Radius Health, Inc.: Third Quarter 2020 Operating Results

November 5, 2020

- TYMLOS® U.S. net sales of $50 million with 8% year-over-year growth; Total Revenues of $78 million
- Q3 commercial pivot to focus on high risk fracture segment is gaining traction: Net New U.S. Patients increased by 7+% in September 2020 vs. previous 3-month moving average and 10 +% in October vs. previous 3 month moving average
- Japan market progress on track with our partner Teijin for expected 2021 abaloparatide injection launch
- Three Pivotal Trial Readouts on track for 2H 2021
- Conference call scheduled for 8:30 a.m. ET today

WALTHAM, Mass., Nov. 05, 2020 (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, 2020, and provided a business update.

“Over the past few months, we have made reasonable progress within the current business,” commented Kelly Martin, CEO of Radius. Martin commented further that, “In the months ahead, we will focus on improving the performance of TYMLOS in the U.S. market, completing the three pivotal trials in a high quality manner, and constructing an attractive equity story for current or future shareholders.”

Selected Highlights:

- Q3 2020 U.S. net sales of TYMLOS were $50.4 million, an 8% year-over-year increase over Q3 2019.
- Year-to-date 2020 net product revenue of $148 million vs. year-to-date of $117 million is a growth of 26%.
- U.S. TYMLOS “Net New Patients” grew at 7+% in September vs. previous 3-month moving average.
  - October Net New Patients showed 10 % growth vs. previous 3-month moving average.
  - AACE guidelines include abaloparatide in the treatment recommendations as an initial therapy for postmenopausal osteoporosis patients with a recent fracture.
  - Commercial business market segmentation and reengineering remains a central focus.
  - Progress on implementation of a streamlined and institutional distribution channel strategy nearly complete.
- Clinical Development
  - ATOM study, evaluating abaloparatide for use in osteoporotic men at high risk for fracture, completed final recruitment of 228 patients.
  - wearABLe study, evaluating the effects on bone mineral density of abaloparatide delivered via a novel transdermal system, completed final recruitment of 511 patients.
  - EMERALD study, with our partner, Menarini Group, evaluating use of elacestrant to treat ER+/HER2- advanced or metastatic breast cancer completed final recruitment of 478 patients.
  - Histomorphometry Phase 2 Study: data presented at American Society for Bone and Mineral Research (ASBMR) in September. Assessed early effect of abaloparatide at the tissue level. Results demonstrated significant increases in bone formation after three months in postmenopausal women with osteoporosis.
- Japan: Pivotal Phase III trial of abaloparatide injection to treat both men and postmenopausal women with high risk of fracture by Radius partner, Teijin Pharma, achieved primary endpoint. Japan market progression remains on track.
- Europe: seeking guidance and clarity regarding possible regulatory re-submission.

Financial Metric:

- End of Q3 2020 total cash balance at $126 million
- Q3 vs. Q2, 2020 cash burn approximately zero
- Note: in Q3, Radius received a one-time payment from Menarini of $30M

Third Quarter 2020 Financial Results

Three Months Ended September 30, 2020

For the three months ended September 30, 2020, Radius reported a net loss of $6.3 million, or $0.14 per share, compared to a net loss of $30.0

million, or $0.65 per share, for the three months ended September 30, 2019.

For the three months ended September 30, 2020, non-GAAP adjusted net income, 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 $7.0 million, or $0.15 per share, compared to non-GAAP adjusted net loss of $20.4 million, or $0.44 per share, for the three months ended September 30, 2019.

For the three months ended September 30, 2020, TYMLOS net product revenues were $50.4 million compared to approximately $46.8 million for the three months ended September 30, 2019.

For the three months ended September 30, 2020, research and development expense was $39.5 million compared to $31.8 million for the three months ended September 30, 2019, an increase of $7.7 million, or 24%. This increase was primarily driven by a $11.5 million increase in abaloparatide transdermal system program costs. This increase was primarily offset by a $2.2 million decrease in elacestrant program costs, which is comprised of a $13.2 million increase in gross program expenses offset by $15.4 million of billed reimbursable expenses. We will be reimbursed for the costs incurred in connection with the elacestrant project pursuant to the terms of the TSA with Berlin-Chemie, under which the Company will perform certain services for Berlin-Chemie related to the EMERALD Phase 3 monotherapy study until the earlier of the completion of the contemplated services or the filing with the FDA of a NDA for elacestrant.

For the three months ended September 30, 2020, selling, general and administrative expenses were $33.7 million compared to $35.6 million for the three months ended September 30, 2019, a decrease of $1.9 million, or 5%. This decrease was primarily the result of a $0.8 million decrease in travel and entertainment expenses, a $2.3 million decrease in professional support costs, a $0.5 million decrease in compensation cost, and a $0.1 million decrease in other operating costs. These decreases were partially offset by a $1.8 million increase in occupancy and depreciation costs.

