Radius Health Announces Fourth Quarter and Full-Year 2019 Operating Results

February 27, 2020

TYMLOS® U.S. net sales grew to $56 million in the fourth quarter of 2019,

totaling $173M for full-year 2019, exceeding the Company's guidance of $168 to 172M

TYMLOS exited 2019 with majority share in new patients[1], on track for market leadership in 2020

2020 TYMLOS U.S. net revenue expected to be between $220 and $235M and full-year cash burn expected to be below $80M

Recruitment of three Phase 3 studies is advancing and expected to be completed in 2020, with anticipated data read-outs in the second half of 2021

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

WALTHAM, Mass, Feb. 27, 2020 (GLOBE NEWSWIRE) -- Radius Health, Inc. ("Radius" or the "Company") (Nasdaq: RDUS), today reported its financial and operating results for the fourth quarter and full-year ended December 31, 2019 and provided a business update.

"I am very pleased that TYMLOS exited 2019 with a December majority share of postmenopausal osteoporosis patients starting on anabolic therapy in the U.S. market. In 2020, we have three critical objectives: continue expanding our market share for TYMLOS, reach anabolic total market share leadership, and complete recruitment in our three pivotal Phase 3 studies," said Jesper Hoeiland, President and Chief Executive Officer of Radius.

TYMLOS (abaloparatide) injection

- Fourth quarter 2019 U.S. net sales of TYMLOS were $55.7 million, a 19% increase over the prior quarter and 62% increase from the fourth quarter of 2018. Full-year 2019 U.S. net sales of TYMLOS were $173.3 million, a 75% increase over full-year 2018.
- In 2019, TYMLOS captured, on average, 36% of the U.S. anabolic osteoporosis market (based on Patient Months on Therapy, TRx PMOT). In the fourth quarter of 2019, TYMLOS' average U.S. anabolic market share rose to 41% and it achieved a 50% share of new anabolic patient starts. Radius remains confident TYMLOS® will become the anabolic market leader (based on TRx[2]) in 2020.
- TYMLOS is covered for approximately 290 million U.S. insured lives, 99% of Commercial and 83% of Medicare Part D insured lives. The Medicare Part D coverage has increased 16 percentage points from 2019 due to decisions from Aetna, CIGNA and Anthem to cover TYMLOS for their Medicare Part D beneficiaries in 2020.

Pipeline Highlights

Abaloparatide-SC

- Radius expects to complete recruitment of the ATOM Phase 3 Study, which is assessing the efficacy and safety of abaloparatide-SC in male osteoporosis, this year and report top-line data in the second half of 2021.

Abaloparatide-Patch

- The wearABLe Phase 3 study is open for enrollment at more than 60 clinical sites in the U.S., reflecting strong interest from investigators. The Company has implemented a revised enrollment plan, added more clinical sites in the U.S., and made progress filing regulatory submissions to expand sites outside the U.S. The screen failure rate which started higher than expected at the initiation of the study is improving, driven by higher screening success at targeted bone specialty sites.
- Radius expects to report top-line data from the study in the second half of 2021.

Elacestrant

- The EMERALD Phase 3 study is currently enrolling patients in multiple countries and is on track to complete recruitment of 466 patients in the third quarter of 2020.

Financial Highlights and Guidance

- With 2019 TYMLOS U.S. net sales reaching $173 million, Radius exceeded its 2019 full-year net sales guidance of $168 to $172 million. Radius closed 2019 with $161 million cash, cash equivalents and investments balance, driven by

productivity initiatives, in line with its year-end guidance to exceed $130 million.

