Radius Health, Inc.
Form 8-K
July 21, 2015

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 16, 2015**

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:

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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On July 16, 2015, the Board of Directors (the Board) of Radius Health, Inc. (the Company) elected Debasish Roychowdhury as a Class I director of the Company.

Dr. Roychowdhury will participate in the Company s standard compensation program for non-employee directors (the Non-Employee Director Compensation Program), including an annual retainer of $35,000 for service as a non-employee director and an initial award of an option to purchase 30,000 shares of the Company s common stock (the Initial Award). The Initial Award has an exercise price equal to $77.64, the closing price per share of the Company s common stock on the date of grant, and will vest and become exercisable in equal installments on each of the first four anniversaries of the date of grant, subject to continued service on the Board through each such vesting date, provided that such option will vest and become exercisable in full immediately prior to a Change of Control (as defined in the Company s 2011 Equity Incentive Plan) that occurs during Dr. Roychowdhury s continuous service as a non-employee member of the Board. Dr. Roychowdhury has also entered into the Company s standard indemnification agreement for directors and officers.

Item 8.01. Other Events.

Radius Health, Inc., which is referred to in this Item 8.01 as the Company, we, us or our , recently updated its business information as follows:

In May 2015, we re-submitted our previously denied request for breakthrough therapy designation for abaloparatide-SC, including the 18-month top-line results of our ACTIVE trial. In July 2015, the FDA denied our request. We are evaluating our options for re-submission for breakthrough therapy designation based on the data from both our ACTIVE and ACTIVExtend trials and/or to apply for one of the other FDA expedited review programs for new drugs that address unmet medical needs in the treatment of serious or life threatening conditions.

Risk Factor

The risk factor described below updates the risk factor related to the uncertainty of the regulatory approval and commercialization process that appears in our Quarterly Report on Form 10-Q filed on May 6, 2015 (the Quarterly Report). The risk factor below should be read in conjunction with the other risk factors that appear in the Quarterly Report.

We are heavily dependent on the success of abaloparatide-SC which is under clinical development. We cannot be certain that abaloparatide-SC will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

Abaloparatide-SC is our only product candidate in late-stage clinical development, and our business currently depends heavily on its successful development, regulatory approval and commercialization. We have no drug products for sale currently and may never be able to develop approved and marketable drug products. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other foreign regulatory authorities in the United States and other countries, which

regulations differ from country to country. We are not permitted to market abaloparatide-SC in the United States unless and until we receive approval of a New Drug Application, or NDA, from the FDA, or in any foreign countries unless and until we receive the requisite approval from regulatory authorities in foreign countries. In addition, the approval of abaloparatide-TD as a line extension to abaloparatide-SC is dependent on the earlier approval of abaloparatide-SC. We have not submitted an NDA to the FDA or comparable applications to regulatory authorities in other countries. Obtaining approval of a product candidate is an extensive, lengthy, expensive and uncertain process, and any approval of abaloparatide-SC may be delayed, limited or denied for many reasons, including:

- we may not be able to demonstrate that abaloparatide is safe and effective as a treatment for reduction of fracture risk in postmenopausal women with severe osteoporosis to the satisfaction of the FDA or other foreign regulatory authorities;

- the results of our clinical studies may not meet the level of statistical or clinical significance required for marketing approval;

- the FDA or other foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical studies;

- any clinical research organizations, or CROs, that we have retained or may in the future retain, to conduct clinical studies may take actions outside of our control that materially adversely impact our clinical studies;

- the FDA or other foreign regulatory authorities may not find the data from preclinical studies and clinical studies sufficient to demonstrate that abaloparatide s clinical and other benefits outweigh its safety risks;

- the FDA or other foreign regulatory authorities may disagree with our interpretation of data from our preclinical studies and clinical studies or may require that we conduct additional studies;

- the FDA or other foreign regulatory authorities may not accept data generated at our clinical study sites;

- the FDA or other foreign regulatory authorities may not agree with our proposed labeling and may require labeling that undermines or otherwise significantly impairs the commercial value of the product if it were to be approved with such labeling;

- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval;

- if our NDA is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical studies, limitations on approved labeling or distribution and use restrictions; or

- the FDA or other foreign regulatory authorities may identify deficiencies in the manufacturing processes or facilities of our third-party manufacturers.

In addition, the FDA or other foreign regulatory authorities may change its approval policies or adopt new regulations. For example, on February 15, 2012, we received a letter from the FDA stating that, after internal consideration, the FDA believes that a minimum of 24-month fracture data are necessary for approval of new products for the treatment of postmenopausal osteoporosis. Our abaloparatide-SC pivotal Phase 3 clinical trial is designed to produce fracture data based on an 18-month primary endpoint. Based on our discussions with the FDA, we believe that continued use of the 18-month primary endpoint will be acceptable, provided that our NDA includes the 24-month fracture data derived from the first six months extension of the abaloparatide 80 μg and placebo groups in our Phase 3 study, which groups will receive an approved alendronate (generic Fosamax) therapy for osteoporosis management. We plan to submit our NDA with the 24-month fracture data. We cannot be certain that the FDA will be supportive of this plan, will not change this approval policy again or will not adopt other approval policies or regulations that adversely affect any NDA that we may submit, the occurrence of any of which may further delay FDA approval.

The NDA that we plan to submit to the FDA for abaloparatide-SC as a proposed treatment for osteoporosis, will need to include the 24-month fracture data from the first six months of the alendronate extension study of the abaloparatide and placebo groups from our Phase 3 clinical trial. We also must complete several additional studies, including, but not limited to, a thorough QT Phase 1 study and a Phase 1 pharmacokinetic study in renal patients. The results of these studies will have an important bearing on the approval of abaloparatide.

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates, including abaloparatide-SC, abaloparatide-TD, RAD1901 and RAD140, or any product candidate we may acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from the regulatory authorities in foreign jurisdictions to commercialize our product

candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its indicated use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA s regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for proposed uses.

In 2007, we entered into a global pharmacovigilance agreement with Teijin Limited, or Teijin, a Japanese pharmaceutical company, that provides for the exchange of information related to serious and non-serious adverse reactions to abaloparatide by patients enrolled in clinical studies. The purpose of the agreement is to enable safety reporting to global health agencies. We believe Teijin has fully enrolled a Phase 2 clinical study of abaloparatide-SC in Japan for the treatment of postmenopausal osteoporosis that is expected to report results later this year. Should Teijin advise us in accordance with our agreement of a serious adverse event experienced by patients enrolled in their study, we would need to report the serious adverse event to the FDA and EMA, which could adversely affect or delay our ability to obtain regulatory approvals in the United States and Europe.

In addition, the FDA has substantial discretion in the drug approval process and may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during its regulatory review, such as the request we received from the FDA with respect to providing a minimum of 24-month fracture data for approval of abaloparatide. Delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; and
- diminish any competitive advantages that we may otherwise enjoy.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We may never obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire any product candidate.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize any drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates for sale outside the United States.

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 21, 2015	By:	/s/ B. Nicholas Harvey B. Nicholas Harvey Chief Financial Officer