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 8, 2021

RADIUS HEALTH, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-35726**	**80-0145732**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

22 Boston Wharf Road, 7th Floor, Boston, MA	**02210**
(Address of principal executive offices)	(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 8, 2021, Radius Health, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2021. 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

Exhibit No.	Description
99.1	Radius Health, Inc. Press Release dated November 8, 2021
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 8, 2021

By: /s/ Steven Helwig
Name: Steven Helwig
Title: Principal Finance and Accounting Officer

Exhibit 99.1

Radius Health, Inc.: Third Quarter 2021 Results

- TYMLOS® Q3, 2021 net revenue: $57 million, +13% vs. Q3, 2020
- Added 4,461 new patients on TYMLOS in Q3, 2021, +10% vs. Q3, 2020
- Adjusted EBITDA of ($11) million vs. $9 million in Q3, 2020 which included elacestrant license revenue
- ATOM Pivotal Study evaluating abaloparatide-SC for use in males with osteoporosis met primary and key secondary endpoints; sNDA filing is expected Q1, 2022
- Resubmitted abaloparatide-SC to the European Medicines Agency (EMA) on November 4, 2021
- wearABLe Pivotal Study (abaloparatide-TD) topline readout remains on track for Q4, 2021
- EMERALD Pivotal Study evaluating elacestrant in breast cancer was positive as a monotherapy vs. standard of care in patients with ER+/HER2- mBC, including ESR1 patients
  - Working with our partner – Menarini Group – on U.S. and Europe regulatory submissions in 2022
  - Menarini Group is planning several combination trials with elacestrant
  - Data to be shared at the San Antonio Breast Cancer Symposium taking place in December, 2021
- Return of Capital: Radius intends to utilize a minimum of 50% of the up to $300 million in potential future sales milestones from elacestrant to strengthen its capital structure

Boston, Mass., November 8, 2021 – Radius Health, Inc. (“Radius” or the “Company”) (Nasdaq: RDUS), today reported its results for the third quarter ended September 30, 2021.

Q3, 2021 FINANCIAL HIGHLIGHTS:

- TYMLOS Net Revenue: $57 million in Q3, 2021 vs. $50 million in Q3, 2020, +13% year-over-year
- Total Company Headcount: 285 in Q3, 2021 vs. 317 in Q3, 2020 a 10% reduction
- TYMLOS Net Revenue per commercial employee: 50% increase in productivity in Q3, 2021 vs. Q3, 2020
- Total Net Revenue: $57 million in Q3, 2021 vs. $78 million in Q3, 2020, -27% year-over-year due to $27 million in upfront license revenue received from Menarini Group for the elacestrant asset
- Total Company Adjusted EBITDA: ($11) million in Q3, 2021 vs. $9 million in Q3, 2020, down year-over-year as 2020 results included the elacestrant upfront license revenue
- RAD011 expenses increased by $5.5 million driven by life cycle planning and key talent recruitment
- Total Operating Expenses: $69 million in Q3, 2021 vs. $73 million in Q3, 2020
- Liquidity position: $110 million of cash, cash equivalents and marketable securities as of 9/30/2021

Our shift from a general osteoporosis sales approach to one that focuses on – primarily – the fracture patient segment continues to evolve. We have made progress and expect to make more in the future. However, due to lower-than-expected year-to-date TYMLOS net revenue, the Company is making the following changes to full year 2021 forecasts:

- TYMLOS Net Revenue FY 2021: now $210 to $220 million vs. previous forecast of $240 million
- Total Company FY 2021 Adjusted EBITDA: now ($5) to ($15) million vs. previous forecast of $10 million

ELACESTRANT:

On October 20, 2021, Radius announced along with its partner the Menarini Group that EMERALD, a pivotal study evaluating elacestrant in breast cancer, was positive as a monotherapy vs. the standard of care for patients with ER+/HER2- advanced or metastatic breast cancer (mBC), including those with the Estrogen Receptor Mutation (ESR1). The study met both primary endpoints for the overall population as well as the ESR1 mutation subgroup.

