



## Radius Health Announces Fourth Quarter and Full-Year 2018 Operating Results

February 28, 2019

*TYMLOS® U.S. net sales continued to increase, reaching \$34.4 million in the fourth quarter of 2018 and totaling \$99.2 million for full-year 2018, exceeding the Company's guidance of \$95-98 million.*

*Elacestrant's Phase 3 study was initiated at the end of 2018 and is open for enrollment.*

*Radius maintains its financial guidance for 2019 with full-year TYMLOS U.S. net sales expected to be between \$155 to \$175 million and year-end cash, cash equivalents & investments expected to exceed \$100 million.*

*Conference call scheduled for 4:30 p.m. ET today*

WALTHAM, Mass., Feb. 28, 2019 (GLOBE NEWSWIRE) -- Radius Health, Inc. ("Radius" or the "Company") (Nasdaq: RDUS), today reported its financial and operating results for the fourth quarter and full-year ended December 31, 2018 and provided a business update.

"I am very pleased with the continued strong performance of TYMLOS in the U.S. market. In 2019, we expect to continue expanding our market share for TYMLOS in the U.S. anabolic market and advancing our late-stage clinical pipeline with our pivotal elacestrant and abaloparatide-patch Phase 3 studies," said Jesper Hoeiland, President and Chief Executive Officer of Radius.

### **TYMLOS (abaloparatide) injection**

- Fourth quarter 2018 U.S. net sales of TYMLOS were \$34.4 million, a 25% increase over the prior quarter and 349% increase from the fourth quarter of 2017. Full-year 2018 U.S. net sales of TYMLOS were \$99.2 million, a more than sevenfold increase from full-year 2017.
- In 2018, TYMLOS captured, on average, 20% of the U.S. anabolic osteoporosis market (based on Patient Months on Therapy, TRx PMOT). In the fourth quarter of 2018, TYMLOS' average U.S. anabolic market share rose to 26% and it achieved a 39% share of new anabolic patient starts. In the first six weeks of 2019, TYMLOS has reached, on average, a 29% share of the U.S. anabolic osteoporosis market and over 40% of new anabolic patient starts.
- The growth trajectory of the U.S. anabolic market since TYMLOS launched in May 2017 continued in the fourth quarter of 2018, showing 7% volume growth as compared to the fourth quarter of 2017 and 8% volume growth in full-year 2018 as compared to full-year 2017.
- A 5.9% price increase for TYMLOS took effect on January 1, 2019.
- As of January 1, 2019, TYMLOS was covered for approximately 283 million U.S. insured lives, representing approximately 99% of U.S. commercial, 67% of Medicare and 96% Medicaid/Other insured lives. 2019 Medicare Part D coverage for TYMLOS increased to approximately 26 million lives, or 67% of those enrolled in Medicare Part D plans in the U.S., from 18 million lives, or 44% enrollees, in 2018, after decisions from SilverScript Insurance Company (CVS), WellCare Health Plans, Inc., Prime Therapeutics and others to cover TYMLOS for their Medicare Part D beneficiaries.
- Effective as of January 1, 2019, manufacturers of brand-name drugs, like TYMLOS, will be required to pay a 70% discount during the coverage gap phase of the Medicare Part D program, up from the 50% coverage gap discount required in 2018.

### **Financial Guidance**

- With 2018 TYMLOS U.S. net sales reaching \$99.2 million, Radius exceeded its 2018 full-year net sales guidance of \$95 to \$98 million. Radius' 2018 year-end cash, cash equivalents and investments balance of \$237 million was in line with its guidance for it to exceed \$220 million.
- Radius maintains its 2019 financial guidance with full-year TYMLOS U.S. net sales expected to be between \$155 to \$175 million and its year-end cash, cash equivalents and investments balance expected to exceed \$100 million.

### **Pipeline Highlights**

#### **Abaloparatide-Transdermal Patch (abaloparatide-patch)**

- In 2018, Radius made substantial progress in its readiness for clinical supplies for its Phase 3 study, which is expected to start in mid-2019. Scale-up of production continues to progress, a significant portion of analytical method validations are near completion and progress is being made on the patch applicator device design qualification. In the second half of

2018, Radius completed further evaluation confirming that a five minute application of abaloparatide-patch to the thigh resulted in a pharmacokinetic profile highly similar (AUC >90%) to abaloparatide-SC. Further evaluation is in progress to confirm that clinical trial subjects will be able to correctly self-administer abaloparatide-patch.

