Radius Health, Inc. First Quarter 2022 Results

May 5, 2022

- Q1 2022 TYMLOS® product net revenue of $43 million vs. $45 million in Q1 2021
  - Q1 results: in-line with previously guided 1H 2022 company target of $97 million
  - Reiterating FY 2022 TYMLOS Net Revenue guidance of $232 million
  - Seasonality, as previously announced: 42% of net revenue in 1H and 58% in 2H 2022
  - Patient Growth: average active patients on therapy increased by 4% compared to Q1 2021
- Productivity improvement continued: revenue per commercial headcount up 32% vs. Q1 2021
- TYMLOS for the Male indication: sNDA filed in Q1 2022 with launch planned for early Q1 2023
- Additional patent granted by USPTO for TYMLOS: extending exclusivity to January 10, 2040
- Elacestrant: on schedule for US regulatory submission in Q2 2022; EU submission to follow
  - Recent competitor trial failures may broaden the opportunity for elacestrant
  - Current focus: robust clinician engagement, life cycle and ‘go to market’ activity
- RAD011: initiating single pivotal studies in Angelman (Q3) and Prader-Willi (Q2) syndromes
  - Hosted a dedicated R&D webcast on April 5, 2022
  - Infantile spasms: this Orphan Drug-Designated program is preparing for regulatory review
  - Dup15q: first company to receive Orphan Drug Designation; strategic life cycle opportunity
- Net Loss of ($18.3) million in Q1 2022 vs. ($15.7) million in Q1 2021

BOSTON, May 05, 2022 (GLOBE NEWSWIRE) -- Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq: RDUS), today reported its financial results for the first quarter ended March 31, 2022. The Company also provided a general business update.

Radius CEO Kelly Martin provided the following commentary covering a variety of topics:

“Failure to meet the prespecified primary endpoint in the long awaited abaloparatide transdermal system pivotal trial resulted in a swift and precipitous 50+% drop in the Radius share price during the month of December. Conversely, our convertible notes, as an indicator for the credit market assessment of the Radius balance sheet, cash flows and business fundamentals, were basically unchanged in price and value during that same period.”

Martin added, “against this dislocation and backdrop, our approach is to ‘control what we can control’ and focus on advancing the Radius business on behalf of shareholders, creditors, patients and employees.”

“To that end, we are working closely with our partner – the Menarini Group – on all aspects of elacestrant. Recent competitor trial failures in the SERD space may expand the potential commercial opportunity – and subsequent value – for the asset if approved. Our financial participation is realized through achievement of both milestones and royalties and, importantly, incorporates all indications, geographies and any combination therapies following the monotherapy data and potential approval. As announced in February, we will return 100% of the value generated by elacestrant to our capital providers – both creditors as well as shareholders.”

“For RAD011, we are progressing this molecule in a deliberate and disciplined manner with a focus on specific genetically based and orphan neurological/behavioral diseases. Interest in the program – post the April R&D webcast – has been, and continues to be, noteworthy. Clear and specific patient need, little to no treatment options, pre-existing data and a concise regulatory path leading to single pivotal trial readouts in 2H 2024 underscore the characteristics of the opportunity.”

“Lastly, for TYMLOS we are preparing for a potential US launch for the male indication, assisting our partners Paladin Labs in Canada and Teijin Pharma in Japan for launches in their respective countries. As per our previously stated goal to ‘expand the global footprint of the asset’ we expect to finalize up to three additional geographic/partner agreements over the coming months, and plan for up to four ex-US market launches in 2023. We have also completed all necessary steps for the EU re-submission and await that decision in 2H 2022.”

In summary, Martin concluded, “as mentioned in our FY 2021 earnings in February, the recent market dislocation in biotechnology has been significant. We expect these challenges to continue throughout 2022. Within this environment, Radius continues to have the opportunity to differentiate itself by remaining active with the balance sheet and monitoring cash flow, managing the risk/reward dynamics of the three assets and, lastly, incorporating overall corporate timelines and potential business inflection points.”