Chhaya Shah, Senior Vice President and clinical program lead for Radius commented, “The study results were certainly encouraging for patients and their families, as the first oral selective estrogen receptor degrader to show positive topline data. We are working with our partner on progressing the program towards regulatory submission in the U.S. as well as Europe in 2022.”

Kelly Martin, Chief Executive Officer of Radius, elaborated, “We work closely with the Menarini Group on all aspects of the elacestrant asset – they are a terrific partner. We are collectively enthusiastic about the opportunities to bring potential benefit to patients by progressing this molecule.”

He added, “Given the significance of the positive topline data to Radius, it is important to outline key aspects of the molecule as well as the financial/business relationship that exists between the Menarini Group and ourselves.”

Martin concluded, “Creating tangible value for our capital providers is a fundamental objective of our business and central to our management approach and operating philosophy. To that end, we intend to utilize a minimum of 50% of the up to $300 million in potential future sales milestones from elacestrant to strengthen the capital structure.”

As to the detail – mentioned above – the following five (5) items are of particular relevance to Radius shareholders, capital providers, and other stakeholders:

- Radius is eligible to receive:
  - Up to $20 million in development and regulatory milestone payments
  - Up to $300 million in sales milestones
  - A tiered net royalty up to 9% that is based on global net sales

- Royalties and sales milestones are:
  - Based on global net sales of elacestrant
  - Inclusive of monotherapy as well as any/all utilization as a combination therapeutic
  - Inclusive of all other potential therapeutic applications

- Intellectual Property – three (3) U.S. issued patents for elacestrant:
  - Composition of matter (August 2026, subject to patent term extension up to August 2030)
  - Method of treatment (October 2034)
  - Polymorph/Crystalline (January 2038)
  - Additional patents are pending

- Exclusivity – as a new chemical entity, elacestrant has the potential to receive regulatory exclusivity of:
  - 5 years in the U.S.
  - 10 years in Europe
  - 8 years in Japan, assuming no generic competitor entrant to the market

- All the above are subject to regulatory approval(s)

- Radius intends to utilize a minimum of 50% of the up to $300 million in potential future sales milestones from elacestrant to strengthen its capital structure

ABALOPARATIDE:

Clinical and Regulatory

- Resubmitted abaloparatide-SC dossier to the EMA for potential approval in the EU on November 4, 2021
- Announced that the ATOM study evaluating abaloparatide-SC for use in males with osteoporosis met its primary endpoint as well as key secondary endpoints with plans to submit a sNDA in Q1, 2022
- Previously announced an update to the MOA section of the TYMLOS label following data from the histomorphometry study that showed TYMLOS stimulated new bone formation in humans
- Assist partner, Paladin Labs Inc., in the abaloparatide regulatory submission in Canada (Q4, 2021)

Commercial

- Added 4,461 new patients on TYMLOS in Q3, 2021, +10% vs. Q3, 2020
- Top 500 TYMLOS prescribers represent 50% of total new patients in Q3, 2021
- Top 50 TYMLOS prescribers had new patient growth of 15% vs. Q2, 2021
- Full year TYMLOS Net Revenue projection has been adjusted to $210 to $220 million vs. $240 million
- Our focus on continuing to position TYMLOS for additional growth:
  - Increase depth vs. breadth in the fracture patient segments
  - Emphasis on best people and talent aligned to the opportunity
  - Properly utilize data – with larger institutions – for patient identification, tracking, and interface
  - Prepare for the possibility of adding male indication to TYMLOS
  - Plan for abaloparatide-TD following pivotal data readout expected in Q4, 2021

RAD011:

All remains on track as previously communicated for Prader-Willi Syndrome (PWS). The seamless pivotal trial (SCOUT) is expected to commence in Q4, 2021 or early Q1, 2022.

