Radius Health, Inc.: Fourth Quarter and Full Year Results

February 25, 2021

- Full year 2020 TYMLOS® U.S. net sales of $208 million was year-over-year growth of 20%
- Q4 2020 TYMLOS U.S. net sales: $60 million was 8% growth vs. Q4 2019 and 19% growth vs. Q3 2020
- New patient starts: increased by 26% in Q4 2020 vs. Q3 2020
- ATOM, wearABLe and EMERALD studies: on schedule for 2H 2021 read-outs
- Japan regulatory process: remains on track
- RAD011 asset integration and forward progress ahead of schedule

BOSTON, Feb. 25, 2021 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq: RDUS), today reported its financial results for the fourth quarter ended December 31, 2020 as well as full year 2020 results. In addition, a number of brief business updates are included.

Q4 2020 FINANCIAL AND BUSINESS HIGHLIGHTS:

- Q4 2020 U.S. net sales of TYMLOS were $60 million, an 8% year-over-year increase vs. Q4 2019
- TYMLOS U.S. new patient starts increased by 26% in Q4 2020 vs. Q3 2020

FY 2020 FINANCIAL AND BUSINESS HIGHLIGHTS:

- FY 2020 U.S. TYMLOS net product revenue was $208 million vs. FY 2019 net product revenue of $173 million – year-over-year growth of 20%
- Balance sheet: approx. $115 million of cash, cash equivalents, and marketable securities at year end
- Reduced actual total company headcount by 25+% vs. full year 2020 budget
- Reduced real estate footprint and infrastructure by approximately 50%
- Pivoted U.S. commercial effort to focus on post-menopausal high risk fracture patients
- Increased U.S. commercial productivity (net rev. per sales person) by approximately 50%
- Completed elacestrant business development out-licensing transaction with the Menarini Group
- Completed RAD140 business development out-licensing transaction with Ellipses Pharma Limited
- Completed abaloparatide business development out-licensing transction with Paladin Labs in Canada
- Completed RAD011 business development acquisition transaction for global rights

OTHER BUSINESS HIGHLIGHTS:

Abaloparatide

- ATOM phase 3 study, evaluating abaloparatide for use in osteoporotic men at high risk for fracture, remains on track for 2H 2021 read-out
- wearABLe phase 3 study, evaluating the effects on bone mineral density of abaloparatide delivered via a novel transdermal system, remains on track for 2H 2021 read-out
- In Japan, our partner Teijin continues to make progress within the Japan regulatory and market processes
- Our partner in Canada – Paladin Labs – is advancing with plans to progress the abaloparatide molecule through the regulatory process
- In the EU, we continue to advance meetings and dialogue regarding a possible re-submission of abaloparatide

RAD011

- A dedicated and experienced team has been created to advance the molecule and asset
- Our initial focus: Prader Willi Syndrome (PWS) for the U.S. and other global markets
- Assessing additional product pathways with focus on other orphan metabolic, endocrine indications

Elacestrant

- EMERALD phase 3 Study, with partner Menarini Group, remains on track for a 2H 2021 read-out

Fourth Quarter 2020 Financial Results

Three Months Ended December 31, 2020

Net Loss
For the three months ended December 31, 2020, Radius reported a net loss of $21.4 million, or $0.46 per share, compared to a net loss of $24.7 million, or $0.54 per share, for the three months ended December 31, 2019.

For the three months ended December 31, 2020, non-GAAP adjusted net income, was $10.8 million, or $0.23 per share, compared to non-GAAP adjusted net loss of $13.3 million, or $0.29 per share, for the three months ended December 31, 2019.

Revenue
For the three months ended December 31, 2020, TYMLOS net product revenues were $59.9 million compared to approximately $55.7 million for the three months ended December 31, 2019.

Costs and Expenses
For the three months ended December 31, 2020, research and development expense was $36.4 million compared to $34.5 million for the three months ended December 31, 2019, an increase of $1.9 million, or 5%. This increase was primarily driven by a $16.0 million increase in RAD011 program expenses, a $3.4 million increase in abaloparatide transdermal system program costs, which was partially offset by a $18.4 million decrease in elacestrant program costs.

