REPROS THERAPEUTICS INC.
Form 10-Q
November 07, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 incorporation or organization)	The Woodlands, Texas 77380 (Address of principal executive offices and zip code)	(IRS Employer Identification No.)

(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 ¨

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 ¨

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 ¨ No x

As of November 1, 2013, there were outstanding 23,009,882 shares of Common Stock, par value $.001 per share, of the Registrant.

REPROS THERAPEUTICS INC.
(A development stage company)

For the Quarter Ended September 30, 2013

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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 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 and nine month periods ended September 30, 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)

	September 30, 2013	December 31, 2012
ASSETS		
Current Assets		
Cash and cash equivalents	$ 81,828	$ 24,212
Prepaid expenses and other current assets	193	406
Total current assets	82,021	24,618
Fixed assets, net	87	53
Other assets, net	2,734	2,161
Total assets	$ 84,842	$ 26,832
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 2,829	$ 3,240
Accrued expenses	382	558
Total current liabilities	3,211	3,798
Commitments and 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, 23,121,959 and 17,272,505 shares issued, respectively and 23,009,609 and 17,160,155 shares outstanding, respectively	23	17
Additional paid-in capital	313,469	234,299
Cost of treasury stock, 112,350 shares	(1,380)	(1,380)
Deficit accumulated during the development stage	(230,481)	(209,902)
Total stockholders' equity	81,631	23,034
Total liabilities and stockholders' equity	$ 84,842	$ 26,832

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

REPROS THERAPEUTICS INC.
(A development stage company)

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

	Three Months Ended September 30,		Nine Months Ended September 30,		From Inception (August 20, 1987) through
	2013	2012	2013	2012	September 30, 2013
Revenues					
Licensing fees	$ -	$ -	$ -	$ -	$ 28,755
Product royalties	-	-	-	-	627
Research and development grants	-	-	-	-	1,219
Interest income	3	1	6	1	16,308
Gain on disposal of fixed assets	-	-	-	-	102
Other Income	-	-	-	-	1,003
Total revenues and other income	3	1	6	1	48,014
Expenses					
Research and development	4,786	3,131	17,132	6,776	212,391
General and administrative	1,215	1,453	3,453	3,348	56,373
Other Expense	-	-	-	-	388
Total expenses	6,001	4,584	20,585	10,124	269,152
Loss from continuing operations	(5,998)	(4,583)	(20,579)	(10,123)	(221,138)
Loss from discontinued operations	-	-	-	-	(1,828)
Gain on disposal of discontinued operation	-	-	-	-	939
Net loss before cumulative effect of change in accounting principle	(5,998)	(4,583)	(20,579)	(10,123)	(222,027)
Cumulative effect of change in accounting principle	-	-	-	-	(8,454)
Net loss	$ (5,998)	$ (4,583)	$ (20,579)	$ (10,123)	$ (230,481)
	$ (0.26)	$ (0.30)	$ (1.03)	$ (0.69)	

Loss per share - basic and diluted:				
Weighted average shares used in loss per share calculation:				
Basic	23,006	15,422	20,066	14,746
Diluted	23,006	15,422	20,066	14,746

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	Treasury Stock		Deficit Accumulated	Total
	Shares	Amount	Paid-in Capital	Shares	Amount	During the Development Stage	Stockholders' Equity
Balance at December 31, 2012	17,272,505	$ 17	$ 234,299	112,350	$ (1,380)	$ (209,902)	$ 23,034
Stock based compensation	-	-	2,258	-	-	-	2,258
Issuance of 871,634 shares of common stock for the cashless exercise of 872,133 Series A Warrants	871,634	1	(1)	-	-	-	-
Issuance of 614,564 shares of common stock for the cashless exercise of 716,463 Series B Warrants	614,564	1	(1)	-	-	-	-
Exercise of 42,849 Series B Warrants to purchase common stock for cash @ $2.49 per share	42,849	-	107	-	-	-	107
Issuance of 5,407 shares of common stock for the cashless exercise of 8,332 stock options	5,407	-	-	-	-	-	-
Exercise of 2,500 stock options to purchase common stock for cash @ $18.74 per share	2,500	-	47	-	-	-	47
Issuance of 4,312,500 shares of common stock at $19.00 per share, net of offering costs of $5.2 million	4,312,500	4	76,760	-	-	-	76,764
Net loss	-	-	-	-	-	(20,579)	(20,579)
Balance at September 30, 2013	23,121,959	$ 23	$ 313,469	112,350	$ (1,380)	$ (230,481)	$ 81,631
Balance at December 31, 2011	12,470,694	$ 12	$ 197,769	112,350	$ (1,380)	$ (191,735)	$ 4,666
	-	-	1,902	-	-	-	1,902

