



May 1, 2017

Radius Health Reports First Quarter 2017 Financial and Operating Results

US FDA approves TYMLOS™ (abaloparatide) on April 28, 2017, first new bone builder in nearly 15 years

US Launch set for May 2017

24-month ACTIVEExtend trial has concluded, Radius to report top-line results in 2Q 2017

WALTHAM, Mass., May 01, 2017 (GLOBE NEWSWIRE) -- Radius Health, Inc. ("Radius" or the "Company") (Nasdaq:RDUS), a fully integrated 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 first quarter ended March 31, 2017, and provided a business update. As of March 31, 2017, Radius had \$282.1 million in cash, cash equivalents and marketable securities.

TYMLOS™ (abaloparatide)

On April 28, 2017, Radius announced that the U.S. Food and Drug Administration (FDA) approved TYMLOS™ (abaloparatide) injection for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. TYMLOS is the first new bone building therapy approved in nearly 15 years.

On February 1, 2017, results from the first six months of the recently completed 24-month ACTIVEExtend trial were published in the Mayo Clinic Proceedings under the title of **"Eighteen Months of Treatment With Subcutaneous Abaloparatide Followed by 6 Months of Treatment With Alendronate in Postmenopausal Women With Osteoporosis: Results of the ACTIVEExtend Trial"**. The 24-month ACTIVEExtend clinical trial has been completed and Radius expects to report the top-line results in the second quarter of 2017.

Pipeline Updates

Abaloparatide-SC

Radius' marketing authorisation application (MAA) to the European Medicines Agency (EMA) for the treatment of postmenopausal women with osteoporosis is currently undergoing regulatory review, and we anticipate receiving an opinion from the Committee for Medicinal Products for Human Use (CHMP) in 2017.

Abaloparatide-TD

In September 2016, at the annual meeting of the American Association for Bone Mineral Research (ASBMR), we presented the positive results from a human replicative clinical evaluation of an optimized abaloparatide transdermal patch. These results established an important demonstration of how we have changed the pharmacokinetic profile in our program to develop a bioequivalent transdermal patch. Currently, we are focused on completing the manufacturing, scale-up, and other required activities needed to initiate a pivotal study to evaluate bioequivalence to TYMLOS. We believe that the transdermal patch program has the potential to allow physicians who treat osteoporosis, but rarely use injectable drugs, an opportunity to expand their practices to include the use of anabolic therapy.

Elacestrant (RAD1901)

We recently completed enrollment in both of our ongoing Phase 1 studies of elacestrant in advanced metastatic breast cancer. In the first half of 2017, we plan to engage with regulatory agencies to gain alignment on defining the next steps for the elacestrant breast cancer program, which would include the design of a Phase 2 trial. We expect to complete and report results from our elacestrant Phase 2b vasomotor trial in mid-2017.

RAD140

An investigational new drug application, or IND, submitted to the FDA for RAD140, a selective androgen receptor modulator, has been accepted. We expect to initiate a first-in-human Phase 1 clinical trial in women with hormone receptor positive breast cancer in 2017.

Radius Expects the Following Upcoming Milestones

- | Abaloparatide-SC
 - | Receive a CHMP opinion regarding the EMA's review of the abaloparatide-SC MAA in 2017
 - | Enter into a partnership for the potential commercialization of abaloparatide-SC prior to commercial launch
 - | Report top-line results from the recently completed 24-month ACTIVEExtend clinical trial in the second quarter of 2017
- | Elacestrant
 - | Complete ongoing Phase 1 breast cancer clinical trials
 - | Engage with regulatory authorities in 2Q 2017 to gain alignment on defining next steps for the program, which would include the design of a Phase 2 breast cancer trial
 - | Present a poster on June 4, 2017 at the American Society of Oncology Annual Meeting (ASCO)
 - | Complete and report results from our ongoing Phase 2b vasomotor trial in mid-2017
- | RAD140
 - | Initiate a first-in-human Phase 1 study in 2017 in women with hormone receptor positive breast cancer

