

RADIUS HEALTH, INC.

FORM 8-K (Current report filing)

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 3, 2017

RADIUS HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-35726
(Commission
File Number)

80-0145732
(IRS Employer
Identification No.)

950 Winter Street,
Waltham, MA
(Address of principal executive offices)

02451
(Zip Code)

Registrant's telephone number, including area code: (617) 551-4000

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition .

On August 3, 2017, Radius Health, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2017. A copy of the press release is attached hereto as Exhibit 99.1.

The information contained in this Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly provided by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated August 3, 2017.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

RADIUS HEALTH, INC.

Date: August 3, 2017

By: /s/ Jose Carmona

Name: Jose Carmona

Title: Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated August 3, 2017.



Radius Health Reports Second Quarter 2017 Financial and Operating Results and Provides Business Update

2Q'17 financial results reflect the first 4 weeks of TYMLOS sales in the U.S.

Managed care contracts in place for coverage of over 130 million lives for TYMLOS™ (68% of all Commercial and 28% of Medicare) point to strong and early acceptance in the US with our sales team having already reached over 90% of the top 7,000 anabolic-writing HCPs with a high frequency of coverage

Radius gained alignment with the FDA on a single-arm monotherapy Phase 2 study of under 200 patients for elacestrant in breast cancer, which could be considered a pivotal trial for accelerated approval

Radius reports results from the positive 24-month ACTIVEExtend trial and will present additional analyses at the American Society for Bone Mineral Research (ASBMR) Annual Meeting September 8-11, 2017

Waltham, Massachusetts – August 3, 2017 (GLOBE NEWSWIRE): Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq:RDUS), a fully integrated science-driven biopharmaceutical company that is committed to developing and commercializing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases, reported its financial results for the second quarter ended June 30, 2017, and provided a business update. As of June 30, 2017, Radius had \$215 million in cash, cash equivalents and marketable securities.

“This is a very exciting time for Radius, as the company builds out its commercial organization and launches TYMLOS™, the first new bone building anabolic approved by the FDA in 15 years. There is a high unmet medical need among postmenopausal women with osteoporosis at high risk for fractures for therapies which can safely and effectively reduce that risk,” said Jesper Høil and, President and CEO of Radius. “I am confident that we have the leadership and resources to build this important brand globally and to continue to advance our strong pipeline assets, including elacestrant.”

“While early in the launch of TYMLOS, we are extremely pleased with the substantial progress we have made and the strong support we have received from payors, physicians, and patients,” said David Snow, Chief Commercial Officer of Radius. “We are already ahead of plan in contracting with managed care organizations with access to over 133 million covered lives across Commercial and Medicare Part D plans, and highly gratified that Express Scripts has aligned with us on TYMLOS to assure that appropriate patients have access to therapy with lower out of pocket costs.”

TYMLOS (abaloparatide)

- Radius received FDA approval for TYMLOS on April 28, 2017, for the treatment of postmenopausal women with osteoporosis at high risk of fracture, and began shipments to wholesalers at the end of May 2017. In the second quarter of 2017, we reported sales of TYMLOS from the first four weeks of launch of approximately \$1.0 million.
- In May 2017, Radius announced positive top-line results from the completed 24-month ACTIVEExtend clinical trial of TYMLOS, which met all of its primary and secondary endpoints. In ACTIVEExtend, patients who had completed 18 months of TYMLOS (abaloparatide) injections or placebo in the ACTIVE Phase 3 trial were transitioned to received 24 additional months of open-label alendronate. For the subset of ACTIVE trial patients that enrolled in the ACTIVEExtend trial, the previous TYMLOS-treated patients had a significant 84% relative risk reduction in the incidence of new vertebral fractures compared with women who received placebo followed by alendronate. They also demonstrated a 39% risk reduction in nonvertebral fractures, a 34% risk reduction in clinical fractures and a 50% risk reduction in major osteoporotic fractures compared with women who received placebo followed by alendronate. At the 43-month time point, for all patients that enrolled in the ACTIVE trial, TYMLOS-treated patients had a statistically

significant risk reduction in new vertebral fractures, nonvertebral fractures, clinical fractures, and major osteoporotic fractures. While not a pre-specified endpoint, there was also a statistically significant risk reduction in hip fractures in the TYMLOS-treated patient group compared with women who received placebo followed by alendronate at the 43-month time point. The adverse events reported during the alendronate treatment period were similar between the previous TYMLOS-treated patients and the previous placebo group. The incidences of cardiovascular adverse events including serious adverse events were similar between groups. There have been no cases of osteonecrosis of the jaw (ONJ) or atypical femoral fracture (AFF) in the entire TYMLOS development program. Additional results from the completed ACTIVEExtend trial will be presented at the American Society for Bone and Mineral Research (ASBMR) Annual Meeting September 8-11, 2017 in Denver, Colorado.

