SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

Filing Date: 2013-01-28 | Period of Report: 2013-01-28 SEC Accession No. 0001171843-13-000281

(HTML Version on secdatabase.com)

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.: 13550103

SIC: 2836 Biological products, (no disgnostic substances)

Mailing Address 2408 TIMBERLOCH PLACE 2408 TIMBERLOCH PL B-7

Business Address SUITE B-7 THE WOODLANDS TX 77380 WOODLANDS TX 77380 2817193400

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) 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)	(Commission File Number)	(IRS Employer Identification No.)	
2408 Timberloch Place, Suite The Woodlands, Texas (Address of principal executive o		77380 (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 8.01. Other Events.	.,	· · · · · · · · · · · · · · · · · · ·	
On January 28, 2013 the Registrant issued a pre by reference. Item 9.01. Financial Statements and I Exhibit 99.1. Press release dated January	Exhibits.	eto as Exhibit 99.1 and is incorporated herein	
	SIGNATURE		
Pursuant to the requirements of the Securities behalf by the undersigned hereunto duly authorized.		duly caused this report to be signed on its	
		Repros Therapeutics Inc.	
		(Registrant)	

January 28, 2013	/s/ KATHI ANDERSON	
	Kathi Anderson	
(Date)	CFO	

Exhibit Index

99.1 Press release dated January 28, 2013

Repros Updates Guidance for Top Line Results From First Pivotal Androxal(R) Study to Q3 2013

- Timing for NDA submission still planned for mid-2014
- Conference call at 8 AM ET on Monday, January 28, 2013

THE WOODLANDS, Texas, Jan. 28, 2013 (GLOBE NEWSWIRE) -- Repros Therapeutics Inc. (Nasdaq:RPRX) today provided a revised date for expected clinical results from the first pivotal study, ZA-301, of Androxal in the treatment of secondary hypogonadism. The Company now plans to provide the data in Q3 2013 instead of Q2 2013.

During the ongoing review of the data it was determined that one site's patient population was markedly different from the other 16 sites from the standpoint of baseline sperm counts. The site in question had enrolled 40 subjects into the 151 subject trial. Though the subjects at the site meet the strict entry criteria for the trial, the clear difference from the other sites begs the question of whether or not this site represents the general population to be treated or is, in fact, a special population. To that end, the Company felt it would be prudent to remove the site from the efficacy studies and replace the subjects with those enrolled at other sites. Preliminary blinded analysis of reported subjects from the identified site indicates these subjects have responded as well or better than the other sites from the standpoints of improved testosterone and maintenance of sperm concentration. Fortunately, the Company is enrolling subjects into the identical pivotal trial ZA-302. The current plan, pending regulatory approval, is to move already enrolled subjects from sites in ZA-302 to ZA-301 to make up the shortfall. Since many of these subjects have recently been enrolled, it will extend the time before the data base

release in Q3 of this year. The Company is attempting to schedule a meeting with the FDA to advise the Agency of Repros' plan. Repros believes this outcome will not affect the timing of the NDA submission currently targeted for mid-2014.

from the first study can be locked and analyzed. The Company believes it can have the data available for top line

Conference Call Details:

Time: Monday, January 28, 2013 – 8AM Eastern Participant Dial In Number: 877-407-0782

International callers: 201-689-8567
Participant Title: Repros Therapeutics

Teleconference Replay will be available until February 4, 2013.

Replay Number: 877-660-6853, Conference ID#: 408375

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.

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 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.

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

Investor Relations: Thomas Hoffmann The Trout Group (646) 378-2931