FORM 8-K

Current report filing

Filing Date: **2013-01-28** | Period of Report: **2013-01-28**
SEC Accession No. 0001144204-13-004220

FILER

REPROS THERAPEUTICS INC.

CIK:**897075**| IRS No.: **760233274** | State of Incorp.:**DE** | Fiscal Year End: **1231**
Type: **8-K** | Act: **34** | File No.: **001-15281** | Film No.: **13551249**
SIC: **2836** Biological products, (no disgnostic substances)

Mailing Address	Business Address
2408 TIMBERLOCH PLACE	*2408 TIMBERLOCH PL*
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THE WOODLANDS TX 77380	*WOODLANDS TX 77380*
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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): January 28, 2013

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))

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.

On January 28, 2013, Repros Therapeutics Inc., a Delaware corporation (the "Company") issued a press release to revise the date for the expected clinical results from the first pivotal study, ZA-301, of Androxal® in the treatment of secondary hypogonadism, from Q2 2013 to Q3 2013. Included in this press release is an announcement that the Company would hold a conference call on Monday, January 28, 2013 at 8:00 a.m., Eastern Time, with the Teleconference Replay to be made available until February 4, 2013. The Company is furnishing herewith as Exhibit 99.1. to this Current Report on Form 8-K, a copy of the slideshow that was referenced during the conference call. 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: January 28, 2013

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Repros Therapeutics Slideshow

ZA-301

Site 9 Evaluation
Blinded Assessment

Repros Disclaimer

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 needed capital on a timely basis in order for it to continue to fund development of its Androxal® and Proellex® programs, have success in the clinical development of its technologies, the reliability of interim results to predict final study outcomes, 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. 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.

ZA-301 Phase 3 Protocol Under an SPA

- **Phase 3 pivotal studies being conducted under SPA**
  - 2 identical trials (BMI > 25, Age ≤ 60)
    - 152 subjects in each trial (114 on Androxal, 38 on placebo)
      - Men with morning T<300 ng/dL assessed twice on two separate days
    - Up-titration from 12.5 to 25
    - 3 month duration
  - Co-Primary endpoints
    - 75% of men achieve T in normal range (300-1040 ng/dL)
    - Non inferior to placebo regarding change in sperm counts

Excerpt: FDA SPA Minutes

1) Proportion of subjects with average serum concentration (Cavg) for T in the normal range (i.e. serum T of 300 ng/dL – 1040 ng/dL).
2) Proportion of subjects with a 50% or greater decrease in sperm concentration from baseline to endpoint.
To demonstrate efficacy with regards to the first endpoint, at least 75% of subjects in the Androxal group should achieve a Cavg for T in the normal range with the lower bound of the 95% confidence interval not below 67%. At least 100 Androxal subjects would be required to demonstrate a point estimate of 75% or better.
For the second endpoint, Androxal should be non-inferior to placebo with respect to the difference in responder rates We have found a 20% non-inferiority margin to be acceptable in prior similar trials.
Values for serum T and sperm concentration at baseline and endpoint should be based on at least two assessments. Semen sampling at each time point (baseline and endpoint) should be separated by at least 48 hours.
Cmax is an important safety issue. The percentage of patients with Cmax above the following three pre-determined limits (listed below) should be a secondary endpoint:
- *Cmax>1500 ng/dL*
- *Cmax>1800 ng/dL and <2499 ng/dL*
- *Cmax>2500 ng/dL*

Outcome Sensitivity

If the response rate is greater than 75%, then the required sample size to have the lower limit exceed 67% decreases considerably. Here's a table with the minimum number of subjects that would be required to have the lower limit exceed 67% for each responder rate. The last column is what the lower limit of the 95% CI will be with N=113.

Responder Rate	N	Lower Limit of 95% CI	Lower Limit of 95% CI with N=113
75%	113	67.02%	67.02%
80%	37	67.11%	72.62%
85%	16	67.50%	78.42%
90%	7	67.78%	84.47%
95%	3	70.34%	90.98%

Consulting Statistician Comments

Assuming that 1% of the placebo group and 10% of the Androxal group experience a 50% or greater decrease in sperm concentration, and a 1:1 randomization ratio, 53 subjects per group (106 subjects total) would be required to show that Androxal is non-inferior to placebo in causing an abnormal sperm count at the 0.05 significance level and assuming a non-inferiority limit of 20%. If you use a 2:1 randomization ratio, 84 subjects in the Androxal group and 42 subjects in the placebo group (126 subjects total) would be required. If you went with 150 subjects total and a 1:2 randomization ratio (100 Androxal + 50 placebo), that would give you 87% power.

- Proportion of subjects with a 50% or greater decrease in sperm concentration from baseline to endpoint.

Using a 3:1 or 4:1 randomization ratio doesn't reduce the required placebo group sample size significantly but it does inflate how many subjects in the Androxal arm would be required (3:1 requires 114 Andoxal/38 placebo/152 total and 4:1 requires 144 Androxal/36 placebo/180 total).

