

# REPROS THERAPEUTICS INC.

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

Filed 11/14/16 for the Period Ending 11/14/16

Address	2408 TIMBERLOCH PL SUITE B-7 WOODLANDS, TX 77380
Telephone	2817193400
CIK	0000897075
Symbol	RPRX
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

---

---

**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): November 14, 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))
- 
- 
-

**Item 7.01. Regulation FD Disclosure.**

On November 14, 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 November 14, 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: November 14, 2016

By: /s/ Kathi Anderson  
Kathi Anderson  
CFO

## Repros Reports Topline Positive Clinical Data After Two 18 Week Courses of Proellex® Delivered Orally and Vaginally for the Treatment of Uterine Fibroids

- Primary endpoint of induction of amenorrhea met for both pooled oral and vaginal delivery compared to placebo,  $p < 0.0001$  and  $p = 0.0071$ , respectively
- Statistically significant reduction in fibroid size from baseline achieved by the combined active arms for the pooled oral dosage form compared to placebo,  $p = 0.0004$
- Statistically significant improvement in Uterine Fibroid Symptom Severity Score (UFSQOL) achieved for the pooled oral dosage form compared to placebo,  $p = 0.0211$
- On the basis of a comparison of oral and vaginal delivery systems, the Company will propose the oral route of administration for Phase 3 development
- The Company plans to submit a request to the FDA before the end of 2016 to discuss the Phase 3 program

THE WOODLANDS, Texas, Nov. 14, 2016 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc.® (Nasdaq:RPRX) today reported the topline results for both its pooled oral and vaginal delivery Phase 2 studies in the treatment of uterine fibroids. Both studies enrolled women with confirmed fibroids by MRI at baseline and who were experiencing more than 80 mL of blood loss during menses as confirmed by alkaline hematin assessment. Proellex® at doses of both 6 and 12 mg, delivered by either route, substantially and significantly reduced excessive menstrual bleeding, the key symptom of uterine fibroids and the primary endpoint of the studies. The study of vaginal delivery enrolled 42 subjects and the oral delivery study's intent-to-treat population included 41 subjects.

Amenorrhea, cessation of menses, is known to occur when a sufficiently high plasma concentration of Proellex® is achieved. Subjects received 18 weeks of blinded treatment and were then withdrawn from the study medication to allow for menses. After menses occurred, a second 18 week course of treatment ensued. The study treatment assignments remained blinded to the subjects, physicians and those managing the study and data.

The incidence of amenorrhea in active treatment groups consistently showed a statistically significant difference from the rate in placebo-treated subjects with both routes of administration. At the end of the second course of treatment (36 weeks total active treatment, or Last Observation Carried Forward, LOCF), 92.9% of oral Proellex®-treated subjects achieved amenorrhea, while only 50% of vaginally treated subjects stopped menses. The oral dosage form provided for consistent suppression of menses with evidence of a dose response. Furthermore, among those women who completed the second 18 week course of oral drug administration, 100% of the women at the 12 mg dose exhibited amenorrhea, whereas 88.9% of women on the 6 mg dose achieved amenorrhea.

Along with changes in menstrual patterns, fibroid size, measured by MRI, was reduced in volume. Fibroid volume decreased in the oral Proellex®-treated arms by a median of 42.0% (LOCF) and was statistically different from the change from baseline volume in the placebo subjects (0%,  $p = 0.0004$ ). For women who completed the two 18 week courses of treatment, fibroid size reduction for the 12 mg oral and 6 mg oral doses was 58.2% and 32.9%, respectively, providing some evidence of a dose response effect.

The Uterine Fibroid Symptom Quality of Life Survey (UFSQOL) was utilized in this study. The UFSQOL assesses distress from both bleeding and the bulk symptoms of uterine fibroids. Bulk symptoms include distress associated with pelvic pressure, frequent urination and fatigue. Proellex®-treated subjects experienced a LOCF median 70.9% improvement while placebo-treated subjects reported a 37.5% improvement ( $p = 0.0211$ ).

The drug was generally well tolerated.

Joseph Podolski, President and CEO of Repros, commented, "We believe the benefit:risk profile of Proellex® could afford a significant advantage over GnRH agonists and antagonists in the treatment of uterine fibroids. The longer treatment period and apparent improvement in efficacy based on the incidence of amenorrhea compared to other selective progesterone antagonists is also encouraging."

The Company plans to request, before the end of this year, a meeting with the FDA to discuss Phase 3 development of the oral dosage form.

### 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](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>.

CONTACT: Investor Relations:  
Thomas Hoffmann  
The Trout Group  
(646) 378-2931  
[thoffmann@troutgroup.com](mailto:thoffmann@troutgroup.com)