REPROS THERAPEUTICS INC.
Form 10-Q
May 10, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2013

or

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-15281

REPROS THERAPEUTICS INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	2408 Timberloch Place, Suite B-7	76-0233274
(State or other jurisdiction of	The Woodlands, Texas 77380	(IRS Employer

incorporation or (Address of principal executive offices and zip code) Identification No.)

organization)

(281) 719-3400

(Registrant's telephone number,
including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or smaller reporting company. See definition of "accelerated filer", "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨ Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

As of May 3, 2013, there were outstanding 18,643,986 shares of Common Stock, par value $.001 per share, of the Registrant.

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REPROS THERAPEUTICS INC.

(A development stage company)

For the Quarter Ended March 31, 2012

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FACTORS AFFECTING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "may," "anticipate," "believe," "expect," "estimate," "project," "suggest," "intend" and similar expressions are intended to identify forward-looking statements. Such statements are subject to certain risks, uncertainties and assumptions. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, expected, estimated, projected, suggested or intended. These risks and uncertainties include risks associated with the Company's ability to continue as a going concern and to continue to be able to raise additional capital on acceptable terms or at all in order to have available funding for the continued development of Androxal® and Proellex®; the success of the clinical trials for Androxal® and Proellex®; uncertainty related to the Company's ability to obtain approval of the Company's products by the Food and Drug Administration, or FDA, and regulatory bodies in other jurisdictions; uncertainty relating to the Company's patent portfolio; and other risks and uncertainties described in the Company's filings with the Securities and Exchange Commission. For additional discussion of such risks, uncertainties and assumptions, see "Part I. Financial Information - Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources" included elsewhere in this quarterly report on Form 10-Q and “Item 1A. Risk Factors” to Part I of Form 10-K for the fiscal year ended December 31, 2012.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

The following unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (which include only normal recurring adjustments) considered necessary for a fair statement of the interim periods presented have been included. The year-end balance sheet data was derived from audited financial statements, but does not include all the disclosures required by accounting principles generally accepted in the United States of America. Operating results for the three month period ended March 31, 2013 are not necessarily indicative of the results that may be expected for the year ended December 31, 2013. For further information, refer to the financial statements and footnotes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2012.

REPROS THERAPEUTICS INC. AND SUBSIDIARY
(A development stage company)

CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited and in thousands except share and per share amounts)

	March 31, 2013	December 31, 2012
ASSETS		
Current Assets		
Cash and cash equivalents	$17,150	$24,212
Prepaid expenses and other current assets	355	406
Total current assets	17,505	24,618
Fixed assets, net	90	53
Other assets, net	2,320	2,161
Total assets	$19,915	$26,832
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$3,221	$3,240
Accrued expenses	405	558
Total current liabilities	3,626	3,798
Commitments & Contingencies (note 5)		
Stockholders' Equity		
Undesignated Preferred Stock, $.001 par value, 5,000,000 shares authorized, none issued and outstanding	-	-
Common Stock, $.001 par value, 75,000,000 shares authorized, 18,756,336 and 17,272,505 shares issued, respectively; 18,643,986 and 17,160,155 shares outstanding, respectively	19	17
Additional paid-in capital	234,926	234,299
Cost of treasury stock, 112,350 shares	(1,380)	(1,380)
Deficit accumulated during the development stage	(217,276)	(209,902)
Total stockholders' equity	16,289	23,034
Total liabilities and stockholders' equity	$19,915	$26,832

The accompanying notes are an integral part of these condensed consolidated financial statements.

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REPROS THERAPEUTICS INC. AND SUBSIDIARY
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited and in thousands except per share amounts)

	Three Months Ended March 31,		From Inception (August 20, 1987) through March 31,
	2013	2012	2013
Revenues and other income			
Licensing fees	$-	$-	$28,755
Product royalties	-	-	627
Research and development grants	-	-	1,219
Interest income	1	-	16,303
Gain on disposal of fixed assets	-	-	102
Other Income	-	-	1,003
Total revenues and other income	1	-	48,009
Expenses			
Research and development	6,308	1,466	201,567
General and administrative	1,067	973	53,987
Other Expense	-	-	388
Total expenses	7,375	2,439	255,942
Loss from continuing operations	(7,374)	(2,439)	(207,933)
Loss from discontinued operations	-	-	(1,828)
Gain on disposal of discontinued operation	-	-	939
Net loss before cumulative effect of change in accounting principle	(7,374)	(2,439)	(208,822)
Cumulative effect of change in accounting principle	-	-	(8,454)
Net loss	$(7,374)	$(2,439)	$(217,276)
Loss per share - basic and diluted	$(0.41)	$(0.17)	
Shares used in loss per share calculation:			
Basic	18,182	13,983	
Diluted	18,182	13,983	

The accompanying notes are an integral part of these condensed consolidated financial statements.

REPROS THERAPEUTICS INC. AND SUBSIDIARY
(A development stage company)

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited and in thousands except share and per share amounts)

	Common Stock		Additional Paid-in	Treasury Stock		Deficit Accumulated During the Development	Total Stockholders'
	Shares	Amount	Capital	Shares	Amount	Stage	Equity
Balance at December 31, 2012	17,272,505	$ 17	$ 234,299	112,350	$ (1,380)	$ (209,902)	$ 23,034
Stock based compensation	-	-	629	-	-	-	629
Issuance of 871,634 shares of common stock for the cashless exercise of 872,133 Series A Warrants	871,634	1	(1)	-	-	-	-
Issuance of 612,197 shares of common stock for the cashless exercise of 713,741 Series B Warrants	612,197	1	(1)	-	-	-	-
Net loss	-	-	-	-	-	(7,374)	(7,374)
Balance at March 31, 2013	18,756,336	$ 19	$ 234,926	112,350	$ (1,380)	$ (217,276)	$ 16,289

The accompanying notes are an integral part of these condensed consolidated financial statements.

