November 3, 2016

# Radius Health Reports Third Quarter 2016 Financial and Operating Results

*ACTIVE Phase 3 trial results published in Journal of American Medical Association and Journal of Bone Mineral Research*

*Radius to present three abstracts on RAD1901 at San Antonio Breast Cancer Symposium in December*

WALTHAM, Mass., Nov. 03, 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 third quarter ended September 30, 2016, and provided a business update. As of September 30, 2016, Radius had $369.8 million in cash, cash equivalents and marketable securities.

"We are working closely with the U.S. Food and Drug Administration and the European Medicines Agency as they review our regulatory submissions for abaloparatide-SC, and building our commercial capabilities for a successful launch, pending favorable review," said Robert Ward, President and Chief Executive Officer of Radius. "We are positioning our company for sustainable growth, and pleased to have made substantial progress in the development of a transdermal patch line extension for abaloparatide and in advancing our two oncology programs."

## Pipeline Updates

### Abaloparatide-SC

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 receiving a CHMP scientific opinion in late 2016 or 2017.

In August 2016, the Phase 3 ACTIVE (Abaloparatide Comparator Trial In Vertebral Endpoints) trial results were published in the Journal of the American Medical Association (JAMA) in a manuscript titled ***"Effect of Abaloparatide vs Placebo on New Vertebral Fractures in Postmenopausal Women With Osteoporosis".***

In September 2016, additional analyses from the Phase 3 ACTIVE trial were published in the Journal of Bone and Mineral Research (JBMR) in an article titled "***Effects of Abaloparatide-SC on Fracture and Bone Mineral Density in Subgroups of Postmenopausal Women with Osteoporosis and Varying Baseline Risk Factors***".

Also in September 2016 at the American Society for Bone and Mineral Research (ASBMR) 2016 Annual Meeting, Radius presented three abstracts on data from the Phase 3 ACTIVE trial demonstrating that abaloparatide provides patients with early reductions in the risk of vertebral, nonvertebral, major osteoporotic and clinical fracture, irrespective of their baseline 10 year fracture probability. The titles for the abstracts presented are:

- "***Abaloparatide-SC is an Effective Treatment Option for Postmenopausal Women with Osteoporosis: Review of the Number Needed to Treat (NNT) Compared with Teriparatide"***
- ***"Effect of Investigational Treatment Abaloparatide-SC for Prevention of Major Osteoporotic Fracture or Any Fracture is Independent of Baseline Fracture Probability"***
- ***"Abaloparatide-SC has Minimal Effects in Subjects with Mild or Moderate Renal Impairment: Results from the ACTIVE trial".***

On Sunday, November 13, 2016, additional data on abaloparatide will be presented at the 2016 American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting in Washington, D.C. in a poster titled "***Abaloparatide-SC Significantly Reduces Vertebral and Nonvertebral Fractures and Increases Bone Mineral Density (BMD) Regardless of Age, BMD T-Score, or Prior Fracture at Baseline***".

Abaloparatide-SC as a treatment for postmenopausal women with osteoporosis is an investigational product and its safety

and efficacy have not been established.

**Abaloparatide-TD**

In December 2015, Radius commenced a human replicative clinical evaluation of the optimized abaloparatide-TD patch with the goal of achieving comparability to abaloparatide-SC. Radius reported results of this pilot pharmacokinetic (PK) study in an oral presentation titled "***Clinical Development of an Optimized Abaloparatide Transdermal Patch***" at the Late-Breaking Abstract Session at the ASBMR 2016.

The pilot PK study of the second-generation transdermal patch in postmenopausal women was successful in demonstrating the ability to modify the PK profile with respect to time to peak concentration (Tmax), half life (T1/2) and area under the curve (AUC). The results of this clinical evaluation will inform the design of a formal bioequivalence study that will be initiated following completion of activities required for the study.

