



## Radius Health Announces Second Quarter 2019 Operating Results

August 7, 2019

*TYMLOS® U.S. net sales were \$41.0 million in the second quarter of 2019, an 81% growth over the second quarter of 2018.*

*TYMLOS continued increasing its share of the U.S. anabolic osteoporosis market capturing an average of 35% total market share and 46% share in new patients in the second quarter of 2019.*

*Radius initiated Phase 3 'wearABLE' Study of abaloparatide-patch following previous SPA agreement with the FDA and presented results from abaloparatide-patch patient assessment study*

*Radius tightens full-year 2019 financial guidance for TYMLOS U.S. net sales to \$165 to \$170 million and increases guidance for its year-end cash, cash equivalents & investments balance to over \$120 million.*

*Conference call scheduled for 4:30 p.m. ET today*

WALTHAM, Mass., Aug. 07, 2019 (GLOBE NEWSWIRE) -- Radius Health, Inc. ("Radius" or the "Company") (Nasdaq: RDUS), today reported its financial and operating results for the second quarter ended June 30, 2019 and provided a business update.

"I am delighted to see continued market share growth of TYMLOS, which puts us on track to attain our goal of anabolic leadership of new patient starts in the second half of 2019," said Jesper Hoeiland, President and Chief Executive Officer of Radius. "Initiation of the Company's Phase 3 abaloparatide-patch study has been a major milestone toward our mission of addressing the needs of osteoporosis patients."

### **TYMLOS (abaloparatide) injection**

- Second quarter 2019 U.S. net sales of TYMLOS were \$41.0 million, an 81% increase from the second quarter of 2018. The anabolic market grew 4% in the first half of 2019 as compared to the first half of 2018.
- In the second quarter of 2019, TYMLOS continued to increase its market share and captured, on average, 35% of the U.S. anabolic osteoporosis market (based on Patient Months on Therapy, TRx PMOT) and 46% of new anabolic patient starts (NBRx).
- 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.

### **Financial Guidance**

- Radius tightens its full-year 2019 financial guidance for TYMLOS U.S. net sales to \$165 to \$170 million and increases guidance for its year-end cash, cash equivalents and investments balance to over \$120 million.

### **Pipeline Highlights**

#### **Abaloparatide-Patch**

- In July 2019, Radius obtained preliminary results from the abaloparatide-transdermal patch (abaloparatide-patch) patient assessment study which evaluated self-administration of abaloparatide-patch over 29 days in 22 postmenopausal women with low bone density. The patients were observed at a study site on the first, 15<sup>th</sup> and 29<sup>th</sup> day of the study. Top-line study results showed that patients were able to follow the instructions for use (IFU) and applied the patches with a 99.7% success rate. The data also measured patient acceptability and indicated changes in patient PINP (procollagen type I propeptide) levels. The mean subject acceptability score on a 5-point scale was  $\geq 4.5$  at each site visit. An exploratory assessment of PINP levels, a biomarker that indicates bone formation, compared the PINP results at one month in this study with the one-month results in the Phase 3 ACTIVE study of TYMLOS (abaloparatide injection). The PINP levels and baseline increase at one month in this study were consistent with those values seen with abaloparatide injection at one month in the ACTIVE trial. At baseline, the median PINP level was 50.5 ng/ml, increasing to a median value of 100.1 ng/ml at day 29. The median PINP values observed with abaloparatide injection in the ACTIVE study were 50.6 ng/ml at baseline and 100.5 ng/ml at one month.
- On August 5, 2019, the first patient was randomized in the Phase 3 wearABLE clinical trial studying the safety and efficacy of abaloparatide-patch in the treatment of postmenopausal patients with osteoporosis at high risk for fracture.
- Prior to initiating the study, the Company achieved a Special Protocol Assessment (SPA) agreement with the U.S. Food

and Drug Administration (FDA) for the acceptability of the overall protocol design. An SPA agreement provides a concurrence with the FDA that the study can be considered adequate and well-controlled in support of a marketing application.

