Radius Health, Inc.
Form 8-K
July 16, 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 15, 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)

¨ 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 7.01. Regulation FD Disclosure.

On July 15, 2015, Radius Health, Inc. announced that preliminary results from a preclinical study of its investigational drug RAD1901 in xenograft breast cancer models showed reductions in tumor growth when treated with RAD1901 alone and in combination with palcociclib and everolimus. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Form 8-K (including Exhibit 99.1) 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 Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 8.01. Other Events.

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

RAD1901

On July 15, 2015, the Company announced that early but promising preclinical data show that its investigational drug RAD1901, in combination with Pfizer s palbociclib, a CDK4/6 inhibitor, and Novartis everolimus, an mTOR inhibitor, Novartis everolimus, was effective in shrinking tumors. In patient-derived xenograft (PDx) breast cancer models with either wild type or mutant ESR1, treatment with RAD1901 resulted in marked tumor growth inhibition, and the combination of RAD1901 with either agent, palbociclib or everolimus, showed anti-tumor activity that was significantly greater than either agent alone. RAD1901 is being evaluated at high doses as a Selective Estrogen Receptor Degrader for potential use in metastatic breast cancer.

The PDx model shown below was established from a patient who had received multiple lines of breast cancer therapies (including chemotherapy and endocrine therapies) and her tumor expressed mutant ESR1, which is known to confer insensitivity to endocrine agents. In this endocrine insensitive PDx model, RAD1901 was associated with significant growth inhibition as a single agent. In addition, combining RAD1901 with palbociclib demonstrated marked anti-tumor activity that was significantly greater than RAD1901 alone in this ESR1 mutant PDX model. In MCF7 xenograft studies shown below, RAD1901 single agent anti-tumor activity was also observed and showed significantly greater activity when combined with either palbociclib or everolimus. In these models all agents were orally dosed on a daily basis. The RAD1901 dose of 60 mg/kg achieves an exposure in these animals that is comparable to the clinical exposure currently being tested in the ongoing Phase 1 breast cancer study.

The Company has also recently completed a pharmacokinetic/ pharmacodynamic study of RAD1901 in healthy volunteers. In total, 52 subjects were treated with doses between 200 mg and 1000mg for up to 7 days. Preliminary data suggested that all doses were generally well tolerated. A subset of subjects received baseline and FES-PET after 7 days to evaluate ER signal attenuation, and the Company expects to report the final results of this study in the third quarter of 2015.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation, the significance of data from preclinical studies of RAD1901, the potential treatment outcomes of RAD1901 alone and in combination with CDK or mTOR inhibitors and the timing of results for the pharmacokinetic/pharmacodynamic study of RAD1901.

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 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 of 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

and maintenance 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 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; as we become involved in drug commercialization, risks related to our inability to successfully manage our growth and expanded operations; 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 influence 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; risks related to securities or industry analysts ceasing to publish research about us or publishing inaccurate or unfavorable information about us, which could cause the price of our common stock to decline; provisions in our charter documents and Delaware law that 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 filed with the Securities and Exchange Commission, or SEC, on May 6, 2015, and 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 Current Report on Form 8-K. Any such forward-looking statements represent management s estimates as of the date of this Current Report on Form 8-K. 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 Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on July 15, 2015

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 16, 2015	By:	/s/ B. Nicholas Harvey
		Name: B. Nicholas Harvey Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued on July 15, 2015