Radius Health, Inc.: First Quarter 2021 Results

May 7, 2021

- Total net revenue: $56 million vs. $48 million in Q1, 2020, +17% year-over-year
- TYMLOS® U.S. product net revenue: $45 million vs. $48 million in Q1, 2020, -6% year-over-year
- Significant operating leverage improvement:
    - Q1, 2021 adjusted EBITDA: ($5) million vs. ($26) million in Q1, 2020
    - Q1, 2021 EPS: ($0.34) vs. ($0.81) in Q1, 2020
- Reiterating $250 million for full year 2021 net revenue guidance for the U.S. TYMLOS product
- Humana added TYMLOS to the formularies of its Medicare Advantage Plans on May 1, 2021
- Abaloparatide pivotal trials: ATOM (male) and wearABLe (TD) on schedule for 2H, 2021 readouts
- Confirming target to resubmit abaloparatide with the EMA in Q4, 2021
- Type C meeting with the FDA for RAD011 on Prader Willi Syndrome (PWS) in June

BOSTON, May 07, 2021 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq: RDUS), today reported its financial results for the first quarter ended March 31, 2021.

The following are key components of Q1, 2021 performance:

Q1, 2021 FINANCIAL HIGHLIGHTS:

- Total net revenue improved by 17% year-over-year: $56 million in 2021 vs. $48 million in 2020
- TYMLOS U.S. product net revenue down 6% year-over-year: $45 million in 2021 vs. $48 million in 2020
    - Reduced unit volumes from inventory channel destocking plus volatility in patient activity as a result of Covid-19 during 2020; there was a partial offset from an increase in net price
- TYMLOS U.S. new patient adds grew by 14% in Q1, 2021 vs. Q4, 2020
- Strong cash balance: $115 million of cash, cash equivalents and marketable securities as of 3/31/2021
- Strategic and proactive management of capital structure:
    - Completed $175 million financing transaction in March, 2021
    - Redeemed ~37% of aggregate principal amount of the existing 3.00% convertible notes
    - Eliminated potential future dilution by ~2 million shares (~4.9% of outstanding shares)
    - Improved financial flexibility with a more balanced mix of secured and unsecured tranches
    - Added cash to the balance sheet to enhance liquidity

BUSINESS HIGHLIGHTS:

Abaloparatide:

- On May 1, 2021, Humana added TYMLOS to the formularies of its Medicare Advantage Plans
    - Impact #1: adds ~5 million beneficiaries, which moves Medicare Part D coverage from 83% to 91%
    - Impact #2: increases coverage for first line PMO patients with history of fracture from 77% to 78%
- Q1 TYMLOS new patient prescribers: 42 of top 50 HCP’s are now orthopedic or specialist bone practices
- New patient growth for this group (the 42) was 26% vs. 14% for total Q1 TYMLOS prescriber activity
- Re-submission of abaloparatide to the EMA targeted to occur in Q4, 2021
- TYMLOS Black Box Warning: FDA process ongoing with clarity expected in Q4, 2021
- Submitted data from the histomorphometry study for inclusion in the abaloparatide label

Elacestrant:

- EMERALD phase 3 trial with our partner, Menarini Group, remains on track for 2H, 2021 topline readout

RAD011:

- Type C meeting with the FDA in June, 2021 for PWS phase 3 protocol review
- RAD011 previous data to be presented at the PWSA/USA conference June 23-25, 2021
- Additional orphan indications being assessed with 2H, 2021 timetable to finalize plan(s)
- Hired Head of Science and Technology for CBD, cannabinoid derivatives, formulations and delivery

First Quarter 2021 Financial Results

Three Months Ended March 31, 2021

Net Loss
For the three months ended March 31, 2021, Radius reported a net loss of $15.7 million, or $0.34 per share, compared to a net loss of $37.7 million, or $0.81 per share, for the three months ended March 31, 2020.

For the three months ended March 31, 2021, non-GAAP adjusted net loss, was $8.6 million, or $0.18 per share, compared to non-GAAP adjusted net loss of $27.4 million, or $0.59 per share, for the three months ended March 31, 2020.

Revenue
For the three months ended March 31, 2021, TYMLOS net product revenues were $45.3 million compared to approximately $47.9 million for the three months ended March 31, 2020.

For the three months ended March 31, 2021, license revenue was $11.0 million. No license revenue was recognized for the three months ended March 31, 2020.

Costs and Expenses
For the three months ended March 31, 2021, research and development expense was $31.4 million compared to $39.0 million for the three months ended March 31, 2020, a decrease of $7.6 million, or 19%. This decrease was primarily driven by a decrease of $3.3 million in abaloparatide-TD program cost, a $4.8 million decrease in compensation expense, which is comprised of a $1.1 million decrease in compensation expense and $3.7 million of billed reimbursable expenses, and a $7.7 million decrease in elacestrant program costs, which is comprised of a $2.9 million increase in gross program expenses offset by $10.6 million of billed reimbursable expenses. These decreases were partially offset by a $5.3 million increase in abaloparatide-SC program costs and a $2.9 million increase in professional fees and other expenses.

For the three months ended March 31, 2021, selling, general and administrative expenses were $34.1 million compared to $36.4 million for the three months ended March 31, 2020, a decrease of $2.3 million, or 6%. This decrease was primarily the result of a $0.4 million decrease in travel and entertainment expenses, a $3.6 million decrease in compensation cost, and a $0.4 million decrease in other operating costs. These decreases were partially offset by a $1.9 million increase in professional support costs, and a $0.2 million increase in occupancy and depreciation costs.