Q1 2022 FINANCIAL HIGHLIGHTS

Revenues

- Total net revenues for the quarter were $43 million compared to $56 million in Q1 2021, which included $11 million in one-time payments received for abaloparatide approval in Japan and licensing in Canada
- TYMLOS net product revenue was $43 million compared to $45 million in Q1 2021, down 5%. This modest decrease was expected in Q1 and was driven primarily by inventory destocking and seasonal payer dynamics
- Patient Growth: average active patients on therapy increased by 4% compared to Q1 2021
- Reiterate full year 2022 guidance of $232 million with 42% of net revenue estimated to come in 1H ($97 million) and 58% ($135 million) in 2H 2022. The Q1 net revenue is on track to meet the 1H guidance

Productivity and Headcount

- Total headcount for the quarter was 258 compared to 294 in Q1 2021, down 12%; and down 31% compared to 376 in Q1 2020
- Dramatic Productivity Improvements: TYMLOS net revenue per commercial employee was $374k in Q1 2022 compared to $283k in Q1 2021, up 32%; compared to Q1 2020, commercial productivity has improved by 66%
- The Company continues to employ a ‘hybrid work environment’. Real estate footprint vs. 2020 has been reduced by nearly 85% and those associated infrastructure costs are down by ~65%

P&L

- Net Loss of ($18.3) million in Q1 2022 vs ($15.7) million in Q1 2021
- Adjusted EBITDA (Non-GAAP) loss of ($9.1) million Q1 2022 vs. ($4.6) million Q1 2021[1]
- Diluted EPS (GAAP): ($0.39) in Q1 2022 vs. ($0.34) in Q1 2021

Balance Sheet

- $72 million of cash, cash equivalents and marketable securities as of March 31, 2022
- Decrease in cash driven by change in net working capital ($19 million), annual bonus payouts, one-time reduction in force (RIF) payouts, and other one-time items

Mark Conley, Chief Financial Officer, commented, “Our first quarter TYMLOS net revenue is in line with our 1H 2022 net revenue guidance of $97 million and today we are reiterating our financial objectives for 2022, including TYMLOS net revenue of $232 million. Our total headcount has reduced further this quarter and our productivity has increased significantly, demonstrating efficient management of our cost structure, and increased operational efficiency.”

Conley added, “We ended the quarter with $72 million in cash, driven by several one-time items. We expect

cash on the balance sheet to increase as the year progresses."

Key Financial Objectives for 2022

Radius reiterates its financial objectives for 2022, as set out in its press release dated February 24, 2022, which included:

- $232 million TYMLOS Net Revenue (42% estimated in 1H and 58% in 2H 2022)
- ($5) to $5 million Net Loss
- $35 to $45 million Company Adjusted EBITDA (Non-GAAP)

ASSETS UPDATE

Elacestrant

Elacestrant is the first and currently only investigational oral SERD to show positive topline results in a pivotal trial as a monotherapy vs. standard of care (SoC) for the treatment of ER+HER2-advanced or metastatic breast cancer (mBC).

- Recent competitor trial failures may broaden the opportunity for elacestrant
- Differentiator of EMERALD from other SERD trials: two primary endpoints, all-comers and ESR1 mutant subgroup
- Current focus: robust clinician engagement, life cycle and 'go to market' activity
- Regulatory submissions: on track to file in the US in Q2 2022 with EU filing to follow the US filing
- Life cycle management: Menarini Group is working to further develop elacestrant in the adjuvant setting, combination therapy, and metastatic breast cancer that has metastasized to the brain

RAD011

RAD011 is the Company's investigational synthetic cannabidiol oral solution which has potential utilization in multiple neuro-endocrine, neurodevelopmental, or neuropsychiatric disease areas.

- Initiating two single pivotal trials in Angelman syndrome (AS) (Q3) and Prader-Willi syndrome (PWS) (Q2)
  - SCOUT-015 study evaluating hyperphagia in PWS is open for recruitment and has begun patient screening in the US
- Plans to follow AS and PWS trials with a Phase 2 infantile spasms (IS) trial evaluating spasm resolution
- Dup15q syndrome: first company to receive Orphan Drug Designation; possible life cycle opportunity
- Orphan Drug Designations have been granted for all four of the above indications in the US
- On April 5, 2022, Radius hosted an R&D webcast dedicated to RAD011; a replay of the webcast and presentation is available on the Company's website (**https://ir.radiuspharm.com/events-and-presentations**)

ABALOPARATIDE

TYMLOS in Male Indication

As previously reported on March 1, 2022, the Company filed a Supplemental New Drug Application (sNDA) with the US Food and Drug Administration (FDA) for TYMLOS (abaloparatide) subcutaneous injection in men with osteoporosis at high risk for fracture.

- 10-month review process and, subject to approval, plan to launch in early Q1 2023
- Estimated that 30% of all hip fractures occur in men and approximately 20% of men over the age of 50 will experience an osteoporosis-related fracture in their lifetime
- The full data set from the ATOM Phase 3 study will be presented at the upcoming American Association of Clinical Endocrinology (AACE) Annual Meeting on May 12-14, 2022

TYMLOS Intellectual Property

- On March 8, 2022, Radius announced the United States Patent and Trademark Office (USPTO) granted patent 11,255,842, which extends TYMLOS exclusivity to January 10, 2040
- This adds to the Company's four issued patents covering TYMLOS, which provide significant depth and breadth in protecting the commercial runway of the asset

Financial Results

Three Months Ended March 31, 2022

Net Loss
For the three months ended March 31, 2022, Radius reported a net loss of $18.3 million, or $0.39 per share, compared to a net loss of $15.7 million, or $0.34 per share, for the three months ended March 31, 2021.