- Radius has also made significant progress scaling up for potential commercial supplies of abaloparatide-patch, and in partnership with 3M Company, selected Patheon, part of Thermo Fisher Scientific, to conduct the abaloparatide-patch coating process and packaging operations. Critical capital equipment for the manufacturing of commercial supplies was purchased and Radius is working with 3M to finalize engineering equipment designs. Build out of the commercial manufacturing facility at Patheon has started and equipment installation at Patheon is planned to start in the first half of 2019.

#### **Elacestrant (RAD1901)**

- Radius initiated its Phase 3 EMERALD study of elacestrant in late November 2018. It is the first Phase 3 study to prospectively evaluate treatment benefit for second- and third-line breast cancer patients following CDK 4/6 inhibitor therapy as well as to prospectively compare outcomes in patients whose tumors harbor estrogen receptor 1 gene (ESR1) mutations. The study is open to enrollment with a planned recruitment period of 18-21 months and potential data read-out in 2021.
- In December 2017, we reported mature data from our multiple-part Phase 1 dose-escalation and expansion study of elacestrant in postmenopausal women with ER-positive and HER2-negative advanced breast cancer. As of the study cut-off date of October 30, 2017, data from 40 patients treated at the 400 mg elacestrant dose in Parts A through C of this study showed an elacestrant single agent objective response rate (ORR) of 27.3%, with six confirmed partial responses out of 22 patients with RECIST measurable disease, a 5.4 month median progression free survival (PFS) rate and 47.4% clinical benefit rate at 24 weeks. These results showed that elacestrant was well-tolerated with the most commonly reported adverse events being low grade nausea, dyspepsia and vomiting.
- A preliminary review of data from a Part D cohort of this study was conducted in January 2019. The Part D Cohort was intended to study the impact of elacestrant in patients who had progressed on at least two prior lines of endocrine therapy for advanced disease, including fulvestrant and prior treatment with a CDK 4/6 inhibitor. Due to a change in the Company's final design of its Phase 3 study of elacestrant, with a shift to target an earlier line of therapy, only 10 of the originally planned 36 subjects were enrolled in the Part D cohort. A preliminary review of the data as of December 27, 2018 showed that overall the subjects in this cohort were more heavily pretreated and a higher proportion of subjects had visceral metastases than subjects in Parts A through C of this study. In addition, out of the nine subjects in this cohort with measurable disease, four had a best response of stable disease, two of them for greater than 24 weeks. No significant differences in safety profiles were seen between Cohorts A through C compared to Cohort D. Combined data, as of December 27, 2018, from all four study Parts (A through D) at 400 mg showed that the overall elacestrant single agent ORR was 19.4% and the median PFS was 4.5 months. As of January 3, 2019, one subject remained on treatment in the Part D cohort.

#### **RAD140**

- The Company's Phase 1 dose escalation study of RAD140 in HR+ breast cancer patients is ongoing and enrollment is expected to remain active through the first quarter of 2019. A provisional maximum tolerated dose (MTD) was identified and an additional cohort has been opened to further confirm tolerability, pharmacokinetics, and on-treatment pharmacodynamics effects of RAD140 at that dose.

#### **Anticipated Milestones in 2019**

- Abaloparatide-patch
  - Initiate Phase 3 study in mid-2019
- Elacestrant
  - Advance recruitment in Phase 3 EMERALD monotherapy study
  - Global co-development/co-commercialization partnership for elacestrant
  - Initiate a combination trial for elacestrant in conjunction with a partner
- TYMLOS/Financial
  - Grow full-year TYMLOS U.S. net sales to between \$155M to \$175M
  - Deliver a strong balance sheet with greater than \$100M cash, cash equivalents and investments balance at year-end

#### **Expected Radius Presentations at Upcoming Conferences in Q1 2019**

- On March 1, 2019, the Company will present and host one-on-one meetings at the Leerink Partners 8<sup>th</sup> Annual Healthcare Conference in New York.
- On March 5, 2019, the Company will host one-on-one meetings at the Credit Suisse Annual Healthcare Conference in London.
- On March 13, 2019, the Company will present and host one-on-one meetings at the Cowen 39<sup>th</sup> Annual Healthcare Conference in Boston.
- On March 19, 2019, the Company will host one-on-one meetings at the Morgan Stanley Healthcare Corporate Access Day in Boston.

