



August 4, 2016

## Radius Health Reports Second Quarter 2016 Financial and Operating Results

*Radius' NDA for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis was accepted for filing by FDA with a PDUFA date of March 30, 2017*

*An oral presentation on the clinical development progress of an optimized abaloparatide transdermal patch has been accepted as an oral Late-Breaker at ASBMR on September 19, 2016*

*Radius provides update on RAD1901 and RAD140 development programs*

WALTHAM, Mass., Aug. 04, 2016 (GLOBE NEWSWIRE) -- Radius Health, Inc. ("Radius" or the "Company") (Nasdaq:RDUS), a science-driven biopharmaceutical company that is committed to developing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases, reported its financial results for the second quarter ended June 30, 2016, and provided a business update. As of June 30, 2016, Radius had \$400.9 million in cash, cash equivalents and marketable securities.

"We are pleased to be working with the U.S. Food and Drug Administration and European Medicines Agency as they review our regulatory submissions for abaloparatide-SC for the treatment of postmenopausal osteoporosis. In anticipation of our first potential launch, we are building our commercial organization in the U.S. and continuing our productive partnering discussions," said Robert Ward, President and Chief Executive Officer of Radius. "At the same time, we continue to make steady progress in the development of an optimized transdermal patch line extension for abaloparatide as well as the advancement of our two oncology programs, both of which we believe can add substantial value to Radius."

### **Pipeline Updates**

#### **Abaloparatide-SC**

In May 2016, Radius' new drug application ("NDA") in the United States for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis was accepted for filing by the FDA and was granted a Prescription Drug User Fee Act (PDUFA) date of March 30, 2017. Radius' marketing authorisation application ("MAA") to the European Medicines Agency ("EMA"), was validated in December 2015 and is currently undergoing regulatory review. We anticipate a CHMP scientific opinion in late 2016 or 2017.

#### **Abaloparatide-TD**

Radius is developing abaloparatide-transdermal, or abaloparatide-TD, based on 3M's patented Microstructured Transdermal System technology for potential use as a short wear-time transdermal patch. Radius commenced a human replicative clinical evaluation of the optimized abaloparatide-TD patch in December 2015 with the goal of achieving comparability to abaloparatide-SC. An abstract submitted to the American Society for Bone Mineral Research 2016 Annual Meeting (ASBMR) was accepted as an oral late-breaking presentation to be made on September 19, 2016 in Atlanta, Georgia.

#### **RAD1901**

In December 2014, Radius commenced a Phase 1 multicenter, open-label, two-part, dose-escalation study of RAD1901 in postmenopausal women with estrogen receptor positive (ER+) and HER2-negative advanced breast cancer in the United States. The Phase 1 study is designed to evaluate escalating doses of RAD1901 in Part A. The Part B expansion cohorts allow for an evaluation of additional safety, tolerability and preliminary efficacy. In addition, in December 2015, Radius commenced a Phase 1 FES-PET study in patients with ER+, HER2-negative advanced breast cancer in the European Union, which includes the use of FES-PET imaging to assess estrogen receptor occupancy in tumor lesions following RAD1901 treatment.

As of the end of July, the Phase I Part B expansion cohort for RAD1901 that initiated in March 2016 at 400 mg daily in ER+, HER2-negative advanced breast cancer has enrolled 19 out of 20 patients. We continue to enroll patients in the European

Phase I FES-PET trial — the first three-patient dosing cohort is enrolled. We are pleased with the progress across these trials and expect to provide an update on the RAD1901 program at an upcoming scientific meeting.

## **RAD140**

We have reported that RAD140 in preclinical xenograft models of breast cancer has demonstrated potent tumor growth inhibition when administered alone or in combinations with CDK4/6 inhibitors. It is estimated that 77% of breast cancers show expression of the androgen receptor. Our preclinical data suggest that RAD140 activity at the androgen receptor stimulates up-regulation of a tumor suppression pathway. We expect to provide an update on the RAD140 program at an upcoming scientific meeting.