For the three months ended March 31, 2022, Adjusted EBITDA (Non-GAAP), was ($9.1) million, or $0.19 per share, compared to Adjusted EBITDA (Non-GAAP) of ($4.6) million, or $0.10 per share, for the three months ended March 31, 2021.

Revenue
For the three months ended March 31, 2022, TYMLOS net product revenues were $43.0 million compared to $45.3 million for the three months ended March 31, 2021.

For the three months ended March 31, 2022, $0.2M in license revenue was recognized compared to $11.0 million recognized for the three months ended March 31, 2021.

Costs and Expenses
For the three months ended March 31, 2022, research and development expense was $22.7 million compared to $31.4 million for the three months ended March 31, 2021, a decrease of $8.7 million, or 28%. This decrease was primarily driven by a decrease of $7.3 million in abaloparatide-TD program costs, a $5.5 million decrease in abaloparatide-SC program costs, a $0.8 million decrease in professional fees driven by billed reimbursable consultant costs, and a $2.1 million decrease in elacestrant program costs, which is comprised of a $7.3 million decrease in gross program expenses as well as a $5.2 million increase in billed reimbursable expenses. These decreases were offset by a $6.1 million increase in RAD011 program costs, a $0.4 million increase in occupancy and depreciation costs, and a $0.4 million increase in compensation expense, which is comprised of a $1.0 million increase in compensation expense related to headcount offset by $0.5 million of billed reimbursable expenses.

For the three months ended March 31, 2022, selling, general and administrative expenses were $30.0 million compared to $34.1 million for the three months ended March 31, 2021, a decrease of $4.1 million, or 12%. This decrease was primarily the result of a $3.5 million decrease in professional support costs and a $1.2 million decrease in wages and employee benefit costs due to a decrease in headcount. These decreases were offset by a $1.4 million increase in occupancy and depreciation costs and other operating costs.

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

	March 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 71,615	$ 111,533
Restricted cash	567	567
Accounts receivable, net	30,280	23,355
Inventory	13,296	11,373

Prepaid expenses	16,273	10,050
Other current assets	13,738	16,201
Total current assets	145,769	173,079
Property and equipment, net	763	647
Intangible assets	4,787	4986
Right of use assets - operating leases	981	835
Other assets	1,848	1,995
Total assets	$ 154,148	$ 181,542
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 15,791	$ 17,625
Accrued expenses and other current liabilities	64,164	76,549
Operating lease liability, current	508	613
Total current liabilities	80,463	94,787
Convertible notes payable	190,686	190,479
Term loan	148,473	148,265
Operating lease liability, long term	473	315
Total liabilities	420,095	433,846
Stockholders' equity (deficit):	5	5
Common stock, 0.0001 par value; 200,000,000 shares authorized,47,564,764 shares and 47,359,573 shares issued and outstanding at March 31, 2022 and December 31, 2021		
Additional paid-in-capital	1,120,299	1,115,672
Accumulated other comprehensive income	6	-
Accumulated deficit	(1,386,257)	(1,367,981)
Total stockholders' equity (deficit)	(265,947)	(252,304)
Total liabilities and stockholders' equity (deficit)	$ 154,148	$ 181,542

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

	Three Months Ended March 31,	
	2022	**2021**
REVENUES:		
Product revenue, net	$ 42,958	$ 45,261
License Revenue	200	11,000
Total revenue	43,158	56,261
OPERATING EXPENSES:		
Cost of sales - product	4,060	3,925
Cost of sales - intangible amortization	200	200
Research and development, net of amounts reimbursable (a)	22,697	31,440
Selling, general, and administrative	30,048	34,097
Loss from operations	(13,847)	(13,401)
OTHER INCOME (EXPENSE):		
Other income (expense)	379	(1)
Interest expense	(4,822)	(4,364)
Interest income	14	57
Gain on extinguishment of debt	-	1,960
NET LOSS	$ (18,276)	$ (15,749)
OTHER COMPREHENSIVE LOSS:		
Foreign currency gain	6	0
Unrealized loss from available-for-sale debt securities	-	(21)
COMPREHENSIVE LOSS	$ (18,270)	$ (15,770)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:	$ (18,276)	$ (15,749)
LOSS PER SHARE:		
Basic and diluted	$ (0.39)	$ (0.34)
WEIGHTED AVERAGE SHARES:		
Basic and diluted	47,441,821	46,981,016

(a) Amounts reimbursable were $9.1 million and $14.3 for the three ended March 31, 2022 and 2021.

