# REPROS THERAPEUTICS INC.

## FORM 8-K
(Current report filing)

Filed 09/11/17 for the Period Ending 09/11/17

| | |
|---|---|
| Address | 2408 TIMBERLOCH PL<br>SUITE B-7<br>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 Filed Pursuant to Section 13 or 15(d) of**
**The Securities Exchange Act of 1934**

**Date of Report**

**(Date of earliest event reported): September 11, 2017**

## REPROS THERAPEUTICS INC.

**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-15281** | **76-0233274** |
|---|---|---|
| **(State or other jurisdiction of incorporation or organization)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

**2408 Timberloch Place, Suite B-7**
**The Woodlands, Texas 77380**
**(Address of principal executive offices and zip code)**

**(281) 719-3400**
**(Registrant's telephone number, including area code)**

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 (see General Instruction A.2 below):

☐ 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 7.01 Regulation FD Disclosure.**

The information in this Current Report is being furnished pursuant to Item 7.01 of Form 8-K and, according to general instruction B.2. thereunder, the information in this Current Report shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be incorporated by reference into any registration statement pursuant to the Securities Act of 1933, as amended.

Representatives of Repros Therapeutics Inc., a Delaware corporation (the "Company") are presenting updates on the Company's Proellex® and Enclomiphene clinical programs to various investors and other interested parties September 11 through September 13, 2017, in New York, NY, using slides containing the information attached to this Current Report on Form 8-K as Exhibit 99.1. These slides contain statements that are "forward-looking statements" subject to the cautionary statement about forward-looking statements set forth therein.

**Item 9.01 Financial Statements and Exhibits.**

| Exhibit Number | Description |
|---|---|
| 99.1 | Repros Therapeutics Slideshow |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934 the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**REPROS THERAPEUTICS INC.**

Date: September 11, 2017

By: /s/ Kathi Anderson
Kathi Anderson
Chief Financial Officer

**EXHIBIT INDEX**

| Exhibit Number | Description |
| --- | --- |
| 99.1 | Repros Therapeutics Slideshow |

Exhibit 99.1

# REPROS THERAPEUTICS

## Dedicated to Treating Male and Female Reproductive Disorders

Corporate Presentation

September 2017

Repros

# Safe Harbor

Any statements made by the Company that are not historical facts contained in these slides (or in any oral accompanying discussion) 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," "potential," "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 anticipated milestones for Enclomiphene and Proellex®, the conduct of planned clinical studies and the timing and nature of the results thereof, the markets for the Company's products and the potential success of the Company in penetrating those markets and that the Company's need for and use of financial resources. 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 the ability to raise additional needed capital on a timely basis in order for it to continue to fund development of its Enclomiphene and Proellex® programs, the ability to have success in the clinical development of its technologies, the reliability of interim results to predict final study outcomes, and such other risks as are identified in the Company's most recent Annual Report on Form 10-K and the subsequent quarterly report on Form 10-Q and in the prospectus supplement and the accompanying prospectus included in the registration statement mentioned below. These documents are available on request from Repros 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.

In this presentation, we rely on and refer to information and statistics regarding the pharmaceutical industry. We obtained this information and these statistics from third-party sources, which we have supplemented where necessary with information from publicly available sources and our own internal estimates. Industry publications and surveys generally state that they have obtained information from sources believed to be reliable, but do not guarantee the accuracy and completeness of such information. While we believe that each of these studies and publications is reliable, we have not independently verified such data, and we make no any representation as to the accuracy of such information. Similarly, we believe our internal research is reliable, but it has not been verified by any independent sources.

# Company Overview and Recent Leadership Appointments

- Originally founded as Zonagen – an animal health company using technology from Baylor University
- IPO 1993
- Key recent developments
  - Patrick Fourteau named as Chairman of the Board
  - Larry Dillaha, M.D. named President and CEO
  - Important patent issuance with coverage until 2027
  - FDA meeting to discuss path forward for Proellex®
  - European filing for Enclomiphene

# Experienced Management Team

- **Larry Dillaha, M.D.** – President and CEO (Feb 2017)
  - *Sanofi, Sciele / Shionogi, Insys Therapeutics*
  - *History of clinical and regulatory success*

- **Kathi Anderson, CPA** – CFO
  - *Joined Repros in 2002*
  - *More than 15 years in biotech, life sciences*

- **Joe Wernicke, M.D., Ph.D.** – Chief Medical Officer
  - *30 years industry experience*
  - *Eli Lilly, Cyberonics*

# Proellex® (Telapristone Acetate) for the Treatment of Uterine Fibroids and Endometriosis

- Licensed from NIH, 1999
- Selective Progesterone Receptor Modulator (SPRM)
- No selectivity for glucocorticoid receptor need for chronic intermittent dosing
- Lead indications:
  - *Treatment of Uterine Fibroids*
  - *Treatment of Endometriosis expected to follow*
- Strong patent protection
  - *NCE related thru 2021*
  - *Off-Drug Interval thru 2027*