REPROS THERAPEUTICS INC. AND SUBSIDIARY
(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited and in thousands)

	Three Months Ended March 31,		From Inception (August 20, 1987) through March 31,
	2013	2012	2013
Cash Flows from Operating Activities			
Net loss	$(7,374)	$(2,439)	$(217,276)
Gain on disposal of discontinued operations	-	-	(939)
Gain on disposal of fixed assets			(102)
Adjustments to reconcile net loss to net cash used in operating activities:			
Noncash financing costs	-	-	316
Noncash inventory impairment	-	-	4,417
Noncash patent impairment	-	-	2,614
Noncash other income			(709)
Noncash decrease in accounts payable	-	-	(1,308)
Depreciation and amortization	53	31	4,354
Noncash stock-based compensation	629	561	12,947
Common stock issued for agreement not to compete	-	-	200
Series B Preferred Stock issued for consulting services	-	-	18
Changes in operating assets and liabilities (net effects of purchase of businesses in 1988 and 1994):			
Increase in receivables	-	-	(199)
Increase in inventory	-	-	(4,447)
(Increase) decrease in prepaid expenses and other current assets	51	(200)	(52)
Increase (decrease) in accounts payable and accrued expenses	(121)	(489)	11,498
Net cash used in operating activities	(6,762)	(2,536)	(188,668)
Cash Flows from Investing Activities			
Change in trading marketable securities	-	-	(191)
Capital expenditures	(45)	(16)	(2,468)
Purchase of other assets	(255)	(215)	(5,789)
Proceeds from sale of fixed assets	-	-	225
Cash acquired in purchase of FTI	-	-	3
Proceeds from sale of subsidiary, less			

$12,345 for operating losses during 1990 phase-out period	-	-	138
Proceeds from sale of the assets of FTI	-	-	2,250
Increase in net assets held for disposal	-	-	(213)
Net cash used in investing activities	(300)	(231)	(6,045)
Cash Flows from Financing Activities			
Proceeds from issuance of common stock and warrants, net of offering costs	-	10,310	207,431
Exercise of stock options & warrants	-	-	797
Proceeds from a shareholder transaction	-	-	327
Proceeds from issuance of preferred stock	-	-	23,688
Purchase of treasury stock	-	-	(21,487)
Proceeds from issuance of notes payable	-	-	2,839
Principal payments on notes payable	-	-	(1,732)
Net cash provided by financing activities	-	10,310	211,863
Net increase (decrease) in cash and cash equivalents	(7,062)	7,543	17,150
Cash and cash equivalents at beginning of period	24,212	4,565	-
Cash and cash equivalents at end of period	$17,150	$12,108	$17,150

The accompanying notes are an integral part of these condensed consolidated financial statements.

REPROS THERAPEUTICS INC. AND SUBSIDIARY

(A development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

March 31, 2013

(Unaudited)

NOTE 1 — Organization, Operations and Liquidity

Repros Therapeutics Inc. (the “Company”, “RPRX,” “Repros,” or “we,” “us” or “our”) was organized on August 20, 1987. We a development stage biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders.

Our primary product candidate, Androxal®, is a single isomer of clomiphene citrate and is an orally active proprietary small molecule compound. We are developing Androxal® for men of reproductive age with low testosterone levels. Androxal® treats the underlying mechanism that causes secondary hypogonadism and restores normal testicular function. We are currently conducting Phase 3 studies for Androxal®, with the pivotal studies being conducted under a Special Protocol Assessment (“SPA”). On March 27, 2013, we announced that the top-line results from our first pivotal Phase 3 study met both co-primary endpoints mandated by the FDA.

Proellex®, our product candidate for female reproductive health, is a new chemical entity that acts as a selective blocker of the progesterone receptor and is being developed for the treatment of symptoms associated with uterine fibroids and endometriosis. We completed a low dose study in late 2011 to demonstrate both safety and signals of efficacy in low oral doses of Proellex® and in November 2012 we initiated a Phase 2 study in the treatment of endometriosis. Additionally, the FDA has accepted an Investigational New Drug Application for vaginally delivered Proellex® and, as a result, we have completed a Phase 1/2 vaginal administration study for uterine fibroids in the first quarter of 2013. In late May 2013, we will meet with the FDA to discuss the Phase 3 development of vaginally delivered Proellex®.

Our product development pipeline is summarized in the table below:

Product Candidate (Indication)	**Status**	**Next Expected Milestone(s)**
Androxal®		
Secondary Hypogonadism	Phase 3	Complete second Phase 3 pivotal study (Q4 2013) Complete open label safety study (Q4 2013) Complete DEXA study (Q1 2014)
Proellex®		
Uterine Fibroids	Phase 2	Initiate a Phase 3 study (vaginal delivery) (Q3 2013)
Endometriosis	Phase 2	Complete Phase 2 study (oral delivery) (Q1 2014)

We also continue to maintain our patent portfolio of our phentolamine-based products for the treatment of sexual dysfunction and in order to create value from these assets in various ways which includes product out-licensing.

