
**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): November 5, 2019

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)

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

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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	RDUS	The NASDAQ Global Market

Item 2.02 Results of Operations and Financial Condition.

On November 5, 2019, Radius Health, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2019. 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	Radius Health, Inc. Press Release dated November 5, 2019
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 5, 2019

By: /s/ Jose Carmona
Name: Jose Carmona
Title: Chief Financial Officer



Radius Health Announces Third Quarter 2019 Results and Corporate Update

TYMLOS U.S. net sales grew to \$47M and is capturing half of anabolic new patient starts¹

Guidance for FY 2019 sales increased to \$168-\$172M (vs. \$165-\$170M prior) and year-end cash, cash equivalents and investments balance increased to over \$130M (vs. over \$120M prior)

Top-line data from Phase 3 wearABLE trial expected in 2H 2021

Radius will strategically focus on TYMLOS, abaloparatide-patch and complementary assets for targeted endocrine diseases; exploring strategic options for oncology assets

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

WALTHAM, Mass., November 5, 2019 -- Radius Health, Inc. ("Radius" or the "Company") (Nasdaq: RDUS), today reported its financial and operating results for the third quarter ended September 30, 2019 and provided a strategic business update.

Radius remains confident TYMLOS[®] will become the anabolic market leader (based on TR²) in 2020. In line with the Company's goal of obtaining majority share in new patients, TYMLOS has been capturing half of new patient starts with an average 50% NBRx market share in October. Effective January 1, 2020, TYMLOS coverage will expand to approximately 290 million U.S. insured lives, representing approximately 99% of U.S. commercial and 79% of Medicare insured lives.

Radius is committed to transforming the use of anabolics to meet the unmet needs of high risk osteoporosis patients with the development and potential launch of abaloparatide-transdermal patch (abaloparatide-patch).

Radius will build on its strong scientific foundation and successful commercial franchise in osteoporosis to accelerate its growth and sharpen its strategic focus in targeted endocrine diseases. Radius will selectively evaluate in-licensing and partnership opportunities to expand its clinical pipeline and commercial assets in high potential targeted endocrine diseases.

In oncology, Radius continues to enroll patients in its EMERALD Phase 3 monotherapy study of elacestrant with completion of recruitment targeted in the third quarter of 2020. Given its focus on bone health and targeted endocrine diseases, the Company is considering all strategic options for its oncology assets to maximize their potential. The value of Radius' oncology assets is expected to be most effectively realized by an oncology focused company with strong capabilities in this area. Radius does not plan to initiate further clinical development for elacestrant or RAD140 beyond the ongoing EMERALD study.

¹ New Patients to Brand, NBRx PMOT. Source: IQVIA

² Total Market Share, TRx PMOT. Source: IQVIA

"I am very pleased with our continued strong performance with TYMLOS. We are on a path to make TYMLOS the treatment of choice for high risk postmenopausal osteoporosis patients and shift the treatment paradigm with the patch," said Jesper Hoeiland, Chief Executive Officer of Radius. "With our refined strategy, we are excited to refocus our future by building on our core strengths and allocating resources efficiently to bring new and innovative medicines to patients and maximize opportunities for our business and shareholders."

TYMLOS (abaloparatide) injection

- Third quarter 2019 U.S. net sales of TYMLOS were \$47 million, a 69% increase from the third quarter of 2018. The anabolic market grew 4% in the third quarter of 2019 as compared to the third quarter of 2018.
- Radius continued increasing its market share with TYMLOS capturing, on average, 38% of the U.S. anabolic osteoporosis market (based on Patient Months on Therapy, TRx PMOT) in the third quarter. In October 2019, TYMLOS achieved an average 50% NBRx share and its total market TRx share further increased to 40%.
- After decisions from Aetna, Cigna and others, 2020 Medicare Part D coverage for TYMLOS will increase from 67% to 79% of those enrolled in Medicare Part D plans in the U.S. Effective January 1, 2020, TYMLOS is expected to be covered for approximately 290 million U.S. insured lives, representing approximately 99% of U.S. commercial and 79% of Medicare insured lives.

Pipeline Highlights

Abaloparatide-Patch

- The wearABLE Phase 3 study which was initiated in August is now open for enrollment at more than 60 clinical sites in the U.S. reflecting strong interest from investigators. The ramp-up in patient enrollment has been slower than expected due to a higher than anticipated screen failure rate. A revised enrollment plan is being implemented that includes identified measures to improve site recruitment efforts, including adding sites outside the U.S. Radius expects to report top-line data from the study in the second half of 2021.