## **Radius Expects the Following Upcoming Milestones**

- | Abaloparatide-SC
- | Receive opinion from the Committee for Medicinal Products for Human Use regarding the EMA's review of the abaloparatide-SC MAA in late 2016 or 2017
- | FDA PDUFA date of March 30, 2017
- | Enter into a collaboration for the potential commercialization of abaloparatide-SC outside the U.S. prior to commercial launch
- | Three abstracts accepted for poster presentations at ASBMR from the Phase 3 ACTIVE clinical trial
- | Abaloparatide-TD
- | Oral late-breaker presentation of the results of the human replicative PK pilot study of an optimized abaloparatide transdermal patch at ASBMR, on September 19, 2016 in Atlanta, Georgia
- | RAD1901
- | Expect to provide an update on the RAD1901 program at an upcoming scientific meeting.
- | RAD140
- | Expect to provide an update on the RAD140 program at an upcoming scientific meeting.

## **Radius Expects To Make Presentations at the Following Upcoming Conferences**

- | Radius President and CEO, Robert E. Ward will make a presentation and company management will host one-on-ones at the Canaccord Genuity Growth Conference, August 10, 2016 at the InterContinental Hotel in Boston, MA.
- | Radius President and CEO, Robert E. Ward, will make a presentation and company management will host one-on-ones at the Rodman & Renshaw 18<sup>th</sup> Annual Global Investment Conference at the Lotte New York Palace Hotel in New York on September 12.
- | Four abstracts for abaloparatide were accepted for presentation at ASBMR September 16-19, 2016 in Atlanta, Georgia. Three data presentations are from the Phase 3 ACTIVE trial for abaloparatide-SC, and the fourth is an oral presentation in the Late-Breaking Abstracts session from the pilot PK human replicative study of an optimized transdermal patch titled: "Clinical Development of an Optimized Abaloparatide Transdermal Patch" on September 19, 2016 at 11:36 AM — 11:48 AM.

## **Recent Corporate Highlights**

- | In July 2016, Radius entered into a pre-clinical collaboration with Takeda Pharmaceutical Company Limited to evaluate the combination of investigational drug RAD1901 with investigational drug TAK-228, an oral mTORC 1/2 inhibitor in Phase 2b development for the treatment of breast, endometrial and renal cancer, with the goal of potentially exploring such combination in a clinical study.
- | In June, Radius announced the opening of its Wayne, Pennsylvania office, which will serve as the Company's Commercial and Medical hub and house marketing, sales, human resources, IT, pharmacovigilance, health economics, outcomes research, medical education, clinical affairs and medical affairs staff.
- | In May, Radius announced that its New Drug Application (NDA) for abaloparatide—SC had been accepted for filing by the U.S. Food and Drug Administration (FDA). The acceptance of the NDA reflects the FDA's determination that the application is sufficiently complete to permit a substantive review. A PDUFA date of March 30, 2017 has been assigned.

Abaloparatide-SC as a treatment for postmenopausal women with osteoporosis is an investigational product and its safety and efficacy have not been established.

## **Second Quarter 2016 Financial Results**

For the three months ended June 30, 2016, Radius reported a net loss of \$43.4 million, or \$1.01 per share, as compared to a net loss of \$23.0 million, or \$0.61 per share for the three months ended June 30, 2015. The increase in net loss for the three months ended June 30, 2016 as compared to the three months ended June 30, 2015 was primarily due to an increase in research and development and general and administrative expenses, partially offset by a decrease in interest expense and an increase in interest income.

Research and development expenses for the three months ended June 30, 2016 were \$26.9 million, compared to \$16.3 million for the same period in 2015. This increase was primarily driven by higher professional contract services costs associated with the development of RAD1901 to support a Phase 1 study in metastatic breast cancer that commenced in late 2014 and a Phase 2b study in postmenopausal vasomotor symptoms that commenced in December 2015. This increase was also a result of an increase in compensation expense, including stock-based compensation, due to an increase in headcount from June 30, 2015 to June 30, 2016.

General and administrative expenses for the three months ended June 30, 2016 were \$17.2 million, compared to \$6.0 million for the same period in 2015. This increase was primarily attributable to an increase in professional support costs and legal fees, including the costs associated with increasing headcount and preparing for the potential commercialization of abaloparatide-SC, subject to a favorable regulatory review.