As of March 31, 2012, we had accumulated losses of $217.3 million, approximately $17.2 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $3.6 million. We believe that our current liquidity will be sufficient to continue our planned clinical trials into the first quarter of 2014; however, significant additional capital will be required for us to complete development of either of our product candidates through New Drug Application ("NDA") approval. We continue to explore potential additional financing alternatives (including corporate partnering opportunities) that would provide sufficient funds to enable us to continue to develop our two product candidates through NDA approval; however, there can be no assurance that we will be successful in raising any such additional funds on a timely basis or at all. The foregoing matters raise substantial doubt about our ability to continue as a going concern.

NOTE 2 — Patents and Patent Applications

As of March 31, 2013, the Company had approximately $2,320,000 in capitalized patent and patent application costs reflected on its balance sheet. Of this amount, $1,679,000 relates to patent and patent application costs for Androxal® and $641,000 relates to patent and patent application costs for Proellex®.

Should the Company not continue development of either drug candidate or should the Company not continue as a going concern, the remaining capitalized patent and patent application costs may not be recoverable, which would result in charges to operating results in future periods.

NOTE 3 — Accrued Expenses

Accrued expenses consist of the following (in thousands):

	March 31, 2013	December 31, 2012
Patent costs	$ 171	$ 245
Research and development costs	152	192
Personnel related costs	39	30
Other	43	91
Total	$ 405	$ 558

NOTE 4 — Loss Per Share

Basic loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share is computed using the average share price for the period and applying the treasury stock method to potentially dilutive outstanding options. In all applicable periods, all potential common stock equivalents were anti-dilutive and, accordingly, were not included in the computation of diluted loss per share.

The following table presents information necessary to calculate loss per share for the three month periods ended March 31, 2013 and 2012 (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2013	2012
Net Loss	$(7,374)	$(2,439)
Average common shares outstanding	18,182	13,983
Basic and diluted loss per share	$(0.41)	$(0.17)

Potential common stock of 3,968,500 and 5,376,023 common shares underlying stock options and warrants for the periods ended March 31, 2013 and 2012, respectively, were excluded from the above calculation of diluted loss per share because they were anti-dilutive. Other potential common stock at March 31, 2013 includes Series A Warrants to purchase 877,137 shares of our common stock at an exercise price of $0.01 and Series B Warrants to purchase 855,680 shares of our common stock at an exercise price of $2.49 issued in our February 8, 2011 public offering. Other potential common stock at March 31, 2012 includes Series A Warrants to purchase 1,749,270 shares of our common stock at an exercise price of $0.01 and Series B Warrants to purchase 1,690,500 shares of our common stock at an exercise price of $2.49 issued in our February 8, 2011 public offering.

NOTE 5 — Commitments and Contingencies

Therapeutic uses of our Androxal® product candidate are covered in the United States by seven issued U.S. patents and five pending patent applications. Foreign coverage of therapeutic uses of our Androxal® product candidate includes 59 issued foreign patents and 53 foreign pending patent applications. The issued patents and pending applications relate to methods for treating certain conditions including the treatment of testosterone deficiency in men, the treatment of diabetes mellitus Type 2, the treatment of metabolic syndrome and conditions associated therewith, and the treatment of infertility in hypogonadal men. Androxal® (the trans-isomer of clomiphene) is purified from clomiphene citrate. A third party individual holds two issued patents related to the use of an anti-estrogen such as clomiphene citrate and others for use in the treatment of androgen deficiency and disorders related thereto. We requested re-examination of one of these patents by the U.S. Patent and Trademark Office ("PTO") based on prior art. The patent holder amended the claims in the re-examination proceedings, which led the PTO to determine that the amended claims were patentable in view of those publications under consideration and a re-examination certificate was issued. We subsequently filed a second request for re-examination by the PTO in light of a number of additional publications. The request was granted and all of the claims were finally rejected by the PTO in the re-examination. The patent holder appealed the rejections to the PTO Board of Patent Appeals and Interferences (the "PTO Board") which ultimately reversed the rejections of several dependent claims in view of those publications under consideration. The patent holder filed a Notice of Appeal to the Federal Circuit on September 28, 2010 contesting the rejections maintained by the PTO Board. A decision was rendered by the Federal Circuit on December 12, 2011, affirming the rejection of the appealed claims. The PTO issued an Ex Parte Reexamination Certificate on April 29, 2013, cancelling the rejected claims and confirming patentability of the remaining claims. Nevertheless, we believe that our development of Androxal® does not infringe any of the remaining claims and that all of the remaining claims are invalid on various grounds including additional prior art publications. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. If necessary, we intend to vigorously defend any and all claims against the holder of such patents in a court of competent jurisdiction in order to develop Androxal® further. Adverse determinations in litigation proceedings could require us to seek licenses which may not be available on commercially reasonable terms, or at all, or subject us to significant liabilities, in which case we may not be able to successfully commercialize or out-license Androxal® until such patents expire or are otherwise no longer in force.

On March 1, 2010, we were served with a lawsuit where we were named as a co-defendant along with one of our clinical regulatory service providers ("CRO") relating to the Proellex® clinical trial study. The lawsuit was filed in the

State of Tennessee, 30th Judicial District Chancery Court at Memphis by an investigator and claims that the CRO did not pay it amounts owing to it relating to the Proellex® study. We did not engage the investigator and under our agreement with the CRO, we believe the CRO is responsible for any such costs or damages regarding such lawsuit. Pursuant to a Settlement Agreement and Mutual Release entered into in October 2009, such CRO, on behalf of itself and its agents, released us from all claims which could be asserted by them against us. We believe such release covers the claims set forth in this lawsuit. The CRO failed to respond to the lawsuit, and a default judgment was entered against it in the amount of $172,901.29. We intend to vigorously defend any and all claims asserted by the investigator. An estimate of the possible costs or expenses to defend ourselves in this matter or risk of exposure under the litigation cannot be made at this time.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") that involve risk and uncertainties. Any statements contained in this quarterly report that are not statements of historical fact may be forward-looking statements. When we use the words "may," "anticipates," "believes," "plans," "expects" and similar expressions, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. The following discussion of financial condition should be read in conjunction with the accompanying consolidated financial statements and related notes.

