Radius Health Announces Third Quarter 2018 Operating Results and Financial Guidance for FY 2018 and FY 2019

November 1, 2018

TYMLOS® U.S. net sales continued to increase in the third quarter of 2018, totaling $27.6 million.
2019 Medicare Part D coverage for TYMLOS increased from 44% to 64%

Elacestrant Phase 3 study to target a broader patient population, comprised of 2nd and 3rd line ER+ mBC, with potential for success in the overall and biomarker-selected populations.
Initiation expected in the fourth quarter of 2018

Full-year TYMLOS net revenues expected to be $95m to $98m for 2018 and $155m to $175m for 2019. Year-end cash, cash equivalents and investments anticipated to exceed $220m for 2018 and $100m for 2019

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

WALTHAM, Mass., Nov. 01, 2018 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq: RDUS) today reported its financial and operating results for the third quarter ended September 30, 2018 and provided a business update.

“I am very pleased with the continued strong trajectory of our launch and success in growing the U.S. anabolic osteoporosis market. Our financial guidance reflects our confidence in continuing to capture further market share gains for TYMLOS and expanding the osteoporosis anabolic market,” said Jesper Hoeiland, President and Chief Executive Officer of Radius.

“With our updated Phase 3 protocol for elacestrant, we are excited to have the opportunity to address a larger patient population with unmet needs. We are on track to deliver on this key milestone and initiate the study in the fourth quarter of this year,” said Dr. Charles Morris, Chief Medical Officer of Radius.

TYMLOS (abaloparatide) injection

- Third quarter 2018 U.S. net sales of TYMLOS were $27.6 million, a 22% increase over the prior quarter and approximately sevenfold increase from the third quarter of 2017. TYMLOS prescriptions in the third quarter of 2018 accounted for 22% of the total U.S. anabolic osteoporosis market on average (based on Patient Months on Therapy, TRx PMOT).
- In October 2018, the U.S. Food and Drug Administration (FDA) approved a labeling supplement for TYMLOS to include additional information from the ACTIVExtend study. The labeling now reflects that after 24 months of open-label alendronate therapy, the vertebral fracture risk reduction achieved with TYMLOS therapy was maintained.
- The growth trajectory of the U.S. anabolic market since TYMLOS launched in May 2017 continued in the third quarter of 2018, showing 9% volume growth as compared to the third quarter of 2017, all driven by TYMLOS.
- Effective January 1, 2019, TYMLOS is expected to be covered for approximately 274 million U.S. insured lives, representing approximately 95% of U.S. commercial and 64% of Medicare insured lives. 2019 Medicare Part D coverage for TYMLOS increased to approximately 26.2 million lives or 64% of those enrolled in Medicare Part D plans in the U.S., after the decisions from SilverScript Insurance Company (CVS), WellCare Health Plans, Inc., Prime Therapeutics and others to cover TYMLOS for their Medicare Part D beneficiaries. The increased access for TYMLOS in Medicare Part D Formularies for 2019 represents an incremental 28% of anabolic volume opportunity in Medicare Part D. Express Scripts, Inc., UnitedHealthcare (AARP), Kaiser Permanente, and EnvisionRx, among others, decided to continue Medicare Part D coverage of TYMLOS through 2019.
- Radius maintains its guidance for TYMLOS to capture on average 19-21% of the U.S. anabolic osteoporosis market in 2018 and its expectations for the U.S. anabolic market to grow at a rate of 7-9% in volume versus 2017.

Financial Guidance

- In 2018, Radius expects full-year TYMLOS U.S. net revenues to be between $95 to $98 million and its year-end cash, cash equivalents and investments balance to exceed $220 million.
- In 2019, Radius expects full-year TYMLOS U.S. net revenues to be between $155 to $175 million and its year-end cash, cash equivalents and investments balance to exceed $100 million.

Pipeline Highlights

Abaloparatide-Transdermal Patch (abaloparatide-patch)

- Radius remains on track with its preparations for the Phase 3 trial and expects to start the study in mid-2019. The Company is in the process of conducting development activities in preparation for the Phase 3 trial and potential NDA filing, including qualification and validation of analytical methods, process development and design control activities.

