Radius Health Announces First Quarter 2019 Operating Results

May 8, 2019

TYMLOS® U.S. net sales were $29.8 million in the first quarter of 2019 doubling over the first quarter of 2018.

TYMLOS continued increasing its share in the U.S. anabolic osteoporosis market capturing an average of 30% total market share and 42% share in new patients in the first quarter of 2019.

Radius expects TYMLOS to assume anabolic market leadership of new patient starts during the second half of 2019, which if achieved, is expected to translate to total TRx market leadership during 2020.

Radius tightens full-year 2019 financial guidance for TYMLOS U.S. net sales from $155 to $175 million to $160 to $175 million and increases guidance for its year-end cash, cash equivalents & investments balance from over $100 million to over $110 million.

Conference call scheduled for 8:00 a.m. ET today

WALTHAM, Mass., May 08, 2019 (GLOBE NEWSWIRE) -- Radius Health, Inc. ("Radius" or the "Company") (Nasdaq: RDUS), today reported its financial and operating results for the first quarter ended March 31, 2019 and provided a business update.

"I am very pleased to see continued strong market share gains by TYMLOS, which we believe is poised to achieve anabolic leadership of new patient starts in the second half of 2019. Our first quarter sales set the stage for continued growth throughout the year as key new account wins come online and temporary Medicare Part D coverage gaps are satisfied," said Jesper Hoeiland, President and Chief Executive Officer of Radius. "We are confident in our ability to deliver on our full-year financial guidance and attain our goal of leadership in the anabolic market."

TYMLOS (abaloparatide) injection

- First quarter 2019 U.S. net sales of TYMLOS were $29.8 million, a 105% increase from the first quarter of 2018. The anabolic market grew 6% in the first quarter of 2019 as compared to the first quarter of 2018.
- First quarter 2019 TYMLOS U.S. net sales were impacted by anabolic market seasonality that showed lower volumes versus the fourth quarter of 2018, higher gross-to-net expenses due to the impact of the Medicare Part D coverage gap on manufacturers and increased support for commercial patient deductibles.
- In the first quarter of 2019, TYMLOS continued to increase its market share and captured, on average, 30% of the U.S. anabolic osteoporosis market (based on Patient Months on Therapy, TRx PMOT) and 42% of new anabolic patient starts (NBRx). TYMLOS continued to increase its market share in April capturing a 34% share of the U.S. anabolic osteoporosis market and over 44% of new anabolic patient starts. During the second half of 2019, Radius expects TYMLOS to become the NBRx anabolic market leader by reaching over 50% of new patient starts. If achieved, the Company further expects this performance would translate to total TRx market leadership for TYMLOS during 2020.
- At the end of the first quarter of 2019, TYMLOS was covered for approximately 283 million U.S. insured lives, representing approximately 99% of U.S. commercial, 67% of Medicare and 97% Medicaid/Other insured lives. After the decisions of SilverScript Insurance Company (CVS), WellCare Health Plans, Inc., and Prime Therapeutics to cover TYMLOS for their Medicare Part D beneficiaries in 2019, TYMLOS volume in new scripts from Medicare Part D business increased by 22% in the first quarter of 2019 as compared to the fourth quarter of 2018. Growth of TYMLOS volume in new scripts in the commercial business was also strong with a 17% increase in the first quarter of 2019 over the fourth quarter of 2018.
- As of its second anniversary since commercial launch, more than 20,000 patients have received TYMLOS. In three separate network meta-analyses[1] of approved osteoporosis treatments published in the first quarter 2019, TYMLOS showed strong efficacy results in vertebral and non-vertebral fracture risk reduction.
- Radius presented a post-hoc subset analysis on postmenopausal osteoporosis patients with Type 2 diabetes from the Phase 3 ACTIVExtend Study at the American Association of Clinical Endocrinologists conference in April 2019. Among this subgroup of patients, abaloparatide for subcutaneous injection (abaloparatide-SC) treatment for 18 months followed by 25 months of alendronate therapy showed numerical reductions in the risk of vertebral, nonvertebral, clinical and major osteoporotic fractures and significant improvements in bone mineral density versus placebo followed by alendronate. Previously, in the ACTIVE Study cohort that included patients with Type 2 Diabetes, use of abaloparatide-SC for 18 months led to significant improvement in lumbar spine TBS (trabecular bone score), suggesting that abaloparatide-SC improved bone microarchitecture. As the incidence of both Type 2 diabetes and osteoporosis increase with age, they frequently coexist and represent a high unmet medical need population with a lower diagnosis rate for osteoporosis, compromised bone quality and higher fracture risk.