Radius Expects To Make Presentations at the Following Upcoming Conferences

- | On May 4, 2017, Radius President and CEO, Robert Ward will make a presentation and host one-on-ones at the 42nd Annual Deutsche Bank Healthcare Conference in Boston
- | On May 16-17, 2017, Radius President and CEO, Robert Ward will make a presentation and will host one-on-ones at the Bank of America Merrill Lynch 2017 Healthcare Conference in Las Vegas
- | On June 4, 2017, at the 2017 ASCO Annual Meeting, the following abstract will be presented as a poster and as part of the Poster Discussion Session: Abstract 1014
 - | ***"Evaluation of Elacestrant (RAD1901), a novel investigational, selective estrogen receptor degrader (SERD), for the treatment of ER-positive (ER+) advanced breast cancer"*** Abstract 1014, 8:00 AM - 11:30 AM, Hall A, Poster Board #6, POSTER SESSION, Breast Cancer-Metastatic
 - | **Discussed at the Poster Discussion Session**, 4:45 PM - 6:00 PM, Hall B1, Aditya Bardia, MD, MPH - First Author, Massachusetts General Hospital Cancer Center and Harvard Medical School
- | On June 13-14, 2017, Radius President and CEO, Robert Ward will make a presentation and will host one-on-ones at the Goldman Sachs 38th Annual Global Healthcare Conference in Palos Verdes, California

First Quarter 2017 Financial Results

For the three months ended March 31, 2017, Radius reported a net loss of \$56.9 million, or \$1.32 per share, as compared to a net loss of \$40.5 million, or \$0.94 per share, for the three months ended March 31, 2016. The increase in net loss for the three months ended March 31, 2017 as compared to the same period in 2016 was primarily due to an increase in general and administrative expenses, including the completion of the build out of our commercial organization in the first quarter of 2017, partially offset by a decrease in research and development expenses.

Research and development expenses for the three months ended March 31, 2017 were \$19.5 million, compared to \$27.5 million for the same period in 2016. This decrease was primarily driven by a decrease in TYMLOS/abaloparatide-SC, abaloparatide-TD and elacestrant program development costs, partially offset by an increase in RAD140 development costs.

General and administrative expenses for the three months ended March 31, 2017 were \$38.1 million, compared to \$13.6 million for the same period in 2016. This increase was primarily attributable to an increase in professional support costs, including the costs associated with increasing headcount in preparation for the commercialization of TYMLOS, including the completion of our build out of our commercial organization in the first quarter of 2017. This increase was also driven by an increase in compensation expense, including stock-based compensation, due to an increase in headcount from March 31, 2016 to March 31, 2017.

As of March 31, 2017, Radius had \$282.1 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, subject to favorable regulatory review, of any of its investigational products, it has sufficient capital to fund its development plans, U.S. commercial scale-up and other operational activities for not less than twelve months from the date of this press release and into 2018.

WEBCAST AND CONFERENCE

In connection with the FDA approval of *TYMLOS* announced on April 28, 2017, and today's reporting of First Quarter Financial Results, Radius will host a conference call and live audio webcast at 7:30 a.m. ET on Monday, May 1, 2017 to discuss the commercial outlook for *TYMLOS*, review the financial results and provide a company update.

Webcast Information:

Date: Monday, May 1, 2017

Time: 7:30 a.m. ET

Live webcast: <http://edge.media-server.com/m/p/z5woy3>

A replay of the will be available on the company's website, www.radiuspharm.com in the Investor section under Events and Presentations for 7 days following the live webcast.

Conference Call Information:

Date: Monday, May 1, 2017

Time: 7:30 a.m. ET

Domestic Dial-in Number: 1-844-401-2425

International Dial-in Number: 1-209-905-5954

A replay of the conference call will be available two hours after the call and can be accessed by dialing:

Domestic Replay Number: 1-855-859-2056

International Replay Number (404) 537-3406

Conference Call ID Number: 16763072

About Radius

Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases. Radius' lead product, *TYMLOS* (abaloparatide) injection, was approved by the U.S. Food and Drug Administration for the treatment of postmenopausal women with osteoporosis at high risk for fracture. Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis is under regulatory review in Europe. The Radius clinical pipeline includes an investigational abaloparatide transdermal patch for potential use in osteoporosis and the investigational drug elacestrant (RAD1901) for potential use in hormone-driven and/or hormone-resistant breast cancer, and vasomotor symptoms in postmenopausal women. Radius' RAD140, a non-steroidal, selective androgen receptor modulator (SARM), is under investigation for potential use in hormone receptor positive breast cancer. For more information, please visit www.radiuspharm.com.