Elacestrant

- The EMERALD Phase 3 study is currently enrolling patients in multiple countries with a majority of sites open and activated. Radius expects to complete patient recruitment in the third quarter of 2020.

Financial Highlights and Guidance

- In the third quarter of 2019, TYMLOS gross profit covered the Company's selling, general and administrative and internal research and development expenses and started partially funding the clinical pipeline projects.
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- Radius increased its full-year 2019 financial guidance for TYMLOS U.S. net revenue to \$168 to \$172 million (from \$165 to \$170 million) and its guidance for year-end cash, cash equivalents and investments balance to over \$130 million (from \$120 million).
- Following an expanded formulary coverage in 2020 and increase in manufacturer reimbursement during the Medicare Part D coverage gap, the net price for TYMLOS is expected to remain flat in FY 2020 versus FY 2019.

Anticipated Milestones in Q4 2019

- Elacestrant
 - Advance recruitment in Phase 3 EMERALD monotherapy study
- TYMLOS/Financial
 - Grow full-year TYMLOS U.S. net sales to between \$168 to \$172 million
 - Deliver greater than \$130 million cash, cash equivalents and investments balance at year-end

Expected Radius Presentations at Upcoming Conferences in Q4 2019

- On November 21, 2019, the Company will present and host one-on-one meetings at the Jefferies 2019 London Healthcare Conference in London, UK.
 - On December 11, 2019, the Company will host one-on-one meetings at the Citi Global Healthcare Conference in New York, NY.
 - On December 12, 2019, the Company will host one-on-one meetings at Jefferies Denver Summit in Denver, CO.
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Third Quarter 2019 Financial Results

Three Months Ended September 30, 2019

For the three months ended September 30, 2019, Radius reported a net loss of \$30.0 million, or \$0.65 per share, compared to a net loss of \$49.8 million, or \$1.09 per share, for the three months ended September 30, 2018.

For the three months ended September 30, 2019, non-GAAP adjusted net loss, which excludes expenses related to stock-based compensation, depreciation, non-cash interest obligations under debt obligations, and amortization of intangible assets, was \$20.4 million, or \$0.44 per share, compared to non-GAAP adjusted net loss of \$38.3 million, or \$0.84 per share, for the three months ended September 30, 2018.

For the three months ended September 30, 2019 we recorded approximately \$46.8 million of net product revenue compared to \$27.6 million for the three months ended September 30, 2018.

For the three months ended September 30, 2019, research and development expense was \$31.8 million compared to \$26.8 million for the three months ended September 30, 2018, an increase of \$5.0 million, or 19%. This increase was primarily driven by a \$3.5 million increase in abaloparatide-patch program costs, a \$2.0 million increase in elacestrant project costs, a \$0.7 million increase in professional support costs, a \$0.6 million increase in abaloparatide-SC program costs, and a \$0.4 million increase in occupancy costs. These increases were partially offset by a \$0.4 million decrease in RAD140 program costs and a \$1.8 million decrease in compensation expense.

For the three months ended September 30, 2019, selling, general and administrative expense was \$35.6 million compared to \$43.7 million for the three months ended September 30, 2018, a decrease of \$8.0 million, or 18%. This decrease was primarily the result of a \$4.6 million decrease in professional support costs, a \$2.1 million decrease in compensation related expenses attributed to a decrease in headcount from 384 selling, general, and administrative employees as of September 30, 2018 to 286 selling, general, and administrative employees as of September 30, 2019, a \$0.9 million decrease in other operating costs, and a \$0.5 million decrease in occupancy and depreciation costs. These decreases were partially offset by a \$0.1 million increase in travel and entertainment expenses.

Nine Months Ended September 30, 2019

For the nine months ended September 30, 2019, Radius reported a net loss of \$108.3 million, or \$2.36 per share, compared to a net loss of \$180.2 million, or \$3.98 per share, for the nine months ended September 30, 2018.

For the nine months ended September 30, 2019, non-GAAP adjusted net loss, which excludes expenses related to stock-based compensation, restructuring plans, depreciation, non-cash interest obligations under debt obligations, impairment of operating lease right of use assets, and amortization of intangible assets, was \$77.6 million, or \$1.69 per share, compared to non-GAAP adjusted net loss of \$133.0 million, or \$2.94 per share, for the nine months ended September, 2018.