We plan to submit an sNDA to the FDA in connection with the ACTIVEExtend results by year end.

- On July 13, 2017, Radius announced that it had entered into a license and development agreement with Teijin Limited in Japan for abaloparatide-SC, which combined with the U.S., provides Radius with access to the largest two markets for bone anabolics, which account for approximately 80% of global sales. Teijin is developing abaloparatide-SC in Japan under an agreement with Ipsen Pharma S.A.S. and has initiated a Phase 3 trial in Japanese patients with osteoporosis. The license agreement provides Teijin with the right to manufacture abaloparatide-SC for commercial supply in Japan, as well as the right to reference Radius' NDA and MAA and regulatory data to support its marketing application in Japan and to use Radius intellectual property, and provides Radius with an option to negotiate a co-promotion agreement for abaloparatide-SC in Japan. Radius will also receive upfront and milestone payments and royalties for the rights granted to Teijin. Teijin is conducting and funding its Japanese Phase 3 development program and the parties may further collaborate in the future in new indications for abaloparatide-SC. Radius maintains full global rights to its development program for abaloparatide-transdermal (abaloparatide-TD), which is not part of the agreement with Teijin.

Pipeline Updates

Eladynos™ (abaloparatide-SC)

- Radius' European Marketing Authorisation Application (MAA) for Eladynos (abaloparatide-SC) for the treatment of postmenopausal women with osteoporosis is under review by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). On July 21, 2017, the CHMP, the scientific committee of the EMA, issued a second Day-180 List of Outstanding Issues. Radius is working with the CHMP to address these issues, and we expect an opinion from the CHMP regarding the MAA for Eladynos prior to the end of 2017.

Elacestrant (RAD1901)

- In June 2017, Radius reported additional positive data from the ongoing Phase 1 dose-escalation and expansion study at the 2017 American Society of Clinical Oncology Annual Meeting (ASCO) in Chicago. As of the study cut-off date of April 28, 2017, the elacestrant single agent objective response rate was 23% in heavily pre-treated patients with advanced ER-positive breast cancer. In the 400 mg patient group of 26 patients with mature data, the median progression free survival was 4.5 months and there were five confirmed partial responses. These results showed that elacestrant was well-tolerated with the most commonly reported adverse events being low grade nausea and dyspepsia. To date, no dose limiting toxicities have been reported in the elacestrant program. We recently completed patient enrollment in both of our ongoing elacestrant Phase 1 breast cancer trials.
- In June 2017, we discussed the data from the ongoing Phase 1 studies with the FDA to gain alignment on defining the next steps for our elacestrant breast cancer program, including the design of a Phase 2 trial. Following this discussion, the FDA agreed that a single-arm monotherapy Phase 2 study of under 200 patients is appropriate and provided additional feedback on the proposed clinical protocol, including confirmation that the primary endpoint will be objective response rate ("ORR"), coupled with durability of response ("DOR"). The FDA indicated that, depending on the study results, which must demonstrate superiority to then available therapies, the single-arm Phase 2 trial could be considered a pivotal study for accelerated approval as long as we have commenced a confirmatory study by the time of our NDA submission. We will provide further study details when the Phase 2 study is started and will continue to pursue additional pathways to accelerated approval.

- Elacestrant is also being evaluated at low doses as an estrogen receptor ligand for the potential relief of the frequency and severity of moderate to severe hot flashes in postmenopausal women with vasomotor symptoms. We expect to report results from our Phase 2b clinical study of elacestrant for the potential treatment of postmenopausal vasomotor symptoms in the second half of 2017.

Abaloparatide-TD

- We are focused on completing the manufacturing, scale-up, production, and other required activities needed to initiate a pivotal study to evaluate bioequivalence to TYMLOS. We believe that the transdermal patch program has the potential to allow physicians who treat osteoporosis, but rarely use injectable drugs, an opportunity to expand their practices to include the use of anabolic therapy. We will provide an update on these activities before the end of 2017.