Twelve Months Ended December 31, 2020

Net Loss
For the twelve months ended December 31, 2020, Radius reported a net loss of $109.2 million, or $2.35 per share, compared to a net loss of $133.0 million, or $2.89 per share, for the twelve months ended December 31, 2019.

For the twelve months ended December 31, 2020, non-GAAP adjusted net loss was $62.3 million, or $1.34 per share, compared to non-GAAP adjusted net loss of $90.9 million, or $1.98 per share, for the twelve months ended December 31, 2019.

Revenue
For the twelve months ended December 31, 2020, TYMLOS net product revenues were $208.4 million compared to approximately $173.3 million for the twelve months ended December 31, 2019.

Costs and Expenses
For the twelve months ended December 31, 2020, research and development expense was $159.7 million compared to $116.8 million for the twelve months ended December 31, 2019, an increase of $43.0 million, or 37%. This increase was primarily a result of an increase of $39.9 million in program spending for the abaloparatide transdermal system project costs and an increase of $16.0 million in other costs due to the Benuvia licensing expense. These increases were partially offset by a $11.9 million decrease in program spending for elacestrant research which is a result of $39.3 million of reimbursable expenses offsetting year to date expenses.

For the twelve months ended December 31, 2020, selling, general and administrative expenses were $144.2 million compared to $152.7 million for the twelve months ended December 31, 2019, a decrease of $8.6 million, or 6%. This decrease was primarily the result of a $6.3 million decrease in professional fees, a $4.0 million decrease compensation related expenses. These decreases were offset by a $1.7 million increase in other costs.

As of December 31, 2020, Radius had $115.3 million in cash, cash equivalents, restricted cash, and marketable securities. Based upon our cash, cash equivalents and marketable securities balance as of December 31, 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)

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 91,436	$ 69,886
Restricted cash	567	567
Marketable securities	23,280	91,015
Accounts receivable, net	20,310	23,289
Inventory	9,174	5,323
Prepaid expenses	13,279	12,131
Other current assets	22,502	846
Total current assets	180,548	203,057
Property and equipment, net	796	2,293
Intangible assets	5,785	6,583
Right of use assets - operating leases	3,933	6,704
Other assets	520	514
Total assets	$ 191,582	$ 219,151

LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 9,925	$ 6,030
Accrued expenses and other current liabilities	59,758	53,030
Deferred revenue	1,000	-
Operating lease liability, current	2,490	2,198
Total current liabilities	73,173	61,258
Convertible notes payable	213,645	195,591
Term loan	24,905	-
Operating lease liability, long term	3,518	4,581
Total liabilities	315,241	261,430
Stockholders' equity (deficit):		
Common stock, $.0001 par value; 200,000,000 shares authorized, 46,779,479 shares and 46,189,870 shares issued and outstanding at December 31, 2020 and 2019, respectively	5	5
Additional paid-in-capital	1,222,137	1,194,327
Accumulated other comprehensive income	21	3
Accumulated deficit	(1,345,822)	(1,236,614)
Total stockholders' equity (deficit)	(123,659)	(42,279)
Total liabilities and stockholders' equity (deficit)	$ 191,582	$ 219,151

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,	
	2020	**2019**	**2020**	**2019**
REVENUES:				
Product revenue, net	$ 59,947	$ 55,665	$ 208,395	$ 173,317
License Revenue	2,836	-	30,250	-
Total revenue	62,783	55,665	238,645	173,317
OPERATING EXPENSES:				
Cost of sales - product	4,633	4,478	16,403	15,287
Cost of sales - intangible amortization	198	198	798	798
Research and development, net of amounts reimbursable (a)	36,372	34,528	159,712	116,757
Selling, general, and administrative	35,798	35,786	144,154	152,704
Income (Loss) from operations	(14,218)	(19,325)	(82,422)	(112,229)
OTHER INCOME (EXPENSE):				
Other income (expense)	(68)	221	(212)	242
Interest expense	(7,230)	(6,435)	(27,977)	(24,935)
Interest income	131	824	1,403	3,929
NET LOSS	$ (21,385)	$ (24,715)	$ (109,208)	$ (132,993)
OTHER COMPREHENSIVE LOSS:				
Unrealized gain (loss) from available-for-sale debt securities	(61)	(18)	18	758
COMPREHENSIVE LOSS	$ (21,446)	$ (24,733)	$ (109,190)	$ (132,235)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:	$ (21,385)	$ (24,715)	$ (109,208)	$ (132,993)
LOSS PER SHARE:				
Basic and diluted	$ (0.46)	$ (0.54)	$ (2.35)	$ (2.89)
WEIGHTED AVERAGE SHARES:				
Basic and diluted	46,650,694	46,176,145	46,459,366	46,026,217