For the nine months ended September 30, 2019 we recorded approximately \$117.7 million of net product revenue compared to \$64.8 million for the nine months ended September 30, 2018.

For the nine months ended September 30, 2019, research and development expense was \$82.2 million compared to \$76.0 million for the nine months ended September 30, 2018, an increase of \$6.3 million, or 8%. This increase was primarily driven by a \$10.4 million increase in abaloparatide-patch project costs, a \$4.4 million increase in elacestrant program costs, a \$1.5 million increase in abaloparatide-SC program costs, and \$0.5 million increase in professional and support fees. These increases were partially offset by a \$1.7 million decrease in RAD140 program costs, a \$0.2 million decrease in occupancy and depreciation costs, a \$0.1 million decrease in travel and entertainment expenses, a \$0.1 million decrease in other operating costs, and a \$8.4 million decrease in compensation and personnel costs due to decreases in stock compensation, severance, temporary services of consultants, and headcount.

For the nine months ended September 30, 2019, selling, general and administrative expense was \$116.9 million compared to \$140.3 million for the nine months ended September 30, 2018, a decrease of \$23.3 million, or 17%. This decrease was primarily the result of a \$13.0 million decrease in compensation related to a decrease in headcount from 384 selling, general, and administrative employees as of September 30, 2018 to 286 selling, general, and administrative employees as of September 30, 2019, a \$5.5 million decrease in professional support fees, a \$2.7 million decrease in travel and entertainment related costs, a \$1.8 million decrease in other operating costs, and a \$0.3 decrease in occupancy and depreciation costs.

As of September 30, 2019, Radius had \$168.7 million in cash, cash equivalents, restricted cash, and marketable securities. Based upon our cash, cash equivalents and marketable securities balance as of September 30, 2019, 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)

	<u>September 30,</u> <u>2019</u>	<u>December 31,</u> <u>2018</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 88,925	\$ 59,321
Restricted cash	565	560
Marketable securities	79,251	177,140
Accounts receivable, net	21,528	16,758
Inventory	4,911	6,210
Prepaid expenses	15,201	13,842
Other current assets	858	1,202
Total current assets	<u>211,239</u>	<u>275,033</u>
Property and equipment, net	2,616	4,003
Intangible assets	6,783	7,382
Right of use assets - operating leases	6,443	-
Other assets	412	544
Total assets	<u>\$ 227,493</u>	<u>\$ 286,962</u>
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 4,608	\$ 4,226
Accrued expenses and other current liabilities	49,082	42,203
Operating lease liability, current	1,904	-
Total current liabilities	<u>55,594</u>	<u>46,429</u>
Notes payable	191,444	179,806
Operating lease liability, long term	4,681	-
Other non-current liabilities	24	95
Total liabilities	<u>251,743</u>	<u>226,330</u>
Stockholders' equity:		
Common stock, \$0.0001 par value; 200,000,000 shares authorized, 46,173,170 shares and 45,563,693 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	5	5
Additional paid-in-capital	1,187,623	1,165,003
Accumulated other comprehensive loss	21	(755)
Accumulated deficit	(1,211,899)	(1,103,621)
Total stockholders' equity (deficit)	<u>(24,250)</u>	<u>60,632</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 227,493</u>	<u>\$ 286,962</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
REVENUES:				
Product revenue, net	\$ 46,766	\$ 27,639	\$ 117,652	\$ 64,815
OPERATING EXPENSES:				
Cost of sales - product	3,971	2,193	10,809	4,884
Cost of sales - intangible amortization	200	200	599	599
Research and development	31,791	26,804	82,230	75,979
Selling, general, and administrative	35,617	43,661	116,918	140,266
Other operating expense	-	-	-	10,801
Loss from operations	(24,813)	(45,219)	(92,904)	(167,714)
OTHER (EXPENSE) INCOME:				
Other income (expense)	59	17	21	83
Interest expense	(6,298)	(5,793)	(18,500)	(17,041)
Interest income	1,008	1,193	3,105	4,433
NET LOSS	\$ (30,044)	\$ (49,802)	\$ (108,278)	\$ (180,239)
OTHER COMPREHENSIVE LOSS:				
Unrealized gain (loss) from available-for-sale debt securities	66	442	776	(534)
COMPREHENSIVE LOSS	\$ (29,978)	\$ (49,360)	\$ (107,502)	\$ (180,773)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:				
	\$ (30,044)	\$ (49,802)	\$ (108,278)	\$ (180,239)
LOSS PER SHARE:				
Basic and diluted	\$ (0.65)	\$ (1.09)	\$ (2.36)	\$ (3.98)
WEIGHTED AVERAGE SHARES:				
Basic and diluted	46,141,217	45,498,909	45,975,691	45,291,176