Stock based option compensation							
Issuance of 100 shares of common stock at a share price of $5.07	100	-	-	-	-	-	-
Issuance of 2,463,537 shares of common stock at a share price of $4.50, net of offering costs of $777	2,463,537	3	10,307	-	-	-	10,310
Exercise of stock options to purchase common stock for cash ($1.33 to $10.88 per share)	16,488	-	121	-	-	-	121
Issuance of 11,173 shares of common stock for the cashless exercise of 27,915 stock options	11,173	-	-	-	-	-	-
Exercise of 121,079 Series B Warrants to purchase common stock for cash @ $2.49 per share	121,079	-	301	-	-	-	301
Issuance of 2,145,636 shares of common stock at a share price of $11.00, net of offering costs of $586	2,145,636	2	23,016	-	-	-	23,018
Net loss	-	-	-	-	-	(10,123)	(10,123)
Balance at September 30, 2012	17,228,707	$ 17	$ 233,416	112,350	$ (1,380)	$ (201,858)	$ 30,195

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

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

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

	Nine Months Ended September 30,		From Inception (August 20, 1987) through September 30,
	2013	2012	2013
Cash Flows from Operating Activities			
Net loss	$ (20,579)	$ (10,123)	(230,481)
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	177	106	4,478
Noncash stock-based compensation	2,258	1,902	14,576
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	213	(352)	110
Increase (decrease) in accounts payable and accrued expenses	(532)	367	11,087
Net cash used in operating activities	(18,463)	(8,100)	(200,369)
Cash Flows from Investing Activities			
Change in trading marketable securities	-	-	(191)
Capital expenditures	(63)	(54)	(2,486)
Purchase of other assets	(776)	(578)	(6,310)
Proceeds from sale of PP&E	-	-	225
Cash acquired in purchase of FTI	-	-	3
	-	-	138

Proceeds from sale of subsidiary, less $12,345 for operating losses during 1990 phase-out period			
Proceeds from sale of the assets of FTI	-	-	2,250
Increase in net assets held for disposal	-	-	(213)
Net cash used in investing activities	(839)	(632)	(6,584)
Cash Flows from Financing Activities			
Proceeds from issuance of common stock, net of offering costs	76,764	33,328	284,195
Exercise of stock options & warrants	154	422	951
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	76,918	33,750	288,781
Net increase in cash and cash equivalents	57,616	25,018	81,828
Cash and cash equivalents at beginning of period	24,212	4,565	-
Cash and cash equivalents at end of period	$ 81,828	$ 29,583	$ 81,828

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
September 30, 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. W 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 have completed two pivotal efficacy Phase 3 studies for Androxal® conducted under a Special Protocol Assessment ("SPA").

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, we have completed a Phase 1/2 vaginal administration study for uterine fibroids in the first quarter of 2013.

Our product development pipeline is summarized in the table below:

Product Candidate (Indication)	Status	Next Expected Milestone(s)
Androxal®		
Secondary Hypogonadism	Phase 3	Complete DEXA study (Q4 2014) pending FDA guidance
Proellex®		
Uterine Fibroids	Phase 2B (vaginal)	Initiate a Phase 2B study (vaginal delivery) (Q1 2014)
	Phase 2 (oral)	Lift full clinical hold and initiate efficacy study (low dose oral) (Q1 2014)
Endometriosis	Phase 2	Complete Phase 2 study (oral delivery) (Q3 2014)

We also continue to maintain our patent portfolio of our phentolamine-based products for the treatment of sexual dysfunction.

On June 25, 2013, we completed a public offering of 4,312,500 shares of our common stock at a price per share of $19.00. Net proceeds to us, after deducting underwriter's fees and offering expenses, were approximately $76.8 million.

