REPROS THERAPEUTICS INC.
Form 10-Q
November 14, 2012

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, 2012

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 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 ¨ Non-accelerated filer ¨ Smaller reporting company x

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 November 6, 2012, there were outstanding 17,116,357 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, 2012

INDEX

2

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, 2011.

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, 2012 are not necessarily indicative of the results that may be expected for the year ended December 31, 2012. 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, 2011.

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, 2012	December 31, 2011
ASSETS		
Current Assets		
Cash and cash equivalents	$ 29,583	$ 4,565
Prepaid expenses and other current assets	451	99
Total current assets	30,034	4,664
Fixed assets, net	59	15
Other assets, net	1,939	1,385
Total assets	$ 32,032	$ 6,064
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 1,508	$ 1,145
Accrued expenses	329	253
Total current liabilities	1,837	1,398
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, 17,228,707 and 12,470,694 shares issued, respectively and 17,116,357 and 12,358,344 shares outstanding, respectively	17	12
Additional paid-in capital	233,416	197,769
Cost of treasury stock, 112,350 shares	(1,380)	(1,380)
Deficit accumulated during the development stage	(201,858)	(191,735)
Total stockholders' equity	30,195	4,666
Total liabilities and stockholders' equity	$ 32,032	$ 6,064

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

5

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 September 30,		Nine Months Ended September 30,		From Inception (August 20, 1987) through September 30,
	2012	2011	2012	2011	2012
Revenues					
Licensing fees	$ -	$ -	$ -	$ -	$ 28,755
Product royalties	-	-	-	-	627
Research and development grants	-	-	-	-	1,219
Interest income	1	-	1	1	16,300
Gain on disposal of fixed assets	-	-	-	-	102
Other Income	-	-	-	-	1,003
Total revenues and other income	1	-	1	1	48,006
Expenses					
Research and development	3,131	3,234	6,776	6,980	188,692
General and administrative	1,453	726	3,348	2,780	51,441
Interest expense and amortization of intangibles	-	-	-	-	388
Total expenses	4,584	3,960	10,124	9,760	240,521
Loss from continuing operations	(4,583)	(3,960)	(10,123)	(9,759)	(192,515)
Loss from discontinued operations	-	-	-	-	(1,828)
Gain on disposal of discontinued operation	-	-	-	-	939
Net loss before cumulative effect of change in accounting principle	(4,583)	(3,960)	(10,123)	(9,759)	(193,404)
Cumulative effect of change in accounting principle	-	-	-	-	(8,454)
Net loss	$ (4,583)	$ (3,960)	$ (10,123)	$ (9,759)	$ (201,858)
Loss per share - basic and diluted:	$ (0.30)	$ (0.32)	$ (0.69)	$ (0.82)	

Weighted average shares used in loss per share calculation:				
Basic	15,422	12,315	14,746	11,840
Diluted	15,422	12,315	14,746	11,840

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, 2011	12,470,694	$ 12	$ 197,769	112,350	$ (1,380)	$ (191,735)	$ 4,666
Stock based option compensation	-	-	1,902	-	-	-	1,902
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,
	2012	2011	2012
Cash Flows from Operating Activities			
Net loss	$ (10,123)	$ (9,759)	(201,858)
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	106	84	4,262
Noncash stock-based compensation	1,902	1,654	11,435
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	(352)	140	(148)
Increase (decrease) in accounts payable and accrued expenses	367	744	9,937
Net cash used in operating activities	(8,100)	(7,137)	(176,511)
Cash Flows from Investing Activities			
Change in trading marketable securities	-	-	(191)
Capital expenditures	(54)	(15)	(2,447)
Capitalization of patents and patent applications	(578)	(247)	(5,534)
Proceeds from sale of PP&E	-	-	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	(632)	(262)	(5,769)
Cash Flows from Financing Activities			
Proceeds from issuance of common stock, net of offering costs	33,328	11,509	207,431
Exercise of stock options & warrants	422	3	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	33,750	11,512	211,863
Net increase (decrease) in cash and cash equivalents	25,018	4,113	29,583
Cash and cash equivalents at beginning of period	4,565	2,957	-
Cash and cash equivalents at end of period	$ 29,583	$ 7,070	$ 29,583

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, 2012

(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. On July 9, 2012, we announced that we reached an agreement with the Food and Drug Administration ("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").