#### Fourth Quarter and Full Year 2018 Financial Results

##### Three Months Ended December 31, 2018

For the three months ended December 31, 2018, Radius reported a net loss of \$41.1 million, or \$0.90 per share, compared to a net loss of \$71.0 million, or \$1.59 per share, for the three months ended December 31, 2017.

For the three months ended December 31, 2018, non-GAAP adjusted net loss, which excludes expenses related to stock-based compensation, restructuring plans, depreciation, non-cash interest obligations under debt obligations, litigation related payments, and amortization of intangible assets, was \$30.0 million, or \$0.66 per share, compared to non-GAAP adjusted net loss of \$60.5 million, or \$1.36 per share, for the three months ended December 31, 2017.

For the three months ended December 31, 2018, TYMLOS net product revenues were \$34.4 million compared to approximately \$7.7 million for the three months ended December 31, 2017.

Research and development expense for the three months ended December 31, 2018 was \$23.9 million compared to \$22.9 million for the three months ended December 31, 2017, an increase of \$1.0 million, or 4%. This increase was primarily driven by increases in elacestrant project costs and abaloparatide-patch project costs.

For the three months ended December 31, 2018, selling, general and administrative expense was \$43.9 million compared to \$50.7 million for the three months ended December 31, 2017, a decrease of \$6.8 million, or 13%. This decrease was primarily the result of \$3.7 million and \$3.0 million decreases in compensation and travel related expenses and professional fees, respectively.

##### Twelve Months Ended December 31, 2018

For the twelve months ended December 31, 2018, Radius reported a net loss of \$221.4 million, or \$4.88 per share, compared to a net loss of \$254.2 million, or \$5.80 per share, for the twelve months ended December 31, 2017.

For the twelve months ended December 31, 2018, non-GAAP adjusted net loss, which excludes expenses related to stock-based compensation, restructuring plans, depreciation, non-cash interest obligations under debt obligations, litigation related payments, and amortization of intangible assets, was \$163.0 million, or \$3.59 per share, compared to non-GAAP adjusted net loss of \$212.0 million, or \$4.84 per share, for the twelve months ended December 31, 2017.

For the twelve months ended December 31, 2018, TYMLOS net product revenues were \$99.2 million compared to approximately \$12.1 million for the twelve months ended December 31, 2017.

Research and development expense for the twelve months ended December 31, 2018 was \$99.9 million compared to \$83.1 million for the twelve months ended December 31, 2017, an increase of \$16.8 million, or 20%. This increase was primarily a result of an increase of \$7.1 million in program spending for the abaloparatide-patch program, a \$5.9 million increase in program spending for continuing research for TYMLOS, a \$4.9 million increase in program spending for elacestrant research, and a \$1.9 million increase in program spending for RAD140 research. These increases were partially offset by a \$1.3 million decrease in R&D support costs as well as a \$1.7 million decrease in compensation related costs primarily due to the decrease in stock compensation expense for the year ended December 31, 2018. We expect our research and development expenses to continue to increase as the result of conducting our elacestrant Phase 3 study and the expected launch in 2019 of our abaloparatide-patch Phase 3 study and related manufacturing scale-up activities.

Selling, general, and administrative expense for the twelve months ended December 31, 2018, was \$184.2 million compared to \$186.7 million for the twelve months ended December 31, 2017, a decrease of \$2.5 million, or 1%. This decrease was primarily due to a \$3.3 million decrease in professional fees related to commercial operations and general and administrative activities. This decrease was partially offset by a \$0.9 million increase in dues and subscriptions.

As of December 31, 2018, Radius had \$237.0 million in cash, cash equivalents, restricted cash, and marketable securities. Based upon our cash, cash equivalents and marketable securities balance as of December 31, 2018, 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.