RAD140

- An investigational new drug application, or IND, submitted to the FDA for RAD140, a selective androgen receptor modulator, has been accepted. We expect to initiate a first-in-human Phase 1 clinical trial in women with hormone receptor positive breast cancer in the second half of 2017.

Radius Anticipates the Following Milestones

- Abaloparatide-SC
 - Receive a CHMP opinion regarding the EMA's review of the abaloparatide-SC MAA prior to the end of 2017
 - Enter into a partnership for the potential commercialization of abaloparatide-SC outside the U.S. and Japan prior to commercial launch in the European Union
 - Report additional clinical results from the recently completed 24-month ACTIVEExtend clinical trial at the ASBMR Annual Meeting in September 2017
 - Submit an sNDA in connection with the ACTIVEExtend data to FDA by year end

- Elacestrant
 - Complete ongoing Phase 1 breast cancer clinical trials
 - Initiate a Phase 2 single-arm monotherapy clinical trial in metastatic breast cancer patients in early 2018 with a goal of accelerated approval
 - Complete and report results from our ongoing Phase 2b vasomotor trial in the second half of 2017
- RAD140
 - Initiate a first-in-human Phase 1 study in the second half of 2017 in women with hormone receptor positive breast cancer

Radius Expects To Make Presentations at the Following Upcoming Conferences

- On August 10, 2017, Radius President and CEO, Jesper Høiland, will make a presentation and host one-on-one meetings at the Canaccord Genuity Growth Conference in Boston.
- On September 6, 2017, Dr. Alison O'Neill, V.P., Clinical Development, will present on a Breast Cancer panel and host one-on-one meetings at the Citi 12th Annual Biotech Conference in Boston.
- On September 8-11, 2017 Radius will be present 7 abstracts regarding abaloparatide-SC at the ASBMR Annual Meeting in Denver, Colorado, including an oral plenary presentation.
- On September 13, 2017, Jesper Høiland, Radius President and CEO, will participate in a fireside chat and host one-on-one meetings at the Morgan Stanley 15th Annual Global Healthcare Conference in New York.
- On September 25, 2017, Jesper Høiland, Radius President and CEO, will present and host one-on-one meetings at the Cantor Fitzgerald Global Healthcare Conference in New York.

Second Quarter 2017 Financial Results

Three Months Ended June 30, 2017

For the three months ended June 30, 2017, Radius reported a net loss of \$68.4 million, or \$1.58 per share, compared to a net loss of \$43.4 million, or \$1.01 per share, for the three months ended June 30, 2016, for an increase of 58%.

For the three months ended June 30, 2017, Radius reported TYMLOS net revenues of about \$1.0 million, which reflects the first four weeks of sales. Radius had no revenues in the three months ended June 30, 2016 as the FDA approved TYMLOS on April 28, 2017.

Research and development expense for the three months ended June 30, 2017, was \$19.7 million compared to \$26.9 million for the three months ended June 30, 2016, a decrease of \$7.2 million, or 27%. This decrease was primarily driven by a \$5.3 million decrease in regulatory and professional fees associated with abaloparatide-SC regulatory applications, a \$5.1 million decrease in elacestrant (RAD1901) project costs, and a \$1.2 million decrease in development costs associated with abaloparatide-TD. This decrease was partially offset by a \$4.5 million increase in compensation expense, including stock-based compensation, due to the increase in headcount, including the medical science liaisons to support the TYMLOS launch.

Selling, general, and administrative expense for the three months ended June 30, 2017, was \$50.1 million compared to \$17.2 million for the three months ended June 30, 2016, an increase of \$32.9 million, or 192%. This increase was primarily the result of an increase of approximately \$9.5 million in professional fees and support costs during the three months ended June 30, 2017, including the costs associated with increasing headcount and preparing for the commercialization of TYMLOS in the United States. This increase was also driven by a \$19.6 million increase in compensation expense, including stock-based compensation, due to an increase in headcount, due largely to the hiring of the U.S. sales force and other functions to support the launch of TYMLOS and general purposes.

Six Months Ended June 30, 2017

For the six months ended June 30, 2017, Radius reported a net loss of \$125.4 million, or \$2.90 per share, compared to a net loss of \$83.9 million, or \$1.95 per share, for the six months ended June 30, 2016, for an increase of 49%.

