

# REPROS THERAPEUTICS INC.

## **FORM 8-K** (Current report filing)

Filed 04/10/17 for the Period Ending 04/10/17

Address	2408 TIMBERLOCH PL SUITE B-7 WOODLANDS, TX 77380
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Sector	Healthcare
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event Reported): April 10, 2017

**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 April 10, 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 April 10, 2017

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**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: April 10, 2017

By: /s/ Kathi Anderson

Kathi Anderson

CFO

**Company Holds Meeting with FDA to Discuss Oral Proellex® in the Treatment of Uterine Fibroids**

THE WOODLANDS, Texas, April 10, 2017 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc.® (Nasdaq:RPRX) today announced that the Company held a meeting with the FDA to discuss the progress and next steps in the development of Proellex® (telapristone acetate) for the treatment of uterine fibroids. Shortly before the meeting, the Company was notified that the meeting would be a type C/Guidance meeting, rather than a type B/End of phase 2 meeting as previously anticipated. At the meeting, the FDA confirmed that Proellex® will continue on the current partial clinical hold while they consult with liver experts within the FDA regarding previously disclosed effects on the liver. Further, the FDA agreed to accept additional information from the Company and its panel of liver experts for consideration by the FDA's internal advisory liver team. The Company expects to submit the additional information and a proposed clinical protocol within a month. The Company intends to announce further information following receipt of additional guidance from the FDA.

Larry Dillaha, M.D., the Company's President and Chief Executive Officer, commented, "The Company is pleased with the guidance received from the FDA, and while we remain on the current partial clinical hold as the FDA internally reviews our data related to the effect of Proellex® on the liver, we will proceed with our development plans by submitting additional phase 2 protocols to the FDA for their review. We are committed to working closely with the FDA as we further our development program for Proellex®."

**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 and submit further information to 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](http://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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