#### Condensed Consolidated Balance Sheets

(Amounts in thousands, except share and per share amounts)

December 31, 2018	December 31, 2017
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**ASSETS**

## Current assets:

Cash and cash equivalents	\$ 59,321	\$ 118,564
Restricted cash	560	55
Marketable securities	177,140	134,714
Accounts receivable, net	16,758	4,441
Inventory	6,210	4,366
Prepaid expenses	13,842	5,175
Other current assets	1,202	2,191
Total current assets	275,033	269,506
Investments	-	176,978
Property and equipment, net	4,003	6,195
Intangible assets	7,382	8,180
Other assets	544	799
Total assets	\$ 286,962	\$ 461,658

**LIABILITIES AND STOCKHOLDERS' EQUITY**

## Current liabilities:

Accounts payable	\$ 4,226	\$ 3,915
Accrued expenses and other current liabilities	42,203	49,512
Total current liabilities	46,429	53,427
Other non-current liabilities	95	189
Notes payable	179,806	166,006
Total liabilities	226,330	219,622

## Stockholders' equity:

Common stock, \$.0001 par value; 200,000,000 shares authorized, 45,563,693 shares and 44,616,586 shares issued and outstanding at December 31, 2018 and 2017, respectively	5	4
Additional paid-in-capital	1,165,003	1,124,630
Accumulated other comprehensive loss	(755 )	(314 )
Accumulated deficit	\$ (1,103,621 )	\$ (882,284 )
Total stockholders' equity	60,632	242,036
Total liabilities and stockholders' equity	\$ 286,962	\$ 461,658

**Condensed 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,	
	2018	2017	2018	2017
REVENUES:				
Product revenue, net	\$ 34,424	\$ 7,663	\$ 99,239	\$ 12,112
License revenue	—	—	—	\$ 10,000
OPERATING EXPENSES:				
Cost of sales - product	2,743	574	7,627	932
Cost of sales - intangible amortization	199	200	799	400
Research and development	23,932	22,900	99,911	83,076
Selling, general and administrative	43,899	50,734	184,164	186,677
Other operating expenses	—	—	10,801	—
Loss from operations	(36,349 )	(66,745 )	(204,063 )	(248,973 )
OTHER (EXPENSE) INCOME:				
Other income (expense)	(25 )	20	59	(192 )
Interest expense	(5,913 )	(5,535 )	(22,955 )	(8,298 )
Interest income	1,189	1,243	5,622	3,226
NET LOSS	(41,098 )	(71,017 )	(221,337 )	(254,237 )
OTHER COMPREHENSIVE LOSS:				
Unrealized gain (loss) from available-for-sale debt securities	\$ 94	\$ (315 )	\$ (441 )	\$ (385 )
COMPREHENSIVE LOSS	(41,004 )	(71,332 )	(221,778 )	(254,622 )
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED	\$ (41,098 )	\$ (71,017 )	\$ (221,337 )	\$ (254,237 )

**LOSS PER SHARE:**

Basic and diluted	\$ (0.90	) \$ (1.59	) \$ (4.88	) \$ (5.80	)
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**WEIGHTED AVERAGE SHARES:**

Basic and diluted	45,549,972	44,602,254	45,356,263	43,804,660
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**Reconciliation of GAAP to Non-GAAP Financial Information**

(Unaudited amounts in thousands, except share and per share amounts)

	Three Months Ended		Twelve Months Ended	
	December 31, 2018	2017	December 31, 2018	2017
<b>Net loss reconciliation:</b>				
GAAP net loss	\$ (41,098	) \$ (71,017	) \$ (221,337	) \$ (254,237
Intangible amortization	199	200	799	400
Stock-based compensation expense	6,433	6,219	28,702	35,003
Restructuring charges	338	-	2,366	-
Depreciation	486	854	1,891	2,031
Non-cash interest	3,626	3,248	13,800	4,816
Legal settlement	35	-	10,836	-
Non-GAAP net loss	\$ (29,981	) \$ (60,496	) \$ (162,943	) \$ (211,987

