# 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 1, 2015**

# Repros Therapeutics Inc.

(Exact name of registrant as specified in its charter)

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

| **2408 Timberloch Place, Suite B-7**<br>**The Woodlands, Texas** | **77380** |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

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

(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 1, 2015 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 1, 2015

## 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.** |
| | (Registrant) |
| **December 1, 2015** | **/s/ KATHI ANDERSON** |
| (Date) | Kathi Anderson<br>*CFO* |

## Exhibit Index

| | |
|---|---|
| 99.1 | Press release dated December 1, 2015 |

EXHIBIT 99.1

# Repros Therapeutics Receives Complete Response Letter From FDA for Enclomiphene

THE WOODLANDS, Texas, Dec. 1, 2015 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc.® (Nasdaq:RPRX) today announced that it has received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for its New Drug Application for enclomiphene for the treatment of secondary hypogonadism in overweight men wishing to restore normal testicular function. A Complete Response Letter is a communication from the FDA that informs companies that an application cannot be approved in its present form.

In the letter, the FDA stated that, based on recent scientific developments, the design of enclomiphene Phase 3 studies is no longer adequate to demonstrate clinical benefit and recommended that Repros conduct an additional Phase 3 study or studies to support approval in the target population. The FDA also noted concerns regarding study entry criteria, titration and bioanalytical method validation in the Phase 3 program.

Repros plans to work with the FDA to determine an appropriate path forward to address these comments. "We are disappointed that the FDA has taken this position without the benefit of an advisory committee recommendation," said Joseph Podolski, President and CEO of Repros. "We plan to work closely with the Agency to gain more information to determine the appropriate next steps regarding the enclomiphene application."

**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 future clinical studies and the timing and nature of the results thereof, possible approval of the NDA by the FDA and the timeline for such approval and potential benefits and uses of the label for the product candidate and its commercial potential. 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 risks that additional clinical studies may not be successfully undertaken or completed, that the FDA may not ultimately approve the product candidate, the risk that any marketing approvals, if granted, may have significant limitations on use, that even if the NDA is approved, the Company may not be able to successfully commercialize the product candidate, 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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