

REPROS THERAPEUTICS INC.

Form 10-Q

November 10, 2011

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, 2011

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 (State or other jurisdiction of incorporation or organization)	2408 Timberloch Place, Suite B-7 The Woodlands, Texas 77380 (Address of principal executive offices and zip code)	76-0233274 (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  No

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

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

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

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

As of November 3, 2011, there were outstanding 12,317,692 shares of Common Stock, par value \$.001 per share, of the Registrant.

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REPROS THERAPEUTICS INC.  
(A development stage company)

For the Quarter Ended September 30, 2011

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## FACTORS AFFECTING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q includes "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "may," "anticipate," "believe," "expect," "estimate," "project," "suggest," "intend" and similar expressions are intended to identify forward-looking statements. Such statements are subject to certain risks, uncertainties and assumptions. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, expected, estimated, projected, suggested or intended. These risks and uncertainties include risks associated with the Company's ability to continue as a going concern and to continue to be able to raise additional capital on acceptable terms or at all in order to have available funding for the continued development of Proellex® and Androxal®; the success of the clinical trials for Proellex® and Androxal®; 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, 2010.

## PART I. FINANCIAL INFORMATION

### Item 1. Financial Statements

The following unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (which include only normal recurring adjustments) considered necessary for a fair statement of the interim periods presented have been included. The year-end balance sheet data was derived from audited financial statements, but does not include all the disclosures required by accounting principles generally accepted in the United States of America. Operating results for the three month and nine month periods ended September 30, 2011 are not necessarily indicative of the results that may be expected for the year ended December 31, 2011. 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, 2010.

**REPROS THERAPEUTICS INC.**  
(A development stage company)

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

September 30,	December 31,
2011	2010

ASSETS		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 7,070	\$ 2,957
Prepaid expenses and other current assets	188	328
Total current assets	7,258	3,285
Fixed assets, net	17	7
Other assets, net	1,341	1,173
<b>Total assets</b>	<b>\$ 8,616</b>	<b>\$ 4,465</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 1,694	\$ 1,151
Accrued expenses	348	147
Total current liabilities	2,042	1,298
Commitments and contingencies (note 5)		
<b>Stockholders' Equity</b>		
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, 12,430,042 and 9,042,372 shares issued, respectively and 12,317,692 and 8,930,022 shares outstanding, respectively	12	9
Additional paid-in capital	196,945	183,782
Cost of treasury stock, 112,350 shares	(1,380 )	(1,380 )
Deficit accumulated during the development stage	(189,003 )	(179,244 )
Total stockholders' equity	6,574	3,167
<b>Total liabilities and stockholders' equity</b>	<b>\$ 8,616</b>	<b>\$ 4,465</b>

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

**REPROS THERAPEUTICS INC.**  
(A development stage company)

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

From Inception  
(August 20, 1987)  
through

	Three Months Ended September 30, 2011	Three Months Ended September 30, 2010	September 30, 2011	September 30, 2010	September 30, 2011
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Revenues	\$ -	\$ -	\$ -	\$ -	\$ 28,755
Licensing fees	\$ -	\$ -	\$ -	\$ -	\$ 28,755
Product royalties	-	-	-	-	627
Research and development grants	-	-	-	-	1,219
Interest income	-	-	1	-	16,298
Gain on disposal of fixed assets	-	-	-	-	102
Other Income	-	85	-	138	1,003
Total revenues and other income	-	85	1	138	48,004
Expenses					
Research and development	3,234	736	6,980	1,950	180,214
General and administrative	726	533	2,780	1,772	47,062
Interest expense and amortization of intangibles	-	-	-	-	388
Total expenses	3,960	1,269	9,760	3,722	227,664
Loss from continuing operations	(3,960 )	(1,184 )	(9,759 )	(3,584 )	(179,660 )
Loss from discontinued operations	-	-	-	-	(1,828 )
Gain on disposal of discontinued operation	-	-	-	-	939
Net loss before cumulative effect of change in accounting principle	(3,960 )	(1,184 )	(9,759 )	(3,584 )	(180,549 )
Cumulative effect of change in accounting principle	-	-	-	-	(8,454 )
Net loss	\$ (3,960 )	\$ (1,184 )	\$ (9,759 )	\$ (3,584 )	\$ (189,003 )
Loss per share - basic and diluted:	\$ (0.32 )	\$ (0.13 )	\$ (0.82 )	\$ (0.46 )	
Weighted average shares used in loss per share calculation:					
Basic	12,315	8,875	11,840	7,763	
Diluted	12,315	8,875	11,840	7,763	

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

**REPROS THERAPEUTICS INC.**  
(A development stage company)

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

	Common Stock Shares	Additional Paid-in Capital	Treasury Stock Shares	Stock Amount	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
Balance at December 31, 2010	9,042,372	\$ 9	\$ 183,782	112,350	\$ (1,380 ) \$ (179,244)	\$ 3,167
Stock based compensation	-	-	1,654	-	-	1,654
Issuance of 286,187 shares of common stock at a weighted average share price of \$2.90, net of offering costs of \$35	286,187	-	831	-	-	831
Exercise of 320,730 Series A Warrants to purchase common stock for cash @ \$0.01 per share	320,730	-	3	-	-	3
Issuance of 690,000 units at a price of \$17.15, net of offering costs of \$1,155	2,760,000	3	10,675	-	-	10,678
Issuance of 20,753 shares of common stock for the cashless exercise of 63,225 stock options	20,753	-	-	-	-	-
Net loss	-	-	-	-	(9,759 )	(9,759 )
Balance at September 30, 2011	12,430,042	\$ 12	\$ 196,945	112,350	\$ (1,380 ) \$ (189,003)	\$ 6,574