Repros Therapeutics Inc.

Repros Therapeutics Inc. (the “Company,” “Repros,” or “we,” “us” or “our”) was organized on August 20, 1987. We are a development stage biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders. Both of our product candidates have exhibited strong efficacy results in every study completed to date, and we believe the studies presently underway or scheduled to start in 2013 will place both programs on a clear late stage clinical development path.

We are developing Androxal®, an oral therapy that normalizes testicular function, for the treatment of low testosterone due to secondary hypogonadism. Secondary hypogonadism is associated with obesity and we believe it is among the most common causes of low testosterone in men. It is estimated that 13 million men in the U.S. experience low levels of testosterone, and the condition is becoming recognized with more frequency. In 2012, sales of preparations for the treatment of low testosterone exceeded $1 billion in the U.S. and first tier pharmaceutical companies have entered the low testosterone marketplace.

The Company believes Androxal® is highly differentiated from currently marketed testosterone treatments or those treatments in late stage development because it is an oral therapy and it treats the cause of secondary hypogonadism, which is inadequate pituitary hormones. We believe that by treating the cause of secondary hypogonadism Androxal® also has the potential to maintain reproductive status and potentially improve overall metabolic profiles.

In December 2011, we completed a Phase 2B study of Androxal® in men with secondary hypogonadism, but naïve to testosterone treatment, at the Food and Drug Administration’s (the “FDA”) recommendation. Top line results of this study demonstrated that Androxal® was generally well tolerated compared to placebo and that there were no drug related serious adverse events that led to discontinuation. We met with the FDA in May 2012 to discuss the design of pivotal Phase 3 efficacy studies for Androxal® as well as the components of the overall drug development program required for a New Drug Application (“NDA”) submission. During this meeting, we agreed upon registration

requirements for Androxal® oral therapy for the treatment of secondary hypogonadism. In July 2012, we announced that we reached an agreement with the FDA for the design of the pivotal efficacy studies for Androxal® for the treatment of secondary hypogonadism. The pivotal studies are being conducted under a Special Protocol Assessment ("SPA"). On March 27, 2013, we announced that the top-line results from our first pivotal Phase 3 study, ZA-301, met both co-primary endpoints mandated by the FDA. Additionally, we have completed enrollment into a 500 subject open label safety study in February 2013 and completed enrollment into a one year dual-energy X ray absorptiometry ("DEXA") study in January 2013. Depending on study enrollment and the completion of other studies, we believe we may be able to submit an NDA by mid 2014.

We are also developing Proellex®, an orally administered selective blocker of the progesterone receptor in women, for the treatment of uterine fibroids and endometriosis. Uterine fibroids and endometriosis affect millions of women of reproductive age. Proellex® has shown statistically significant results in previous Phase 2 studies for endometriosis and uterine fibroids. We completed a low dose escalating study as permitted by the FDA in late 2011, to determine both signals of efficacy and safety for low oral doses of the drug. There was no evidence of elevations of liver enzymes over baseline, suggesting these lower doses avoid the type of adverse events seen at much higher doses in earlier studies. In October 2012, we announced that the FDA has agreed to a reclassification of the full clinical hold to a partial clinical hold on low dose oral Proellex® to allow us to conduct a Phase 2 study in the treatment of endometriosis. We initiated this 90 subject, four month active dosing study in November 2012.

The FDA has accepted an Investigational New Drug Application ("IND") for vaginally delivered Proellex® and, as a result, we commenced a Phase 2 vaginal administration study for uterine fibroids in the first quarter of 2012 and reported final study results in January 2013. We then requested, and were granted, an end of Phase 2 meeting with the FDA, scheduled for the last half of May 2013, to discuss a Phase 3 study design for the vaginally delivered Proellex® as a treatment for uterine fibroids. Additionally, we have begun enrolling subjects who completed the Phase 2 study into a one year open label safety trial in order to begin collecting long term safety data which we expect the FDA to require in connection with the submission of an NDA.

Our Research and Development Program

Our product development pipeline is summarized in the table below:

Product Candidate (Indication)	**Status**	**Next Expected Milestone(s)**
Androxal®		
		Complete second Phase 3 pivotal study (Q4 2013)
Secondary Hypogonadism	Phase 3	Complete open label safety study (Q4 2013)
		Complete DEXA study (Q1 2014)
Proellex®		
		Initiate a Phase 3 study (vaginal delivery) (Q3 2013)
Uterine Fibroids	Phase 2	
Endometriosis		Complete Phase 2 study (oral delivery) (Q1 2014)
	Phase 2	

As of March 31, 2013, we had accumulated losses of $217.3 million, approximately $17.2 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $3.6 million. We believe that our current liquidity will be sufficient to continue our planned clinical trials into the first quarter of 2014; however, significant additional capital will be required for us to complete development of either of our product candidates through New Drug Application ("NDA") approval. We continue to explore potential additional financing alternatives (including corporate partnering opportunities) that would provide sufficient funds to enable us to continue to develop our two product candidates through NDA approval; however, there can be no assurance that we will be successful in raising any such additional funds on a timely basis or at all. The foregoing matters raise substantial doubt about our ability to continue as a going concern.