- The wearABLE Phase 3 study is a pivotal, randomized, open label, active-controlled, bone mineral density (“BMD”) non-inferiority bridging study that will evaluate the efficacy and safety of abaloparatide-patch versus TYMLOS (abaloparatide injection) in approximately 470 patients with postmenopausal osteoporosis at high risk of fracture. The primary endpoint of the study is the percentage of change in lumbar spine BMD at 12 months. Non-inferiority of abaloparatide-patch to abaloparatide injection will be concluded if the lower bound of the 2-sided 95% confidence interval for the estimated treatment difference (abaloparatide-patch minus abaloparatide injection) in the percentage change from baseline in lumbar spine BMD at 12 months is above -2.0%. A non-inferiority margin of 2% preserves ~77% of the historical effect of TYMLOS based on the data from the Phase 3 ACTIVE Study which showed placebo-adjusted increase in lumbar spine BMD of 9.1% (95% CI: 8.6%, 9.6%) at 12 months.
- The wearABLE Phase 3 study is currently open for enrollment at multiple clinical sites. Radius plans to complete patient recruitment in this study by the end of 2019.

#### **Anticipated Milestones in 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 \$165M to \$170M
  - Deliver greater than \$120M cash, cash equivalents and investments balance at year-end

#### **Expected Radius Presentations at Upcoming Conferences in Q2 2019**

- On September 5, 2019, the Company will host one-on-one meetings at the Citi's 14<sup>th</sup> Annual Biotech Conference in Boston, MA.
- On September 11, 2019, the Company will present and host one-on-one meetings at the Morgan Stanley 17<sup>th</sup> Annual Global Healthcare Conference in New York City, NY.

#### **Second Quarter 2019 Financial Results**

##### **Three Months Ended June 30, 2019**

For the three months ended June 30, 2019, Radius reported a net loss of \$35.5 million, or \$0.77 per share, compared to a net loss of \$68.9 million, or \$1.52 per share, for the three months ended June 30, 2018.

For the three months ended June 30, 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 \$25.4 million, or \$0.55 per share, compared to non-GAAP adjusted net loss of \$44.6 million, or \$0.98 per share, for the three months ended June 30, 2018.

For the three months ended June 30, 2019, TYMLOS net product revenues were \$41.0 million compared to approximately \$22.6 million for the three months ended June 30, 2018.

For the three months ended June 30, 2019, research and development expense was \$27.2 million compared to \$26.3 million for the three months ended June 30, 2018, an increase of \$0.9 million, or 3%. This increase was primarily driven by a \$5.0 million increase in abaloparatide-patch project costs, and a \$0.5 million increase in abaloparatide-SC project costs. These increases were partially offset by a \$0.7 million decrease in project costs for elacestrant, a \$0.3 million decrease in professional costs, and a \$3.6 million decrease in compensation expenses.

For the three months ended June 30, 2019, selling, general and administrative expense was \$40.1 million compared to \$48.6 million for the three months ended June 30, 2018, a decrease of \$8.5 million, or 17%. This decrease was primarily the result of a \$6.2 million decrease in compensation related expenses attributed to a decrease in headcount from 338 selling, general, and administrative employees as of June 30, 2018 to 289 selling, general, and administrative employees as of June 30, 2019, a \$1.2 million decrease in professional costs, a \$0.3 million decrease in travel and expense related costs, and a \$0.8 million decrease in occupancy, depreciation, and other operating costs.

##### **Six Months Ended June 30, 2019**

For the six months ended June 30, 2019, Radius reported a net loss of \$78.2 million, or \$1.70 per share, compared to a net loss of \$130.4 million, or \$2.89 per share, for the six months ended June 30, 2018.

For the six months ended June 30, 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 \$57.2 million, or \$1.25 per share, compared to non-GAAP adjusted net loss of \$94.7 million, or \$2.10 per share, for the six months ended June 30, 2018.

