REPROS THERAPEUTICS INC.

FORM 8-K
(Current report filing)

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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): December 12, 2016

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 December 12, 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 December 12, 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: December 12, 2016

By: /s/ Kathi Anderson
Kathi Anderson
CFO

EXHIBIT 99.1

Repros Requests Meeting With FDA to Discuss Phase 3 Requirements for Proellex® in the Treatment of Symptomatic Uterine Fibroids

- *Focus on oral formulation*
- *Phase II complete*

THE WOODLANDS, Texas, Dec. 12, 2016 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc.® (Nasdaq:RPRX) today announced it has requested a meeting to discuss Phase 3 requirements for the development of Proellex® (telapristone acetate) for the treatment of symptomatic uterine fibroids. The Company anticipates a meeting will be scheduled during the first half of 2017.

The Company has completed studies on both oral and vaginal delivery and will propose further development of the oral form of the drug. The objective of the meeting with the FDA is primarily to agree on the Phase 3 clinical program. To date, the Company has administered Proellex® at various doses and strengths in over 700 women. In efficacy studies of uterine fibroids the formulations of Proellex® have consistently exhibited both clinically and statistically significant reduction of excessive menstrual bleeding due to the presence of uterine fibroids. This clinical feature is due to the action of Proellex® which induces a state of amenorrhea (cessation of menses). In addition to induction of amenorrhea, the studies have shown that Proellex® reduces fibroid volume which can significantly reduce the bulk symptoms many women with fibroids experience.

The Company has also completed a thorough toxicity panel in animal models that meets ICH guidelines. This includes two successfully completed carcinogenicity studies. Of particular note, in the two year rat study, animals dosed with Proellex® exhibited a lower incidence of mammary tumors than control animals.

The Company has also completed a full battery of drug interaction and special population studies, including a pilot QT interval study at significant multiples of the highest intended dose, 12 mg, that did not exhibit QT prolongation.

The current formulation of Proellex® allows for continuous dosing for up to 18 weeks which, is 50% longer than a competing product. In addition, the Proellex® studies have not demonstrated any apparent racial or BMI effect on overall efficacy.

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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