**Reconciliation of diluted loss per share:**

GAAP loss per share	(0.90	) (1.59	) (4.88	) (5.80
Intangible amortization	-	-	0.02	-
Stock-based compensation expense	0.14	0.14	0.63	0.80
Restructuring charges	0.01	-	0.05	-
Depreciation	0.01	0.02	0.04	0.05
Non-cash interest	0.08	0.07	0.31	0.11
Legal settlement	-	-	0.24	-
Non-GAAP loss per share	\$ (0.66	) \$ (1.36	) (3.59	) \$ (4.84

**Reconciliation of shares used in loss per share calculation:**

GAAP shares used in loss per share	45,549,972	44,602,254	45,356,263	43,804,660
Non-GAAP dilutive share adjustments	-	-	-	-
Non-GAAP shares used in loss per share	45,549,972	44,602,254	45,356,263	43,804,660

**Webcast and Conference Call**

In connection with today's reporting of Fourth Quarter and Full Year 2018 Financial Results, Radius will host a conference call and live audio webcast at 4:30 p.m. ET today, February 28, 2019, to discuss the commercial outlook for TYMLOS, review the financial results and provide a Company update.

**Conference Call Information:****Date:** February 28, 2019**Time:** 4:30 p.m. ET**Domestic Dial-in Number:** (866) 323-7965**International Dial-in Number:** (346) 406-0961**Conference ID:** 2468547**Live webcast:** <https://edge.media-server.com/m6/p/5c5c6u5k>

For those unable to participate in the conference call or webcast, a replay will be available from February 28, 2019 at 7:30 p.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 2468547.

A live audio webcast of the call can be accessed from the Investors section of the Company's website, [www.radiuspharm.com](http://www.radiuspharm.com). 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: 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 and twelve months ended December 31, 2017 and 2018 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 in the areas of osteoporosis 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 an investigational abaloparatide-patch for potential use in osteoporosis; the investigational drug elacestrant (RAD1901) for potential use in hormone-receptor positive breast cancer; 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](http://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. Radius also is developing abaloparatide-patch based on 3M Company's patented Microstructured Transdermal System technology for potential use as a treatment for postmenopausal women with osteoporosis.

#### **About Elacestrant (RAD1901)**

Elacestrant is a selective estrogen receptor degrader (SERD), which is being evaluated for potential use as a once daily oral treatment for hormone-receptor positive breast cancer. Elacestrant is currently being investigated for potential use in women with advanced estrogen receptor positive, HER2 negative, breast cancer, the most common form of the disease. 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.

#### **About RAD140**

RAD140 is a non-steroidal selective androgen receptor modulator (SARM). The androgen receptor (AR) is frequently expressed in many estrogen receptor (ER)-positive, ER-negative, and triple-negative breast cancers. Because of its receptor and tissue selectivity, potent activity, oral bioavailability, and long half-life, RAD140 could have clinical potential in the treatment of breast cancer. RAD140 resulted from an internal drug discovery program focused on the androgen receptor pathway and exhibits a differentiated mechanism of action compared to ER-targeted therapy.

#### **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 for full-year TYMLOS U.S. net sales and our year-end cash, cash equivalents and investments balance; our expectations regarding commercialization of TYMLOS in the U.S., including expectations for continuing to expand our share of the U.S. anabolic osteoporosis market; our expectations regarding our regulatory submissions, including the timing thereof; our expectations regarding our clinical trials, including the design and timing thereof; our entry into potential collaborations, including the timing thereof, including our plans to enter into a global co-development, co-commercialization partnership for elacestrant; the progress in the development of our product candidates, including abaloparatide-patch, elacestrant (RAD1901) and RAD140; each of the statements under the headings "Anticipated Milestones in 2019," and "Expected Radius Presentations at Upcoming Conferences in Q1 2019;" the sufficiency of our cash, cash equivalents, restricted cash, marketable securities and investments balance; and the potential clinical uses and therapeutic and other benefits of our product candidates, including abaloparatide-patch, elacestrant and RAD140.

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: we expect to need to raise additional funding, which may not be available; risks related to raising additional capital; 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 agreements and any executed collaboration agreements failing to be successful; 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, 2018 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](mailto:ewebb@radiuspharm.com)

Phone: 617-551-4011



Source: Radius Health Inc.