# Selective Progesterone Receptor Modulator (SPRM)

- Evolved from progesterone antagonists
  - *Mifepristone*
  - *Limited use because of high affinity for glucocorticoid receptor over progesterone receptor*
    - Recognizing need for more selective progesterone receptor activity; SPRMs developed
- Mixed agonist and antagonist activity at progesterone receptor
  - *Relative activity is tissue specific*
  - *Minimizing activity on other steroidal receptors*

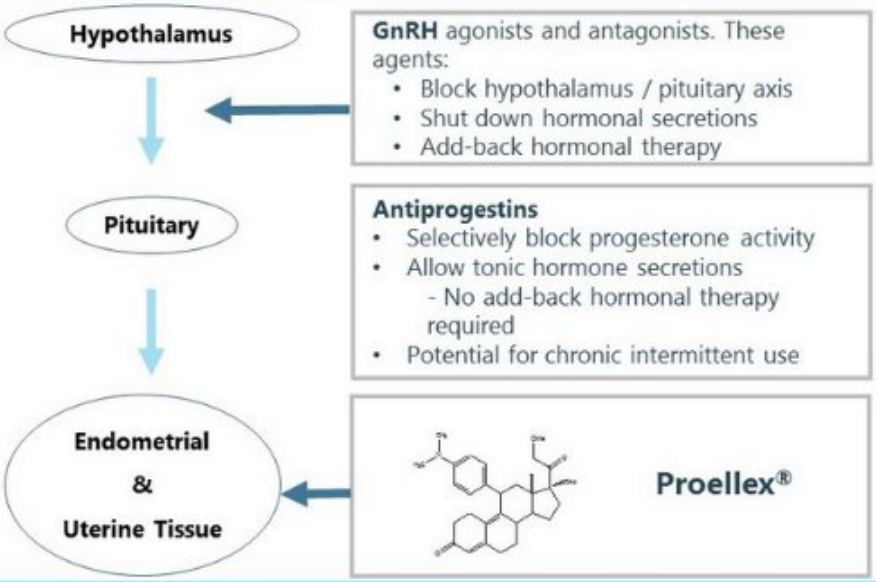
# Uterine Fibroids

- Benign smooth muscle tumors of uterus (leiomyomas)
- Most common tumor of female reproductive tract
  - *20-77% of women aged 35-55*
- Quality of Life often impacted
  - *Heavy menstrual bleeding*
  - *Discomfort and pain*
- Current Therapy
  - *Medications*
    - NSAIDS, OCPs, GnRH agonists, Progestin releasing IUDs
  - *Minimally Invasive Procedures*
    - Uterine artery embolization, myomectomy, ablation
  - *Surgery*
    - Hysterectomy – most common reason for hysterectomy – over half of the 600,000 done annually

# Endometriosis

- Endometrial tissue growing outside the uterus
  - *Infertility – pain, including pelvic pain*
  - *Dyspareunia*
  - *Dysmenorrhea*
  - *11% of women aged 15-44*
  - *25-40% of all cases of infertility*
  - *71-87% of women with chronic pelvic pain*
  - *53% teenagers with dysmenorrhea*
- Impact on QoL
- Current Therapy
  - *Medication*
    - NSAIDs, opioids, OCPs, Lupron, danazol
  - *Surgery*
    - Laparoscopic procedures – high rates of recurrence

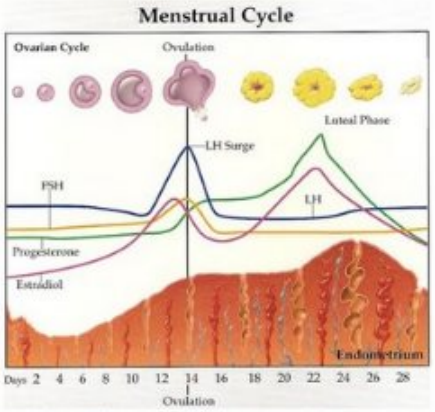
# How Antiprogestins Like Proellex® Work



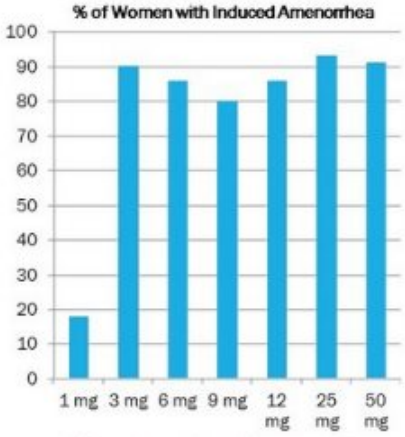
# Proellex® Effectiveness in Patients

**AN EFFECTIVE ORAL DOSE OF PROELLEX® STOPS MENSTRUATION (AMENORRHEA) IN MAJORITY OF WOMEN**

Induction of amenorrhea relieves key symptoms of uterine fibroids and endometriosis