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. On October 8, 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 and expect to complete enrollment in the second quarter of 2013. Additionally, 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 intend to report final study results around year end 2012.

Our product development pipeline is summarized in the table below:

Product Candidate (Indication)	Status	Next Expected Milestone(s)
Androxal®		
Secondary Hypogonadism	Phase 3	Complete first Phase 3 pivotal study (Q2 2013) Complete open label safety study (Q4 2013) Complete DEXA study (Q1 2014)
Proellex®		
Uterine Fibroids	Phase 2	Complete Phase 2 study (vaginal delivery) (Q4 2012)
Endometriosis	Phase 2	Initiate Phase 2 study (oral delivery) (Q4 2012)

9

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.

On February 1, 2012, we completed a registered direct offering to certain institutional investors, including certain existing shareholders, of 2,463,537 shares of our common stock at a price per share of $4.50. Net proceeds to us, after deducting placement agent's fees and offering expenses, were approximately $10.3 million.

On May 9, 2012, we announced that we held a meeting with the FDA 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 with the FDA upon the registration requirements for Androxal® oral therapy for the treatment of secondary hypogonadism, including a safety database comprising of safety data for 100 subjects exposed to Androxal® for one year and 800 subjects exposed for six months, with a focus on overweight men under 60 years of age. The FDA further advised that a one year dual-energy X-ray absorptiometry (“DEXA”) study be conducted to ensure that there is no bone loss.

On July 9, 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. The first pivotal study is fully enrolled in November 2012 and we have begun enrolling subjects into the second pivotal study. Additionally, we began enrolling men into a 500 subject open label safety study in June 2012 and began enrolling men into a one year DEXA study in the third quarter of 2012. Depending on study enrollment and the completion of other studies, we believe we may be able to submit an NDA in the first half of 2014.

At the end of July 2012, we satisfied our enrollment requirement of study subjects in the ongoing ZPV-200 Phase 2 study for the use of Proellex®-V, the proprietary vaginal delivery formulation of telapristone acetate, in the treatment of uterine fibroids and we intend to report the final study results around year end 2012. Additionally, we have begun enrolling subjects who completed the ZPV-200 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.

On September 7, 2012, we completed a private placement of 2,145,636 shares of our common stock at a price per share of $11.00. Net proceeds to us, after deducting offering expenses, were approximately $23 million.

As of September 30, 2012, we had accumulated losses of $201.9 million, approximately $29.6 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $1.8 million. We anticipate that our current liquidity will be sufficient to continue these planned studies into the second quarter of 2014; however, significant additional capital will be required for us to complete the development of our product candidates through 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 September 30, 2012, we had approximately $1,939,000 in capitalized patent and patent application costs reflected on its balance sheet. Of this amount, $1,594,000 relates to patent and patent application costs for Androxal® and $345,000 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, 2012	December 31, 2011
Patent costs	$ 123	$ 51
Research and development costs	44	87
Personnel related costs	28	70
Other	134	45
Total	$ 329	$ 253

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, 2012 and 2011 (in thousands, except per share amounts):

	Three Months Ended Sept. 30,		Nine Months Ended Sept. 30,	
	2012	2011	2012	2011
Net Loss	$ (4,583)	$ (3,960)	$ (10,123)	$ (9,759)
Average common shares outstanding	15,422	12,315	14,746	11,840
Basic and diluted loss per share	$ (0.30)	$ (0.32)	$ (0.69)	$ (0.82)

Potential common stock of 5,264,207 and 5,260,795 common shares underlying stock options and warrants for the periods ended September 30, 2012 and 2011, respectively, were excluded from the above calculation of diluted loss per share because they were anti-dilutive. Potential common stock for the periods ended September 30, 2012 and 2011, includes Series A Warrants to purchase 1,749,270 shares of our common stock at an exercise price of $0.01. Also included in potential common stock for the periods ended September 30, 2012 and 2011, are Series B Warrants to purchase 1,569,421 and 1,690,500 shares, respectively, of our common stock at an exercise price of $2.49 issued in

our February 8, 2011 public offering.