Androxal®

Product Overview

Our primary product candidate, Androxal®, is a single isomer of clomiphene citrate and is an orally active proprietary small molecule compound. We are developing Androxal® for men of reproductive age with low testosterone levels. Androxal® treats the underlying mechanism that causes secondary hypogonadism and restores normal testicular function. Unlike testosterone replacement which suppresses testicular function, Androxal® does not impair the reproductive status of men being treated for low testosterone.

Testosterone is an important male hormone. Testosterone deficiency in men is linked to several negative physical and mental conditions, including loss of muscle tone, reduced sexual desire and deterioration of memory and certain other cognitive functions. Testosterone production normally decreases as men age and this decline can be accelerated by obesity, sometimes leading to testosterone deficiency. The leading therapy for low testosterone is AndroGel®, a commercially available testosterone replacement cream marketed by Abbott Laboratories for the treatment of low testosterone, which we believe has had and continues to have significant sales in North America.

Based on our own clinical trial screening data, we believe over 70% of men that have low testosterone suffer from secondary hypogonadism, a pituitary defect which is characterized by suboptimal levels of LH (luteinizing hormone) and FSH (follicle stimulating hormone). LH and FSH are the pituitary hormones that stimulate testicular testosterone and sperm production, respectively. Men with secondary hypogonadism can be readily distinguished from those that have primary testicular failure via assessment of the levels of secretions of pituitary hormones, as men with primary testicular failure experience elevated secretions of pituitary hormones. In secondary hypogonadism, the low levels of LH and FSH fail to provide adequate hormone signaling to the testes, causing testosterone levels to drop to a level where we believe pituitary secretions fall under the influence of estrogen, which is enhanced in obese men, thus further suppressing the testicular stimulation from the pituitary.

Androxal® acts centrally to restore testicular function and, hence, normal testosterone in the body. The administration of exogenous testosterone can restore serum testosterone levels, but does not restore testicular function and thereby generally leads to the cessation of, or significant reduction in, sperm production. Androxal®, by contrast, restores levels of both LH and FSH, which stimulate testicular testosterone and sperm production, respectively.

We tested Androxal® in two studies designed to show that Androxal® improved testosterone levels as well as AndroGel® in men with secondary hypogonadism. These studies indicated that Androxal® had a superior ability to improve testosterone levels when compared to AndroGel® and that the improvement was statistically significant. In the meeting held in November 2010, the FDA determined that improved testosterone levels would be sufficient provided that both placebo and Androxal® maintained sperm counts in a statistically significant manner as compared to an approved topical testosterone.

Androxal® is required to undergo the full regulatory approval process, including pivotal Phase 3 trials, long-term open label safety studies and a dual-energy X ray absorptiometry (DEXA) study, as well as other requirements. Androxal® is closely related chemically to the drug, Clomid®, which is approved for use in women to treat certain infertility disorders. Clomid® contains both the trans and cis isomers of clomiphene citrate; Androxal® contains only the trans isomer. The FDA has indicated that testicular tumors, gynecomastia and adverse ophthalmologic events, which have been reported in males taking Clomid®, are potential risks that should be included in informed consent forms for our Androxal® clinical trials. We do not believe that Androxal® will present with the same adverse events given its reduced half-life and lack of cis isomer as compared to Clomid®. In our preclinical studies and our clinical trials to date, we have observed no evidence of any of these events except for certain ophthalmologic events in our preclinical dog study at doses significantly higher than those administered in the clinical trials. All clinical trial results

are subject to review by the FDA and the FDA may disagree with our conclusions about safety and efficacy.

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Treatment for Secondary Hypogonadism in Men Wishing to Preserve Testicular Function (Reproductive Status)

In November 2010, we held a Type B meeting with the FDA to discuss whether the FDA would review our protocols for a Phase 3 trial of Androxal® in men with secondary hypogonadism under an SPA. In the meeting, the FDA recommended that a Phase 2B study in men with secondary hypogonadism but naïve to testosterone treatment be conducted if we desired the protocols to be reviewed under an SPA. The FDA further opined that such Phase 2B study would provide for a more solid data base for design of Phase 3 studies and eventual approval of such studies under an SPA.

We have completed the Phase 2B trial which consisted of four arms; placebo, two doses of Androxal® and topical testosterone. In this study, at baseline the men exhibited morning testosterone less than 250 ng/dl and there was no statistical difference between the groups in testosterone at baseline. At the end of the three month dosing period, median morning testosterone levels were placebo (196 ng/dl), 12.5 mg Androxal® (432 ng/dl), 25 mg Androxal® (416 ng/dl) and Testim® (393 ng/dl). A comparison of final median morning testosterone in all three of the active arms to placebo showed them to be highly statistically different and there was no statistical difference observed between these active arms. This trial also showed that Androxal® was able to maintain sperm counts in men being treated for their low testosterone levels, whereas Testim® resulted in suppressed sperm levels.