Planning for the facility build-out is also ongoing at the commercial manufacturing site, including scaling up equipment and ensuring readiness for the manufacture of commercial abaloparatide-patches.

Elacestrant (RAD1901)

- In the third quarter 2018, *the Company finalized the Phase 3 study protocol for elacestrant based on regulatory feedback and additional considerations.* The Phase 3 trial will be a single, randomized, open label, active-controlled study of elacestrant as a second- or third-line monotherapy in approximately 460 patients with ER+/HER2- advanced/metastatic breast cancer who have received prior treatment with one or two lines of endocrine therapy, including a cyclin-dependent kinase (CDK) 4/6 inhibitor. Patients in the study will be randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent. The primary endpoint of the study will be progression-free survival ("PFS"), which the Company will analyze in the overall patient population and in patients with estrogen receptor 1 gene (ESR1) mutations. Secondary endpoints will include evaluation of overall survival (OS), objective response rate (ORR), and duration of response (DOR). Depending on the results, this single trial is intended to support applications for marketing approvals for elacestrant as a second- and third-line monotherapy in the U.S., European Union (EU), and other markets.
- Radius expects to initiate the Phase 3 study in the fourth quarter of 2018 with a planned recruitment period of 18-21 months and potential data read-out in 2021.

RAD140

- Patient enrollment is ongoing in the Phase 1 study evaluating the safety and maximum tolerated dose of RAD140, a nonsteroidal selective androgen receptor modulator (SARM), in patients with hormone receptor-positive, locally advanced or metastatic breast cancer. The Company expects to present two posters on RAD140 at the San Antonio Breast Cancer Symposium (SABCS) and to provide an update on the RAD140 Phase 1 development program by the end of 2018.

Anticipated Upcoming Milestones

- Elacestrant
  • Initiate a Phase 3 clinical trial as second or third-line monotherapy in advanced/metastatic ER-positive/HER2-negative breast cancer patients in the fourth quarter of 2018
  • Clinical collaboration agreement for elacestrant combination therapy
- RAD140
  • Continue enrollment in the Phase 1 study and provide a program update by the end of 2018
- Abaloparatide
  • Enter into a partnership for the potential commercialization of abaloparatide-SC outside the U.S. and Japan

Expected Radius Presentations at Upcoming Conferences

- On January 7-10, 2019, the Company will present and host one-on-one meetings at the JP Morgan Annual Healthcare Conference in San Francisco.

Third Quarter 2018 Financial Results

Three Months Ended September 30, 2018

For the three months ended September 30, 2018, Radius reported a net loss of $49.8 million, or $1.09 per share, compared to a net loss of $57.8 million, or $1.31 per share, for the three months ended September 30, 2017.

For the three months ended September 30, 2018, non-GAAP adjusted net loss, which excludes expenses related to stock-based compensation, restructuring plans, non-cash interest obligations under debt obligations, and amortization of intangible assets, was $38.8 million, or $0.85 per share, compared to non-GAAP adjusted net loss of $49.3 million, or $1.12 per share, for the three months ended September 30, 2017.

For the three months ended September 30, 2018, TYMLOS net product revenues were $27.6 million compared to approximately $3.5 million for the three months ended September 30, 2017.

Research and development expense for the three months ended September 30, 2018 was $26.8 million compared to $21.0 million for the three months ended September 30, 2017, an increase of $5.8 million, or 28%. This increase was primarily driven by a $2.8 million increase in elacestrant project costs, a $2.3 million increase in abaloparatide-patch project costs, a $1.0 million increase in abaloparatide-SC project costs, and a $0.8 million increase in RAD140 project costs. These increases were partially offset by a $0.2 million decrease in other project related spending, and $0.5 million decrease in personnel related spending attributed to a decrease in headcount from 105 research and development employees as of September 30, 2017 to 95 research and development employees as of September 30, 2018.