11

NOTE 5 — Commitments and Contingencies

Therapeutic uses of our Androxal® product candidate are covered in the United States by five issued U.S. patents and seven pending patent applications. Foreign coverage of therapeutic uses of our Androxal® product candidate includes 55 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. We expect that a re-examination certificate will be issued confirming the patentability of the remaining claims; however, if such a re-examination certificate were to issue, we believe that our development of Androxal® would 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.

NOTE 6 — Subsequent Events

On October 31, 2012, Dr. Jean Fourcroy, MD, PhD, MPH, a member of Repros Therapeutics Inc.'s (the "Company") board of directors (the "Board") resigned her position as a member of the Board. Such resignation was not a result of any disagreements relating to the Company's operations, policies or practices.

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 2012 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. As of 2011, sales of preparations for the treatment of low testosterone have exceeded $1 billion in the U.S. and first tier pharmaceutical companies have entered the low testosterone marketplace.

We believe 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 was 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. On July 9, 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"). The first pivotal study is fully enrolled in November 2012 and we have begun enrolling subjects into the second pivotal study. Additionally, we began enrolling men into a 500 subject open label safety study in June 2012 at 28 U.S. clinical sites and began enrolling men into a one year dual-energy X ray absorptiometry ("DEXA") study in the third quarter of 2012 at 10 U.S. clinical sites. We anticipate these two studies to be fully enrolled in March 2013. Depending on study enrollment and the completion of other studies, we believe we may be able to submit an NDA in the first half of 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. On October 8, 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 and expect to complete enrollment in the second quarter of 2013.

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. At the end of July 2012, we satisfied our enrollment requirement of subjects for the Phase 2 study and intend to report final study results around the end of 2012. We will then request an end of Phase 2 meeting with the FDA, so that we can commence a Phase 3 vaginal administration study 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 first Phase 3 pivotal study (Q2 2013)
		Complete open label safety study (Q4 2013)
Secondary Hypogonadism	Phase 3	
		Complete DEXA study (Q1 2014)
Proellex®		
Uterine Fibroids	Phase 2	Complete a Phase 2 study (vaginal delivery) (Q4 2012)

Endometriosis	Initiate Phase 2 study (oral delivery) (Q4 2012)	Phase 2

As of September 30, 2012, we had accumulated losses of $201.9 million, approximately $29.6 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $1.8 million. On February 1, 2012, we completed a registered direct offering to certain institutional investors, including certain existing shareholders, of 2,463,537 shares of our common stock at a price per share of $4.50. Net proceeds to us, after deducting placement agent's fees and offering expenses, were approximately $10.3 million. On September 7, 2012, we completed a private placement of 2,145,636 shares of our common stock at a price per share of $11.00. Net proceeds to us, after deducting offering expenses, were approximately $23 million. We anticipate that our current liquidity will be sufficient to continue these planned studies into the second quarter of 2014; however, significant additional capital will be required for us to complete the development of our product candidates through 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 on November 8, 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® will be 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. We caution that the results discussed herein are based on data from non-pivotal trials and that any necessary pivotal Phase 3 and long-term Open Label Safety Trial data may not agree with these results which will be based upon significantly larger and more diverse patient populations treated for longer periods of time.

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

On November 8, 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.

On July 9, 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 first pivotal study is fully enrolled in November 2012 and we have begun enrolling subjects into our second pivotal study. Based on the completed enrollment into our first pivotal study, we believe we will have top line results from this study in April 2013.