For the six months ended June 30, 2017 Radius reported TYMLOS net revenues of about \$1.0 million, which reflects the first four weeks of sales. Radius had no revenues in the six months ended June 30, 2016 as the FDA approved TYMLOS on April 28, 2017.

Research and development expense for the six months ended June 30, 2017, was \$39.2 million compared to \$54.4 million for the six months ended June 30, 2016, for a decrease of \$15.2 million, or 28%. This decrease was primarily driven by a \$12.1 million decrease in abaloparatide-SC project costs, a \$10.4 million decrease in elacestrant

(RAD1901) project costs, and a \$2.7 million decrease in development costs associated with abaloparatide-TD. This decrease was partially offset by a \$9.1 million increase in compensation expense, including stock-based compensation, due to an increase in headcount, including the hiring of the medical science liaisons to support the U.S. launch of TYMLOS.

Selling, general, and administrative expense for the six months ended June 30, 2017, was \$88.2 million compared to \$30.8 million for the six months ended June 30, 2016, an increase of \$57.4 million, or 186%. This increase was primarily the result of an increase of approximately \$17.9 million in professional fees and support costs during the six months ended June 30, 2017, including the costs associated with increasing headcount and preparing for the commercialization of TYMLOS in the United States. This increase was also driven by a \$34.2 million increase in compensation expense, including stock-based compensation, due to an increase in headcount, particularly the sales force and other support functions necessary to launch TYMLOS in the U.S. and for general purposes.

As of June 30, 2017, Radius had \$215 million in cash, cash equivalents and marketable securities. Based upon our cash, cash equivalents and marketable securities balance as of June 30, 2017, we believe that, prior to the consideration of proceeds from partnering and/or collaboration activities, we have sufficient capital to fund our development plans, U.S. commercial and other operational activities for not less than twelve months from the date of this press release.

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

	June 30, 2017	December 31, 2016
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 135,110	\$ 258,567
Restricted cash	47	47
Marketable securities	79,606	73,880
Trade receivables, net	1,211	-
Inventory	1,636	-
Prepaid expenses and other current assets	5,940	2,315
Total current assets	223,550	334,809
Property and equipment, net	6,738	4,922
Intangible assets	8,579	-
Other assets	558	551
Total assets	\$ 239,425	\$ 340,282
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,396	\$ 6,128
Accrued expenses and other current liabilities	27,378	26,597
Total current liabilities	31,774	32,725
Other non-current liabilities	331	379
Total liabilities	32,105	33,104
Stockholders' equity:		
Common stock, \$.0001 par value; 200,000,000 shares authorized, 43,502,335 shares and 43,141,134 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	\$ 4	\$ 4
Additional paid-in-capital	960,736	935,671
Accumulated other comprehensive income	3	71
Accumulated deficit	(753,423)	(628,568)
Total stockholders' equity	207,320	307,178
Total liabilities and stockholders' equity	\$ 239,425	\$ 340,282

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
REVENUES:				
Product revenue, net	\$ 980	\$ -	\$ 980	\$ -
OPERATING EXPENSES:				
Cost of sales	105	-	105	-
Research and development	19,652	26,891	39,179	54,374
Selling, general, and administrative	50,121	17,193	88,220	30,839
Loss from operations	(68,898)	(44,084)	(126,524)	(85,213)
OTHER INCOME (EXPENSE):				
Other income (expense), net	(97)	(95)	(17)	(96)
Interest income	557	744	1,164	1,411
NET LOSS	\$ (68,438)	\$ (43,435)	\$ (125,377)	\$ (83,898)
OTHER COMPREHENSIVE INCOME:				
Unrealized (loss) gain from marketable securities	(32)	(49)	(69)	183
COMPREHENSIVE LOSS	\$ (68,470)	\$ (43,484)	\$ (125,446)	\$ (83,715)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:				
	\$ (68,438)	\$ (43,435)	\$ (125,377)	\$ (83,898)
LOSS PER SHARE:				
Basic and diluted	\$ (1.58)	\$ (1.01)	\$ (2.90)	\$ (1.95)
WEIGHTED AVERAGE SHARES:				
Basic and diluted	43,410,053	43,042,883	43,300,243	43,027,903

WEBCAST AND CONFERENCE

In connection with today's reporting of Second Quarter Financial Results, Radius will host a conference call and live audio webcast at 4:30 p.m. ET on Thursday, August 3, 2017 to discuss the commercial outlook for TYMLOS, review the financial results and provide a company update.