For the three months ended September 30, 2018, selling, general and administrative expense was $43.7 million compared to $47.7 million for the three months ended September 30, 2017, a decrease of $4.1 million, or 9%. This decrease was primarily the result of $2.8 million and $0.9 million decreases in compensation and travel related expenses, respectively.

Nine Months Ended September 30, 2018

For the nine months ended September 30, 2018, Radius reported a net loss of $180.2 million, or $3.98 per share, compared to a net loss of $183.2 million, or $4.21 per share, for the nine months ended September 30, 2017.

For the nine months ended September 30, 2018, non-GAAP adjusted net loss, which excludes expenses related to stock-based compensation, restructuring plans, non-cash interest obligations under debt obligations, litigation related payments, and amortization of intangible assets, was $134.4 million, or $2.97 per share, compared to non-GAAP adjusted net loss of $154.2 million, or $3.54 per share, for the nine months ended September 30, 2017.

For the nine months ended September 30, 2018, TYMLOS net product revenues were $64.8 million compared to approximately $4.4 million for the nine months ended September 30, 2017.

Research and development expense for the nine months ended September 30, 2018 was $76.0 million compared to $60.2 million for the nine months ended September 30, 2017, an increase of $15.8 million, or 26%. This increase was primarily driven by a $7.6 million increase in elacestrant project costs, a $4.0 million increase in abaloparatide-SC project costs, a $3.8 million increase in abaloparatide-patch project costs, and a $2.1 million increase in RAD140 project costs. These increases were partially offset by a $0.7 million decrease in other project related spending and a $0.9 million decrease in compensation and travel related expenses attributed to a decrease in headcount from 105 research and development employees as of September 30, 2017 to 95 research and development employees as of September 30, 2018.

Selling, general, and administrative expense for the nine months ended September 30, 2018, was $140.3 million compared to $135.9 million for the nine months ended September 30, 2017, an increase of $4.3 million, or 3%. This increase was primarily the result of $2.5 million and $0.7 million increases in compensation and travel related expenses, respectively attributed to an increase in headcount from 361 selling, general and administrative employees as of September 30, 2017 to 384 selling, general and administrative employees as of September 30, 2018. Additionally, there was a $0.8 million increase in professional fees and other operating expenses.

As of September 30, 2018, Radius had $276.9 million in cash, cash equivalents, restricted cash, marketable securities and investments. Based upon our cash, cash equivalents, marketable securities and investments balance as of September 30, 2018, 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 not less than twelve months from the date of this press release.

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

	September 30, 2018 (unaudited)	**December 31, 2017**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 62,014	$ 118,564
Restricted cash	558	55
Marketable securities	172,120	134,714
Accounts receivable, net	12,908	4,441
Inventory	5,546	4,366
Prepaid expenses	10,097	5,175
Other current assets	1,193	2,191
Total current assets	264,436	269,506
Investments	42,235	176,978
Property and equipment, net	4,561	6,195
Intangible assets	7,581	8,180
Other assets	589	799
Total assets	$ 319,402	$ 461,658
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,294	$ 3,915
Accrued expenses and other current liabilities	41,759	49,512
Total current liabilities	48,053	53,427
Other non-current liabilities	118	189
Notes payable	176,180	166,006
Total liabilities	224,351	219,622
Stockholders’ equity:		
Common stock, $.0001 par value; 200,000,000 shares authorized, 45,539,516 shares and 44,616,586 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	5	4
Additional paid-in-capital	1,158,417	1,124,630
Accumulated other comprehensive loss	(848)	(314)
Accumulated deficit	$ (1,062,523)	$ (882,284)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
REVENUES:				
Product revenue, net	$ 27,639	$ 3,469	$ 64,815	$ 4,449
License revenue	—	$ 10,000	—	$ 10,000
OPERATING EXPENSES:				
Cost of sales - product	2,193	253	4,884	358
Cost of sales - intangible amortization	200	200	599	200
Research and development	26,804	20,997	75,979	60,176
Selling, general and administrative	43,661	47,723	140,266	135,943
Other operating expenses	—	—	10,801	—
Loss from operations	(45,219)	(55,704)	(167,714)	(182,228)
OTHER (EXPENSE) INCOME:				
Other income (expense)	17	(195)	83	(212)
Interest expense	(5,793)	(2,763)	(17,041)	(2,763)
Interest income	1,193	819	4,433	1,983
NET LOSS	(49,802)	(57,843)	(180,239)	(183,220)
OTHER COMPREHENSIVE LOSS:				
Unrealized gain (loss) from available-for-sale debt securities	$ 442	$ (1)	$ (534)	$ (70)
COMPREHENSIVE LOSS	(49,360)	(57,844)	(180,773)	(183,290)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED	$ (49,802)	$ (57,843)	$ (180,239)	$ (183,220)
LOSS PER SHARE:				
Basic and diluted	$ (1.09)	$ (1.31)	$ (3.98)	$ (4.21)
WEIGHTED AVERAGE SHARES:				
Basic and diluted	45,498,909	43,999,451	45,291,176	43,535,874