We began enrolling men into a 500 subject, six month open label safety study in June 2012 at 28 U.S. clinical sites. Currently, this study has enrolled 280 subjects and we anticipate full enrollment in March 2013. Incoming results from the first group of subjects in this study (n=62) to have completed six weeks of dosing have surpassed the FDA threshold of 75% above the lower limit of normal testosterone level, 300 ng/dL. 80.6% of the men would be considered responders via this criteria. The men included in the study meet the same criteria as the pivotal trial except that men currently using approved testosterone gels are allowed in the open label study following a washout period. Approximately one-third of the men in the open label study are current or previous testosterone users. The mean testosterone at the end of the first six weeks of dosing was 428 ng/dL as compared to a mean baseline level of 206 ng/dL. This highly statistically significant shift is even more impressive given the number of men who had washed out

of recent testosterone use. No men achieved testosterone levels outside the normal range.

We began enrolling men into a one year, 150 subject DEXA study in the third quarter of 2012 at 10 U.S. clinical sites. Currently, this study has enrolled 53 subjects and we anticipate full enrollment in March 2013. 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 in the first half of 2014.

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 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 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.

On July 16, 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, on October 8, 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 and anticipate full enrollment in the second quarter of 2013. Depending on study enrollment, we expect to release results from this study in the fourth quarter of 2013.

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 since 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. At the end of July 2012, we satisfied our enrollment requirement of subjects into our Phase 2 vaginal administration study for uterine fibroids. We intend to report the final study results around year end 2012 and request an end of Phase 2 meeting with the FDA, so that we can commence a Phase 3 vaginal administration study for uterine fibroids. The Company has reviewed preliminary results from the women that have completed dosing at 3, 6 and 12 mg of the drug. 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. Exposure levels of the drug after vaginal administration of the 12 mg dose were extremely low, yet these low levels were able to produce significant clinical benefit. The two lower doses did not achieve the same level of improvement and the 12 mg dose was able to achieve separation from the two lower doses that approached or were significant. The 12 mg dose was well tolerated.

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 roll 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 2 vaginal administration trial, and a subsequent Phase 3 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 second 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, 2011 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 September 30, 2012, we had accumulated losses of $201.9 million, approximately $29.6 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $1.8 million. We believe we have sufficient funding to continue all of the clinical trials currently underway for Proellex® and Androxal®, and to commence planned subsequent clinical trials in 2012; however, based on the current and planned clinical trials, we will need to raise additional capital no later than the second quarter of 2014. Significant additional capital will be required for us to complete development of our product candidates through 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.

19

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 second quarter of 2014 in order to complete 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 we 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 21 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, 2012 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. Our public offerings completed on February 5, 2007, October 2, 2008, September 11, 2009, October 13, 2009, February 8, 2011, February 1, 2012, the private placement completed on September 7, 2012, the sale and issuance of the ATM Shares and the issuance of unregistered shares as part of previously-disclosed settlements of certain claims may have created a change of ownership for Federal income tax purposes. We have not undertaken 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, 2012, other assets consist of capitalized patent and patent application costs in the amount of $1,939,000. Patent costs, which include legal and application costs related to the patent portfolio, are being amortized over 20 years, or the lesser of the legal or the estimated economic life of the patent. Amortization of patent costs was $34,000 and $28,000 for the three month periods ended September, 30, 2012 and 2011, respectively, and was $96,000 and $80,000 for the nine month periods ended September 30, 2012 and 2011, respectively. Of the $1,939,000 in capitalized patent and patent application costs, $1,594,000 related to Androxal® and $345,000 related to Proellex®.

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, 2012.

