Radius Health Announces Second Quarter 2020 Operating Results

August 10, 2020

TYMLOS® U.S. net sales of $50 million, with 22% year over year growth

Completion of enrollment in ATOM Phase 3 expected this week

Phase 3 Trials: wearABLe and EMERALD remain on track

Conference call scheduled for 8:30 a.m. ET today

WALTHAM, Mass., Aug. 10, 2020 (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, 2020 and provided a business update.

"Completing the elacestrant transaction was an important step forward for the company, centering our clinical and regulatory strategy while strengthening ourselves from a financial perspective," said Kelly Martin, CEO of Radius Health. Martin commented further that "in the near-term, our focus will include completing our Phase 3 pivotal trial enrollments while adjusting our commercial and marketing efforts to focus on high-risk osteoporosis patients."

Business Update

Commercial

- Second quarter 2020 U.S. net sales of TYMLOS were $50.1 million, a 22% increase over the second quarter of 2019.

Business Development

- In July, Radius entered into an exclusive global license agreement for development and commercialization of elacestrant with Menarini Group. Under the agreement, Menarini Group will be responsible for worldwide commercialization of elacestrant, after the completion of EMERALD Phase 3 study and, assuming positive results, successful registration of elacestrant.

- Radius will continue to be responsible for the conduct and completion of the Phase 3 EMERALD study through NDA filing. The Company expects over $100 million of expenses associated with this activity will be reimbursed by Menarini.

- As part of the agreement, Radius received an upfront payment of $30 million, and is eligible to receive up to $20 million on the achievement of certain development and regulatory milestones and up to $300 million on the achievement of certain sales milestones. Menarini Group will make tiered, low to mid-teen percentage royalty payments to Radius Health on global net sales.

Clinical Development Update

Abaloparatide-patch

- The wearABLe Phase 3 study with abaloparatide-patch in postmenopausal osteoporosis continues to advance its enrollment globally. Completion of enrollment remains on track for the later part of third quarter of 2020.

Abaloparatide-SC

- The ATOM Phase 3 Study, which is assessing the efficacy and safety of abaloparatide-SC in men with osteoporosis, is expected to complete recruitment this week with the enrollment of one more patient.

- Teijin Pharma Limited, Radius' partner for abaloparatide-SC in Japan, submitted a New Drug Application for abaloparatide-SC in Japan for the treatment of osteoporosis in patients who are at high risk for fractures, based on the positive results of their Phase III study. The study achieved its efficacy endpoint and showed an acceptable safety profile. Detailed results of this trial are planned to be presented at a global medical conference in the second half of this year.

Elacestrant

- The EMERALD Phase 3 study is on schedule to complete target recruitment in the fourth quarter of 2020.

Second Quarter 2020 Financial Results

Three Months Ended June 30, 2020

For the three months ended June 30, 2020, Radius reported a net loss of $43.9 million, or $0.95 per share, compared to a net loss of $35.5 million, or $0.77 per share, for the three months ended June 30, 2019.

For the three months ended June 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 $31.2 million, or $0.67 per share, compared to non-GAAP adjusted net loss of $25.4 million, or $0.55 per share, for the three months ended June 30, 2019.

For the three months ended June 30, 2020, TYMLOS net product revenues were $50.1 million compared to approximately $41.0 million for the three months ended June 30, 2019.

For the three months ended June 30, 2020, research and development expense was $44.9 million compared to $27.2 million for the three months ended June 30, 2019, an increase of $17.7 million, or 65%. This increase was primarily driven by a $13.9 million increase in abaloparatide-patch program costs, a $5.2 million increase in elacestrant program costs, a $0.2 million increase in abaloparatide-SC program costs, and a $0.2 million increase in compensation expenses. These increases were offset by a decrease of $0.8 million in RAD140 program cost, a $0.4 million decrease in occupancy and depreciation, a $0.4 million decrease in travel and entertainment expense, a $0.1 million decrease in professional fees, and a $0.1 million decrease in other operating costs.