- For 2020, Radius expects full-year TYMLOS U.S. net revenue to be between $220 and $235 million and its full-year cash burn to be below $80 million.
- On January 10, 2020, the Company entered into a secured, non-dilutive credit facility for up to an aggregate amount of $95 million, comprised of a term loan of up to $55 million and a $20 million revolving credit facility based on accounts receivable and inventory, with the right, subject to certain conditions, to increase the revolver by $20 million. The credit facility has a maturity date of June 1, 2024. This funding is intended to support pre-launch activities for abaloparatide-patch, evaluation of opportunities in targeted endocrine diseases, and to strengthen the Company's minimum cash balance toward profitability.
- Over the next three years (2020-2022) Radius expects TYMLOS revenue to grow at a greater than 20% compound annual growth rate and the Company to achieve profitability.

Anticipated Milestones in 2020

- Clinical Pipeline
  - Complete recruitment in Phase 3 ATOM study
  - Complete recruitment in Phase 3 wearABLe study
  - Complete recruitment in Phase 3 EMERALD study
- TYMLOS
  - Grow full-year TYMLOS U.S. net sales to between $220 and $235 million
  - Capture anabolic TRx market leadership in 2H 2020

Expected Radius Presentations at Upcoming Conferences in Q1 2020

- On February 27, 2020, the Company will present and host one-on-one meetings at the 9th Annual SVB Leerink Global Healthcare Conference in New York.
- On March 4, 2020, the Company will present and host one-on-one meetings at Cowen 40th Annual Health Care Conference in Boston.
- On March 17, 2020, the Company will host one-on-one meetings at the Morgan Stanley Healthcare Corporate Access Day in Boston.

Fourth Quarter and Full-Year 2019 Financial Results

Three months ended December 31, 2019

For the three months ended December 31, 2019, Radius reported a net loss of $24.7 million, or $0.54 per share, compared to a net loss of $41.1 million, or $0.90 per share, for the three months ended December 31, 2018.

For the three months ended December 31, 2019, non-GAAP adjusted net loss, which excludes expenses related to stock-based compensation, depreciation, non-cash interest obligations under debt obligations, and amortization of intangible assets, was $13.3 million, or $0.29 per share, compared to non-GAAP adjusted net loss of $30.0 million, or $0.66 per share, for the three months ended December 31, 2018.

For the three months ended December 31, 2019 we recorded approximately $55.7 million of net product revenue compared to $34.4 million for the three months ended December 31, 2018.

For the three months ended December 31, 2019, research and development expense was $34.5 million compared to $23.9 million for the three months ended December 31, 2018, an increase of $10.6 million, or 44%. This increase was primarily driven by increases in elacestrant project costs and abaloparatide-patch project costs of $5.4 million and $5.7 million, respectively.

For the three months ended December 31, 2019, selling, general and administrative expense was $35.7 million compared to $43.9 million for the three months ended December 31, 2018, a decrease of $8.2 million, or 19%. This decrease was primarily the result of a $4.4 million decrease in professional fees, a $2.3 million decrease in compensation and travel costs, and a $0.9 million decrease in other operating costs.

Twelve months Ended December 31, 2019

For the twelve months ended December 31, 2019, Radius reported a net loss of $133.0 million, or $2.89 per share, compared to a net loss of $221.4 million, or $4.88 per share, for the twelve months ended December 31, 2018.

For the twelve months ended December 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 $90.9 million, or $1.98 per share, compared to non-GAAP adjusted net loss of $163.0 million, or $3.59 per share, for the twelve months ended December 31, 2018.

For the twelve months ended December 31, 2019 we recorded approximately $173.3 million of net product revenue compared to $99.2 million for the twelve months ended December 31, 2018.

For the twelve months ended December 31, 2019, research and development expense was $116.8 million, as compared to $99.9 million for the twelve months ended December 31, 2018, an increase of $16.8 million, or 17%. This increase was primarily a result of an increase of $16.1 million in program spending for the abaloparatide-patch program, a $9.8 million increase in program spending for elacestrant research, a $1.7 million increase in professional services, and $0.6 million increase in program spending for the abaloparatide-SC program. These increases were partially offset by a $1.9 million decrease in program spending for RAD-140 program, a $0.3 million decrease in R&D support costs as well as an $9.2 million decrease in compensation related costs.