As of September 30, 2013, we had accumulated losses of $230.5 million, approximately $81.8 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $3.2 million. We anticipate that

our current liquidity will be sufficient to continue the development of our product candidates through the NDA filing of both products. We continue to explore potential 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 our current liquidity will be sufficient to fund all of our product development needs.

NOTE 2 Patents and Patent Applications

As of September 30, 2013, we had approximately $2,734,000 in capitalized patent and patent application costs reflected on its balance sheet. Of this amount, $1,726,000 relates to patent and patent application costs for Androxal® and $1,008,000 relates to patent and patent application costs for Proellex®.

Should we not continue development of either drug candidate or should we 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):

	September 30, 2013	December 31, 2012
Patent costs	$ 152	$ 245
Research and development costs	87	192
Personnel related costs	42	30
Other	101	91
Total	$ 382	$ 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 and nine month periods ended September 30, 2013 and 2012 (in thousands, except per share amounts):

	Three Months Ended Sept. 30,		Nine Months Ended Sept. 30,	
	2013	2012	2013	2012
Net Loss	$ (5,998)	$ (4,583)	$ (20,579)	$ (10,123)
Average common shares outstanding	23,006	15,422	20,066	14,746
Basic and diluted loss per share	$ (0.26)	$ (0.30)	$ (1.03)	$ (0.69)

Potential common stock of 3,975,430 and 5,264,207 common shares underlying stock options and warrants for the periods ended September 30, 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 September 30, 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 810,109 shares of our common stock at an exercise price of $2.49 issued in February 2011. Other potential common stock at September 30, 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 1,569,421 shares of our common stock at an exercise price of $2.49 issued in February, 2011.

NOTE 5 Commitments and Contingencies

Therapeutic uses of our Androxal product candidate are covered in the United States by eight issued U.S. patents and four pending patent applications. Foreign coverage of therapeutic uses of our Androxal product candidate includes 61 issued foreign patents and 52 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 from patent holders which may not be available on commercially reasonable terms, or at all, or may 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 July 19, 2013, we received a letter from Dr. Harry Fisch threatening to file a lawsuit against us and two of our executive officers (Joseph S. Podolski, President and Chief Executive Officer and Ron Wiehle, Executive Vice President), seeking addition of Dr. Harry Fisch as an inventor on three of our patents, U.S. Patent Nos. 7,173,064, 7,737,185 and 7,759,360, covering therapeutic uses of Androxal®. We believe that these allegations are without merit and on August 2, 2013, we commenced a lawsuit against Dr. Fisch in the U.S. District Court for the Southern District of Texas seeking a declaratory judgment that he should not be added as inventor to any of these patents. On October 2, 2013, Dr. Fisch filed his answer and counterclaims to our complaint. Dr. Fisch asserted counterclaims seeking correction of inventorship of the three patents at issue to name Dr. Fisch as a co-inventor of the applications leading these patents. Dr. Fisch also seeks reasonable attorney's fees. Due to the preliminary status of the lawsuit and uncertainties related to litigation, we are unable to evaluate the likelihood of either a favorable or unfavorable outcome.

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 ar 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 consistent efficacy results in studies that we have completed to date, and we believe the studies presently underway or scheduled to start this year will significantly progress both clinical development programs.

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.

We believe that 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.

We have completed two Phase 3 pivotal efficacy studies for the treatment of secondary hypogonadism conducted under a Special Protocol Assessment, or SPA. On September 16, 2013, we announced that the top-line results from our second pivotal Phase 3 study, ZA-302, met both co-primary endpoints mandated by the Food and Drug Administration (“FDA”) and that Androxal was generally well tolerated in the six-month safety study, ZA-300. Additionally, on October 22, 2013, we announced that we received guidance from the FDA on the Androxal clinical program, instructing the Company to request a meeting to discuss the adequacy of ZA-301 and ZA-302 as evidence of pivotal efficacy. Furthermore, the FDA now wants to ensure that the DEXA study is conducted for one year after up-titration of subjects at the time of the New Drug Application (“NDA”) submission. This requirement will delay the NDA submission until the third quarter of 2014. If the FDA requires that the expanded DEXA study (the Company increased the study size from 150 men to 300 men to insure overall exposure requirements are met) be included in the NDA submission, then the submission would occur during the fourth quarter of 2014. In addition to the above guidance, the FDA has now agreed to allow the Company to run head-to-head studies against approved testosterone replacement products.