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

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 114,124	$ 91,436
Restricted cash	567	567
Marketable securities	-	23,280
Accounts receivable, net	26,305	20,310
Inventory	9,430	9,174
Prepaid expenses	14,291	13,279
Other current assets	29,967	22,502
Total current assets	194,684	180,548
Property and equipment, net	745	796
Intangible assets	5,585	5,785
Right of use assets - operating leases	3,575	3,933
Other assets	520	520
Total assets	$ 205,109	$ 191,582
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 7,782	$ 9,925
Accrued expenses and other current liabilities	70,452	59,758
Deferred revenue	-	1,000
Operating lease liability, current	2,165	2,490
Total current liabilities	80,399	73,173
Convertible notes payable	189,859	213,645
Term loan	147,640	24,905
Operating lease liability, long term	3,221	3,518
Total liabilities	421,119	315,241

Stockholders' equity (deficit):		
Common stock, 0.0001 par value; 200,000,000 shares authorized, 47,241,098 shares and 46,779,479 shares issued and outstanding at March 31, 2021 and December 31, 2020	5	5
Additional paid-in-capital	1,097,539	1,222,137
Accumulated other comprehensive income	-	21
Accumulated deficit	(1,313,554)	(1,345,822)
Total stockholders' equity (deficit)	(216,010)	(123,659)
Total liabilities and stockholders' equity (deficit)	$ 205,109	$ 191,582

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

	Three Months Ended March 31,	
	2021	**2020**
REVENUES:		
Product revenue, net	$ 45,261	$ 47,923
License Revenue	11,000	-
Total revenue	56,261	47,923
OPERATING EXPENSES:		
Cost of sales - product	3,925	3,861
Cost of sales - intangible amortization	200	200
Research and development, net of amounts reimbursable (a)	31,440	39,009
Selling, general, and administrative	34,097	36,433
Income (Loss) from operations	(13,401)	(31,580)
OTHER INCOME (EXPENSE):		
Other income (expense)	(1)	11
Interest expense	(4,364)	(6,756)
Interest income	57	671
Gain on extinguishment of debt	1,960	-
NET LOSS	$ (15,749)	$ (37,654)
OTHER COMPREHENSIVE LOSS:		
Unrealized loss from available-for-sale debt securities	(21)	(669)
COMPREHENSIVE LOSS	$ (15,770)	$ (38,323)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:	$ (15,749)	$ (37,654)
LOSS PER SHARE:		
Basic and diluted	$ (0.34)	$ (0.81)
WEIGHTED AVERAGE SHARES:		
Basic and diluted	46,981,016	46,271,123

(a) Amounts reimbursable were $14.3 million and $0 for the three ended March 31, 2021 and 2020.

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

	Three Months Ended March 31,	
	2021	**2020**
Net loss reconciliation:		
GAAP net loss	$ (15,749)	$ (37,654)
Intangible amortization	200	200
Stock-based compensation expense	5,410	5,459
Depreciation	52	292
Non-cash interest	309	4,289
Gain on extinguishment of debt	(1,960)	-
Debt refinancing charges	3,143	-

Non-GAAP net loss	$ (8,595)	$ (27,414)
Reconciliation of diluted loss per share:		
GAAP loss per share	$ (0.34)	$ (0.81)
Intangible amortization	-	-
Stock-based compensation expense	0.12	0.12
Depreciation	-	0.01
Non-cash interest	0.01	0.09
Gain on extinguishment of debt	(0.04)	-
Debt refinancing charges	0.07	-
Non-GAAP loss per share	$ (0.18)	$ (0.59)
Reconciliation of shares used in loss per share calculation:		
GAAP shares used in loss per share	46,981,016	46,271,123
Non-GAAP dilutive share adjustments	-	-
Non-GAAP shares used in loss per share	46,981,016	46,271,123

Webcast and Conference Call

In connection with today's reporting of First Quarter 2021 Financial Results, Radius will host a conference call and live audio webcast at 8:30 a.m. ET today, May 7, 2021, to review the commercial, research and development, and financial highlights and provide a Company update.

Conference Call Information:
Date: May 7, 2021
Time: 8:30 a.m. ET
Domestic Dial-in Number: (866) 323-7965
International Dial-in Number: (346) 406-0961
Conference ID: 3363277
Live webcast: https://edge.media-server.com/mmc/p/x2uo3odi

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 Friday, May 7 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 3363277.

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 March 31, 2021 and 2020 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

About Radius
Radius is a commercial biopharmaceutical company committed to serving patients with unmet medical needs in endocrinology and other therapeutic areas. 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).

About RAD011
Investigational drug RAD011 is a pharmaceutical-grade synthetic cannabidiol oral solution, manufactured utilizing traditional pharmaceutical manufacturing processes. The product has purity specifications that meet standardized regulatory and quality control requirements and, compared to the process of developing a plant-derived product, the synthetic manufacturing process usually enables increased consistency and greater precision in the product supply. RAD011 has been assessed in over 150 patients across multiple indications and has potential utilization in multiple endocrine and metabolic orphan diseases. Radius is initially targeting Prader-Willi syndrome (PWS), and anticipates initiating a pivotal Phase 2/3 study for patients with PWS in the second half of 2021 pending regulatory discussion with the U.S. Food and Drug Administration (FDA).

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 about our expectations regarding continued commercialization of TYMLOS in the U.S.; our expectations with respect to our net revenues; our expectations regarding our current and planned clinical trials or studies, including our wearABLe and ATOM Phase 3 clinical trials, the EMERALD Phase 3 clinical trial, and a planned clinical trial for RAD011; the progress in the development of our product candidates, including the abaloparatide transdermal system, RAD011 and elacestrant (RAD1901); our expectations regarding our regulatory submissions and other regulatory actions; 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; 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.