Webcast Information:

Date : Thursday, August 3, 2017

Time : 4:30 p.m. ET

Live webcast: <http://edge.media-server.com/m/p/jn39azn4>

A replay of the webcast will be available on the company's website, www.radiuspharm.com in the Investor section under Events and Presentations for 7 days following the live webcast.

Conference Call Information:

Date : Thursday, August 3, 2017

Time : 4:30 p.m. ET

Domestic Dial-in Number: (866) 323-7965

International Dial-in Number: (346) 406-0961

Conference ID: 44592313

For those unable to participate in the conference call or webcast, a replay will be available beginning August 3, 2017 at 7:00 p.m. ET until August 17, 2017 at 11:59 p.m. ET. To access the replay, dial (855) 859-2056 for U.S. or (404) 537-3406 for International. The replay pin number is 44592313.

A live audio webcast of the call can be accessed from the Investors section of the Company's website, www.radiuspharm.com, where a webcast replay will be also available for 14 days. The full text of the announcement and financial results will also be available on the Company's website.

About Radius

Radius is a science-driven fully integrated biopharmaceutical company that is committed to developing and commercializing innovative therapeutics in the areas of osteoporosis, oncology and endocrine diseases. 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. Radius' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of postmenopausal women with osteoporosis is under regulatory review in Europe. The Radius clinical pipeline includes an investigational abaloparatide transdermal patch for potential use in osteoporosis and the investigational drug elacestrant (RAD1901) for potential use in hormone-driven and/or hormone-resistant breast cancer, and vasomotor symptoms in postmenopausal women. Radius' RAD140, a non-steroidal, selective androgen receptor modulator (SARM), is under investigation for potential use in hormone receptor positive breast cancer. For more information, please visit www.radiuspharm.com.

About *TYMLOS* (abaloparatide)

TYMLOS (abaloparatide) 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' Marketing Authorisation Application (MAA) for abaloparatide-SC for the treatment of women with postmenopausal osteoporosis was validated and is currently undergoing regulatory review by the European Medicines Agency (EMA).

Radius also is developing abaloparatide-transdermal (abaloparatide-TD) based on 3M's patented Microstructured Transdermal System technology for potential use as a treatment for postmenopausal women with osteoporosis.

About *ACTIVE* and *ACTIVE*Extend

The Phase 3 *ACTIVE* (Abaloparatide Comparator Trial In Vertebral Endpoints) trial was a randomized, double-blind, placebo-controlled, comparative, multicenter, 18 month international study in 2,463 postmenopausal women with osteoporosis designed to evaluate the efficacy and safety of abaloparatide-SC 80 mcg to reduce the risk of vertebral and nonvertebral fractures. The results of *ACTIVE* were published in the Journal of the American Medical Association in August of 2016. *ACTIVE*Extend, an extension of *ACTIVE*, enrolled patients who had completed 18 months of abaloparatide-SC or placebo in *ACTIVE* to receive up to 24 additional months of open-label alendronate. The results of the first six months of *ACTIVE*Extend were published in the Mayo Clinic Proceedings in February of 2017.

About Elacestrant (*RAD1901*)

Elacestrant is a selective estrogen receptor down-regulator/degrader (SERD), which at high doses is being evaluated for potential use as an oral non-steroidal treatment for hormone-driven, or hormone-resistant, breast cancer. Elacestrant is currently being investigated for potential use in postmenopausal women with estrogen receptor positive 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.

Additional information on the clinical trial program of elacestrant (*RAD1901*) is available on www.clinicaltrials.gov.

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 the progress of abaloparatide-SC in the regulatory process with the EMA and the expected timing of potential regulatory actions, the potential accelerated regulatory pathway for elacestrant, the entry into potential collaboration agreements, including the timing of any such entry, our plans for commercialization of TYMLOS in the U.S., the progress in the development of our product candidates, including abaloparatide-TD, elacestrant (RAD1901) and RAD140, each of the statements under the heading "Radius Anticipates The Following Milestones," upcoming events and presentations, the sufficiency of our cash, cash equivalents and marketable securities, and the potential clinical uses and therapeutic and other benefits of our product candidates, including abaloparatide-TD, 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 and any 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 most recent Quarterly Report on Form 10-Q 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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