Should we not continue development of either drug candidate or should we 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, 2012, 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 we have 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 we have 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. Our public offerings completed on February 5, 2007, October 2, 2008, September 11, 2009, October 13, 2009, February 8, 2011, February 1, 2012, the private placement completed on September 7, 2012, the sale and issuance of the ATM Shares and the issuance of unregistered shares as part of previously-disclosed settlements of certain claims may have created a change of ownership for Federal income tax purposes. We have not undertaken 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, 2012 and 2011

Revenues and Other Income

Total revenues and other income increased to $1,000 for the three month period ended September 30, 2012 as compared to zero for the same period in the prior year. Total revenue and other income was $1,000 for both nine month periods ended September 30, 2012 and 2011. The increase for the three month period ended September 30, 2012 was primarily due to an increase of $1,000 in interest income as a result of the private placement completed on September 7, 2012 for net proceeds of approximately $23 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 decreased 3% or approximately $103,000 to $3.1 million for the three month period ended September 30, 2012 as compared to $3.2 million for the same period in the prior year. Our primary R&D expenses for the three month periods ended September 30, 2012 and 2011 are shown in the following table (in thousands):

Research and Development	Three-months ended September 30, 2012	Three-months ended September 30, 2011	Variance	Change (%)
Androxal® clinical development	$ 1,969	$ 2,138	$ (169)	(8)%
Proellex® clinical development	389	277	112	40 %
Payroll and benefits	543	421	122	29 %
Operating and occupancy	230	398	(168)	(42)%
Total	$ 3,131	$ 3,234	$ (103)	(3)%

R&D expenses decreased 3% or approximately $204,000 to $6.8 million for the nine month period ended September 30, 2012 as compared to $7.0 million for the same period in the prior year. Our primary R&D expenses for the nine month periods ended September 30, 2012 and 2011 are shown in the following table (in thousands):

Research and Development	Nine-months ended September 30, 2012	Nine-months ended September 30, 2011	Variance	Change (%)
Androxal® clinical development	$ 3,275	$ 4,366	$ (1,091)	(25)%
Proellex® clinical development	1,287	820	467	57 %
Payroll and benefits	1,455	875	580	66 %
Operating and occupancy	759	919	(160)	(17)%
Total	$ 6,776	$ 6,980	$ (204)	(3)%

22

The decrease in R&D expenses for both the three and nine month periods ended September 30, 2012 as compared to the same periods in the prior year, is primarily due to the decreased clinical development expenses related to Androxal® due to the completion of the Phase 2b study in men with secondary hypogonadism, partially offset by an increase in clinical development expenses related to Proellex® due to the commencement 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, 2012 as compared to the same period in the prior year due to increased headcount in R&D employees. Operating and occupancy expenses decreased for the three month period ended September 30, 2012 as compared to the same period in the prior year due to a decrease in costs associated with our patent portfolio. Operating and occupancy expenses decreased for the nine month period ended September 30, 2012 as compared to the same period in the prior year due to a decrease in costs associated with our patent portfolio, partially offset by an increase in consulting and other outside services.

To date through September 30, 2012 we have incurred approximately $23.1 million for the development of Androxal® and approximately $58.5 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, increased 100% or approximately $727,000 to $1.5 million for the three month period ended September 30, 2012 as compared to $726,000 for the same period in the prior year. Our primary G&A expenses for the three month period ended September 30, 2012 and 2011 are shown in the following table (in thousands):

General and Administrative	Three-months ended Sept. 30, 2012	Three-months ended Sept. 30, 2011	Variance	Change (%)
Payroll and benefits	$ 953	$ 469	$ 484	103 %
Operating and occupancy	500	257	243	95 %
Total	$ 1,453	$ 726	$ 727	100 %

G&A payroll and benefits expenses include salaries, bonuses, 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 $653,000 for the three month period ended September 30, 2012 as compared to $299,000 for the same period in the prior year. Additionally, salaries for the three month period ended September 30, 2012 were $275,000 as compared to $150,000 for the same period in the prior year. The increase in salaries is primarily due to an increase in headcount and the discontinuation of the salary reduction program put in place in August 2009.

G&A operating and occupancy expenses, which include expenses to operate as a public company, increased 95% or approximately $243,000 to $500,000 for the three month period ended September 30, 2012 as compared to $257,000 for the same period in the prior year. The increase is primarily due to an increase in professional services and travel expenses.