For the six months ended June 30, 2019, TYMLOS net product revenues were \$70.9 million compared to approximately \$37.2 million for the six months ended June 30, 2018.

For the six months ended June 30, 2019, research and development expense was \$50.4 million compared to \$49.2 million for the six months ended June 30, 2018, an increase of \$1.3 million, or 3%. This increase was primarily driven by a \$6.8 million increase in abaloparatide-patch project costs, a \$2.4 million increase in project costs for elacestrant, and a \$0.9 million increase in abaloparatide-SC project costs. These increases were partially offset by a \$1.2 million decrease in RAD140 project costs, a \$0.5 million decrease in occupancy and depreciation costs, a \$0.4 million decrease in other operating and support costs, and a \$6.7 million decrease in compensation expenses.

For the six months ended June 30, 2019, selling, general and administrative expense was \$81.3 million compared to \$96.6 million for the six months ended June 30, 2018, a decrease of \$15.3 million, or 16%. This decrease was primarily the result of a \$10.8 million decrease in compensation related expenses attributed to a decrease in headcount from 338 selling, general, and administrative employees as of June 30, 2018 to 289 selling, general, and administrative employees as of June 30, 2019, a \$2.8 million decrease in travel and expense related costs, a \$1.0 decrease in professional fees, and a \$1.0 million decrease in other operating costs. These decreases were partially offset by a \$0.3 million increase in occupancy and depreciation expenses.

As of June 30, 2019, Radius had \$189.0 million in cash, cash equivalents, restricted cash, and marketable securities. Based upon our cash, cash equivalents and marketable securities balance as of June 30, 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)

	June 30, 2019	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 66,901	\$ 59,321
Restricted cash	563	560
Marketable securities	121,576	177,140
Accounts receivable, net	23,649	16,758
Inventory	5,157	6,210
Prepaid expenses	8,186	13,842
Other current assets	873	1,202
Total current assets	226,905	275,033
Property and equipment, net	2,983	4,003
Intangible assets	6,982	7,382
Right of use assets - operating leases	6,940	-
Other assets	486	544
Total assets	\$ 244,296	\$ 286,962
<b>LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 6,041	\$ 4,226
Accrued expenses and other current liabilities	43,759	42,203
Operating lease liability, current	2,029	-
Total current liabilities	51,829	46,429
Notes payable	187,434	179,806
Operating lease liability, long term	5,120	-
Other non-current liabilities	47	95
Total liabilities	244,430	226,330
Stockholders' equity:		
Common stock, \$.0001 par value; 200,000,000 shares authorized, 46,125,197 shares and 45,563,693 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	5	5
Additional paid-in-capital	1,181,761	1,165,003
Accumulated other comprehensive loss	(45)	(755)
Accumulated deficit	(1,181,855)	(1,103,621)

Total stockholders' equity (deficit)	(134	)	60,632
Total liabilities and stockholders' equity (deficit)	\$ 244,296		\$ 286,962

### Condensed Consolidated Statement of Operations and Comprehensive Loss –

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
REVENUES:				
Product revenue, net	\$ 41,042	\$ 22,629	\$ 70,886	\$ 37,176
OPERATING EXPENSES:				
Cost of sales - product	3,808	1,603	6,838	2,691
Cost of sales - intangible amortization	200	200	399	399
Research and development	27,179	26,324	50,439	49,175
Selling, general, and administrative	40,115	48,579	81,301	96,605
Other operating expense	-	10,801	-	10,801
Loss from operations	(30,260 )	(64,878 )	(68,091 )	(122,495 )
OTHER (EXPENSE) INCOME:				
Other income (expense)	(42 )	171	(38 )	66
Interest expense	(6,165 )	(5,683 )	(12,202 )	(11,248 )
Interest income	993	1,508	2,097	3,240
NET LOSS	\$ (35,474 )	\$ (68,882 )	\$ (78,234 )	\$ (130,437 )
OTHER COMPREHENSIVE LOSS:				
Unrealized gain (loss) from available-for-sale debt securities	236	192	710	(976 )
COMPREHENSIVE LOSS	\$ (35,238 )	\$ (68,690 )	\$ (77,524 )	\$ (131,413 )
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:	\$ (35,474 )	\$ (68,882 )	\$ (78,234 )	\$ (130,437 )
LOSS PER SHARE:				
Basic and diluted	\$ (0.77 )	\$ (1.52 )	\$ (1.70 )	\$ (2.89 )
WEIGHTED AVERAGE SHARES:				
Basic and diluted	46,109,193	45,430,678	45,891,557	45,185,588