For the three months ended June 30, 2020, selling, general and administrative expense was $38.2 million compared to $40.1 million for the three months ended June 30, 2019, a decrease of $1.9 million, or 5%. This decrease was primarily the result of a $2.0 million decrease in travel and entertainment expenses, a $1.1 million decrease in professional support costs, a $0.3 million decrease in occupancy and depreciation costs, and a $0.3 million decrease in other operating costs. These decreases were partially offset by a $1.8 million increase in compensation costs.

Six Months Ended June 30, 2020

For the six months ended June 30, 2020, Radius reported a net loss of $81.5 million, or $1.76 per share, compared to a net loss of $78.2 million, or $1.70 per share, for the six months ended June 30, 2019.

For the six months ended June 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 $58.6 million, or $1.26 per share, compared to non-GAAP adjusted net loss of $57.2 million, or $1.25 per share, for the six months ended June 30, 2019.

For the six months ended June 30, 2020, TYMLOS net product revenues were $98.0 million compared to approximately $70.9 million for the six months ended June 30, 2019.

For the six months ended June 30, 2020, research and development expense was $83.9 million compared to $50.4 million for the six months ended June 30, 2019, an increase of $33.5 million, or 66%. This increase was primarily driven by a $25.0 million increase in abaloparatide-patch project costs, a $8.7 million increase in project costs for elacestrant, a $0.6 million increase in abaloparatide-SC project costs, a $0.8 million increase in professional fees services, and a $0.4 million increase in compensation expenses. These increases were partially offset by a $1.0 million decrease in RAD140 project costs, a $0.3 million decrease in occupancy and depreciation costs, and a $0.7 million decrease in travel and entertainment expenses.

For the six months ended June 30, 2020, selling, general and administrative expense was $74.7 million compared to $81.3 million for the six months ended June 30, 2019, a decrease of $6.6 million, or 8%. This decrease was primarily the result of a $4.0 million decrease in professional fees, a $2.5 million decrease in travel and entertainment expenses, a $0.8 million decrease in occupancy and depreciation costs and a $0.2 million decrease in other operating expense. These decreases were offset by a $0.8 million increase in compensation related expenses.

As of June 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 June 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)

	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 56,239	$ 69,886
Restricted cash	567	567
Marketable securities	69,495	91,015
Accounts receivable, net	17,899	23,289
Inventory	5,906	5,323
Prepaid expenses	7,921	12,131
Other current assets	1,838	846

Total current assets	159,865	203,057
Property and equipment, net	1,747	2,293
Intangible assets	6,184	6,583
Right of use assets - operating leases	6,787	6,704
Other assets	514	514
Total assets	$ 175,097	$ 219,151
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 11,718	$ 6,030
Accrued expenses and other current liabilities	51,756	53,030
Operating lease liability, current	2,180	2,198
Total current liabilities	65,654	61,258
Convertible notes payable	204,315	195,591
Term loan	9,940	-
Operating lease liability, long term	4,607	4,581
Total liabilities	284,516	261,430
Stockholders' equity (deficit):		
Common stock, $0.0001 par value; 200,000,000 shares authorized, 46,448,491 shares and 46,189,870 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	5	5
Additional paid-in-capital	1,208,616	1,194,327
Accumulated other comprehensive income (loss)	108	3
Accumulated deficit	(1,318,148)	(1,236,614)
Total stockholders' equity (deficit)	(109,419)	(42,279)
Total liabilities and stockholders' equity (deficit)	$ 175,097	$ 219,151

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
REVENUES:				
Product revenue, net	$ 50,113	$ 41,042	$ 98,037	$ 70,886
OPERATING EXPENSES:				
Cost of sales - product	4,070	3,808	7,931	6,838
Cost of sales - intangible amortization	200	200	399	399
Research and development	44,881	27,179	83,890	50,439
Selling, general, and administrative	38,231	40,115	74,664	81,301
Loss from operations	(37,269)	(30,260)	(68,847)	(68,091)
OTHER (EXPENSE) INCOME:				
Other income (expense)	(68)	(42)	(59)	(38)
Interest expense	(6,922)	(6,165)	(13,678)	(12,202)
Interest income	379	993	1,050	2,097
NET LOSS	$ (43,880)	$ (35,474)	$ (81,534)	$ (78,234)
OTHER COMPREHENSIVE LOSS:				