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 study in November 2012. To date, we have experienced difficulty enrolling subjects into this study due to changes in the current treatment of this disorder. Depending on study enrollment, we believe we can release results from this study in the third quarter of 2014.

On October 31, 2013, the Company held a meeting with the FDA to discuss the clinical development plan for low dose oral Proellex® in the treatment of uterine fibroids. During the meeting, the FDA provided guidance for endpoints it believed acceptable for the treatment of uterine fibroids in an efficacy study and instructed the Company to submit a request for lifting the full clinical hold. The Company will follow the FDA's recommendations and submit a protocol and the request for the full hold lift in a timely fashion. The Company believes it may be able to initiate this study in early 2014.

The FDA has accepted an Investigational New Drug Application, or 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 held an end of Phase 2 meeting with the FDA, in the last half of May 2013, to discuss a Phase 3 study design for the vaginally delivered Proellex as a treatment for uterine fibroids. The FDA recommended that a Phase 2B study should be conducted prior to commencing a Phase 3 program. The Company believes it may be able to initiate the Phase 2B study in early 2014. 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)	Androxal® Status	Next Expected Milestone(s)
Secondary Hypogonadism	Phase 3	Complete DEXA study (Q4 2014) pending FDA guidance
Proellex®		
Uterine Fibroids	Phase 2B (vaginal)	Initiate a Phase 2B study (vaginal delivery) (Q1 2014)
	Phase 2 (oral)	Lift full clinical hold and initiate efficacy study (low dose oral) (Q1 2014)
Endometriosis	Phase 2	Complete Phase 2 study (oral delivery) (Q3 2014)

On June 25, 2013, we completed a public offering of 4,312,500 shares of our common stock at a price per share of $19.00. Net proceeds to us, after deducting underwriter's fees and offering expenses, were approximately $76.8 million.

As of September 30, 2013, we had accumulated losses of $230.5 million, approximately $81.8 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $3.2 million. We anticipate that our current liquidity will be sufficient to continue the development of our product candidates through the NDA filing of both products. We continue to explore potential 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 our current liquidity will be sufficient to fund all of our product development needs.

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. The FDA determined that improved testosterone levels would be sufficient provided that both placebo and Androxal® maintained sperm counts in a statistically significant manner.

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.

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

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. On September 16, 2013, we announced that the top-line results from our second pivotal Phase 3 study, ZA-302, met both co-primary endpoints mandated by the FDA. On October 22, 2013, we announced that we received guidance from the FDA on the Androxal clinical program, instructing the Company to request a meeting to discuss the adequacy of ZA-301 and ZA-302 as evidence of pivotal efficacy. The Company believes that both pivotal studies meet the FDA mandated co-primary endpoints.

Additionally, on September 16, 2013, we reported top-line results from the 500 subject, six month open label safety study, ZA-300. Top line data suggested that Androxal was generally well tolerated and there were no dose dependent adverse events in this study.

We have completed enrollment into a one year, 150 subject DEXA study in January 2013, however, the Company expanded the study size to 300 men to insure overall exposure requirements were met. The FDA now wants to ensure that the DEXA study is conducted for one year after up-titration of subjects at the time of the NDA submission. This requirement will delay the NDA submission until the third quarter of 2014. If the FDA requires that the full expanded DEXA study be included in the NDA submission, then the submission would occur during the fourth quarter of 2014.

In addition to the above guidance, the FDA has now agreed to allow the Company to run head-to-head studies against approved testosterone replacement products. The Company believes it may be able to initiate these studies in December 2013.

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.

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.

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 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.

Low Dose 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 due to changes in the current treatment of this disorder. Depending on study enrollment, we believe we can release results from this study in the third quarter of 2014.