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Net loss reconciliation:				
GAAP net loss	$ (49,802)	$ (57,843)	$ (180,239)	$ (183,220)
Intangible amortization	200	200	599	200
Stock-based compensation expense	6,700	8,252	22,270	28,785
Restructuring charges	628	-	2,028	-
Non-cash interest	3,506	-	10,174	-
Ipsen payment	-	-	10,801	-
Non-GAAP net loss	$ (38,768)	$ (49,391)	$ (134,367)	$ (154,235)
Reconciliation of diluted loss per share:				
GAAP loss per share	(1.09)	(1.31)	(3.98)	(4.21)
Intangible amortization	0.00	-	0.01	-
Stock-based compensation expense	0.15	0.19	0.49	0.67
Restructuring charges	0.01	-	0.05	-
Non-cash interest	0.08	-	0.22	-
Ispen payment	-	-	0.24	-
Non-GAAP loss per share	$ (0.85)	$ (1.12)	$ (2.97)	$ (3.54)
Reconciliation of shares used in loss per share calculation:				
GAAP shares used in loss per share	45,498,909	43,999,451	45,291,176	43,535,874
Non-GAAP dilutive share adjustments	-	-	-	-

Non-GAAP shares used in loss per share	45,498,909	43,999,451	45,291,176	43,535,874

Webcast and Conference Call

In connection with today's reporting of Third Quarter Financial Results, Radius will host a conference call and live audio webcast at 8:00 a.m. ET today, November 1, 2018, to discuss the commercial outlook for TYMLOS, review the financial results and provide a Company update.

Conference Call Information:
Date: November 1, 2018
Time: 8:00 a.m. ET
Domestic Dial-in Number: (866) 323-7965
International Dial-in Number: (346) 406-0961
Conference ID: 3875777
Live webcast: https://edge.media-server.com/m6/p/mweubehx

For those unable to participate in the conference call or webcast, a replay will be available from November 1, 2018 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 3875777.

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: 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 regarding Radius' operating performance. 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 and nine months ended September 30, 2017 and 2018 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 ACTIVE and ACTIVExtend
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. ACTIVExtend, 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 ACTIVExtend were published in the Journal of Clinical Endocrinology & Metabolism (JCEM) in May 2018.

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. 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 our expectations for full-year TYMLOS net revenues and our cash, cash equivalents and investments balance; our expectations regarding commercialization of TYMLOS in the U.S., including market access coverage expectations and expectations for capturing a share of the U.S. anabolic osteoporosis market and growth of the anabolic market; our efforts to make abaloparatide-SC available outside the U.S.; 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; the progress in the development of our product candidates, including abaloparatide-patch, elacestrant (RAD1901) and RAD140; each of the statements under the headings “Anticipated Upcoming Milestones,” and “Expected Radius Presentations at Upcoming Conferences;” 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 and 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; 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, 2017 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.