(1) Moreno PB, Kapoor Asi N, et al. Efficacy of pharmacological therapies for the prevention of fractures in postmenopausal women; a network meta-analysis; J Clin Endocrinol Metab. 2019; 104(5)

Abaloparatide for risk reduction of nonvertebral and vertebral fractures in postmenopausal women with osteoporosis: a network meta-analysis Reginster et Al;Osteoporosis International 2019

Drug efficacies on bone mineral density and fracture rate for the treatment of postmenopausal osteoporosis: a network meta-analysis. Yang et Al; Review for Medical and Pharmacological Sciences 2019

Financial Guidance

- Radius tightens its full-year 2019 financial guidance for TYMLOS U.S. net sales from $155 to $175 million to $160 to $175 million and increases guidance for its year-end cash, cash equivalents and investments balance from over $100 million to over $110 million.

Pipeline Highlights

Abaloparatide-Transdermal Patch (abaloparatide-patch)

In the first quarter of 2019, Radius made continued progress in its readiness for clinical supplies for its planned Phase 3 study, reaching targeted scale-up of production and completing analytical method validations. Clinical supplies are planned to be manufactured in the second quarter of 2019 for the Phase 3 study, which the Company expects to initiate in August 2019.

Anticipated Milestones in 2019

- Abaloparatide-patch
    - Initiate Phase 3 study in August 2019
- Elacestrant
    - Advance recruitment in Phase 3 EMERALD monotherapy study
    - Global co-development/co-commercialization partnership for elacestrant
    - Initiate a combination trial for elacestrant in conjunction with a partner
- TYMLOS/Financial
    - Grow full-year TYMLOS U.S. net sales to between $160M to $175M
    - Deliver a strong balance sheet with greater than $110M cash, cash equivalents and investments balance at year-end

Expected Radius Presentations at Upcoming Conferences in Q2 2019

- On May 16, 2019, the Company will present and host one-on-one meetings at the Bank of America Merrill Lynch 2019 Health Care Conference in Las Vegas.
- On June 11-13, 2019, the Company will host one-on-one meetings at the Goldman Sachs 40th Annual Global Healthcare Conference in Palos Verdes, CA.

First Quarter 2019 Financial Results

Three Months Ended March 31, 2019

For the three months ended March 31, 2019, Radius reported a net loss of $42.8 million, or $0.94 per share, compared to a net loss of $61.6 million, or $1.37 per share, for the three months ended March 31, 2018.

For the three months ended March 31, 2019, non-GAAP adjusted net loss, which excludes expenses related to stock-based compensation, restructuring plans, depreciation, non-cash interest obligations under debt obligations, impairment of operating lease right of use assets, and amortization of intangible assets, was $31.8 million, or $0.70 per share, compared to non-GAAP adjusted net loss of $50.1 million, or $1.11 per share, for the three months ended March 31, 2018.

For the three months ended March 31, 2019, TYMLOS net product revenues were $29.8 million compared to approximately $14.5 million for the three months ended March 31, 2018.

Research and development expense for the three months ended March 31, 2019 was $23.3 million compared to $22.9 million for the three months ended March 31, 2018, an increase of $0.4 million, or 2%. This increase was primarily driven by a $3.1 million increase in elacestrant project costs, a $1.8 million increase in abaloparatide-patch project costs, and a $0.4 million increase in abaloparatide-SC project costs. These increases were partially offset by a $1.2 million decrease in other project related spending, a $0.5 million decrease in occupancy and depreciation costs, a $0.1 million decrease in other operating and support costs, and a $3.1 million decrease in personnel related spending attributed to a decrease in headcount from 131 research and development employees as of March 31, 2018 to 95 research and development employees as of March 31, 2019.

For the three months ended March 31, 2019, selling, general and administrative expense was $41.2 million compared to $48.0 million for the three months ended March 31, 2018, a decrease of $6.8 million, or 14%. This decrease was primarily the result of a $4.6 million decrease in compensation related expenses attributed to a decrease in headcount from 405 selling, general, and administrative employees as of March 31, 2018 to 284 selling, general, and administrative employees as of March 31, 2019, a $2.5 million decrease in travel and expense related costs, and a $0.3 million decrease

in other operating costs. These decreases were partially offset by a $0.4 million increase in occupancy and depreciation expenses and a $0.2 million increase in professional fees and support costs.