(a) Amounts reimbursable for the three and twelve months ended December 31, 2020 were $23.9 million and $39.3 million, respectively and $0 for the three and twelve months ended December 31, 2019.

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,	
	2020	2019	2020	2019
Net loss reconciliation:				
GAAP net loss	$ (21,385)	$ (24,715)	$ (109,208)	$ (132,993)
Intangible amortization	198	198	798	798
Stock-based compensation expense	4,879	6,704	24,698	23,615
Restructuring charges	-	-	-	(8)
Depreciation	(126)	322	895	1,509
Non-cash interest	4,745	4,147	18,058	15,785
Operating Lease Impairment	900	-	2,410	339
Non-GAAP net income (loss)	$ (10,789)	$ (13,344)	$ (62,349)	$ (90,955)
Reconciliation of diluted loss per share:				
GAAP loss per share	$ (0.46)	$ (0.54)	$ (2.35)	$ (2.89)
Intangible amortization	0.01	-	0.02	0.02
Stock-based compensation expense	0.10	0.15	0.53	0.51
Restructuring charges	-	-	-	-
Depreciation	-	0.01	0.02	0.03
Non-cash interest	0.10	0.09	0.39	0.34
Operating Lease Impairment	0.02	-	0.05	0.01
Non-GAAP earnings (loss) per share	$ (0.23)	$ (0.29)	$ (1.34)	$ (1.98)
Reconciliation of shares used in loss per share calculation:				
GAAP shares used in loss per share	46,650,694	46,176,145	46,459,366	46,026,217
Non-GAAP dilutive share adjustments	-	-	-	-
Non-GAAP shares used in earnings (loss) per share	46,650,694	46,176,145	46,459,366	46,026,217

Webcast and Conference Call

In connection with today's reporting of Fourth Quarter 2020 Financial Results, Radius will host a conference call and live audio webcast at 8:30 a.m. ET today, February 25, 2021, to review the commercial, research and development, and financial highlights and provide a Company update.

Conference Call Information:
Date: February 25, 2021
Time: 8:30 a.m. ET
Domestic Dial-in Number: (866) 323-7965
International Dial-in Number: (346) 406-0961
Conference ID: 8266586
Live webcast: https://edge.media-server.com/mmc/p/6vihxxkr

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 25th 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 8266586.

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, 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 and other 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 investigational abaloparatide injection for potential use in the treatment of men with osteoporosis; an investigational abaloparatide transdermal system for potential use in the treatment of postmenopausal women with osteoporosis; the investigational drug, elacestrant (RAD1901), for potential use in the treatment of hormone-receptor positive breast cancer out-licensed to Menarini Group; and the investigational drug RAD011, a synthetic cannabidiol oral solution with potential utilization in multiple endocrine and metabolic orphan diseases, initially targeting Prader-Willi syndrome.

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 continued commercialization of TYMLOS in the U.S.; our expectations regarding our clinical trials or studies, including our wearABLe and ATOM Phase 3 clinical trials and the EMERALD Phase 3 clinical trial; the progress in the development of our product candidates, including the abaloparatide transdermal system, RAD011 and elacestrant (RAD1901); our expectations regarding our license agreements with Teijin Pharma Limited and Paladin Labs and the timing of the launch of abaloparatide injection in Japan and Canada; regulatory resubmission in the European Union; 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; 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, 2020 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.