This increase was also driven by an increase in compensation expense due to an increase in headcount from June 30, 2015 to June 30, 2016.

As of June 30, 2016, Radius had \$400.9 million in cash, cash equivalents and marketable securities. Based upon Radius' cash, cash equivalents and marketable securities balance, Radius believes that, prior to the consideration of revenue from the potential future sales of any of its investigational products that may receive regulatory approval or proceeds from collaboration activities, it has sufficient capital to fund its development plans, U.S. commercial scale-up and other operational activities into 2018.

## **Conference Call and Webcast**

In connection with the earnings release, Radius will host a conference call and live audio webcast at 8:00 a.m. ET on Thursday, August 4, 2016 to discuss the financial results, and give an update on the Company's progress.

Conference Call Information:

Date: Thursday, August 4, 2016

Time: 8:00 a.m. ET

Domestic Dial-in Number: 1-877-705-6003

International Dial-in Number: 1-201-493-6725

Live webcast: <http://public.viavid.com/index.php?id=120380>

For those unable to participate in the conference call or live webcast, a replay will be available until August 18 at 11:59 p.m. ET. To access the replay, dial domestic 1-877-870-5176, international 1-858-384-5517. The replay passcode is 13635038.

A live audio webcast of the call will also be available on the Investors section of the Company's website, [www.radiuspharm.com](http://www.radiuspharm.com). A webcast replay will be available for two weeks on the Radius website, [www.radiuspharm.com](http://www.radiuspharm.com).

## **About Radius**

Radius is a science-driven biopharmaceutical company that is committed to developing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases. Radius' lead product candidate, the investigational drug abaloparatide for subcutaneous injection, has completed Phase 3 development for potential use in the reduction of fracture risk in postmenopausal women with osteoporosis. Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis is under regulatory review in Europe and a New Drug Application (NDA) has been accepted for filing by the FDA with a PDUFA date of March 30, 2017. The Radius clinical pipeline also includes an investigational abaloparatide transdermal patch for potential use in osteoporosis and the investigational drug RAD1901 for potential use in hormone-driven and/or hormone-resistant breast cancer, and vasomotor symptoms in postmenopausal women. Radius' preclinical pipeline includes RAD140, a non-steroidal, selective androgen receptor modulator (SARM) under investigation for potential use in cancer. For more information, please visit [www.radiuspharm.com](http://www.radiuspharm.com)

## **About Abaloparatide**

Abaloparatide is an investigational therapy for the potential treatment of women with postmenopausal osteoporosis who are at an increased risk for a fracture. Abaloparatide is a novel synthetic peptide that engages the parathyroid hormone receptor (PTH1 receptor) and was selected for clinical development based on its favorable bone building activity.

Abaloparatide has completed Phase 3 development for potential use as a daily self-administered injection (abaloparatide-SC). In the fourth quarter of 2015, Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of patients with postmenopausal osteoporosis was validated and is currently undergoing regulatory review by the European Medicines Agency (EMA). Radius submitted a New Drug Application (NDA) for abaloparatide-SC to the US Food and Drug Administration (FDA) at the end of the first quarter of 2016, which has been accepted for filing with a PDUFA date of March 30, 2017. Radius also is developing abaloparatide-transdermal (abaloparatide-TD) based on 3M's patented Microstructured Transdermal System technology for potential use as a treatment for osteoporosis.

### **About RAD1901**

RAD1901 is a selective estrogen receptor down-regulator/degrader (SERD), which at high doses is being evaluated for potential use as an oral non-steroidal treatment for hormone-driven, or hormone-resistant, breast cancer. RAD1901 is currently being investigated for potential use in postmenopausal women with estrogen receptor positive (ER+), HER2-negative advanced breast cancer, the most common form of the disease. Studies completed to date indicate that the compound has the potential for use as a single agent or in combination with other therapies for the treatment of breast cancer.

RAD1901 also is being evaluated in a Phase 2b study at low doses for potential relief of the frequency and severity of moderate to severe hot flashes in postmenopausal women with vasomotor symptoms. Additional information on the clinical trial program of RAD1901 is available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **About RAD140**

RAD140 is a nonsteroidal selective androgen receptor modulator. The androgen receptor (AR) is highly expressed in many estrogen receptor (ER)-positive, ER-negative, and triple-negative receptor breast cancers. Because of its receptor and tissue selectivity, potent activity, oral bioavailability, and long half-life, RAD140 could have clinical potential in the treatment of breast cancer. RAD140 resulted from an internal drug discovery program focused on the androgen receptor pathway, which is highly expressed in many breast cancers.

