

# SECURITIES AND EXCHANGE COMMISSION

## FORM 8-K

Current report filing

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### FILER

#### **REPROS THERAPEUTICS INC.**

CIK: **897075** | IRS No.: **760233274** | State of Incorpor.: **DE** | Fiscal Year End: **1231**  
Type: **8-K** | Act: **34** | File No.: **001-15281** | Film No.: **111185367**  
SIC: **2836** Biological products, (no diagnostic substances)

#### Mailing Address

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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) **November 7, 2011**

**Repros Therapeutics Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-15281**  
(Commission File Number)

**76-0233274**  
(IRS Employer Identification No.)

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

**77380**  
(Zip Code)

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

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(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 8.01. Other Events.**

On November 7, 2011 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 7, 2011

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**SIGNATURE**

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

**Repros Therapeutics Inc.**

(Registrant)

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**November 7, 2011**

(Date)

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**/s/ JOSEPH S. PODOLSKI**

## **Exhibit Index**

99.1 Press release dated November 7, 2011

## Oral Androxal(R) Achieves Equivalent 24 Hour Average Testosterone Levels Compared to Leading FDA Approved Testosterone Gel

### Androxal Demonstrated Persistent Effect, While Men on Topical Gel Exhibited Numerically Lower Morning Testosterone Compared to Baseline One Week After Administration is Stopped

THE WOODLANDS, Texas, Nov. 7, 2011 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc.® (Nasdaq:RPRX) today announced data from its recently completed ZA-204 study demonstrated that the 25 mg dose of Androxal showed statistically equivalent efficacy to the leading FDA-approved topical gel used per manufacturer's instructions. Additionally, after the six week dosing period was completed, men were followed for an additional seven days. All the men in the Androxal arms exhibited improved morning testosterone compared to baseline at the end of the seven day follow-up period. At the same time point, men in the topical gel arm exhibited morning testosterone levels numerically worse than the baseline values. Repros believes the numerical drops in the Androgel arm is indicative of the suppressive effects caused by exogenous testosterone on pituitary function. Androxal stimulates the pituitary which in turn stimulates the testes. This stimulatory effect seems to persist for a period of time post dosing, avoiding potential drops below baseline after discontinuation of drug which were seen with topical testosterone therapy.

#### Summary of Study ZA-204 Results:

Dose	Baseline T ng/dl (stdev)	Week 6 T ng/dl (stdev)	Follow-up T ng/dl (stdev)	ITT LOCF* ng/dl (stdev)	24 hr avg. T ng/dl (stdev)	24hr T < 300ng/dl @ Week 6	Any T > 1100 ng/dl @ Week 6
6.25 mg	247 (75.6)	392 (154.2)	341 (150.7)	n=15 402 (159.3)	n=12 392 (152.8)	4 out of 12	0 out of 12
12.5 mg	312 (110.5)	495 (170.4)	437 (188.2)	n=14 493 (163.9)	n=10 461 (129.20)	2 out of 10	0 out of 10
25 mg	248 (114.8)	577 (133.4)	612 (125.4)	n=16 541.4 (159.0)	n=13 587 (142.1)	0 out of 13	0 out of 13
Androgel	293 (117.5)	452 (243.0)	242 (89.3)	n=14 452 (243.1)	n=13 544 (230.1)	2 out of 13	3 out of 13

\*ITT LOCF – Intent to treat last observation carried forward

At follow-up, the Androxal 25 mg ( $p < 0.00001$ ) and 12.5 mg ( $p < 0.003$ ) arms showed statistically significant improvement over the Androgel arm, while the comparison to the 6.25 mg dose nearly missed significance ( $p=0.056$ ). In addition no patients in any of the Androxal arms (0/34) had levels of testosterone greater than 1100 ng/dl at week 6, while approximately 23% (3/13) patients using Androgel had testosterone concentrations above that level. As in previous studies topical testosterone significantly suppressed LH, in many cases to castration levels. Also, as seen in previous studies of Androxal, a single morning's testosterone level was highly correlated to both the maximum and average testosterone levels observed for a given subject. Thus, a single morning blood draw may be able to accurately predict both maximum testosterone, and average testosterone: correlations were much lower, and not statistically significant in the Androgel arm. Almost all dropouts in the study were a result of patient reluctance to undergo the intensive 24 hour blood draws required.

"We are very pleased with the strong and durable results seen in the ZA-204 trial," said Joseph Podolski, President and Chief Executive Officer. "We observed a clear dose response in the Androxal arms which individually and collectively yielded highly statistically significant correlations. We believe the product's differentiated mechanism and the ease of monitoring Androxal's effect with a single morning sample will be major advantages in clinical practice."

#### About Study ZA-204

The study was designed to test three doses of oral Androxal against Androgel used per manufacturer's instructions. Up to 60 men were to be enrolled in the trial. Men were to have a morning testosterone level not greater than 350 ng/dl to be included in the study. The men were dosed for 6 weeks. Once randomized to an Androxal dose the subjects remained on that dose for the remainder of the study. Men on the Androgel arm were allowed to up or down titrate their dose as per manufacturer's instructions. Subjects in all arms visited the clinic every 2 weeks. At the end of the 6<sup>th</sup> week all subjects still in the trial returned to the clinic to have a 24 hour assessment for average testosterone based on hourly blood draws. Luteinizing hormone (LH) was also assessed hourly.

The average age of men in the study was 53.1 (10.1) and their average BMI was 31.8 (6.1). The average age and BMI is consistent in all the studies that Repros has run to date except the study in diabetic men wherein the age and BMI was higher.

**About Repros Therapeutics Inc.**

Repros Therapeutics focuses on the development of oral small molecule drugs for major unmet medical needs that treat male and female reproductive disorders.

The Repros Therapeutics Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=7738>

*Any statements made by the Company that are not historical facts contained in this release are forward-looking statements that involve risks and uncertainties, including the ability to raise additional capital necessary for completion of clinical development of its product candidates, including Androxal, have success in the clinical development of its technologies, and such other risks which 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: Repros Therapeutics Inc.

Joseph Podolski (281) 719-3447

President and Chief Executive Officer