Nine Months Ended September 30, 2020

For the nine months ended September 30, 2020, Radius reported a net loss of $87.8 million, or $1.89 per share, compared to a net loss of $108.3 million, or $2.36 per share, for the nine months ended September 30, 2019.

For the nine months ended September 30, 2020, 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 $51.6 million, or $1.11 per share, compared to non-GAAP adjusted net loss of $77.6 million, or $1.69 per share, for the nine months ended September 30, 2019.

For the nine months ended September 30, 2020, TYMLOS net product revenues were $148.5 million compared to approximately $117.7 million for the nine months ended September 30, 2019.

For the nine months ended September 30, 2020, research and development expense was $123.3 million compared to $82.2 million for the nine months ended September 30, 2019, an increase of $41.1 million, or 50%. This increase was primarily driven by a $36.5 million increase in abaloparatide transdermal system project costs, and a $6.4 million increase in project costs for elacestrant. These increases were partially offset by a $1.0 million decrease in RAD140 project costs. We will be reimbursed for the costs incurred in connection with the elacestrant project pursuant to the terms of the TSA with Berlin-Chemie, under which the Company will perform certain services for Berlin-Chemie related to the EMERALD Phase 3 monotherapy study until the earlier of the completion of the contemplated services or the filing with the FDA of a NDA for elacestrant.

For the nine months ended September 30, 2020, selling, general and administrative expenses were $108.4 million compared to $116.9 million for the nine months ended September 30, 2019, a decrease of $8.6 million, or 7%. This decrease was primarily the result of a $6.3 million decrease in professional fees, a $3.3 million decrease in travel and entertainment expenses and a $0.3 million decrease in other operating expenses. These decreases were offset by a $0.3 million increase in compensation related expenses and an $1.0 million increase in occupancy and depreciation.

As of September 30, 2020, Radius had $126.3 million in cash, cash equivalents, restricted cash, and marketable securities. Based upon our cash, cash equivalents and marketable securities balance as of September 30, 2020, 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)

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 81,830	$ 69,886
Restricted cash	567	567
Marketable securities	43,873	91,015
Accounts receivable, net	21,175	23,289
Inventory	7,506	5,323
Prepaid expenses	11,346	12,131
Other current assets	17,078	846

Total current assets	183,375	203,057
Property and equipment, net	1,276	2,293
Intangible assets	5,984	6,583
Right of use assets - operating leases	4,832	6,704
Other assets	484	514
Total assets	$ 195,951	$ 219,151
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 15,767	$ 6,030
Accrued expenses and other current liabilities	63,662	53,030
Operating lease liability, current	2,229	2,198
Total current liabilities	81,658	61,258
Convertible notes payable	208,902	195,591
Term loan	9,941	-
Operating lease liability, long term	4,031	4,581
Total liabilities	304,532	261,430
Stockholders' equity (deficit):		
Common stock, 0.0001 par value; 200,000,000 shares authorized, 46,548,201 shares and 46,189,870 shares issued and outstanding at September 30, 2020 and December 31, 2019	5	5
Additional paid-in-capital	1,215,769	1,194,327
Accumulated other comprehensive income	82	3
Accumulated deficit	(1,324,437)	(1,236,614)
Total stockholders' equity (deficit)	(108,581)	(42,279)
Total liabilities and stockholders' equity (deficit)	$ 195,951	$ 219,151

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
REVENUES:				
Product revenue, net	$ 50,412	$ 46,766	$ 148,448	$ 117,652
License Revenue	27,414	-	27,414	-
Total revenue	77,826	46,766	175,862	117,652
OPERATING EXPENSES:				
Cost of sales - product	3,839	3,971	11,771	10,809
Cost of sales - intangible amortization	200	200	599	599
Research and development, net of amounts reimbursable (a)	39,450	31,791	123,340	82,230
Selling, general, and administrative	33,692	35,617	108,356	116,918
Income (Loss) from operations	645	(24,813)	(68,204)	(92,904)
OTHER INCOME (EXPENSE):				
Other income (expense)	(87)	59	(144)	21
Interest expense	(7,069)	(6,298)	(20,747)	(18,500)

Interest income	222	1,008	1,272	3,105
NET LOSS	$ (6,289)	$ (30,044)	$ (87,823)	$ (108,278)
OTHER COMPREHENSIVE LOSS:				
Unrealized gain (loss) from available-for-sale debt securities	(26)	66	79	776
COMPREHENSIVE LOSS	$ (6,315)	$ (29,978)	$ (87,744)	$ (107,502)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:	$ (6,289)	$ (30,044)	$ (87,823)	$ (108,278)
LOSS PER SHARE:				
Basic and diluted	$ (0.14)	$ (0.65)	$ (1.89)	$ (2.36)
WEIGHTED AVERAGE SHARES:				
Basic and diluted	46,493,126	46,141,217	46,395,124	45,975,691

(a) Amounts reimbursable for the three and nine months ended September 30, 2020 were $15,382 and $0 for the three and nine months ended September 30, 2019.