In July 2012, we announced that we reached an agreement with the FDA for the design of the pivotal efficacy studies for Androxal® for the treatment of secondary hypogonadism. The pivotal studies are being conducted under an SPA. The primary testosterone endpoint in the pivotal studies require that 75% of the subjects in the drug arm exhibit a 24 hour average total testosterone in the normal range (300 – 1040 ng/dL) at the end of 12 weeks of treatment. After six weeks of dosing, men are allowed to up-titrate from the 12.5 mg dose to the 25 mg dose if their morning testosterone is below 300 ng/dL. The co-primary sperm count endpoint prescribed by the FDA is that the drug is to exhibit non-inferiority to placebo with respect to the percent of subjects whose sperm count drops greater than 50% from baseline. The first pivotal study was fully enrolled in November 2012 and we completed enrollment into our second pivotal study on May 2, 2013. On March 27, 2013, we reported top-line results from our first pivotal study, ZA-301. Results for the Intent-to-Treat population in this study met both co-primary endpoints mandated by the FDA. 79% of the Androxal® subjects exhibited 24 hour average testosterone levels in the normal range (300 – 1040 ng/dL), with no subjects elevated beyond the normal range. Additionally, Androxal®'s impact on sperm concentration met the non-inferiority threshold as compared to placebo.

The 500 subject, six month open label safety study completed enrollment in February 2013 at 28 U.S. clinical sites. Additionally, we have completed enrollment into a one year, 150 subject DEXA study in January 2013 at 10 U.S. clinical sites. This study is on the critical path to submission of the NDA. Depending on study enrollment and the completion of other studies, we believe we may be able to submit an NDA by mid 2014.

In addition, the Company continues to consider the potential for use of Androxal® as an adjuvant therapy in hypogonadal men with Type 2 diabetes. The Company has an active IND open with the Division of Endocrine and Metabolic Products at the FDA for this indication. We believe there may be an association between the restoration of normal pituitary function and improvement of metabolic conditions such as Type 2 diabetes. Research has been published which demonstrates that increased insulin resistance, a characteristic implicated in Type 2 diabetes, is associated with the onset of secondary hypogonadism. Based on our own clinical trial screening data from our previously conducted Phase 2 study, we have found hypogonadism, obesity and Type 2 diabetes to be co-morbid conditions in a significant number of men. The results from this Phase 2 study indicated that the Androxal® treated subjects showed statistically significant improvement in HbA1c and insulin, as well as HOMA-IR compared to placebo in men less than 65 years of age.

Unlike testosterone replacement therapies, Androxal® maintains the normal daily rhythm of testosterone peaks and valleys. We previously conducted three studies in which 24 hour testosterone levels were obtained and, unlike topical testosterone, morning testosterone was the maximum concentration observed, consistent with the normal circadian rhythm in men. These studies provide evidence that one assessment of testosterone between 8 a.m. and 10 a.m. correlates to the maximum value of testosterone for a given subject on a given day. Additionally, we conducted one additional 24 hour study which showed that Androxal®’s action in maintaining the normal rhythm is both predictable and dose-dependent.

We believe the advantages of oral delivery, maintenance of testicular function and additional metabolic benefits will be important differentiating factors for Androxal®, should it be approved. There can be no assurance, however, that we will be successful in implementing this strategy or that the FDA will approve our drug for commercial use.

Proellex®

Product Overview

Proellex®, our product candidate for female reproductive health, is a new chemical entity that acts as a selective blocker of the progesterone receptor and is being developed for the treatment of symptoms associated with uterine fibroids and endometriosis. There are currently no FDA-approved orally administered drug treatments for the long-term treatment of either uterine fibroids or endometriosis. The National Uterine Fibroids Foundation estimates that 80% of all women in the U.S. have uterine fibroids, and one in four of these women have symptoms severe enough to require treatment. According to the Endometriosis Association, endometriosis affects 6.3 million women in the U.S. and Canada and millions more worldwide.

The current standards of care for uterine fibroids and endometriosis consist of surgery or short-term treatment with gonadotropin-releasing hormone ("GnRH") agonists drugs, such as Lupron®. GnRH agonists induce a low estrogen, menopausal-like state and promote bone loss and are not recommended for use for more than six months.

We have conducted numerous studies with Proellex® dosing approximately 700 women with the drug. All Proellex® studies completed to date exhibited strong efficacy signals, whether in uterine fibroids or endometriosis. In a 120 patient study of Proellex® as a treatment of uterine fibroids conducted in the United States (roughly 40 subjects per arm), both a 12.5 and 25 mg dose of Proellex® were compared to placebo. In this study each of the 12.5 and 25 mg doses achieved highly statistically significant results when compared to placebo when menstrual bleeding was assessed ($p<0.0001$). The two doses also achieved highly statistically significant improvement in quality of life measures using the Uterine Fibroid Symptom Quality of Life questionnaire developed and validated by Georgetown University and used in the development of device like treatments of uterine fibroids such as uterine artery embolization. There was no statistical difference in efficacy measures between the two doses. Importantly, in the Phase 2 U.S. trial a significant percentage of women stopped menstruating. Proellex® resulted in the induction of amenorrhea (cessation of menses), which we believe is a strong surrogate signal of efficacy. Over 80% of women on both the 12.5 and 25 mg doses exhibited no menses during the three month trial, whereas all women on placebo exhibited at least one menses.

Up until the summer of 2009, all side effects exhibited in the studies were considered manageable and the benefit of Proellex® far outweighed the risk. However, in Phase 3 efficacy and larger Phase 3 safety studies in diverse populations, a small number of subjects exhibited serious adverse effects associated with elevated liver enzymes. As a

result of these findings, we elected to stop the trials and the FDA subsequently placed Proellex® on full clinical hold. All women that experienced elevated liver enzymes and returned for follow-up visits returned to baseline conditions with no overnight hospitalization necessary. An analysis of all the subjects that experienced such serious adverse effects showed that the effect only occurred in a small percentage of subjects that were exposed to the 50 mg dose of the drug for any period of time. Based on these findings, we petitioned the FDA to allow us to conduct a low dose study to demonstrate both safety and signals of efficacy in low oral doses of Proellex®, up to 12 mg administered per day. The FDA upgraded the full clinical hold to a partial hold to allow the low dose study to be conducted. In addition, we undertook two related initiatives: (i) the exploration of vaginal delivery as an alternative administrative route to bypass first-pass liver effects and reduce systemic exposure, which is currently in a Phase 2 study; and (ii) the screening of second generation molecules that do not possess the specific structures that may have induced the liver toxicity exhibited at higher doses of Proellex®.