On October 31, 2013, the Company held a meeting with the FDA to discuss the clinical development plan for low dose oral Proellex® in the treatment of uterine fibroids. During the meeting, the FDA provided guidance for endpoints it believed acceptable for the treatment of uterine fibroids in an efficacy study and instructed the Company to submit a request for lifting the full clinical hold. The Company will follow the FDA's recommendations and submit a protocol and the request for the full hold lift in a timely fashion. The Company believes it may be able to initiate this study in early 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 and reported final study results in January 2013. We held an end of Phase 2 meeting with the FDA, in the last half of May 2013, to discuss a Phase 3 study design for the vaginally delivered Proellex as a treatment for uterine fibroids. The FDA recommended that a Phase 2B study should be conducted prior to commencing a Phase 3 program. The Company believes it may be able to initiate the Phase 2B study in early 2014. 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

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 2B vaginal administration trial for Proellex® for uterine fibroids; (iii) conducting a Phase 2 trial for low dose oral Proellex® for endometriosis and (iv) conducting an efficacy trial for low dose oral Proellex® for uterine fibroids. We anticipate that our current liquidity will be sufficient to continue the development of our product candidates through the NDA filing of both products. We continue to explore potential 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 our current liquidity will be sufficient to fund all of our product development needs.

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 anticipate that our current liquidity will be sufficient to continue the development of our product candidates through the NDA filing of both products. We continue to explore potential 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 our current liquidity will be sufficient to fund all of our product development needs.

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 September 30, 2013, we had accumulated losses of $230.5 million, approximately $81.8 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $3.2 million.

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 25 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 September 30, 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, June 25, 2013, 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 September 30, 2013, other assets consist of capitalized patent and patent application costs in the amount of $2,734,000. 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 $51,000 and $34,000 for the three month periods ended September 30, 2013 and 2012, respectively, and was $148,000 and $96,000 for the nine month periods ended September 30, 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 September 30, 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 expense research and development costs in the period they are incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research on our behalf.

Share-Based Compensation

We had one stock-based compensation plan at September 30, 2013, the 2011 Equity Incentive Plan. Accounting for stock based compensation generally requires the recognition of the cost of employee services for share-based compensation based on the grant date fair value of the equity or liability instruments issued. We use the Black-Scholes option pricing model to estimate the fair value of our stock options. Expected volatility is determined using historical volatilities based on historical stock prices for a period equal to the expected term. The expected volatility assumption is adjusted if future volatility is expected to vary from historical experience. The expected term of options represents the period of time that options granted are expected to be outstanding and falls between the options' vesting and contractual expiration dates. The risk-free interest rate is based on the yield at the date of grant of a zero-coupon U.S. Treasury bond whose maturity period equals the option's expected term.

Income Taxes

Our losses from inception to date have resulted principally from costs incurred in conducting clinical trials and in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. We have recorded a deferred tax asset for our net operating losses ("NOL"); however, as the Company has incurred losses since inception, and since there is no certainty of future profits, a valuation allowance has been provided in full on our deferred tax assets in the accompanying consolidated financial statements. If the Company has an opportunity to use this NOL to off-set tax liabilities in the future, the use of this asset would be restricted based on Internal Revenue Service, state and local NOL use guidelines. 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, June 25, 2013, 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.

Results of Operations

Comparison of the three-month and nine-month periods ended September 30, 2013 and 2012

Revenues and Other Income

Total revenues and other income increased to $3,000 for the three month period ended September 30, 2013 as compared to $1,000 for the same period in the prior year. Total revenue and other income was $6,000 for the nine month period ended September 30, 2013 as compared to $1,000 for the same period in the prior year. The increase for the three and nine month periods ended September 30, 2013 as compared to the same periods in the prior year was primarily due to increased cash balances as a result of the public offering completed on June 25, 2013 for net proceeds of approximately $76.8 million.

Research and Development Expenses

Research and development, or R&D, expenses include contracted services relating to our clinical product development activities which include preclinical studies, clinical trials, regulatory affairs and bulk manufacturing scale-up activities and bulk active ingredient purchases for preclinical and clinical trials primarily relating to our two products in clinical development, which are Androxal® and Proellex®. Research and development expenses also include internal operating expenses relating to our general research and development activities. R&D expenses increased 53% or approximately $1.7 million to $4.8 million for the three month period ended September 30, 2013 as compared to $3.1 million for the same period in the prior year. Our primary R&D expenses for the three month periods ended September 30, 2013 and 2012 are shown in the following table (in thousands):

Research and Development	Three-months ended September 30, 2013	Three-months ended September 30, 2012	Variance	Change (%)	
Androxal® clinical development	$ 2,743	$ 1,969	$ 774	39	%
Proellex® clinical development	422	389	33	8	%
Payroll and benefits	1,058	543	515	95	%
Operating and occupancy	563	230	333	145	%
Total	$ 4,786	$ 3,131	$ 1,655	53	%