ZA-301

- Mean Age
  - Site 9 (n=40): 45.9
  - Other 16 sites: 46.6
- Mean BMI
  - Site 9: 29.6
  - Other 16 Sites: 31.9

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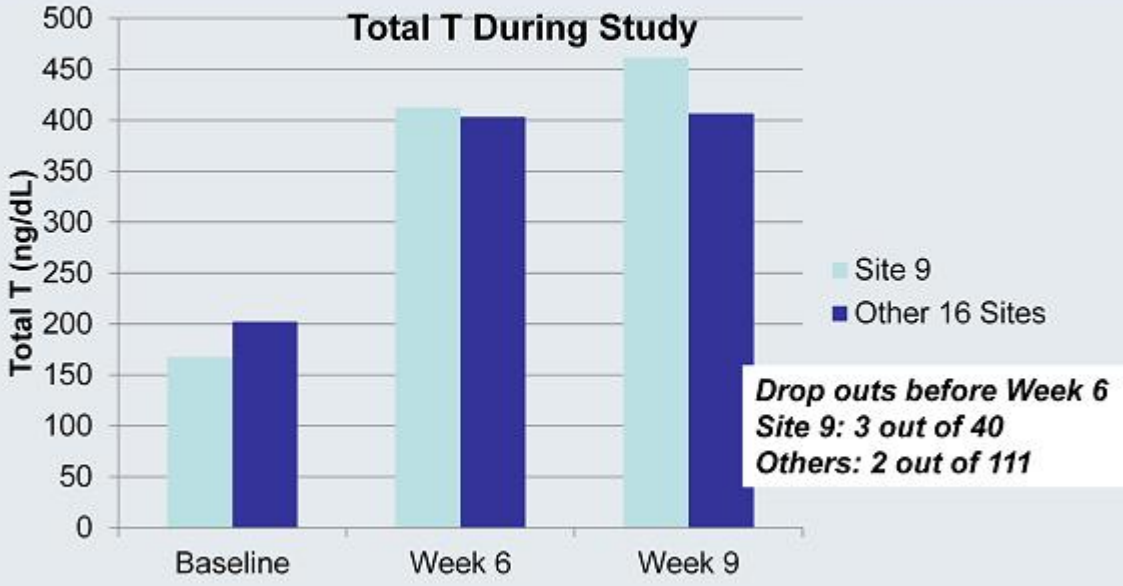
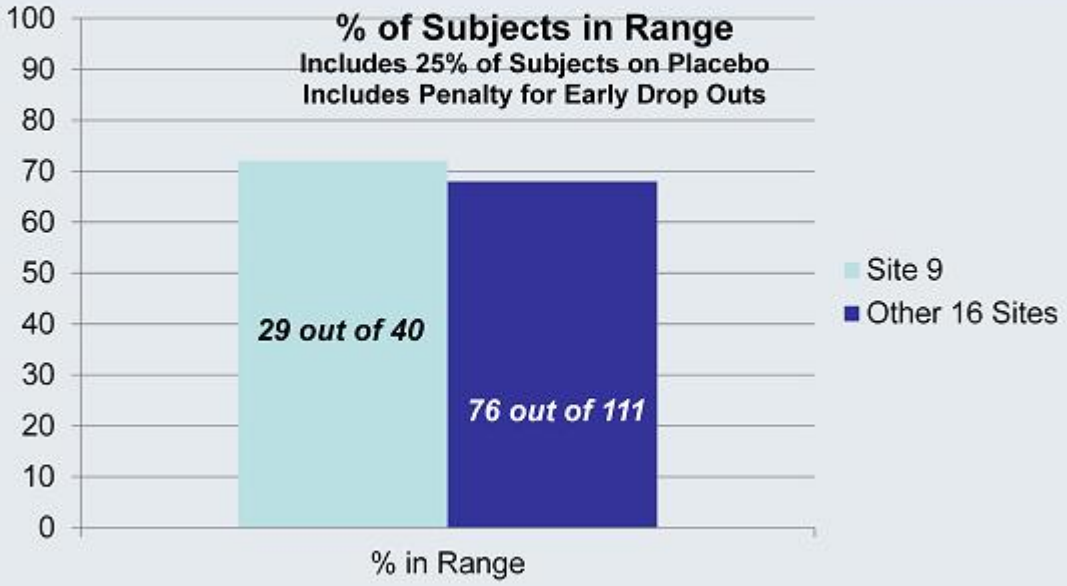
- Baseline Sperm Concentration
  - Site 9: 17.6×10^6 sperm/mL
  - Other 16 Sites: 80.7×10^6 sperm/ml
- Baseline T
  - Site 9: 167 ng/dL
  - Other 16 Sites: 202 ng/dL

ZA-301



ZA-301 Testosterone Endpoint



Blinded Mean Sperm Counts Subjects Completing Study