### Reconciliation of GAAP to Non-GAAP Financial Information

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2019	2018	2019	2018
<b>Net loss reconciliation:</b>				
GAAP net loss	\$ (35,474 )	\$ (68,882 )	\$ (78,234 )	\$ (130,437 )
Intangible amortization	200	200	399	399
Stock-based compensation expense	5,748	8,020	11,863	15,570
Restructuring charges	(155 )	1,400	(8 )	1,400
Depreciation	387	469	820	941
Non-cash interest	3,878	3,390	7,628	6,668
Operating Lease Impairment	-	-	339	-
Ipsen payment	-	10,801	-	10,801
Non-GAAP net loss	\$ (25,416 )	\$ (44,602 )	\$ (57,193 )	\$ (94,658 )
<b>Reconciliation of diluted loss per share:</b>				
GAAP loss per share	\$ (0.77 )	\$ (1.52 )	\$ (1.70 )	\$ (2.89 )
Intangible amortization	0.01	0.01	0.01	0.01
Stock-based compensation expense	0.12	0.18	0.25	0.34
Restructuring charges	-	0.03	-	0.03
Depreciation	0.01	0.01	0.02	0.02
Non-cash interest	0.08	0.07	0.16	0.15

Operating Lease Impairment	-	-	0.01	-
Ipsen payment	-	0.24	-	0.24
Non-GAAP loss per share	\$ (0.55 )	\$ (0.98 )	\$ (1.25 )	\$ (2.10 )

**Reconciliation of shares used in loss per share calculation:**

GAAP shares used in loss per share	46,109,193	45,430,678	45,891,557	45,185,588
Non-GAAP dilutive share adjustments	-	-	-	-
Non-GAAP shares used in loss per share	46,109,193	45,430,678	45,891,557	45,185,588

**Webcast and Conference Call**

In connection with today's reporting of Second Quarter 2019 Financial Results, Radius will host a conference call and live audio webcast at 4:30 p.m. ET today, August 7, 2019, to review the commercial, research and development, and financial highlights and provide a Company update.

**Conference Call Information:**

**Date:** August 7, 2019

**Time:** 4:30 pm ET

**Domestic Dial-in Number:** (866) 323-7965

**International Dial-in Number:** (346) 406-0961

**Conference ID:** 7599558

**Live webcast:**

<https://edge.media-server.com/mmc/p/ysdq6fi>

For those unable to participate in the conference call or webcast, a replay will be available on Wednesday, August 7, 2019 at 7:30 p.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 7599558.

A live audio webcast of the call can be accessed from the Investors section of the Company's website, [www.radiuspharm.com](http://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 June 30, 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](http://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.

**About Abaloparatide-Patch**

Abaloparatide-patch was developed in a collaboration between Radius and 3M Company with the application of 3M's innovative microstructured transdermal patch technology. The Phase 3 wearABLE abaloparatide-patch study is the first pivotal study to evaluate treatment of a novel non-injectable delivery of an anabolic therapy.

**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.

**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. 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 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; the potential benefits of the SPA agreement for abaloparatide-patch and results from the patient assessment study of abaloparatide-patch; 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.

#### **Investor & Media Relations Contact:**

Elhan Webb, CFA

Email: [ewebb@radiuspharm.com](mailto:ewebb@radiuspharm.com)

Phone: 617-551-4011



Source: Radius Health Inc.