R&D expenses increased 153% or approximately $10.4 million to $17.1 million for the nine month period ended September 30, 2013 as compared to $6.8 million for the same period in the prior year. Our primary R&D expenses for the nine month periods ended September 30, 2013 and 2012 are shown in the following table (in thousands):

Research and Development	Nine-months ended September 30, 2013	Nine-months ended September 30, 2012	Variance	Change (%)	
Androxal® clinical development	$ 11,609	$ 3,275	$ 8,334	254	%
Proellex® clinical development	1,104	1,287	(183)	(14)	%
Payroll and benefits	2,835	1,455	1,380	95	%
Operating and occupancy	1,584	759	825	109	%
Total	$ 17,132	$ 6,776	$ 10,356	153	%

The increase in R&D expenses for both the three and nine month periods ended September 30, 2013 as compared to the same periods in the prior year, is primarily due to the increased clinical development expenses related to Androxal® as a result of the ongoing Phase 3 studies, including two pivotal studies being conducted under an SPA, a six month open label safety study and a one year DEXA study. Clinical development expenses related to Proellex® for both the three and nine month periods ended September 30, 2013 as compared to the same periods in the prior year decreased due to the completion of the Phase 2 vaginal administration study for uterine fibroids.

Payroll and benefits expenses increased for both the three and nine month periods ended September 30, 2013 as compared to the same periods in the prior year by $515,000 and $1.4 million, respectively. Included in payroll and benefits expenses is a charge for non-cash stock based compensation of $506,000 and $1.3 million for the three and nine month periods ended September 30, 2013, respectively, as compared to $227,000 and $633,000 for the same periods in the prior year. Additionally, salaries for the three and nine month periods ended September 30, 2013 were $459,000 and $1.2 million, respectively, as compared to $251,000 and $670,000 for the same periods in the prior year. The increase in both non-cash stock based compensation and salaries expenses is due to increased headcount in R&D employees.

Operating and occupancy expenses increased for the three and nine month periods ended September 30, 2013 as compared to the same periods in the prior year due to an increase in costs associated with our patent portfolio, increased travel and professional services.

To date through September 30, 2013 we have incurred approximately $40.0 million for the development of Androxal® and approximately $60.2 million for the development of Proellex®. These accumulated costs exclude any internal operating expenses.

General and Administrative Expenses

General and administrative expenses, or G&A, decreased 16% or approximately $238,000 to $1.2 million for the three month period ended September 30, 2013 as compared to $1.5 million for the same period in the prior year. Our primary G&A expenses for the three month period ended September 30, 2013 and 2012 are shown in the following table (in thousands):

General and Administrative	Three-months ended September 30, 2013	Three-months ended September 30, 2012	Variance	Change (%)	
Payroll and benefits	$ 626	$ 953	$ (327)	(34)	%
Operating and occupancy	589	500	89	18	%
Total	$ 1,215	$ 1,453	$ (238)	(16)	%

G&A payroll and benefits expenses include salaries, bonuses, relocation expense, severance costs, non-cash stock based compensation expense and fringe benefits. Included in payroll and benefits expense is a charge for non-cash stock based compensation of $368,000 for the three month period ended September 30, 2013 as compared to $653,000 for the same period in the prior year. Additionally, salaries for the three month period ended September 30, 2013 were $230,000 as compared to $275,000 for the same period in the prior year.

G&A operating and occupancy expenses, which include expenses to operate as a public company, increased 18% or approximately $89,000 to $589,000 for the three month period ended September 30, 2013 as compared to $500,000 for the same period in the prior year. The increase in operating and occupancy expenses for the three month period ended September 30, 2013 as compared to the same period in the prior year is primarily due to an increase in professional services.

