

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 2, 2022

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.)

22 Boston Wharf Road, 7th Floor, Boston, MA

(Address of principal executive offices)

02210

(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 1.02 Termination of a Material Definitive Agreement.

On June 2, 2022, Radius Health, Inc. (the “Company”) provided Kindeva Drug Delivery, L.P., as successor to 3M Company and 3M Innovative Properties Company, (“Kindeva”), with a written notice of termination to terminate the Scale-Up and Commercial Supply Agreement, dated February 27, 2018 (as amended on May 1, 2022, the “Agreement”), by and between the Company and Kindeva. Pursuant to the Agreement, Kindeva agreed to exclusively manufacture Phase 3 and global commercial supplies of an abaloparatide-coated transdermal system (the “Product”). The Company provided notice of its termination of the Agreement because the Company has decided to cease development and commercialization of the Product. The termination shall be effective on June 10, 2022.

As a result of the termination of the agreement, the Company will not owe Kindeva any facility fees for the months of May, June or July of 2022 and Kindeva will not begin Product third-party contract manufacturer facility fees in July 2022, for which the Company shall not owe Kindeva any payments. In addition, Kindeva will act diligently to minimize all wind-down costs that may be incurred upon receipt of the termination notice.

Item 8.01 Other Events.

On June 8, 2022, the Company issued a press release providing an update on the global business expansion of TYMLOS (abaloparatide) subcutaneous injection. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Radius Health, Inc. Press Release dated June 8, 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 8, 2022

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

Radius Health Expands Non-US Market Footprint for TYMLOS

- Globalization has been a key priority for the Company over the past two years
- Three additional market agreements now signed and executed:
 - Labatec Pharma SA: Switzerland, Middle East & North Africa (MENA) countries
 - Pharmbio Korea Inc.: South Korea
 - Biosidus: Colombia, South America
- Economics: upfront payments, regulatory & commercial milestones, and COGS margin
- Adds 13 new countries to the current non-US countries of Japan and Canada
- Japan: regulatory approval of 14-day cartridge anticipated in 2H 2022 followed by launch
- Canada: regulatory decision expected by the end of 2022
- EU and subsequently UK regulatory decisions expected in 2H 2022

Boston, Mass., June 8, 2022 – Radius Health, Inc. (“Radius” or the “Company”) (NASDAQ: RDUS) provided an update on the global business expansion of TYMLOS (abaloparatide) subcutaneous injection.

Radius has entered into agreements with the following companies and markets for TYMLOS:

- Labatec Pharma SA: Switzerland and the MENA region including Bahrain, Iraq, Jordan, Kuwait, Oman, Qatar, Saudi Arabia, UAE, Algeria, and Morocco
- Pharmbio Korea Inc.: South Korea
- Biosidus: Colombia, South America

These agreements add 13 new countries to the current non-US countries of Japan, partnered with Teijin Pharma Limited, and Canada, partnered with Paladin Labs Inc.

In accordance with the terms of the agreements, each company will register, commercialize, and distribute TYMLOS on an exclusive basis in their respective territories. These counterparties will be responsible for all commercial activities related to TYMLOS including sales, marketing, medical affairs, pricing, and reimbursement. Radius will be responsible for supplying the drug to each company.

Radius will receive upfront payments, regulatory and commercial milestones, and a portion of the total consideration as part of the Cost of Goods Sold (COGS).

“Expanding the global footprint of TYMLOS has been a key priority for the company over the past two years”, commented Chhaya Shah, SVP, who leads the clinical and regulatory activity for abaloparatide. She added “across all of our partners, we expect up to four ex-US market launches in 1H 2023. Importantly this includes Japan, as the world’s largest anabolic market, as well as Canada.”

The EU and subsequently the UK regulatory decisions are on track for the second half of this year. We will provide further updates on our EU and UK business development efforts as well as the expected Q1 2023 TYMLOS male launch in the US, as appropriate.

About Radius

Radius is a global biopharmaceutical company focused on addressing unmet medical needs in the areas of bone health, orphan neurosciences 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.

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.

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.

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, 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 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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