### **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 progress of abaloparatide-SC in the regulatory process with the FDA and the EMA and the timing of potential regulatory actions, the timing of potential collaboration agreements, the progress in development of abaloparatide-TD and in the development of RAD1901 and RAD140, each of the statements under the heading "Radius Expects The Following Upcoming Milestones," upcoming events and presentations, the sufficiency of cash, cash equivalents and marketable securities and the potential clinical uses for 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 no product revenues 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 abaloparatide-SC, and our inability to ensure that abaloparatide-SC will obtain regulatory approval or be successfully commercialized; any collaboration agreements failing to be successful; 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; and delays in enrollment of patients in our clinical trials, which could delay or prevent regulatory approvals. These and other important factors discussed under the caption "Risk Factors" in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on February 25, 2016, 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 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.

	<b>June 30, 2016</b>	<b>December 31, 2015</b>
	<b>(unaudited)</b>	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 120,554	\$ 159,678
Marketable securities	280,302	313,661
Prepaid expenses and other current assets	5,197	6,969
Total current assets	<u>406,053</u>	<u>480,308</u>
Property and equipment, net	2,945	1,897
Other assets	448	260
Total assets	<u><u>\$ 409,446</u></u>	<u><u>\$ 482,465</u></u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,027	\$ 6,228
Accrued expenses and other current liabilities	16,545	14,952
Total current liabilities	<u>19,572</u>	<u>21,180</u>
Total liabilities	<u>\$ 19,572</u>	<u>\$ 21,180</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.0001 par value; 200,000,000 shares authorized, 43,060,593 shares and 42,984,243 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	4	4
Additional paid-in-capital	919,343	907,040
Accumulated other comprehensive income (loss)	188	5
Accumulated deficit	<u>(529,661)</u>	<u>(445,764)</u>
Total stockholders' equity	<u>389,874</u>	<u>461,285</u>
Total liabilities and stockholders' equity	<u><u>\$ 409,446</u></u>	<u><u>\$ 482,465</u></u>

### Condensed Consolidated Statements of Comprehensive Loss

(Unaudited)

(In thousands, except share and per share amounts)

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
<b>OPERATING EXPENSES:</b>				
Research and development	\$ 26,891	\$ 16,278	\$ 54,374	\$ 27,837
General and administrative	17,193	6,000	30,839	10,756
Loss from operations	<u>(44,084)</u>	<u>(22,278)</u>	<u>(85,213)</u>	<u>(38,593)</u>
<b>OTHER (EXPENSE) INCOME:</b>				
Other (expense) income, net	(95)	(78)	(96)	(128)
Interest income	744	185	1,411	290
Interest expense	-	(794)	-	(1,591)
<b>NET LOSS</b>	<u><b>\$ (43,435)</b></u>	<u><b>\$ (22,965)</b></u>	<u><b>\$ (83,898)</b></u>	<u><b>\$ (40,022)</b></u>
<b>OTHER COMPREHENSIVE LOSS, NET OF TAX:</b>				
Unrealized gain (loss) from available-for-sale securities	(49)	(31)	183	31
<b>COMPREHENSIVE LOSS</b>	<u><b>\$ (43,484)</b></u>	<u><b>\$ (22,996)</b></u>	<u><b>\$ (83,715)</b></u>	<u><b>\$ (39,991)</b></u>
<b>LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED (Note 10)</b>	<u><b>\$ (43,435)</b></u>	<u><b>\$ (22,965)</b></u>	<u><b>\$ (83,898)</b></u>	<u><b>\$ (40,022)</b></u>

LOSS PER SHARE:

Basic and diluted

\$ (1.01) \$ (0.61) \$ (1.95) \$ (1.08)

WEIGHTED AVERAGE SHARES:

Basic and diluted

43,042,883 37,895,651 43,027,903 37,089,642

Radius Health

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