As of March 31, 2019, Radius had $204.7 million in cash, cash equivalents, restricted cash, and marketable securities. Based upon our cash, cash equivalents and marketable securities balance as of March 31, 2019, we believe that, prior to the consideration of potential proceeds from partnering and/or collaboration activities, we have sufficient capital to fund our development plans, U.S. commercial and other operational activities for at least twelve months from the date of this press release.

Condensed Consolidated Balance Sheets
(Amounts in thousands, except share and per share amounts)

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 71,504	$ 59,321
Restricted cash	562	560
Marketable securities	132,679	177,140
Accounts receivable, net	20,750	16,758
Inventory	5,646	6,210
Prepaid expenses	12,372	13,842
Other current assets	2,651	1,202
Total current assets	246,164	275,033
Property and equipment, net	3,570	4,003
Intangible assets	7,182	7,382
Right of use assets - operating leases	7,450	-
Other assets	501	544
Total assets	$ 264,867	$ 286,962
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,880	$ 4,226
Accrued expenses and other current liabilities	35,632	42,203
Operating lease liability, current	$ 2,168	$ -
Total current liabilities	47,680	46,429
Notes payable	183,556	179,806
Operating lease liability, long term	5,556	-
Other non-current liabilities	71	95
Total liabilities	236,863	226,330
Stockholders' equity:		
Common stock, $.0001 par value; 200,000,000 shares authorized, 45,967,080 shares and 45,563,693 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	5	5
Additional paid-in-capital	1,174,661	1,165,003
Accumulated other comprehensive loss	(281)	(755)
Accumulated deficit	$ (1,146,381)	$ (1,103,621)
Total stockholders' equity	28,004	60,632
Total liabilities and stockholders' equity	$ 264,867	$ 286,962

Condensed Consolidated Statement of Operations and Comprehensive Loss –
(Amounts in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2019	2018
REVENUES:		
Product revenue, net	$ 29,844	$ 14,547
OPERATING EXPENSES:		
Cost of sales - product	3,030	1,088
Cost of sales - intangible amortization	200	200
Research and development	23,259	22,851

Selling, general and administrative	41,186	48,025
Loss from operations	(37,831)	(57,617)
OTHER (EXPENSE) INCOME:		
Other income (expense)	4	(104)
Interest expense	(6,037)	(5,566)
Interest income	1,104	1,732
NET LOSS	(42,760)	(61,555)
OTHER COMPREHENSIVE LOSS:		
Unrealized gain (loss) from available-for-sale debt securities	$ 474	$ (1,169)
COMPREHENSIVE LOSS	(42,286)	(62,724)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED	$ (42,760)	$ (61,555)
LOSS PER SHARE:		
Basic and diluted	$ (0.94)	$ (1.37)
WEIGHTED AVERAGE SHARES:		
Basic and diluted	45,671,502	44,937,776

Reconciliation of GAAP to Non-GAAP Financial Information
(Unaudited amounts in thousands, except share and per share amounts)

	Three Months Ended March 31, 2019	2018
Net loss reconciliation:		
GAAP net loss	$ (42,760)	$ (61,555)
Intangible amortization	200	200
Stock-based compensation expense	6,115	7,549
Restructuring charges	147	-
Depreciation	433	471
Non-cash interest	3,750	3,278
Operating Lease Impairment	339	-
Non-GAAP net loss	$ (31,776)	$ (50,057)
Reconciliation of diluted loss per share:		
GAAP loss per share	(0.94)	(1.37)
Intangible amortization	-	-
Stock-based compensation expense	0.14	0.17
Restructuring charges	-	-
Depreciation	0.01	0.01
Non-cash interest	0.08	0.08
Operating Lease Impairment	0.01	-
Non-GAAP loss per share	$ (0.70)	$ (1.11)
Reconciliation of shares used in loss per share calculation:		
GAAP shares used in loss per share	45,671,502	44,937,776
Non-GAAP dilutive share adjustments	-	-
Non-GAAP shares used in loss per share	45,671,502	44,937,776

Webcast and Conference Call

In connection with today's reporting of First Quarter 2019 Financial Results, Radius will host a conference call and live audio webcast at 8:00 a.m. ET today, May 8, 2019, to discuss the commercial outlook for TYMLOS, review the financial results and provide a Company update.

