 5,969,095), Australia, Canada, China, Hong Kong, Hungary, Mexico, New Zealand, Poland, Singapore, South Korea, and Taiwan. These cases have a normal patent expiration date of 2016, absent any U.S. patent term extension under the Hatch-Waxman Act. We believe that European Patent No. 0847278, which claimed the composition of matter of abaloparatide, has lapsed for failure to pay annuities by our licensor Ipsen. While we are seeking to address the lapse of right, we believe that the data and market exclusivity provided in Europe for a new chemical entity (8+2+1) coupled with the need to conduct clinical trials will likely provide a longer barrier to entry than the patent protection provided by the original European patent term (2016) plus a five year maximum Supplemental Protection Certificate. The Phase 3 clinical dosage of abaloparatide by the subcutaneous route for use in treating osteoporosis is covered by U.S. Patent No. 7,803,770 until 2028 (statutory term extended with 175 days of patent term adjustment due to delays in patent prosecution by the United States Patent and Trademark Office (USPTO)) in the United States (absent any patent term extension under the Hatch-Waxman Act). The intended therapeutic formulation for abaloparatide-SC is covered by U.S. Patent No. 8,148,333 until 2027 (statutory term extended with 36 days of patent term adjustment due to delays in patent prosecution by the USPTO) in the United States (absent any patent term extension under the Hatch-Waxman Act). A corresponding European application is pending with claims to the intended therapeutic formulation for abaloparatide-SC. Examination has been requested, but substantive examination has not yet commenced. Upon grant, this patent could be validated in any designated contracting or extension states and potentially could be considered for a Supplemental Protection Certificate depending upon the timing of its grant. Related cases granted in the United States, Australia, China, Japan, Mexico, New Zealand, Russia, Singapore, and Ukraine, and currently pending in Brazil, Canada, China, Europe, Hong Kong, India, Israel, New Zealand, Norway, Singapore, and South Korea will have a normal

un-extended patent expiration date of 2027. Patent applications which cover various aspects of abaloparatide for microneedle application are pending in the United States, Australia,

Brazil, Canada, China, Europe, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Russia, Singapore, South Korea, and Ukraine. Any claims that might issue from these applications will have a normal expiration date no earlier than 2032.

The composition of matter of, and method of using, RAD 140 is covered by U.S. Patent No. 8,067,448 (effective filing date February 19, 2009, and a statutory term extended to September 25, 2029, with 218 days of patent term adjustment due to delays by the USPTO) and U.S. Patent No. 8,268,872 (effective filing date February 19, 2009, expires on September 25, 2029, with 232 days of patent term adjustments due to delays by the USPTO and subjected to a terminal disclaimer to U.S. Patent Nos. 8,067,448 and 8,455,525).

Forward-Looking Statements

Some of the information contained in this report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. In this report, the words anticipates, believes, expects, intends, future, coul estimates, plans, would, should, potential, continues and similar words or expressions (as well as other words or expressions referencing f events, conditions or circumstances) identify forward-looking statements. These forward-looking statements involve 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: we have no product revenues; our need for additional funding, which may not be available; we are not currently profitable and may never become profitable; restrictions imposed on our business by our credit facility, and risks related to default on our obligations under our credit facility; risks related to raising additional capital; our limited operating history; quarterly fluctuation in our financial results; our dependence on the success of abaloparatide-SC, and our inability to ensure that abaloparatide-SC will obtain regulatory approval or be successfully commercialized; risks related to clinical trials, including having most of our products in early stage 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; 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; risks related to the use of our limited resources on particular product candidates and not others; delays in enrollment of patients in our clinical trials, which could delay or prevent regulatory approvals; the dependence of our drug development program upon third-parties who are outside our control; the risk that a regulatory or government official will determine that third-parties with a financial interest in the outcome of the Phase 3 study of abaloparatide-SC affected the reliability of the data from the study; our reliance on third parties to formulate and manufacture our product candidates; failure to establish additional collaborations; our lack of experience selling, marketing and distributing products and our lack of internal capability to do so; failure to compete successfully against other drug companies; developments by competitors may render our products or technologies obsolete or non-competitive; risks related to the fact that our drugs may sell for inadequate prices or patients may be unable to obtain adequate reimbursement; effects of product liability lawsuits on commercialization of our products; failure to comply with obligations of our intellectual property licenses; failure to protect our intellectual property or failure to secure necessary intellectual property related to abaloparatide-SC, abaloparatide-TD, RAD1901 and/or RAD140; our or our licensors inability to obtain and maintain patent protection for technology and products; risks related to our compliance with patent application requirements; failure to protect the confidentiality of our trade secrets; risks related to our infringement of third parties rights; risks associated with intellectual property litigation, including expending substantial resources and distracting personnel from their normal responsibilities; risks related to employees disclosure of former employers trade secrets; risks associated with healthcare reform; our failure to comply with healthcare laws and regulations; our exposure to claims associated with the use of hazardous materials and chemicals; inability to successfully manage our growth; risks relating to business combinations and acquisitions; our reliance on key executive officers and advisors; our inability to hire additional qualified personnel; volatility in the price of our common stock; capital appreciation is the only source of gain for our common stock; risks related to increased costs and compliance initiatives associated with operating as a public company; our directors, executive officers and principal stockholders have substantial control over us and could delay or prevent a change in control; future sales of our common stock could depress the price of our common stock; inaccurate or unfavorable information about us could cause the price of our common stock to decline; provisions in our charter documents and Delaware law could discourage takeover attempts; and our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. These and other important factors discussed under the caption Risk Factors in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2014, filed with the Securities and Exchange Commission (the SEC) on August 12, 2014, along with 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 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: October 1, 2014	By:	/s/ B. Nicholas Harvey Name: B. Nicholas Harvey Title: Chief Financial Officer