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,	
	2020	**2019**	**2020**	**2019**
Net loss reconciliation:				
GAAP net loss	$ (6,289)	$ (30,044)	$ (87,823)	$ (108,278)
Intangible amortization	200	200	599	599
Stock-based compensation expense	6,520	5,048	19,819	16,911
Restructuring charges	-	-	-	(8)
Depreciation	473	367	1,021	1,187
Non-cash interest	4,588	4,010	13,313	11,638
Operating Lease Impairment	1,510	-	1,510	339
Non-GAAP net income (loss)	$ 7,002	$ (20,419)	$ (51,561)	$ (77,612)
Reconciliation of diluted loss per share:				
GAAP loss per share	$ (0.14)	$ (0.65)	$ (1.89)	$ (2.36)
Intangible amortization	0.01	0.00	0.01	0.01
Stock-based compensation expense	0.14	0.11	0.43	0.37
Restructuring charges	-	-	-	-
Depreciation	0.01	0.01	0.02	0.03
Non-cash interest	0.10	0.09	0.29	0.25
Operating Lease Impairment	0.03	-	0.03	0.01
Non-GAAP earnings (loss) per share	$ 0.15	$ (0.44)	$ (1.11)	$ (1.69)
Reconciliation of shares used in loss per share calculation:				
GAAP shares used in loss per share	46,493,126	46,141,217	46,395,124	45,975,691
Non-GAAP dilutive share adjustments	91,387	-	-	-
Non-GAAP shares used in earnings (loss) per share	46,584,513	46,141,217	46,395,124	45,975,691

Webcast and Conference Call

In connection with today's reporting of Third Quarter 2020 Financial Results, Radius will host a conference call and live audio webcast at 8:30 a.m. ET

today, November 5, 2020, to review the commercial, research and development, and financial highlights and provide a Company update.

Conference Call Information:
Date: November 5, 2020
Time: 8:30 a.m. ET
Domestic Dial-in Number: (866) 323-7965
International Dial-in Number: (346) 406-0961
Conference ID: 9147422
Live webcast: https://edge.media-server.com/mmc/p/zktf48g4

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, November 5, 2020 at 11:30 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 9147422.

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 September 30, 2019 and 2020 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. 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 injection in 228 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 The Abaloparatide Transdermal System and wearABLe Phase 3 Study
The abaloparatide transdermal system was developed in a collaboration between Radius and Kindeva Drug Delivery ("Kindeva") (formerly 3M Drug Delivery Systems) with the application of Kindeva's innovative microstructured transdermal system technology. The Phase 3 wearABLe study is the first pivotal study to evaluate treatment using a novel non-injectable delivery of an anabolic therapy. The wearABLe 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 transdermal system versus TYMLOS (abaloparatide) injection in approximately 500 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) and EMERALD Phase 3 Study
Elacestrant is a selective estrogen receptor degrader (SERD), out-licensed to Menarini Group, which is being evaluated for potential use as a once daily oral treatment in patients with ER+/ HER2- advanced breast cancer. 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. The EMERALD Phase 3 trial is a randomized, open label, active-controlled study evaluating elacestrant as second- or third-line monotherapy in ER+/HER2- advanced/metastatic breast cancer patients. The study has enrolled 466 patients 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 were randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent. The primary endpoint of the study is progression-free survival (PFS) in the overall patient population and in patients with estrogen receptor 1 gene (ESR1) mutations. Secondary endpoints include evaluation of overall survival (OS), objective response rate (ORR), and duration of response (DOR).

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 regarding commercialization of TYMLOS in the U.S., including our adjustment to focus on new and high-risk osteoporosis patients; our expectations regarding our clinical trials or studies, including the design of our wearABLe and ATOM Phase 3 clinical trials, the EMERALD Phase 3 clinical trial, and our Histomorphometry Phase 2 study; the progress in the development of our product candidates, including the abaloparatide transdermal system and elacestrant (RAD1901); our expectations regarding our license agreement with Teijin Pharma Limited and the timing of the launch of abaloparatide injection in Japan;; 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 the abaloparatide

transdermal system and elacestrant.

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: the adverse impact the ongoing COVID-19 pandemic is having and is expected to continue to have on our business, financial condition and results of operations, including our commercial operations and sales, clinical trials, preclinical studies, and employees; we may need to raise additional funding, which may not be available; risks related to raising additional capital, including as a result of the COVID-19 pandemic; 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, partnership, license or similar agreements; our collaborators or partners, including Teijin Pharma Limited or Menarini Group, failing to obtain regulatory approval for their product candidates or, if approved, to be successful in commercialization, including as a result of risks related to coverage, pricing and reimbursement, manufacturing, supply and distribution, and potential adverse impacts on their businesses from the ongoing COVID-19 pandemic; risks related to clinical trials, including our reliance on third parties to conduct key portions of our clinical trials and uncertainty that the results of those trials 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.

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Source: Radius Health Inc.