**RAD1901**

During the third quarter of 2016, we completed enrollment with 20 patients at the 400 mg dose in the Phase I Part B expansion cohort for RAD1901 in ER+, HER2-negative advanced breast cancer. Radius has disclosed that multiple confirmed clinical responses have been reported in this study of heavily pretreated patients, and to date, no dose limiting toxicities have been reported in the RAD1901 program.

We continue to enroll patients in the European Phase I FES-PET trial — the first three-patient dosing cohort at 400 mg has been enrolled and these 3 patients achieved a reduction equal to or greater than 75% in FES-PET signal intensity.

On December 8, 2016, Radius will present three abstracts from the RAD1901 program at the San Antonio Breast Cancer Symposium (SABCS) titled:

- **"A phase 1 study of RAD1901, a novel, oral selective estrogen receptor degrader, for the treatment of ER-positive advanced breast cancer"**
- **"A phase 1 study of RAD1901, an oral selective estrogen receptor degrader, to determine changes in the 18F-FES uptake and tumor responses in ER-positive, HER2-negative, advanced breast cancer patients"**
- **"RAD1901 demonstrates anti-tumor activity in multiple models of ER-positive breast cancer treatment resistance".**

**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.

On December 1, 2016, at the EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Meeting in Munich, Germany, Radius will present new nonclinical data on RAD140 in a poster titled ***"RAD140, an orally available selective androgen receptor modulator, exhibits potent anti-tumor activity in ER+AR+ breast cancer models".***

**Radius Expects the Following Upcoming Milestones**

- Abaloparatide-SC
  - Receive scientific 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 commercialization of abaloparatide-SC prior to commercial launch
- RAD1901
  - Expect to report additional clinical results from the ongoing Phase I expansion cohort and FES-PET studies in metastatic breast cancer at SABCS on December 8, 2016
  - Radius will host an investor panel presentation with Key Opinion Leaders in San Antonio, Texas on December 8, 2016 to provide an update on the progress of its oncology programs. Details for this event can be found under Events & Presentations on the IR section of the company's website at www.radiuspharm.com.
- RAD140
  - Expect to submit an IND in 2016 and initiate first-in-human study in 2017.

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

- On November 6-7, 2016, Radius President and CEO, Robert E. Ward will make a presentation and will host one-on-ones at the 25th Annual Credit Suisse Healthcare Conference, at the Phoenician in Scottsdale, Arizona.
- On Sunday, November 13, 2016 Radius will present a poster at the 2016 American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting in Washington, D.C.
- On November 29, 2016, Radius President and CEO, Robert E. Ward, will make a presentation and company management will host one-on-ones at the Nasdaq 35th Investor Program in London.
- On December 1, 2016, at the EORTC-NCI-AACR Molecular Targets and Cancer Therapeutics Meeting in Munich, Germany, Radius will present new nonclinical data on RAD140.
- On December 8, 2016, at the SABCS, Radius will present three posters on RAD1901.
- On December 14, 2016, Radius President and CEO, Robert Ward, will make a presentation and host one-on-ones at the BMO Healthcare Conference in New York.
- On December 14, 2016, Radius Chief Commercial Officer, David Snow, will host one-on-one meetings at the Bank of America Merrill Lynch Midwest Healthcare Conference in Chicago, Illinois.

**Third Quarter 2016 Financial Results**

For the three months ended September 30, 2016, Radius reported a net loss of $46.2 million, or $1.07 per share, as compared to a net loss of $28.3 million, or $0.68 per share for the three months ended September 30, 2015. The increase in net loss for the three months ended September 30, 2016 as compared to the three months ended September 30, 2015 was primarily due to an increase in research and development and general and administrative expenses, partially offset by a decrease in loss on retirement of note payable, a decrease in interest expense and an increase in interest income.

Research and development expenses for the three months ended September 30, 2016 were $27.5 million, compared to $18.2 million for the same period in 2015. This increase was primarily driven by higher research and development 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 September 30, 2015 to September 30, 2016.