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

	Three Months Ended March 31,	
	2022	2021
Net loss reconciliation:		
GAAP net loss	$ (18,276)	$ (15,749)
Intangible amortization	200	200
Share-based compensation expense	4,145	5,410
Restructuring charges	408	
Depreciation	41	52
Interest expense, net	4,808	4,307
Gain on extinguishment of debt	$ -	$ (1,960)
Debt refinancing charges	-	3,143
Other	(379)	1
Adjusted EBITDA	$ (9,053)	$ (4,596)
Reconciliation of diluted loss per share:		
GAAP loss per share	$ (0.39)	$ (0.34)
Intangible amortization	0.00	0.00
Share-based compensation expense	0.09	0.12
Restructuring charges	0.01	0.00
Depreciation	0.00	0.00
Interest expense, net	0.10	0.09
Gain on extinguishment of debt	0.00	(0.04)
Debt refinancing charges	0.00	0.07
Other	(0.01)	0.00
Adjusted EBITDA per share	$ (0.19)	$ (0.10)
Reconciliation of shares used in loss per share calculation:		
GAAP shares used in loss per share	47,441,821	46,981,016
Non-GAAP dilutive share adjustments	-	-
Non-GAAP shares used in earnings (loss) per share	47,441,821	46,981,016

Webcast and Conference Call

In connection with today's reporting of First Quarter 2022 Financial Results, Radius will host a conference call and live audio webcast at 8:30 a.m. ET today, May 5, 2022, to review financial results and provide a Company update.

Conference Call Information:
Date: May 5, 2022
Time: 8:30 a.m. ET
Domestic Dial-In Number: 1 (866) 323-7965
International Dial-In Number: 1 (346) 406-0961
Conference ID: 5844208
Webcast Link: https://edge.media-server.com/mmc/p/nmcknbsv

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.

A replay of the conference call will be available on May 5th at 11:30 a.m. ET. A live audio webcast of the call will be archived on the Company's website for 12 months. To access the replay, dial (855) 859-2056 or (404) 537-3406 for International, using conference ID number 5844208. The live audio webcast of the call can be accessed from the Investors section of the Company's website, https://ir.radiuspharm.com/events-and-presentations. 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 in this press release: Adjusted EBITDA and Adjusted EBITDA per share. The Company defines adjusted EBITDA as net income before interest, taxes, depreciation and amortization,

adjusted for the impact of certain additional non-cash and other items that management does not consider in its evaluation of ongoing performance of the Company's core operations. These items include stock-based compensation expense and other one-time expenses. 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, 2022 and 2021 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

This release includes forward-looking guidance for adjusted EBITDA. The Company is not able to provide, without unreasonable effort, a reconciliation of the guidance for adjusted EBITDA to the most directly comparable GAAP measure because the Company does not currently have sufficient data to accurately estimate the variables and individual adjustments included in the most directly comparable GAAP measure that would be necessary for such reconciliations, including (a) one-time items or other expenses that we do not believe are indicative of our ongoing operations. These adjustments are inherently variable and uncertain and depend on various factors that are beyond our control and as a result we are also unable to predict their probable significance. Therefore, because management cannot estimate on a forward-looking basis without unreasonable effort the impact these variables and individual adjustments will have on its reported results in accordance with GAAP, it is unable to provide a reconciliation of the non-GAAP measures included in its 2022 guidance.

About Radius

Radius is a global biopharmaceutical company focused on addressing unmet medical needs in the areas of bone health, orphan diseases, 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 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 neuro-endocrine, neurodevelopmental, or neuropsychiatric disease areas, initially targeting Prader-Willi syndrome, Angelman syndrome, and infantile spasms.

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 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 prior to EMERALD indicated 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 was 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 enrolled 466 patients who had 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 was progression-free survival (PFS) in the overall patient population and in patients with estrogen receptor 1 gene (ESR1) mutations. Secondary endpoints included 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 125 patients across multiple indications and has potential utilization in multiple neuro-endocrine, neurodevelopmental, or neuropsychiatric disease areas. Radius plans to study RAD011 in patients with Angelman syndrome, Prader-Willi syndrome, and infantile spasms.

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.

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, 2021 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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[1] Adjusted EBITDA is not calculated or presented in accordance with generally accepted accounting principles in the United States (GAAP). For more information about how we use this non-GAAP financial measures in our business, the limitations of these measures, and a reconciliation of these measures to the most directly comparable GAAP measures, please see "Use of Non-GAAP Financial Measures" and the reconciliation tables that accompany this release.