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REPROS THERAPEUTICS INC.

FORM 8-K
(Current report filing)

Filed 01/30/17 for the Period Ending 01/30/17

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SIC Code	2836 - Biological Products, Except Diagnostic Substances
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): January 30, 2017

Repros Therapeutics Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-15281**	**76-0233274**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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))

Item 7.01. Regulation FD Disclosure.

On January 30, 2017, 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 January 30, 2017

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: January 30, 2017

By: /s/ Kathi Anderson
Kathi Anderson
CFO

EXHIBIT 99.1

FDA Grants End of Phase 2 Meeting to Discuss Phase 3 Requirements for Oral Proellex® in the Treatment of Uterine Fibroids

THE WOODLANDS, Texas, Jan. 30, 2017 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc. ® (Nasdaq:RPRX) today announced the FDA has granted an "end of Phase 2" meeting to discuss the Phase 3 requirements to demonstrate both efficacy and safety for the development of Proellex® (telapristone acetate) for the treatment of uterine fibroids. The meeting is scheduled to occur before the end of April 2017.

In the Phase 2 study, leading up to the meeting request, Proellex ® successfully induced amenorrhea (cessation of menses) in greater than 90% (LOCF, p-value <0.0001 pooled 6 and 12 mg doses compared to placebo) of subjects after two 18 week treatment cycles separated by an off drug interval to allow for menstruation. Subject's improvement in the Uterine Fibroid Symptom Severity Score from the UFSQOL questionnaire was statistically better for those treated with Proellex ® (LOCF, p = 0.0038).

The study was conducted in the US with the average age of study participants >40 years of age, with a body mass index >30 and over 90% of the subjects were African American. African American women are 3 times more likely to develop symptomatic fibroids and much earlier in life than Caucasians.

The drug was generally well tolerated.

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 ongoing and future clinical studies and the timing and results thereof, the Company's plans to communicate with the FDA, possible submission of one or more NDAs and the commercial potential of Proellex ® , 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.

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