Unrealized gain (loss) from available-for-sale debt securities	774	236	105	710
COMPREHENSIVE LOSS	$ (43,106)	$ (35,238)	$ (81,429)	$ (77,524)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:	$ (43,880)	$ (35,474)	$ (81,534)	$ (78,234)
LOSS PER SHARE:				
Basic and diluted	$ (0.95)	$ (0.77)	$ (1.76)	$ (1.70)
WEIGHTED AVERAGE SHARES:				
Basic and diluted	46,420,046	46,109,193	46,345,585	45,891,557

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Net loss reconciliation:				
GAAP net loss	$ (43,880)	$ (35,474)	$ (81,534)	$ (78,234)
Intangible amortization	200	200	399	399
Stock-based compensation expense	7,841	5,748	13,299	11,863
Restructuring charges	-	(155)	-	(8)
Depreciation	253	387	548	820
Non-cash interest	4,436	3,878	8,725	7,628
Operating Lease Impairment	-	-	-	339
Non-GAAP net loss	$ (31,150)	$ (25,416)	$ (58,563)	$ (57,193)
Reconciliation of diluted loss per share:				
GAAP loss per share	$ (0.95)	$ (0.77)	$ (1.76)	$ (1.70)
Intangible amortization	0.01	0.01	0.01	0.01
Stock-based compensation expense	0.16	0.11	0.29	0.26
Restructuring charges	-	-	-	-
Depreciation	0.01	0.01	0.01	0.02
Non-cash interest	0.10	0.08	0.19	0.17
Operating Lease Impairment	-	-	-	0.01
Non-GAAP loss per share	$ (0.67)	$ (0.55)	$ (1.26)	$ (1.25)
Reconciliation of shares used in loss per share calculation:				
GAAP shares used in loss per share	46,420,046	46,109,193	46,345,585	45,891,557
Non-GAAP dilutive share adjustments	-	-	-	-
Non-GAAP shares used in loss per share	46,420,046	46,109,193	46,345,585	45,891,557

Webcast and Conference Call

In connection with today's reporting of Second Quarter 2020 Financial Results, Radius will host a conference call and live audio webcast at 8:30 a.m. ET today, August 10, 2020, to review the commercial, research and development, and financial highlights and provide a Company update.

Conference Call Information:
Date: August 10, 2020
Time: 8:30 a.m. ET
Domestic Dial-in Number: (866) 323-7965
International Dial-in Number: (346) 406-0961

Conference ID: 6334188
Live webcast: https://edge.media-server.com/mmc/p/whbw94tn

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, August 10, 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 6334188.

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, 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. 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 the investigational use of abaloparatide injection for the treatment of 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 out-licensed to Menarini Group; 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 Kindeva Drug Delivery ("Kindeva") (formerly 3M Drug Delivery Systems) with the application of Kindeva'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) 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 advanced estrogen receptor positive, HER2 negative, 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 advanced/metastatic ER-positive (ER+)/HER2- breast cancer patients. The study will enroll approximately 460 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 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) 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).

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 high-risk osteoporosis patients; our expectations regarding our clinical trials, including the design and our expected timing for completing enrollment in our wearABLe and ATOM Phase 3 clinical trials, as well as the EMERALD Phase 3 clinical trial; the progress in the development of our product candidates, including abaloparatide-patch and RAD140, as well as elacestrant (RAD1901); our expectations regarding our license agreement with Teijin Pharma Limited and the timing of detailed results from their Phase 3 clinical trial of abaloparatide-SC; our expectations regarding our license agreement with Menarini for elacestrant, including the potential achievement of development, regulatory and sales milestones related to, and potential royalties on sales of, elacestrant; 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 and RAD140, as well as 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 or partnership agreements and any collaborators or partners, including Teijin Pharma Limited or Menarini Group, failing to obtain regulatory approval for their product candidates or to be successful in commercialization, if approved, including as a result of risks related to coverage, pricing and reimbursement, manufacturing, supply and distribution, and potential adverse impacts their business 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 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

Source: Radius Health Inc.