We will provide a further update on the RAD011 molecule in the near term. We plan to add at least two additional neurological orphan disease indications and progress those forward with pivotal trials.

Third Quarter 2021 Financial Results

Three Months Ended September 30, 2021

Net Loss
For the three months ended September 30, 2021, Radius reported a net loss of $22.0 million, or $0.47 per share, compared to a net loss of $6.3 million, or $0.14 per share, for the three months ended September 30, 2020.

For the three months ended September 30, 2021, non-GAAP adjusted net loss, was $15.3 million, or $0.32 per share, compared to non-GAAP adjusted net income of $7.0 million, or $0.15 per share, for the three months ended September 30, 2020.

Revenue
For the three months ended September 30, 2021, TYMLOS net product revenues were $56.8 million compared to $50.4 million for the three months ended September 30, 2020.

For the three months ended September 30, 2021, no license revenue was recognized compared to $27.4 million recognized for the three months ended September 30, 2020.

Costs and Expenses
For the three months ended September 30, 2021, research and development expense was $34.7 million compared to $39.5 million for the three months ended September 30, 2020, a decrease of $4.7 million, or 12%. This decrease was primarily driven by a decrease of $7.6 million in abaloparatide-TD program costs, a decrease of $1.0 million in RAD140 expenses, a $0.7 million decrease in compensation expense, which is comprised of a $2.2 million increase in compensation expense related to headcount and $2.9 million of billed reimbursable expenses, and a $9.9 million decrease in elacestrant program costs, which is comprised of a $6.0 million decrease in gross program expenses as well as a decrease of $3.9 million in billed reimbursable expenses. These decreases were offset by a $6.1 million increase in abaloparatide-SC program costs, a $3.2 million increase in RAD011 program costs, a $4.6 million increase in professional fees and other expenses, and a $0.2 million increase in occupancy and depreciation costs.

For the three months ended September 30, 2021, selling, general and administrative expenses were $34.3 million compared to $33.7 million for the three months ended September 30, 2020, an increase of $0.6 million, or 2%. This increase was primarily the result of a $4.3 million increase in professional support costs. This increase was offset by a $2.1 million decrease in wages and employee benefit costs due to a decrease in headcount and a $1.9 million decrease in occupancy and depreciation costs and other operating costs.

Nine Months Ended September 30, 2021

Net Loss
For the nine months ended September 30, 2021, Radius reported a net loss of $54.6 million, or $1.16 per share, compared to a net loss of $87.8 million, or $1.89 per share, for the nine months ended September 30, 2020.

For the nine months ended September 30, 2021, non-GAAP adjusted net loss, was $34.3 million, or $0.73 per share, compared to non-GAAP adjusted net loss of $51.6 million, or $1.11 per share, for the nine months ended September 30, 2020.

Revenue
For the nine months ended September 30, 2021, TYMLOS net product revenues were $153.9 million compared to $148.4 million for the nine months ended September 30, 2020.

For the nine months ended September 30, 2021, license revenue was $11.0 million compared to $27.4 million recognized for the nine months ended September 30, 2020.

Costs and Expenses

For the nine months ended September 30, 2021, research and development expense was $93.1 million compared to $123.3 million for the nine months ended September 30, 2020, a decrease of $30.2 million, or 24%. This decrease was primarily driven by a decrease of $21.6 million in abaloparatide-TD program costs, a $1.2 million decrease in RAD140 program costs, a $12.9 million decrease in compensation expense, which is comprised of a $3.5 million decrease in compensation expense related to headcount and $9.4 million of billed reimbursable expenses, and a $24.3 million decrease in elacestrant program costs, which is comprised of a $0.3 million decrease in gross program expenses offset by $23.8 million of billed reimbursable expenses. These decreases were offset by a $12.2 million increase in abaloparatide-SC program costs, a $10.3 million increase in RAD011 program costs, and a $7.1 million increase in professional fees and other expenses.