Low Dose Oral Study

Pursuant to the terms of the partial clinical hold currently in place as a result of the liver toxicity exhibited by Proellex®, the FDA allowed us to run a single study to test low oral doses of Proellex® for signals of safety and efficacy. The study tested 5 different doses of Proellex® (1, 3, 6, 9 and 12 mg), with 1 mg being the first dose tested. Each dose was then compared to placebo with weekly assessments of liver function during both the placebo and drug period. Subjects were dosed with the active drug for 10 weeks, which allowed for adequate time to determine the impact of a given dose on trends in liver function. Each dose was tested in up to 12 different subjects and assessment of pharmacokinetic parameters was obtained at the start of dosing and the end of the dosing period to determine overall and maximum drug exposure for a given dose. We also monitored changes in menstrual bleeding patterns and ovulation as well as changes in endometrial thickness. The FDA required that an independent Drug Safety Monitoring Board be established and that the informed consent clearly state the liver toxicity previously experienced with Proellex®. We have completed this study and have announced that there was no evidence of elevations of liver enzymes over baseline, suggesting these lower doses avoid the type of adverse events seen at much higher doses in earlier studies.

In July 2012, we announced that we held a teleconference with the FDA to discuss the development of low dose oral Proellex® as a treatment for endometriosis. Subsequently, in October 2012, we announced that the FDA has agreed to reclassify the full clinical hold to a partial clinical hold on low dose oral Proellex® to allow us to conduct a Phase 2 study in the treatment of endometriosis. We initiated this 90 subject, four month active dosing study in November 2012. To date, we have experienced difficulty enrolling subjects into this study. Depending on study enrollment, we believe we can release results from this study in the first quarter of 2014.

Vaginal Administration

We are assessing vaginal administration of Proellex® to avoid first pass liver effects and achieve higher reproductive tract concentrations of the drug while minimizing systemic exposure. We reported results from two in vivo animal studies which confirmed reduced maximum circulating concentrations of the drug when administered vaginally, as well as efficacy signals at substantially lower doses than oral administration. The FDA has accepted an IND for vaginally delivered Proellex® and, as a result, we commenced a Phase 2 vaginal administration study for uterine fibroids in the first quarter of 2012. In January 2013, we reported the final study results which indicated the 12 mg dose achieved statistically significant improvement in menstrual bleeding, uterine fibroid symptoms and reduction in fibroid volume even with the low number of subjects enrolled into the study (n=12 @ 12 mg). Based on these findings, the Company believes the 12 mg dose is appropriate for further development. We have requested, and were granted, an end of Phase 2 meeting with the FDA, scheduled for the last half of May 2013, to discuss a Phase 3 study design for the vaginally delivered Proellex® as a treatment for uterine fibroids.

Additionally, we have begun enrolling subjects who completed the Phase 2 study into a one year open label safety trial in order to begin collecting long term safety data which we expect the FDA to require in connection with the submission of an NDA. The majority of the women being dosed with 12 mg in the Phase 2 study have elected to enroll into the open label safety study.

Other Products

We continue limited out-licensing efforts for our phentolamine-based product candidates, including VASOMAX®, which had previously been approved for marketing in several countries in Latin America for the treatment of male erectile dysfunction under the brand name Z-Max. VASOMAX® has been on partial clinical hold in the U.S. since 1998, and no further development activities are planned.

Business Strategy

We plan to focus our clinical program on (i) conducting Phase 3 secondary hypogonadism trials for Androxal®, (ii) conducting a Phase 3 vaginal administration trial for Proellex® for uterine fibroids and (iii) conducting a Phase 2 trial for low dose oral Proellex® for endometriosis. We anticipate that our current liquidity will be sufficient to continue these planned studies into the first quarter of 2014; however, significant additional capital will be required for us to complete the development of our product candidates through NDA approval. We will continue to explore corporate partnering opportunities for assistance in the clinical development funding and commercialization of our products, as appropriate; however, there can be no assurance that an acceptable corporate partnering opportunity will be successfully completed or that we will be successful in raising the additional funds.

Risks Affecting Us

Our business is subject to numerous risks as discussed more fully in “Item 1A. Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2012 and the section entitled “Risk Factors” in this quarterly report. We are investigating a variety of sources for raising capital. No assurance can be given that we will be successful in obtaining financing on acceptable terms or at all. We anticipate that if we are able to secure financing, that such financing will result in significant dilution of the ownership interests of our current stockholders and may provide certain rights to the new investors senior to the rights of our current stockholders, including but not limited to voting rights and rights to proceeds in the event of a sale or liquidation of the Company. In the event that we are unable to obtain adequate financing to meet our future needs, we will pursue other options, including but not limited to, reductions of expenses, sale of the Company, sale or license of a portion or all of our assets or the liquidation of the Company.