For the twelve months ended December 31, 2019, selling, general, and administrative expense was $152.7 million, as compared to $184.2 million for the twelve months ended December 31, 2018, a decrease of $31.5 million, or 17%. This decrease was primarily due to a $10.0 million decrease in professional fees related to commercial operations and general and administrative activities, a $17.9 million decrease in compensation and travel entertainment costs and a $3.6 million decrease in other costs.

As of December 31, 2019, Radius had $161.5 million in cash, cash equivalents, restricted cash, and marketable securities. Based upon our cash, cash equivalents and marketable securities balance as of December 31, 2019 and funds available to us through our credit facilities, 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.

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

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 69,886	$ 59,321
Restricted cash	567	560
Marketable securities	91,015	177,140
Accounts receivable, net	23,289	16,758
Inventory	5,323	6,210
Prepaid expenses	12,131	13,842
Other current assets	846	1,202
Total current assets	203,057	275,033
Property and equipment, net	2,293	4,003
Intangible assets	6,583	7,382
Right of use assets - operating leases	6,704	-
Other assets	514	544
Total assets	$ 219,151	$ 286,962
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 6,030	$ 4,226
Accrued expenses and other current liabilities	53,030	42,203
Operating lease liability, current	2,198	-
Total current liabilities	61,258	46,429
Notes payable	195,591	179,806
Operating lease liability, long term	4,581	-
Other non-current liabilities	-	95
Total liabilities	261,430	226,330

Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 200,000,000 shares authorized, 46,189,870 shares and 45,563,693 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	5	5
Additional paid-in-capital	1,194,327	1,165,003
Accumulated other comprehensive income (loss)	3	(755)
Accumulated deficit	(1,236,614)	(1,103,621)
Total stockholders' equity (deficit)	(42,279)	60,632
Total liabilities and stockholders' equity (deficit)	$ 219,151	$ 286,962

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	**2018**	**2019**	**2018**
REVENUES:				
Product revenue, net	$ 55,665	$ 34,424	$ 173,317	$ 99,239
OPERATING EXPENSES:				
Cost of sales - product	4,478	2,743	15,287	7,627
Cost of sales - intangible amortization	198	199	798	799
Research and development	34,528	23,932	116,757	99,911
Selling, general, and administrative	35,786	43,899	152,704	184,164
Other operating expense	-	-	-	10,801
Loss from operations	(19,325)	(36,349)	(112,229)	(204,063)
OTHER (EXPENSE) INCOME:				
Other income (expense)	221	(25)	242	59
Interest expense	(6,435)	(5,913)	3,929	5,622
Interest income	824	1,189	(24,935)	(22,955)
NET LOSS	$ (24,715)	$ (41,098)	$ (132,993)	$ (221,337)
OTHER COMPREHENSIVE LOSS:				
Unrealized gain (loss) from available-for-sale debt securities	(18)	94	758	(441)
COMPREHENSIVE LOSS	$ (24,733)	$ (41,004)	$ (132,235)	$ (221,778)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:	$ (24,715)	$ (41,098)	$ (132,993)	$ (221,337)
LOSS PER SHARE:				
Basic and diluted	$ (0.54)	$ (0.90)	$ (2.89)	$ (4.88)
WEIGHTED AVERAGE SHARES:				
Basic and diluted	46,176,145	45,549,972	46,026,217	45,356,263

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2019	**2018**	**2019**	**2018**
Net loss reconciliation:				
GAAP net loss	$ (24,715)	$ (41,098)	$ (132,993)	$ (221,337)
Intangible amortization	198	199	798	799
Stock-based compensation expense	6,704	6,433	23,615	28,702
Restructuring charges	-	338	(8)	2,366