For the nine months ended September 30, 2021, selling, general and administrative expenses were $100.5 million compared to $108.4 million for the nine months ended September 30, 2020, a decrease of $7.9 million, or 7%. This decrease was primarily the result of a $6.3 million decrease in wages and employee benefit costs due to a decrease in headcount, a $1.8 million decrease in stock-based compensation expense and a $1.9 million decrease in other operating costs. These decreases were offset by an increase of $2.3 million in professional support costs.

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 109,559	$ 91,436
Restricted cash	567	567
Marketable securities	-	23,280
Accounts receivable, net	26,545	20,310
Inventory	11,604	9,174
Prepaid expenses	9,131	13,279
Other current assets	20,070	22,502
Total current assets	177,476	180,548
Property and equipment, net	660	796
Intangible assets	5,186	5,785
Right of use assets - operating leases	720	3,933
Other assets	2,141	520
Total assets	$ 186,183	$ 191,582
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 13,548	$ 9,925
Accrued expenses and other current liabilities	75,766	59,758
Deferred Revenue	-	1,000
Operating lease liability, current	725	2,490
Total current liabilities	90,039	73,173
Convertible notes payable	190,272	213,645
Term loan	148,057	24,905
Operating lease liability, long term	364	3,518
Total liabilities	428,732	315,241
Stockholders’ equity (deficit):		
Common stock, $0.0001 par value; 200,000,000 shares authorized, 47,325,993 shares and 46,779,479 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	5	5
Additional paid-in-capital	1,109,843	1,222,137
Accumulated other comprehensive income (loss)	-	21
Accumulated deficit	(1,352,397)	(1,345,822)
Total stockholders’ equity (deficit)	(242,549)	(123,659)
Total liabilities and stockholders’ equity (deficit)	$ 186,183	$ 191,582

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,	
	2021	2020	2021	2020
REVENUES:				
Product revenue, net	$ 56,810	$ 50,412	$ 153,867	$ 148,448
License Revenue	-	27,414	11,000	27,414
Total Revenue	56,810	77,826	164,867	175,862
OPERATING EXPENSES:				
Cost of sales - product	4,873	3,839	13,192	11,771
Cost of sales - intangible amortization	200	200	599	599
Research and development, net of amounts reimbursable (a)	34,738	39,450	93,128	123,340
Selling, general, and administrative	34,256	33,692	100,496	108,356
Income (Loss) from operations	(17,257)	645	(42,548)	(68,204)
OTHER (EXPENSE) INCOME:				
Other income (expense)	90	(87)	10	(144)
Interest expense	(4,873)	(7,069)	(14,084)	(20,747)
Interest income	7	222	70	1,272
Gain on extinguishment of debt	-	-	1,960	-
NET LOSS	$ (22,033)	$ (6,289)	$ (54,592)	$ (87,823)
OTHER COMPREHENSIVE LOSS:				
Unrealized gain (loss) from available-for-sale debt securities	-	(26)	(21)	79
COMPREHENSIVE LOSS	$ (22,033)	$ (6,315)	$ (54,613)	$ (87,744)
LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS - BASIC AND DILUTED:	$ (22,033)	$ (6,289)	$ (54,592)	$ (87,823)
LOSS PER SHARE:				
Basic and diluted	$ (0.47)	$ (0.14)	$ (1.16)	$ (1.89)
WEIGHTED AVERAGE SHARES:				
Basic and diluted	47,288,212	46,493,126	47,173,337	46,395,124

(a) Amounts reimbursable for the three and nine months ended September 30, 2021 were $14.6 million and $47.4 million, respectively, and $15.4 million for the three and nine months ended September 30, 2020.