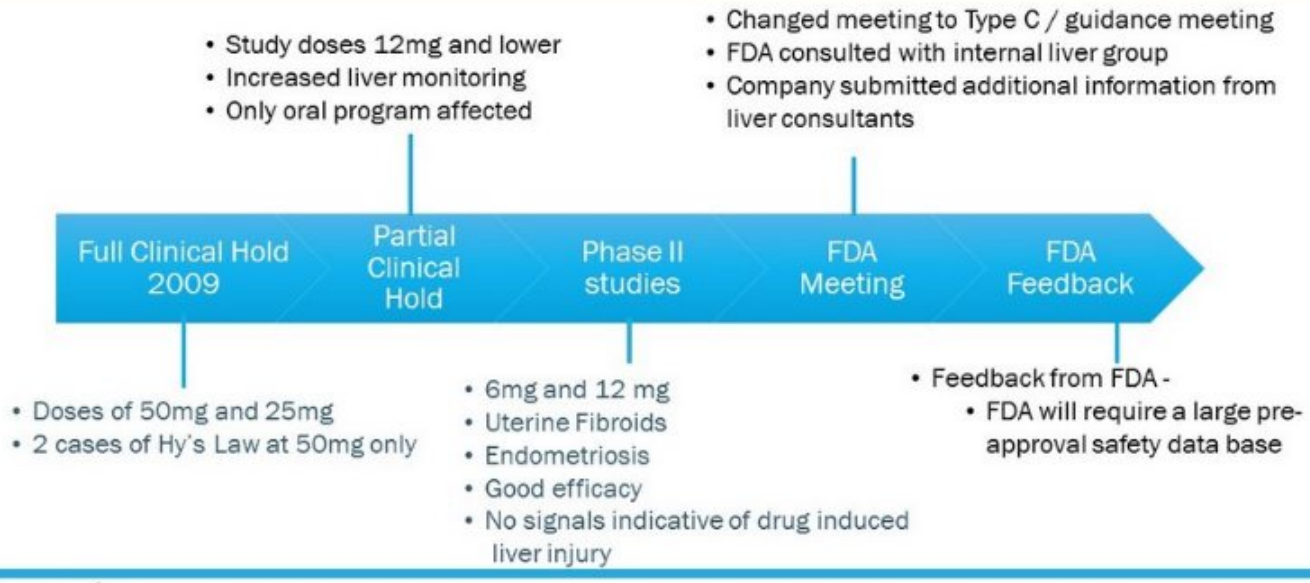



- Proellex® induced amenorrhea (no ovulation)
- Mimics early follicular phase without progesterone while maintaining tonic estrogen levels




Efficacy shown thru wide range of doses

# Proellex Regulatory / Development History



# Broad Patent Position on Proellex®

- Off-Drug Interval
  - Recent issuance of patent '074 – expires 2027
  - Relates to the use of Selective Progesterone Receptor Modulators (SPRM), in particular Telapristone Acetate (Proellex®) or Ulipristal Acetate, with an Off-Drug Interval (ODI) for the treatment of estrogen-dependent hyperproliferative uterine conditions, such as uterine fibroids and endometriosis
- NIH NCE patents
  - *Coverage until 2021*
- Vaginal Delivery Patent coverage

# Potential Advantages of Vaginal Delivery of Telapristone

- Leverage vaginal-uterine local circulation
  - *Reduce first pass hepatic metabolism*
  - *Allows for reduced systemic blood levels*
- Clinical work to date suggests good efficacy
  - *Current data on once daily vaginal capsules*
  - *Lower systemic blood levels compared to oral delivery*
- Potential improvement on formulation
  - *Vaginal ring delivery potentially attractive*
  - *Differentiated product*
  - *Expect to offer less than once per day dosing*
  - *Would target dosing every 2 - 4 weeks*

# Significant Market Opportunity and Investment in this Therapeutic Area

- Ulipristal Acetate
  - *Gedeon Richter product partnered with Allergan for US market*
  - *On market in EU*
    - Esmya 5 mg for Tx of UF
  - *Recently completed phase III*
    - Venus II trial
  - *Publicly stated intent to file NDA in 2H17*
  - *$1 bil opportunity* †
- Vilaprisan
  - *Bayer asset*
  - *Recently completed phase II program*
  - *Projected 1 billion euros per year* ‡
- GnRH Agonists / Antagonists

Repros

† Allergan R&D Presentation 2015, slide #90
‡ Bayer News Release, 9/20/16 – "Meet Management" investor conference

# Enclomiphene for the Treatment of Secondary Hypogonadism

- NDA submitted January 2015 – CRL received November 2015
- EMA filing September 2016
  - *currently under review*
- Opinion date is anticipated in 1Q 2018
- Actively seeking partnering opportunities outside of the U.S.

# Repros: Next steps and Milestones

- Uterine fibroid and endometriosis program with vaginal delivery treatment
- Maximize value from patent position
- FDA feedback makes oral development unlikely
- New management has experience and successful track record
- Actively seeking partnering opportunities for vaginal Proellex® in the US, global or regional markets for vaginal delivery formulations
- EMA filing under review for Enclomiphene for secondary hypogonadism
- Actively seeking partnering opportunities for Enclomiphene outside of the U.S.