G&A expenses increased 3% or approximately $105,000 to $3.5 million for the nine month period ended September 30, 2013 as compared to $3.3 million for the same period in the prior year. Our primary G&A expenses for the nine month period ended September 30, 2013 and 2012 are shown in the following table (in thousands):

General and Administrative	Nine-months ended September 30, 2013	Nine-months ended September 30, 2012	Variance	Change (%)	
Payroll and benefits	$ 1,725	$ 2,026	$ (301)	(15)	%
Operating and occupancy	1,728	1,322	406	31	%
Total	$ 3,453	$ 3,348	$ 105	3	%

G&A payroll and benefits expenses include salaries, bonuses, relocation expense, severance costs, non-cash stock option compensation expense and fringe benefits. Included in payroll and benefits expense is a charge for non-cash stock based compensation expense of $937,000 for the nine month period ended September 30, 2013 as compared to $1.3 million for the same period in the prior year. Additionally, salaries for the nine month period ended September 30, 2013 were $687,000 as compared to $664,000 for the same period in the prior year.

G&A operating and occupancy expenses, which include expenses to operate as a public company, increased 31% or approximately $406,000 to $1.7 million for the nine month period ended September 30, 2013 as compared to $1.3 million for the same period in the prior year. The increase is primarily due to an increase in professional services.

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Off-Balance Sheet Arrangements

As of September 30, 2013, the only off-balance sheet arrangement we have is the operating lease relating to our facility.

Liquidity and Capital Resources

Since our inception, we have financed our operations primarily with proceeds from private placements and public offerings of equity securities and with funds received under collaborative agreements.

On June 25, 2013, we completed a public offering of 4,312,500 shares of our common stock at a price per share of $19.00 (the "2013 Public Offering"). Net proceeds to us, after deducting underwriter's fees and offering expenses, were approximately $76.8 million.

Our primary use of cash to date has been in operating activities to fund research and development, including preclinical studies and clinical trials, and general and administrative expenses. We had cash and cash equivalents of approximately $81.8 million as of September 30, 2013 as compared to $24.2 million as of December 31, 2012. All cash and cash equivalents as of September 30, 2013 and December 31, 2012 were held in an account backed by U.S. government securities.

Net cash of approximately $18.5 million and $8.1 million was used in operating activities during the nine month periods ended September 30, 2013 and 2012, respectively. The major use of cash for operating activities for the nine month period ended September 30, 2013 was to fund our clinical development programs and associated administrative costs. Cash used in investing activities during the nine month period ended September 30, 2013 was approximately $839,000 primarily for capitalized patent and patent application costs for Androxal® and Proellex®. Cash provided by financing activities during the nine month period ended September 30, 2013 was approximately $76.9 million as a result of completing the 2013 Public Offering.

We have experienced negative cash flows from operations since inception. We will require substantial funds for research and development, including preclinical studies and clinical trials of our product candidates, and to commence sales and marketing efforts if appropriate, if the FDA or other regulatory approvals are obtained. Based on our current and planned clinical activities, we believe that our current liquidity will be sufficient to continue the development of our product candidates through the NDA filing of both products. It is possible that our 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. Our capital requirements will depend on many factors, which are discussed in detail in "Item 1A. Risk Factors" to Part I of Form 10-K for the fiscal year ended December 31, 2012. Additionally, as discussed in Note 5, there is a third party individual patent holder that claims priority over our patent application for Androxal®.

Our results of operations may vary significantly from quarter to quarter and year to year, and depend on, among other factors, our ability to raise additional capital on acceptable terms or at all, our ability to be successful in our clinical trials, the regulatory approval process in the United States and other foreign jurisdictions and the ability to complete strategic licenses and product development agreements. The timing of our revenues may not match the timing of our associated product development expenses. To date, research and development expenses have usually exceeded revenue in any particular period and/or fiscal year.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. We had cash and cash equivalents of approximately $81.8 million at September 30, 2013 which is held in an account backed by U.S. government securities. Although this cash account is subject to fluctuations in interest rates and market conditions, no significant gain or loss on this account is expected to be recognized in earnings. We do not invest in derivative securities.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e)) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), were effective as of September 30, 2013.