G&A expenses increased 20% or approximately $568,000 to $3.3 million for the nine month period ended September 30, 2012 as compared to $2.8 million for the same period in the prior year. Our primary G&A expenses for the nine month period ended September 30, 2012 and 2011 are shown in the following table (in thousands):

General and Administrative	Nine-months ended Sept. 30, 2012	Nine-months ended Sept. 30, 2011	Variance	Change (%)
Payroll and benefits	$ 2,026	$ 1,762	$ 264	15 %
Operating and occupancy	1,322	1,018	304	30 %
Total	$ 3,348	$ 2,780	$ 568	20 %

G&A payroll and benefits expenses include salaries, bonuses, 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 approximately $1.3 million for both nine month periods ended September 30, 2012 and 2011. Additionally, salaries for the nine month period ended September 30, 2012 were $664,000 as compared to $380,000 for the same period in the prior year. The increase in salaries is primarily due to an increase in headcount and the discontinuation of the salary reduction program put in place in August 2009.

G&A operating and occupancy expenses, which include expenses to operate as a public company, increased 30% or approximately $304,000 to $1.3 million for the nine month period ended September 30, 2012 as compared to $1.0 million for the same period in the prior year. The increase is primarily due to an increase in professional services and travel expenses.

Off-Balance Sheet Arrangements

As of September 30, 2012, 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 February 12, 2010, we entered into an Equity Distribution Agreement (the “Equity Distribution Agreement”) with Ladenburg Thalmann & Co. Inc. (“Ladenburg”), pursuant to which we may issue and sell from time to time through Ladenburg, as sales agent and/or principal, shares of our common stock having an aggregate offering price of up to $10 million (the “ATM Shares”). Ladenburg is not required to sell on our behalf any specific number or dollar amount of the ATM Shares, but Ladenburg, upon acceptance of written instructions from us, agreed to use its commercially reasonable efforts consistent with its customary trading and sales practices, to sell the ATM Shares up to the amount

specified, and otherwise in accordance with the terms of a placement notice delivered to Ladenburg. We have no obligation to sell any ATM Shares under the Equity Distribution Agreement, and may at any time suspend sales under the Equity Distribution Agreement, provided that such suspension shall not affect either party's obligations with respect to the ATM Shares sold prior to the receipt of notice of such suspension. Ladenburg receives a commission of 4% of the gross sales price of all ATM Shares sold through it under the Equity Distribution Agreement. The ATM Shares are issued pursuant to our shelf registration statement on Form S-3, as amended (File No. 333-163648). Between January 1, 2012 and September 30, 2012, we sold an aggregate of 100 ATM Shares at a weighted average share price of $5.07, for proceeds of approximately $500, net of expenses. Cumulative through September 30, 2012, we have sold 2,775,476 ATM Shares at a weighted average share price of $2.67, for proceeds of approximately $7.4 million, net of expenses. Pursuant to General Instruction I.B.6. of Form S-3, in the event that the aggregate market value of our common stock held by non-affiliates ("Public Float") is less than $75 million, we are limited to the amount of shares we can sell under this Form S-3 to no more than one-third of the Public Float, during a period of 12 calendar months immediately prior to, and including, the date of such sale of such common stock. As of the date of this filing, we are not restricted by such rule, however, should our Public Float fall below $75 million in the future, we will again be subject to such limitation.

On February 1, 2012, we completed a registered direct offering to certain institutional investors, including certain existing shareholders, of 2,463,537 shares of our common stock at a price per share of $4.50 (the “2012 Public Offering”). Net proceeds to us, after deducting placement agent's fees and offering expenses, were approximately $10.3 million.

On September 7, 2012, we completed a private placement of 2,145,636 shares of our common stock at a price per share of $11.00. Net proceeds to us, after deducting offering expenses, were approximately $23 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 $29.6 million as of September 30, 2012 as compared to $4.6 million as of December 31, 2011. All cash and cash equivalents as of September 30, 2012 and December 31, 2011 were held in an account backed by U.S. government securities.