Reconciliation of GAAP to Non-GAAP Financial Information

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss reconciliation:				
GAAP net loss	\$ (30,044)	\$ (49,802)	\$ (108,278)	\$ (180,239)
Intangible amortization	200	200	599	599
Stock-based compensation expense	5,048	6,700	16,911	22,270
Restructuring charges	-	628	(8)	2,028
Depreciation	367	465	1,187	1,406
Non-cash interest	4,010	3,506	11,638	10,174
Operating Lease Impairment	-	-	339	-
Ipsen payment	-	-	-	10,801
Non-GAAP net loss	<u>\$ (20,419)</u>	<u>\$ (38,303)</u>	<u>\$ (77,612)</u>	<u>\$ (132,961)</u>
Reconciliation of diluted loss per share:				
GAAP loss per share	\$ (0.65)	\$ (1.09)	\$ (2.36)	\$ (3.98)
Intangible amortization	-	-	0.01	0.01
Stock-based compensation expense	0.11	0.15	0.37	0.49
Restructuring charges	-	0.01	-	0.05
Depreciation	0.01	0.01	0.03	0.03
Non-cash interest	0.09	0.08	0.25	0.22
Operating Lease Impairment	-	-	0.01	-
Ipsen payment	-	-	-	0.24
Non-GAAP loss per share	<u>\$ (0.44)</u>	<u>\$ (0.84)</u>	<u>\$ (1.69)</u>	<u>\$ (2.94)</u>
Reconciliation of shares used in loss per share calculation:				
GAAP shares used in loss per share	46,141,217	45,498,909	45,975,691	45,291,176
Non-GAAP dilutive share adjustments	-	-	-	-
Non-GAAP shares used in loss per share	<u>46,141,217</u>	<u>45,498,909</u>	<u>45,975,691</u>	<u>45,291,176</u>

Webcast and Conference Call

In connection with today's reporting of Third Quarter 2019 Financial Results, Radius will host a conference call and live audio webcast at 4:30 p.m. ET today, November 5, 2019, to review the commercial, research and development, and financial highlights and provide a Company update.

Conference Call Information:

Date: November 5, 2019

Time: 4:30 p.m. ET

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

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

Conference ID: 2490257

Live webcast:

<https://edge.media-server.com/mmc/p/ysdqe6fi>

For those unable to participate in the conference call or webcast, a replay will be available on Tuesday, November 5, 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 2490257.

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.

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 September 30, 2018 and 2019 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. 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.

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 Abaloparatide-Patch and wearABLE Phase 3 Study

Abaloparatide-patch was developed in a collaboration between Radius and 3M Company with the application of 3M's innovative microstructured transdermal patch technology. The Phase 3 wearABLE abaloparatide-patch study is the first pivotal study to evaluate treatment of a novel non-injectable delivery of an anabolic therapy. The wearABLE Phase 3 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-patch versus TYMLOS (abaloparatide injection) in approximately 470 patients with postmenopausal osteoporosis at high risk of fracture. The primary endpoint of the study is the percentage of change in lumbar spine BMD at 12 months.

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.

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 that it will become the leader in the U.S. anabolic osteoporosis market and

the timing thereof, projected increases in insurance coverages and expectations for the net sales price of TYMLOS in 2020; our expectations regarding our regulatory submissions, including the timing thereof; our expectations regarding our clinical trials, including the design and timing thereof and our expectations to report top-line data from our Phase 3 wearABLE trial of abaloparatide-patch in the second half of 2021 and to complete enrollment in our Phase 3 EMERALD trial of elacestrant in the third quarter of 2020; our plans to focus on building an endocrine franchise; our entry into potential collaborations and partnerships, including the timing thereof, including our plans to consider strategic options for elacestrant and RAD140; 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 Q4 2019," and "Expected Radius Presentations at Upcoming Conferences in Q4 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 or partnership agreements and any executed collaboration or partnership 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

Phone: 617-551-4011