

REPROS THERAPEUTICS INC.

FORM 8-K (Current report filing)

Filed 10/05/16 for the Period Ending 10/05/16

Address	2408 TIMBERLOCH PL SUITE B-7 WOODLANDS, TX 77380
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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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): October 5, 2016

Repros Therapeutics Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-15281
(Commission File Number)

76-0233274
(I.R.S. Employer Identification Number)

2408 Timberloch Place, Suite B-7, The Woodlands, Texas 77380

(Address of Principal Executive Offices) (Zip Code)

(281) 719-3400

(Registrant's telephone number, including area code)

(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:

- 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))
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Item 7.01. Regulation FD Disclosure.

On October 5, 2016, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1. Press release dated October 5, 2016

SIGNATURE

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.

Repros Therapeutics Inc.

Date: October 5, 2016

By: /s/ Kathi Anderson

Kathi Anderson

CFO

Repros Announces Acceptance of Dossier for Enclomiphene for Secondary Hypogonadism by European Authorities

THE WOODLANDS, Texas, Oct. 05, 2016 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc.® (Nasdaq:RPRX) today announced that it has received confirmation of acceptance of its September 12, 2016 filing for enclomiphene in the treatment of secondary hypogonadism in Europe.

- Analogous to acceptance of an NDA by U.S. Food and Drug Administration
- Responses expected by end of January 2017

The MAA was submitted to the European Medicines Agency (EMA) by Renable Pharma Limited, the UK subsidiary of Repros.

As has been described in previous communications, the typical time from submission to authorization of a medicinal product through the EMA's centralized procedure is 13-16 months and culminates in one authorization being obtained which is valid in all European Union and European Economic Area countries, i.e. 31 in total. The centralized procedure allows for a pan-EU review of the data, led by the Rapporteur's and Co-Rapporteur's assessment teams, and is governed by set timelines; therefore the review time is well defined. In this context, the Company expects to receive all questions relating to the application by the end of January 2017.

Dr. Michael Wyllie, Independent Director of Repros, commented: "The acceptance of the dossier by the EMA represents a key milestone toward the commercialization of enclomiphene and signals the acceptability and adequacy of the data for formal review. At a defined time point, 'day 120', toward the end of January, we expect to get an initial reaction from the examiners."

About Repros Therapeutics Inc.®

Repros Therapeutics focuses on the development of small molecule drugs for major unmet medical needs that treat male and female reproductive disorders.

Forward-Looking Statements

Any statements made by the Company that are not historical facts contained in this release are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and are subject to various risks, uncertainties and other factors that could cause the Company's actual results, performance or achievements to differ materially from those expressed or implied by such forward-looking statements. These statements often include words such as "may," "will," "expect," "anticipate," "continue," "estimate," "project," "intend," "believe," "plan," "seek," "could," "can," "should" or similar expressions. These statements are based on assumptions that the Company has made in light of the Company's experience in the industry, as well as the Company's perceptions of historical trends, current conditions, expected future developments and other factors the Company believes are appropriate in these circumstances. Forward-looking statements include, but are not limited to, those relating to the timing and nature of the results of clinical studies and the impact of such results. Such statements are based on current expectations that involve a number of known and unknown risks, uncertainties and other factors that may cause actual events to be materially different from those expressed or implied by such forward-looking statements, including risks that the EMA may not ultimately grant the marketing authorization, on the expected timeline or at all, the risk that the marketing authorization, if granted, may have significant limitations on use, that even if the marketing authorization is ultimately granted, the Company may not be able to successfully commercialize the product candidate, risks relating to the Company's ability to protect its intellectual property rights and such other risks as are identified in the Company's most recent Annual Report on Form 10-K and in any subsequent quarterly reports on Form 10-Q. These documents are available on request from Repros Therapeutics or at www.sec.gov. Repros disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

For more information, please visit the Company's website at <http://www.reprosrx.com>.

CONTACT:

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