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,	
	2021	2020	2021	2020
Net loss reconciliation:				
GAAP net loss	$ (22,033)	$ (6,289)	$ (54,592)	$ (87,823)
Intangible amortization	200	200	599	599
Stock-based compensation expense	6,083	6,522	17,197	19,821
Restructuring charges	-	-	-	-
Depreciation	42	472	137	1,020
Non-cash interest	415	4,588	1,189	13,313
Gain on extinguishment of debt	-	-	(1,960)	-
Debt refinancing charges	-	-	3,143	-
Operating lease impairment	-	1,510	-	1,510
Non-GAAP net loss	$ (15,293)	$ 7,003	$ (34,287)	$ (51,560)
Reconciliation of diluted loss per share:				
GAAP loss per share	$ (0.47)	$ (0.14)	$ (1.16)	$ (1.89)
Intangible amortization	0.00	0.00	0.01	0.01
Stock-based compensation expense	0.13	0.14	0.36	0.43
Restructuring charges	-	-	-	-
Depreciation	0.00	0.01	0.00	0.02
Non-cash interest	0.01	0.10	0.03	0.29
Gain on extinguishment of debt	-	-	(0.04)	-
Debt refinancing charges	-	-	0.07	-
Operating lease impairment	-	0.03	-	0.03
Non-GAAP loss per share	$ (0.32)	$ 0.15	$ (0.73)	$ (1.11)
Reconciliation of shares used in loss per share calculation:				
GAAP shares used in loss per share	47,288,212	46,493,126	47,173,337	46,395,124
Non-GAAP dilutive share adjustments	-	-	-	-
Non-GAAP shares used in loss per share	47,288,212	46,493,126	47,173,337	46,395,124

Webcast and Conference Call

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

Conference Call Information:
Date: November 8, 2021
Time: 8:30 a.m. ET
Domestic Dial-In Number: 1 (866) 323-7965

International Dial-In Number: 1 (346) 406-0961
Conference ID: 9322858
Webcast Link: https://edge.media-server.com/mmc/p/945gpbaj

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 November 8 at 11:30 a.m. ET and the audio webcast of the call will be archived on the Company's website for ninety days. To access the replay, dial (855) 859-2056 or (404) 537-3406 for International, using conference ID number 9322858. 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: 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, 2021 and 2020 are included in the tables accompanying this press release after the unaudited condensed consolidated financial statements.

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 endocrine and metabolic orphan diseases, initially targeting Prader-Willi Syndrome.

About TYMLOS (abaloparatide) injection
TYMLOS (abaloparatide) injection was approved by the U.S. Food and Drug Administration for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as history of osteoporotic fracture,

multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

About ATOM Phase 3 Study
The ATOM Phase 3 study is a randomized, double-blind, placebo-controlled study to assess efficacy and safety of abaloparatide injection in 228 men with osteoporosis. The primary endpoint is change in lumbar spine BMD at 12 months compared with placebo, and it is expected to form the basis of a supplemental NDA seeking to expand the use of TYMLOS to treat men with osteoporosis at high risk for fracture.

About the Abaloparatide Transdermal System and wearABLe Phase 3 Study
The abaloparatide transdermal system was developed in a collaboration between Radius and Kindeva Drug Delivery ("Kindeva") (formerly 3M Drug Delivery Systems) with the application of Kindeva's innovative microstructured transdermal system technology. The wearABLe study is a pivotal, randomized, open label, active-controlled, bone mineral density ("BMD") non-inferiority bridging study that will evaluate the efficacy and safety of abaloparatide transdermal system versus TYMLOS (abaloparatide) injection in approximately 500 patients with postmenopausal osteoporosis at high risk for fracture. The primary endpoint of the study is the percentage change in lumbar spine BMD at 12 months.