Changes in Internal Control over Financial Reporting

In connection with the evaluation described above, we identified no change in internal control over financial reporting that occurred during the quarter ended September 30, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

Therapeutic uses of our Androxal product candidate are covered in the United States by eight issued U.S. patents and four pending patent applications. Foreign coverage of therapeutic uses of our Androxal product candidate includes 61 issued foreign patents and 52 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 from patent holders which may not be available on commercially reasonable terms, or at all, or may 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 July 19, 2013, we received a letter from Dr. Harry Fisch threatening to file a lawsuit against us and two of our executive officers (Joseph S. Podolski, President and Chief Executive Officer and Ron Wiehle, Executive Vice President), seeking addition of Dr. Harry Fisch as an inventor on three of our patents, U.S. Patent Nos. 7,173,064, 7,737,185 and 7,759,360, covering therapeutic uses of Androxal®. We believe that these allegations are without merit and on August 2, 2013, we commenced a lawsuit against Dr. Fisch in the U.S. District Court for the Southern District of Texas seeking a declaratory judgment that he should not be added as inventor to any of these patents. On October 2, 2013, Dr. Fisch filed his answer and counterclaims to our complaint. Dr. Fisch asserted counterclaims seeking correction of inventorship of the three patents at issue to name Dr. Fisch as a co-inventor of the applications leading these patents. Dr. Fisch also seeks reasonable attorney's fees. Due to the preliminary status of the lawsuit and uncertainties related to litigation, we are unable to evaluate the likelihood of either a favorable or unfavorable outcome.

Item 1A. Risk Factors

There were no material changes from the risk factors previously disclosed in the registrant's Form 10-K for the fiscal year ended December 31, 2012 in response to "Item 1A. Risk Factors" to Part I of Form 10-K.

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Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None

Item 3. Defaults Upon Senior Securities.

None

Item 4. Mine Safety Disclosures.

None

Item 5. Other Information

None

Item 6. Exhibits

3.1(a)	Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Company's Registration Statement on Form SB-2 (No. 33-57728-FW), as amended ("Registration Statement")).
3.1(b)	Certificate of Amendment to the Company's Restated Certificate of Incorporation, dated as of May 2, 2006 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K as filed with the Securities and Exchange Commission (the "Commission") on May 2, 2006).
3.1(c)	Certificate of Amendment to the Company's Restated Certificate of Incorporation, as amended, dated as of December 16, 2008 (incorporated by reference to Exhibit 3.1(d) to the Company's Current Report on Form 8-K as filed with the Commission on December 23, 2008).
3.1(d)	Certificate of Designation of Series One Junior Participating Preferred Stock dated September 2, 1999 (incorporated by reference to Exhibit A to Exhibit 4.1 to the Company's Registration Statement on Form 8-A as filed with the Commission on September 3, 1999).
3.1(e)	Certificate of Amendment to Restated Certificate of Incorporation, dated as of November 18, 2009. Exhibit 3.1(e) to the Company’s Current Report on Form 8-K dated November 19, 2009 is incorporated herein by reference.
3.1(f)	Certificate of Amendment to Restated Certificate of Incorporation, dated October 14, 2010. Exhibit 3.1(f) to the Company’s Current Report on Form 8-K dated October 14, 2010 is incorporated herein by reference.
3.2	Restated Bylaws of the Company (incorporated by reference to Exhibit 3.4 to the Registration

Statement).

4.1 Form of Series A Warrant Certificate. Exhibit 4.10 to the Company's Registration Statement on Form S-1/A (No. 333-171196) as filed with the Commission on February 2, 2011 is incorporated herein by reference.

4.2 Form of Series B Warrant Certificate. Exhibit 4.11 to the Company's Registration Statement on Form S-1/A (No. 333-171196) as filed with the Commission on February 2, 2011 is incorporated herein by reference.

4.3	Series A Warrant Agreement dated February 8, 2011 by and among the Company and Computershare Inc. and its wholly-owned subsidiary, Computershare Trust Company, N.A. Exhibit 4.1 to the Company's Current Report on Form 8-K as filed with the Commission on February 9, 2011 is incorporated herein by reference.
4.4	Series B Warrant Agreement dated February 8, 2011 by and among the Company and Computershare Inc. and its wholly-owned subsidiary, Computershare Trust Company, N.A. Exhibit 4.2 to the Company's Current Report on Form 8-K as filed with the Commission on February 9, 2011 is incorporated herein by reference.
31.1*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).
31.2*	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).
32.1*	Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).
32.2*	Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).
*	Filed herewith.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

REPROS THERAPEUTICS INC.

Date: November 7, 2013

By: /s/ Joseph S. Podolski
Joseph S. Podolski
Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 7, 2013

By: /s/ Katherine A. Anderson
Katherine A. Anderson
Chief Financial Officer
(Principal Financial Officer)