Net cash of approximately $8.1 million and $7.1 million was used in operating activities during the nine month periods ended September 30, 2012 and 2011, respectively. The major use of cash for operating activities for the nine month period ended September 30, 2012 was to fund our operations. Cash used in investing activities during the nine month period ended September 30, 2012 was approximately $632,000 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, 2012 was approximately $33.8 million as a result of completing the 2012 Public Offering on February 1, 2012 and the private placement on September 7, 2012.

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 will need to raise additional capital no later than the second quarter of 2014 or seek additional funding in the public or private capital markets through corporate collaborations or other financing vehicles in order to continue our development activities through NDA approval. There can be no assurance that any such funding will be available to us on favorable terms or at all. If we are successful in obtaining additional financing, the terms of such financing may have the effect of diluting or adversely affecting the holdings or the rights of holders of our common stock. 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, 2011. Additionally, as discussed in Note 5, there is a third party individual patent holder that claims priority over our patent application for Androxal®. The uncertainties relating to the foregoing matters raise substantial doubt about our ability to continue as a going concern.

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, on 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 $29.6 million at September 30, 2012 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, 2012.

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, 2012 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 five issued U.S. patents and seven pending patent applications. Foreign coverage of therapeutic uses of our Androxal® product candidate includes 55 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. We expect that a re-examination certificate will be issued confirming the patentability of the remaining claims; however, if such a re-examination certificate were to issue, we believe that our development of Androxal® would 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 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, 2011 in response to "Item 1A. Risk Factors" to Part I of Form 10-K.

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

On September 7, 2012, we completed a private placement of 2,145,636 shares of our common stock at a price per share of $11.00 (the "Shares"), with certain institutional investors (the "Investors"). The net proceeds to us, after deducting offering expenses, were approximately $23 million. The Shares were sold without registration pursuant to Section 4(2) and/or Rule 506 of Regulation D promulgated under the Securities Exchange Act of 1933, as amended. In accordance with the terms of the private placement, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with the Investors and in connection therewith, a Registration Rights Agreement (the "Registration Rights Agreement"), pursuant to which we agreed to file a registration statement to register the resale of the Shares by the Investors to the public within sixty (60) days of closing. We filed such registration statement on Form S-3 (Registration No. 333-184159) on September 28, 2012, as failure to do so before the expiration of the sixty (60) day period would have resulted in penalty payments being owed to the Investors. We however, still need to maintain compliance with all public filings necessary for the Investors to sell their Shares pursuant to Rule 144, as failure to do so will result in significant penalties for the Company.

Subsequent to the execution of the Purchase Agreement by the Investors, we entered into an agreement (the "Trout Agreement") with Trout Capital LLC ("Trout"), whereby the Company agreed to pay Trout a fee for its assistance in connection with the placement of the Shares. Pursuant to the Trout Agreement, Trout had no commitment to purchase any of the Shares and only acted as an agent in obtaining indications of interest for the Shares from the Investors who purchased the Shares directly from the Company, with the Company retaining final authority on all matters. The Trout Agreement also required the Company to indemnify Trout against certain liabilities arising from their services relating to the sale and issuance of the Shares.

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.
10.1	Securities Purchase Agreement dated August 31, 2012 by and among the Company and certain institutional investors. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on September 12, 2012 is incorporated herein by reference.
10.2	Registration Rights Agreement dated August 31, 2012 by and among the Company and certain institutional investors. Exhibit 10.2 to the Company's Current Report on Form 8-K as filed with the Commission on September 12, 2012 is incorporated herein by reference.
10.3	Agreement dated September 4, 2012 by and between the Company and Trout Capital LLC. Exhibit 10.3 to the Company's Current Report on Form 8-K as filed with the Commission on September 12, 2012 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 14, 2012

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

Date: November 14, 2012

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