Depreciation	322	486	1,509	1,891
Non-cash interest	4,147	3,626	15,785	13,800
Operating Lease Impairment	-	-	339	-
Ipsen payment	-	35	-	10,836
Non-GAAP net loss	$ (13,344)	$ (29,981)	$ (90,955)	$ (162,943)
Reconciliation of diluted loss per share:				
GAAP loss per share	$ (0.54)	$ (0.90)	$ (2.89)	$ (4.88)
Intangible amortization	-	-	0.02	0.02
Stock-based compensation expense	0.15	0.14	0.51	0.63
Restructuring charges	-	0.01	-	0.05
Depreciation	0.01	0.01	0.03	0.04
Non-cash interest	0.09	0.08	0.34	0.31
Operating Lease Impairment	-	-	0.01	-
Ipsen payment	-	-	-	0.24
Non-GAAP loss per share	$ (0.29)	$ (0.66)	$ (1.98)	$ (3.59)
Reconciliation of shares used in loss per share calculation:				
GAAP shares used in loss per share	46,176,145	45,549,972	46,026,217	45,356,263
Non-GAAP dilutive share adjustments	-	-	-	-
Non-GAAP shares used in loss per share	46,176,145	45,549,972	46,026,217	45,356,263

Webcast and Conference Call

In connection with today's reporting of Fourth Quarter and Full Year 2019 Financial Results, Radius will host a conference call and live audio webcast at 8:00 a.m. ET today, February 27, 2020, to review the commercial, research and development, and financial highlights and provide a Company update.

Conference Call Information:
Date: February 27, 2020
Time: 8:00 a.m. ET
Domestic Dial-in Number: (866) 323-7965
International Dial-in Number: (346) 406-0961
Conference ID: 2998060
Live webcast: https://edge.media-server.com/mmc/p/kpudy8gx

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.

For those unable to participate in the conference call or webcast, a replay will be available on Thursday, February 27, 2020 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 2998060.

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 December 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. 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 abaloparatide-SC under investigation for potential use in men with osteoporosis; 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.

About ATOM Phase 3 Study
The ATOM Phase 3 study is a randomized, double-blind, placebo-controlled study to assess efficacy and safety of abaloparatide-SC in approximately 225 men with osteoporosis. The primary endpoint is change in lumbar spine BMD at 12 months compared with placebo, and if successful, will form the basis of a supplemental NDA seeking to expand the use of TYMLOS to treat men with osteoporosis at high risk for fracture.

About Abaloparatide-Patch and wearABLe Phase 3 Study
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 using a novel non-injectable delivery of an anabolic therapy. 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 for fracture. The primary endpoint of the study is the percentage change in lumbar spine BMD at 12 months.

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 full-year cash burn; our expectations regarding achieving profitability and the timing thereof; 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, that TYMLOS revenue will grow at greater than a twenty percent compound annual growth rate over the years 2020 to 2020, and projected increases in insurance coverages for TYMLOS; our expectations regarding our regulatory submissions, including the timing thereof; our expectations regarding our clinical trials, including the design and timing thereof and our expectations to report top-line data from our Phase 3 wearABLe trial of abaloparatide-patch, Phase 3 EMERALD trial of elacestrant, and Phase 3 ATOM trial in male osteoporosis in the second half of 2021, to complete enrollment in our Phase 3 EMERALD trial of elacestrant in the third quarter of 2020 and to complete enrollment in our Phase 3 ATOM and wearABLe trials in 2020; our plans to focus on building an endocrine franchise; our entry into potential collaborations and partnerships, including the timing thereof, including our plans to consider strategic options for elacestrant and RAD140; 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 2020," and "Expected Radius Presentations at Upcoming Conferences in Q1 2020;" the sufficiency of our cash, cash equivalents, restricted cash, and marketable securities 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 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; risks related to our ability to successfully enter into collaboration or partnership agreements and any executed collaboration or partnership 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, 2019 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
Phone: 617-551-4011

[1] US Anabolic Osteoporosis Market; New Patients to Brand: NBRx PMOT. (Source: IQVIA)

[2] Total Market Share, TRx PMOT. Source: IQVIA

Source: Radius Health Inc.