About Elacestrant (RAD1901) and EMERALD Phase 3 Study
Elacestrant is a selective estrogen receptor degrader (SERD), out-licensed to Menarini Group, which is being evaluated for potential use as a once daily oral treatment in patients with ER+/ HER2- advanced breast cancer. Studies completed prior to EMERALD indicate that the compound has the potential for use as a single agent or in combination with other therapies for the treatment of breast cancer. The EMERALD Phase 3 trial is a randomized, open label, active-controlled study evaluating elacestrant as second- or third-line monotherapy in ER+/HER2- advanced/metastatic breast cancer patients. The study has enrolled 466 patients who have received prior treatment with one or two lines of endocrine therapy, including a cyclin-dependent kinase (CDK) 4/6 inhibitor. Patients in the study were randomized to receive either elacestrant or the investigator's choice of an approved hormonal agent. The primary endpoint of the study is progression-free survival (PFS) in the overall patient population and in patients with estrogen receptor 1 gene (ESR1) mutations. Secondary endpoints include evaluation of overall survival (OS), objective response rate (ORR), and duration of response (DOR).

About Prader-Willi Syndrome
PWS, an orphan disease, is a complex genetic disorder with clinical manifestations on the endocrine and neurological systems. Clinical signs of PWS develop throughout childhood, with hyperphagia and anxiety ranked as the key clinical features seeking medical attention by caregivers of individuals with PWS. Hyperphagia is a relentless, insatiable, pathological drive to eat that requires caregivers to strictly manage access to food through the locking of cabinets and refrigerators. PWS is recognized as the leading genetic cause of life-threatening obesity in children. As life-threatening hyperphagia persists into adulthood, metabolic syndrome expressed through obesity and diabetes can develop and contribute to morbidity and mortality. In addition to food-related behaviors, the behavioral symptoms commonly observed in PWS include high irritability, habitual skin picking, oppositional defiance and cognitive rigidity. There are currently no approved therapies to treat this disorder's hyperphagia, irritability, or metabolic aspects. In the U.S., PWS occurs in approximately one out of every 15,000 births.

About RAD011
Investigational drug RAD011 is a pharmaceutical-grade synthetic cannabidiol oral solution, manufactured utilizing traditional pharmaceutical manufacturing processes. The product has purity specifications that meet standardized regulatory and quality control requirements and, compared to the process of developing a plant-derived product,

the synthetic manufacturing process usually enables increased consistency and greater precision in the product supply. RAD011 has been assessed in over 150 patients across multiple indications and has potential utilization in multiple endocrine and metabolic orphan diseases. Radius is initially targeting Prader-Willi syndrome (PWS) and anticipates initiating a seamless pivotal Phase 2/3 study for patients with PWS in the fourth quarter of 2021 or first quarter of 2022.

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 with respect to the continued commercialization of TYMLOS in the U.S.; clinical trials, studies, results and other regulatory submissions and initiatives of Radius and our partners; our goals for the development and commercialization of our products and product candidates; and our use of proceeds from our license agreement with Menarini.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the adverse impact the ongoing COVID-19 pandemic is having and is expected to continue to have on our business, financial condition and results of operations, including our commercial operations and sales, clinical trials, preclinical studies, and employees; quarterly fluctuation in our financial results; our dependence on the success of TYMLOS, and our inability to ensure that TYMLOS will obtain regulatory approval outside the U.S. or be successfully commercialized in any market in which it is approved, including as a result of risk related to coverage, pricing and reimbursement; risks related to competitive products; risks related to our ability to successfully enter into collaboration, partnership, license or similar agreements; risks related to clinical trials, including our reliance on third parties to conduct key portions of our clinical trials and uncertainty that the results of those trials will support our product candidate claims; the risk that adverse side effects will be identified during the development of our product candidates or during commercialization, if approved; risks related to manufacturing, supply and distribution; and the risk of litigation or other challenges regarding our intellectual property rights. These and other important risks and uncertainties discussed in our filings with the Securities and Exchange Commission, or SEC, including under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ending December 31, 2020 and subsequent filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Investor & Media Relations Contact:
Ethan Holdaway
Email: investor-relations@radiuspharm.com
Phone: (617) 583-2017