About *TYMLOS* (abaloparatide)

TYMLOS (abaloparatide) was approved by the U.S. Food and Drug Administration for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of women with postmenopausal osteoporosis was validated and is currently undergoing regulatory review by the European Medicines Agency (EMA).

Radius also is developing abaloparatide-transdermal (abaloparatide-TD) based on 3M's patented Microstructured Transdermal System technology for potential use as a treatment for postmenopausal women with osteoporosis.

About ACTIVE and ACTIVEExtend

The Phase 3 ACTIVE (Abaloparatide Comparator Trial In Vertebral Endpoints) trial was a randomized, double-blind, placebo-controlled, comparative, multicenter, 18 month international study in 2,463 postmenopausal women with osteoporosis designed to evaluate the efficacy and safety of abaloparatide-SC 80 mcg to reduce the risk of vertebral and nonvertebral fractures. The results of ACTIVE were published in the Journal of the American Medical Association in August of 2016. ACTIVEExtend, an extension of ACTIVE, enrolled patients who had completed 18 months of abaloparatide-SC or placebo in ACTIVE to receive up to 24 additional months of open-label alendronate. The results of the first six months of ACTIVEExtend were published in the Mayo Clinic Proceedings in February of 2017.

About "Together with *TYMLOS*" Program

TYMLOS will be available in the United States in June. For eligible patients, Radius Health will offer the "Together with TYMLOS" support program. For more information please visit www.togetherwithTYMLOS.com or call 1-866-TYMLOS4 (1-866-896-5674) between 8 am and 8 pm EST, Monday through Friday.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF OSTEOSARCOMA

- ▮ **Abaloparatide caused a dose-dependent increase in the incidence of osteosarcoma (a malignant bone tumor) in male and female rats. The effect was observed at systemic exposures to abaloparatide ranging from 4 to 28 times the exposure in humans receiving the 80 mcg dose. It is unknown if TYMLOS will cause osteosarcoma in humans.**
- ▮ **The use of TYMLOS is not recommended in patients at increased risk of osteosarcoma including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton.**
- ▮ **Cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.**

Orthostatic Hypotension: Orthostatic hypotension may occur with TYMLOS, typically within 4 hours of injection. Associated symptoms may include dizziness, palpitations, tachycardia or nausea, and may resolve by having the patient lie down. For the first several doses, TYMLOS should be administered where the patient can sit or lie down if necessary.

Hypercalcemia: TYMLOS may cause hypercalcemia. TYMLOS is not recommended in patients with pre-existing hypercalcemia or in patients who have an underlying hypercalcemic disorder, such as primary hyperparathyroidism, because of the possibility of exacerbating hypercalcemia.

Hypercalciuria and Urolithiasis: TYMLOS may cause hypercalciuria. It is unknown whether TYMLOS may exacerbate urolithiasis in patients with active or a history of urolithiasis. If active urolithiasis or pre-existing hypercalciuria is suspected, measurement of urinary calcium excretion should be considered.

Adverse Reactions: The most common adverse reactions (incidence $\geq 2\%$) are hypercalciuria, dizziness, nausea, headache, palpitations, fatigue, upper abdominal pain and vertigo.

INDICATIONS AND USAGE

TYMLOS is indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, TYMLOS reduces the risk of vertebral fractures and nonvertebral fractures.

Limitations of Use

Because of the unknown relevance of the rodent osteosarcoma findings to humans, cumulative use of TYMLOS and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

For complete TYMLOS prescribing information, including Boxed Warning, please visit www.tymlos.com

About Osteoporosis

Osteoporosis is a silent disease, often displaying no signs or symptoms until a fracture occurs, leaving the majority of patients undiagnosed and untreated, representing a high unmet medical need. Osteoporotic fractures create a significant healthcare burden. An estimated two million osteoporotic fractures occur annually in the United States, and this number is projected to grow to three million by 2025.

The National Osteoporosis Foundation (NOF) has estimated that eight million women already have osteoporosis, and another approximately 44 million may have low bone mass placing them at increased risk for osteoporosis.

The annual incidence of osteoporotic fractures is higher than that of stroke, heart attack and breast cancer combined; osteoporotic fractures also account for more hospitalizations and associated costs than cardiovascular disease and breast cancer.