Conference Call Information:
Date: May 8, 2019
Time: 8:00 a.m. ET
Domestic Dial-in Number: (866) 323-7965
International Dial-in Number: (346) 406-0961
Conference ID: 5856126
Live webcast:
https://edge.media-server.com/m6/p/c3hxzj9k

For those unable to participate in the conference call or webcast, a replay will be available on Wednesday, May 8, 2019 at 11:00 a.m. ET and will be

archived on the Company's website for 90 days. To access the replay, dial (855) 859-2056 for U.S. or (404) 537-3406 for International, using conference ID number 5856126.

A live audio webcast of the call can be accessed from the Investors section of the Company's website, www.radiuspharm.com. The full text of the announcement and financial results will also be available on the Company's website.

Use of Non-GAAP Financial Measures
To supplement our condensed consolidated financial statements, which are prepared and presented in accordance with generally accepted accounting principles in the United States (GAAP), we use the following non-GAAP financial measures in this press release: non-GAAP adjusted net loss and non-GAAP net loss per share. These non-GAAP financial measures exclude certain amounts or expenses from the corresponding financial measures determined in accordance with GAAP. Management believes this non-GAAP information is useful for investors, taken in conjunction with Radius' GAAP financial statements, because it provides greater transparency and period-over-period comparability with respect to Radius' operating performance and can enhance investors' ability to identify operating trends in our business. Management uses these measures, among other factors, to assess and analyze operational results and trends and to make financial and operational decisions. Non-GAAP information is not prepared under a comprehensive set of accounting rules and should only be used to supplement an understanding of Radius' operating results as reported under GAAP, not in isolation or as a substitute for, or superior to, financial information prepared and presented in accordance with GAAP. In addition, these non-GAAP financial measures are unlikely to be comparable with non-GAAP information provided by other companies. The determination of the amounts that are excluded from non-GAAP financial measures is a matter of management judgment and depends upon, among other factors, the nature of the underlying expense or income amounts. Reconciliations between these non-GAAP financial measures and the most comparable GAAP financial measures for the three months ended March 31, 2018 and 2019 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

About Radius
Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine therapeutics in the areas of osteoporosis and oncology. 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. The Radius clinical pipeline includes an investigational abaloparatide-patch for potential use in osteoporosis; the investigational drug elacestrant (RAD1901) for potential use in hormone-receptor positive breast cancer; and the investigational drug RAD140, a non-steroidal, selective androgen receptor modulator (SARM) under investigation for potential use in hormone-receptor positive breast cancer. For more information, please visit www.radiuspharm.com.

About *TYMLOS* (abaloparatide) injection
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 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 also is developing abaloparatide-patch based on 3M Company's patented Microstructured Transdermal System technology for potential use as a treatment for postmenopausal women with osteoporosis.

About Elacestrant (RAD1901)
Elacestrant is a selective estrogen receptor degrader (SERD), which is being evaluated for potential use as a once daily oral treatment for hormone-receptor positive breast cancer. Elacestrant is currently being investigated for potential use in women with advanced estrogen receptor positive, HER2 negative, 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.

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 our expectations for full-year TYMLOS U.S. net sales and our year-end cash, cash equivalents and investments balance; our expectations regarding commercialization of TYMLOS in the U.S., including expectations that it will become the leader in the U.S. anabolic osteoporosis market and the timing thereof; our expectations regarding our regulatory submissions, including the timing thereof; our expectations regarding our clinical trials, including the design and timing thereof; our entry into potential collaborations, including the timing thereof, including our plans to enter into a global co-development, co-commercialization partnership for elacestrant; the progress in the development of our product candidates, including abaloparatide-patch, elacestrant (RAD1901) and RAD140; each of the statements under the headings "Anticipated Milestones in 2019," and "Expected Radius Presentations at Upcoming Conferences in Q2 2019;" the sufficiency of our cash, cash equivalents, restricted cash, marketable securities and investments balance; and the potential clinical uses and therapeutic and other benefits of our product candidates, including abaloparatide-patch, 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 expect to 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; risks related to our ability to successfully enter into collaboration agreements and any executed 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; risks 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 Annual Report on Form 10-K for the year ending December 31, 2018 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.

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Source: Radius Health Inc.