General and administrative expenses for the three months ended September 30, 2016 were $19.2 million, compared to $8.5 million for the same period in 2015. This increase was primarily attributable to an increase in professional support costs, 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, including stock-based compensation, due to an increase in headcount from September 30, 2015 to September 30, 2016.

As of September 30, 2016, Radius had $369.8 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, November 3, 2016 to discuss the financial results, and give an update on the Company's progress.

Conference Call Information:
Date: Thursday, November 3, 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=121469

For those unable to participate in the conference call or live webcast, a replay will be available until November 17 at 11:59 p.m. ET. To access the replay, dial domestic 1-844-512-2921, international 1-412-317-6671. The replay passcode is 13647502.

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

**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.

**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 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; and the risk of litigation regarding our intellectual property rights. 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.

**Condensed Consolidated Balance Sheets**
(In thousands, except share and per share amounts)

| | September 30, 2016 (unaudited) | December 31, 2015 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 198,565 | $ 159,678 |
| Marketable securities | 171,267 | 313,661 |
| Prepaid expenses and other current assets | 3,661 | 6,969 |
| Total current assets | 373,493 | 480,308 |
| Property and equipment, net | 4,057 | 1,897 |
| Other assets | 551 | 260 |
| Total assets | $ 378,101 | $ 482,465 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,665 | $ 6,228 |
| Accrued expenses and other current liabilities | 22,642 | 14,952 |
| Total current liabilities | 25,307 | 21,180 |
| Other non-current liabilities | 402 | - |
| Total liabilities | $ 25,709 | $ 21,180 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Common stock, $.0001 par value; 200,000,000 shares authorized, 43,109,927 shares and 42,984,243 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively | 4 | 4 |
| Additional paid-in-capital | 928,184 | 907,040 |
| Accumulated other comprehensive income (loss) | 52 | 5 |
| Accumulated deficit | (575,848) | (445,764) |
| Total stockholders' equity | 352,392 | 461,285 |
| Total liabilities and stockholders' equity | $ 378,101 | $ 482,465 |

**Condensed Consolidated Statements of Comprehensive Loss**
(Unaudited)
(In thousands, except share and per share amounts)

| | Three Months Ended | Nine Months Ended |
|---|---|---|

| | September 30, | | September 30, | |
|---|---|---|---|---|
| | 2016 | 2015 | 2016 | 2015 |
| OPERATING EXPENSES: | | | | |
| Research and development | $ 27,453 | $ 18,217 | $ 81,827 | $ 46,054 |
| General and administrative | 19,240 | 8,456 | 50,079 | 19,212 |
| Loss from operations | (46,693) | (26,673) | (131,906) | (65,266) |
| OTHER (EXPENSE) INCOME: | | | | |
| Other (expense) income, net | (78) | 1 | (174) | (127) |
| Loss on retirement of note payable | - | (1,572) | - | (1,572) |
| Interest income | 585 | 274 | 1,996 | 564 |
| Interest expense | - | (294) | - | (1,885) |
| NET LOSS | $ (46,186) | $ (28,264) | $ (130,084) | $ (68,286) |
| OTHER COMPREHENSIVE LOSS, NET OF TAX: | | | | |
| Unrealized (loss) gain from available-for-sale securities | (136) | 89 | 47 | 120 |
| COMPREHENSIVE LOSS | $ (46,322) | $ (28,175) | $ (130,037) | $ (68,166) |
| LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED | $ (46,186) | $ (28,264) | $ (130,084) | $ (68,286) |
| LOSS PER SHARE: | | | | |
| Basic and diluted | $ (1.07) | $ (0.68) | $ (3.02) | $ (1.77) |
| WEIGHTED AVERAGE SHARES: | | | | |
| Basic and diluted | 43,092,921 | 41,331,612 | 43,049,734 | 38,525,827 |

Radius Health

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