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): June 22, 2022

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 7.01 Regulation FD Disclosure.

On June 22, 2022, Radius Health, Inc. (the "Company") and The Menarini Group ("Menarini") issued a joint a press release announcing that a New Drug Application (an "NDA") has been submitted to the U.S. Food and Drug Administration ("FDA") for elacestrant in patients with ER+/HER2- advanced breast cancer. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information (including Exhibit 99.1) being furnished pursuant to this Item 7.01 shall not be deemed to be "filed" for the 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 and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Radius Health, Inc. Press Release dated June 22, 2022
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: June 22, 2022

By: /s/ G. Kelly Martin
Name: G. Kelly Martin
Title: President and Chief Executive Officer

EXHIBIT 99.1

Menarini Group and Radius Health Submit New Drug Application to the U.S. FDA for Elacestrant

- Intended for potential treatment of ER+/HER2- advanced or metastatic breast cancer patients
- Priority Review requested; if accepted, anticipate an 8-month FDA review
- Positive EMERALD study data previously announced on October 20, 2021
- First, and currently only, investigational oral SERD with positive topline results
- Additional data presented at SABCS (December 2021) and ASCO (June 2022)
- Plan to file marketing authorization application for elacestrant in the EU in 2H 2022

Florence, Italy and Boston, Mass., June 22, 2022 – The Menarini Group ("Menarini") and Radius Health, Inc. ("Radius") (NASDAQ: RDUS) (collectively, the "Companies") announced that Menarini, with support from Radius, has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for elacestrant in patients with ER+/HER2- advanced or metastatic breast cancer.

As part of the submission, the Companies have requested Priority Review with the FDA. If Priority Review is granted, the Companies anticipate that the FDA would conduct an 8-month review, incorporating a 6-month priority designation review.

The NDA submission is based on positive phase 3 data from the EMERALD study that was previously announced on October 20, 2021. EMERALD met both of its primary endpoints, which were progression-free survival (PFS) in the overall population and PFS in the estrogen receptor 1 (ESR1) mutation subgroup as compared to standard of care (SoC) with the options of fulvestrant or an aromatase inhibitor.

Elacestrant is the first and currently only investigational oral SERD to show positive topline results in a pivotal trial for the treatment of ER+/HER2- advanced or metastatic breast cancer in postmenopausal women, and men. Notably, these results showed elacestrant is also active in patients whose tumors harbor an ESR1 mutation, one of the key resistance mechanisms that develops in later treatment lines of metastatic breast cancer.

Following the completion of EMERALD, data from the study was presented at the San Antonio Breast Cancer Symposium (SABCS) on December 8, 2021, published in the Journal of Clinical Oncology (JCO) on May 18, 2022, and further subset analyses were presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting on June 6, 2022.

Elcin Barker Ergun, the Chief Executive Officer of Menarini, commented, "We are excited about the potential for elacestrant to be approved for treatment of patients with advanced or metastatic ER+/HER2- breast cancer, which constitutes about 70% of breast cancer and remains an area of significant unmet medical need." Barker Ergun continued, "Elacestrant has shown statistically significant efficacy over current standard of care medications both for overall population and in patients whose tumors harbor an ESR1 mutation, one of the most difficult to treat mechanisms of acquired resistance that develops in the later stages of metastatic/advanced breast cancer."

Chhaya Shah, SVP of Clinical and Regulatory at Radius, commented, "We enrolled and completed the EMERALD trial in a high-quality manner, delivered positive topline results, and prepared the submission of the NDA to the FDA. The submission is a significant milestone for both companies, and we appreciate the strong, collaborative effort of many hard-working employees at Radius and Menarini, investigators, patients, and their families. Together we look forward to advancing elacestrant and providing the opportunity to benefit patients."

Nassir Habboubi, Global Head of Pharma R&D of Menarini Group, added, “The Menarini and Radius teams have done an excellent job working together since our partnership began in July of 2020.” Habboubi continued, “We plan to test elacestrant in earlier treatment lines, combination trials, and metastatic breast cancer that has metastasized to the brain. These details are to be communicated by us throughout 2H 2022 and 1H 2023.”

With the submission of the NDA, based on the original agreement of the Companies, Menarini takes over activities and will be responsible for registration and commercialization. Menarini plans to use its fully owned subsidiary in the U.S., Stemline Therapeutics, to commercialize elacestrant if approved by the FDA.

About Elacestrant (RAD1901) and EMERALD Phase 3 Study

Elacestrant is an investigational 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. In 2018, elacestrant received fast track designation from the FDA. Preclinical 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 enrolled 477 patients who have received prior treatment with one or two lines of endocrine therapy, including a CDK 4/6 inhibitor. Patients in the study were randomized to receive either elacestrant or the investigator’s choice of an approved hormonal agent. The primary endpoint of the study was progression-free survival (PFS) in the overall patient population and in patients with estrogen receptor 1 gene (ESR1) mutations. Secondary endpoints included evaluation of overall survival (OS), objective response rate (ORR), and duration of response (DOR).

About Menarini

The Menarini Group is a leading international pharmaceutical and diagnostics company, with a turnover of over $4 billion and over 17,000 employees. Menarini is focused on therapeutic areas with high unmet needs with products for cardiology, oncology, pneumology, gastroenterology, infectious diseases, diabetology, inflammation, and analgesia. With 18 production sites and 9 Research and Development centers, Menarini’s products are available in 140 countries worldwide. For further information, please visit www.menarini.com.

About Radius

Radius is a global biopharmaceutical company focused on addressing unmet medical needs in the areas of bone health, neuroscience 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; the investigational drug, elacestrant (RAD1901), for potential use in the treatment of hormone-receptor positive breast cancer out-licensed to Menarini Group; and the investigational drug RAD011, a synthetic cannabidiol oral solution with potential utilization in multiple neuro-endocrine, neurodevelopmental, or neuropsychiatric disease areas, initially targeting Prader-Willi syndrome, Angelman syndrome, and infantile spasms.

Forward-Looking Statements of Radius

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 potential for elacestrant for the treatment of patients with advanced ER+/HER2- breast cancer, including the potential to be a new standard of care, the length of priority review, if granted, of the elacestrant NDA by the FDA, the

expected regulatory submission in the European Union; and ongoing clinical development activities with respect to elacestrant.

These forward-looking statements are based on Radius 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, including the delay of reviews and approvals by the FDA and other regulatory authorities, delays in the supply of drug product, risks related to Radius' collaboration with Menarini, including its ability to scale its sales and marketing operations if elacestrant is approved for marketing; Menarini's ability to obtain favorable pricing and reimbursement for elacestrant, if approved; the risk that the potential market for elacestrant is not as anticipated; the risk of adverse side effects related to elacestrant are identified; risks related to manufacturing, supply and distribution of elacestrant; and the risk of litigation or other challenges regarding Radius' intellectual property rights. These and other important risks and uncertainties discussed in Radius' filings with the Securities and Exchange Commission (SEC), including under the caption "Risk Factors" in Radius' Annual Report on Form 10-K for the year ending December 31, 2021 and subsequent filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent Radius' management's estimates as of the date of this press release. While Radius may elect to update such forward-looking statements at some point in the future, Radius disclaims 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 Radius' views as of any date subsequent to the date of this press release.

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