About Elacestrant (RAD1901)

Elacestrant 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. Elacestrant is currently being investigated for potential use in postmenopausal women with estrogen receptor positive 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.

Additional information on the clinical trial program of elacestrant (RAD1901) is available on www.clinicaltrials.gov.

About RAD140

RAD140 is a non-steroidal selective androgen receptor modulator (SARM). The androgen receptor (AR) is frequently expressed in many estrogen receptor (ER)-positive, ER-negative, and triple-negative 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, and exhibits a differentiated mechanism of action compared to ER-targeted therapy.

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 EMA and the expected timing of potential regulatory actions, the expected timing of potential collaboration agreements, our plans for commercialization of TYMLOS, in the U.S., including the expected timing of the commercial launch and availability of TYMLOS, the progress in the development of our product candidates, including abaloparatide-TD, elacestrant (RAD1901) and RAD140, each of the statements under the heading "Radius Expects The Following Upcoming Milestones," upcoming events and presentations, the sufficiency of our cash, cash equivalents and marketable securities, and the potential clinical uses and therapeutic and other benefits of our product candidates, including abaloparatide-TD, elacestrant 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 TYMLOS, and our inability to ensure that TYMLOS will obtain regulatory approval outside the U.S. or be successfully commercialized in any market in which it is approved, including as a result of risk related to coverage, pricing and reimbursement; risks related to competitive products, 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 or during commercialization, if approved; risk related to manufacturing, supply and distribution; and the risk of litigation or other challenges regarding our intellectual property rights. These and other important risks and uncertainties discussed in our filings with the Securities and Exchange Commission, or SEC, including under the caption "Risk Factors" in our most recent Annual Report on Form 10-K and subsequent filings 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

(Amounts in thousands, except share and per share amounts)

	March 31, 2017	December 31, 2016
ASSETS		
Current assets:		

Cash and cash equivalents	\$ 174,621	\$ 258,567
Restricted cash	47	47
Marketable securities	107,486	73,880
Prepaid expenses and other current assets	<u>6,548</u>	<u>2,315</u>
Total current assets	288,702	334,809
Property and equipment, net	6,106	4,922
Other assets	<u>551</u>	<u>551</u>
Total assets	<u>\$ 295,359</u>	<u>\$ 340,282</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	\$ 6,727	\$ 6,128
Accrued expenses and other current liabilities	<u>26,277</u>	<u>26,597</u>
Total current liabilities	33,004	32,725
Other non-current liabilities	<u>260</u>	<u>379</u>
Total liabilities	<u>33,264</u>	<u>33,104</u>
Stockholders' equity:		
Common stock, \$.0001 par value; 200,000,000 shares authorized, 43,245,804 shares and 43,141,134 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	\$ 4	\$ 4
Additional paid-in-capital	947,042	935,671
Accumulated other comprehensive income	34	71
Accumulated deficit	<u>(684,985)</u>	<u>(628,568)</u>
Total stockholders' equity	<u>262,095</u>	<u>307,178</u>
Total liabilities and stockholders' equity	<u>\$ 295,359</u>	<u>\$ 340,282</u>

Condensed Consolidated Statement of Operations and Comprehensive Loss

(Amounts in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	<u>2017</u>	<u>2016</u>
OPERATING EXPENSES:		
Research and development	\$ 19,527	\$ 27,483
General and administrative	<u>38,099</u>	<u>13,646</u>
Loss from operations	(57,626)	(41,129)
OTHER INCOME (EXPENSE):		
Other income (expense), net	80	(1)
Interest income	<u>607</u>	<u>667</u>
NET LOSS	<u>\$ (56,939)</u>	<u>\$ (40,463)</u>
OTHER COMPREHENSIVE INCOME, NET OF TAX:		
Unrealized (loss) gain from marketable securities	<u>(37)</u>	<u>232</u>
COMPREHENSIVE LOSS	<u>\$ (56,976)</u>	<u>\$ (40,231)</u>
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:	<u>\$ (56,939)</u>	<u>\$ (40,463)</u>
LOSS PER SHARE:		
Basic and diluted	<u>\$ (1.32)</u>	<u>\$ (0.94)</u>
WEIGHTED AVERAGE SHARES:		
Basic and diluted	<u>43,185,952</u>	<u>43,012,924</u>

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