In addition, we have not received regulatory approval for any of our product candidates, have not successfully earned any significant commercial revenues from any of our product candidates and may never launch either of our product candidates. If we do not successfully commercialize any of our product candidates, we will be unable to achieve our business objectives. In addition, the reported results of our clinical trials completed to date may not be indicative of results that will be achieved in later-stage clinical trials involving larger and more diverse patient populations. As of March 31, 2013, we had accumulated losses of $217.3 million, approximately $17.2 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $3.6 million. We believe that our current liquidity will be sufficient to continue our planned clinical trials into the first quarter of 2014; however, significant additional capital will be required for us to complete development of either of our product candidates through New Drug Application (“NDA”) approval. We continue to explore potential additional financing alternatives (including corporate partnering opportunities) that would provide sufficient funds to enable us to continue to develop our two product candidates through NDA approval; however, there can be no assurance that we will be successful in raising any such additional funds on a timely basis or at all. The foregoing matters raise substantial doubt about our ability to continue as a going concern and we expect to continue to incur significant losses over the next several years, and we may never become profitable. Our financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Corporate Information

We were organized as a Delaware corporation in August 1987. Our principal executive offices are located at 2408 Timberloch Place, Suite B-7, The Woodlands, Texas, 77380, and our telephone number is (281) 719-3400. We maintain an internet website at www.reprosrx.com. The information on our website or any other website is not incorporated by reference into this quarterly report and does not constitute a part of this quarterly report. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and all amendments to such reports are made available free of charge through the Investor Relations section of our website as soon as

reasonably practicable after they have been filed or furnished with the Securities and Exchange Commission.

General

We have experienced negative cash flows from operations since inception and have funded our activities to date primarily from equity financings and corporate collaborations. Based on our current and planned clinical trials, we will need to raise additional capital no later than the first quarter of 2014 in order to continue our development activities. It is possible that our current and planned clinical trial activities will be more costly and take longer than we anticipate; accordingly, there can be no assurance that additional capital will not be necessary prior to the time anticipated. We believe that we will secure sufficient capital to continue our ongoing and planned clinical programs assuming that the results of our current or planned clinical trials with Androxal® and Proellex® are favorable. If the results of these trials are unfavorable, there can be no assurance that the Company will be successful in obtaining additional capital in amounts sufficient to continue to fund its operations, which outcome would have a material adverse effect on the Company. The uncertainties relating to the foregoing matters raise substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of these uncertainties.

We have 26 full-time employees. We utilize the services of contract research organizations, contract manufacturers and various consultants to assist us in performing clinical and regulatory services for the clinical development of our products. We are substantially dependent on our various contract groups to adequately perform the activities required to obtain regulatory approval of our products.

We have accumulated net operating losses through March 31, 2013 and the value of the tax asset associated with these accumulated net operating losses can be substantially diminished in value due to various tax regulations, including change in control provisions in the tax code. The Company's public offerings completed on February 5, 2007, October 2, 2008, September 11, 2009, October 13, 2009, February 8, 2011, February 1, 2012, the sale and issuance of the ATM Shares, the issuance of unregistered shares as part of the settlement agreements we entered into with certain of our creditors since October of 2009 and the private placement of shares completed on September 7, 2012, may have created a change of ownership for Federal Income tax purposes. The Company has not completed a study to determine if this has occurred. A change in ownership for Federal income tax purposes may result in a limitation on the use of net operating loss and tax credit carryforwards in future periods.

Losses have resulted principally from costs incurred in conducting clinical trials for our product candidates, in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. There can be no assurance that we will be able to successfully complete the transition from a development stage company to the successful introduction of commercially viable products. Our ability to achieve profitability will depend on, among other things, successfully completing the clinical development of our products in a reasonable time frame and at a reasonable cost, obtaining regulatory approvals, establishing marketing, sales and manufacturing capabilities or collaborative arrangements with others that possess such capabilities, and, if applicable, continuing to raise sufficient funds to finance our activities. There can be no assurance that we will be able to achieve profitability.

Critical Accounting Policies and the Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Capitalized Patent and Patent Application Costs

We capitalize the cost associated with building our patent library for Androxal® and Proellex®. As of March 31, 2013, other assets consist of capitalized patent and patent application costs in the amount of $2,320,000. Patent costs, which include legal and application costs related to the patent portfolio, are being amortized over the lesser of the legal life of the patent (typically 20 years) or the estimated economic life of the patent. Amortization of patent costs was $46,000 and $29,000 for the three month periods ended March, 31, 2013 and 2012, respectively.

We review capitalized patent and patent application costs for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment exists when estimated undiscounted cash flows expected to result from the patent are less than its carrying amount. The impairment loss recognized represents the excess of the patent cost as compared to its estimated fair value. We believe that our remaining capitalized patent and patent application costs are not impaired as of March 31, 2013.

Should the Company not continue development of either drug candidate or should the Company not continue as a going concern, capitalized patent and patent application costs may not be recoverable, which would result in a charge to operating results in future periods.

Accrued Expenses

We estimate accrued expenses as part of our process of preparing financial statements. Examples of areas in which subjective judgments may be required include costs associated with services provided by contract organizations for clinical trials, preclinical development and manufacturing of clinical materials. We accrue for costs incurred as the services are being provided by monitoring the status of the trials or services provided and the invoices received from our external service providers. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in our trials, and we recognize this cost over the estimated term of the study based on the number of patients enrolled in the trial on an ongoing basis, beginning with patient enrollment. As actual costs become known to us, we adjust our accruals. To date, our estimates have not differed significantly from the actual costs incurred. However, subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our balance sheet and results of operations.

R&D Expense

Research and development, or R&D, expenses include salaries and related employee expenses, contracted regulatory affairs activities, insurance coverage for clinical trials and prior product sales, contracted research and consulting fees, facility costs, amortization of capitalized patent costs and internal research and development supplies. We ex