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

**REPROS THERAPEUTICS INC.**  
(A development stage company)

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

	From Inception (August 20, 1987) through		
	Nine Months Ended September 30, 2011	September 30, 2010	September 30, 2011
<b>Cash Flows from Operating Activities</b>			
Net loss	\$ (9,759 )	\$ (3,584 )	(189,003 )
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	-	(138 )	(709 )
Noncash decrease in accounts payable	-	-	(1,308 )
Depreciation and amortization	84	60	4,125
Noncash stock-based compensation	1,654	471	8,904
Common stock issued for agreement not to compete	-	-	200
Series B Preferred Stock issued for consulting services	-	-	18
<b>Changes in operating assets and liabilities</b>			
(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	140	(34 )	115
Increase (decrease) in accounts payable and accrued expenses	744	(536 )	10,214
Net cash used in operating activities	(7,137 )	(3,761 )	(165,784 )
<b>Cash Flows from Investing Activities</b>			
Change in trading marketable securities	-	-	(191 )
Capital expenditures	(15 )	(6 )	(2,393 )
Purchase of technology rights and other assets	(247 )	(297 )	(4,883 )
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	(262 )	(303 )	(5,064 )
<b>Cash Flows from Financing Activities</b>			
Proceeds from issuance of common stock, net of offering costs	11,509	6,394	173,908
Exercise of stock options & warrants	3	-	375

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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	11,512	6,394	177,918
Net increase (decrease) in cash and cash equivalents	4,113	2,330	7,070
Cash and cash equivalents at beginning of period	2,957	1,886	-
Cash and cash equivalents at end of period	\$ 7,070	\$ 4,216	\$ 7,070

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, 2011  
(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 are a development stage biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders.

Our portfolio of products includes:

Androxal®

- Phase 2B study: As a treatment for men of reproductive age with low testosterone levels that spares fertility, unlike testosterone replacement therapy; and
- Phase 2 study: As a treatment for improving glycemic control in hypogonadal men with Type 2 diabetes.

Proellex®

- Phase 2 (low dose) study: As a treatment of symptoms associated with uterine fibroids and endometriosis, subject to the current FDA partial clinical hold on the Proellex® clinical trials; however, the FDA has allowed us to run a single study to explore both safety and signals of efficacy in an escalating dose fashion. The new study is testing 5 different doses of Proellex® (1, 3, 6, 9 and 12mg).

Our product development pipeline is summarized in the table below:

Product Candidate (Indication)

	Status	Next Expected Milestone(s)
Androxal®	Phase 2B	Report top line Phase 2B results (Q4 2011)
Secondary Hypogonadism	Phase 2	Report top line Phase 2 results (Q4 2011)
Type 2 diabetes		
Proellex®		
Uterine Fibroids/Endometriosis	Phase 2	Complete low dose study (year end 2011) Commence Phase 3 studies (2012)
Vaginal Administration	Preclinical	Submit IND to FDA (Q4 2011) Commence Phase 3 studies (late 2012)
Second Generation Compounds	Preclinical	Complete preclinical screen (2012)

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 8, 2011, we completed an underwritten public offering of 690,000 units (including the exercise of the underwriter's over-allotment option), consisting of an aggregate of 2,760,000 shares of our common stock, Series A Warrants to purchase 2,070,000 shares of our common stock and Series B Warrants to purchase 1,690,500 shares of our common stock, at a price per unit of \$17.15. Each unit consisted of four shares of our common stock, Series A Warrants exercisable for three shares of our common stock at an exercise price of \$0.01 per share and Series B Warrants exercisable for 2.45 shares of our common stock at an exercise price of \$2.49 per share. Net proceeds to us, after offering expenses, were approximately \$10.7 million. The fair value of the Series A and Series B Warrants was determined using a Black-Scholes model with the following assumptions: risk-free interest rate of 0.18%; no dividend yield; volatility of 131.66% and an expected term of six months. This resulted in a fair value of the Series A and Series B Warrants of approximately \$5.4 million, which has been recorded in Additional Paid-In Capital on our Condensed Consolidated Balance Sheet. To date, 320,730 shares of our common stock have been issued from the exercise of the Series A Warrants at \$0.01 per share.

As of September 30, 2011, we had accumulated losses of \$189.0 million, approximately \$7.1 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately \$2.0 million. We believe we have sufficient funding to complete all of the Phase 2 and 2B clinical trials currently underway; however, significant additional capital will be required for us to complete development of either of our product candidates. Based on the current or planned clinical trials, we will need to raise additional capital no later than the second quarter of 2012. 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 completion of the outlined clinical trials; 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.

#### NOTE 2 — Patents and Patent Applications

As of September 30, 2011, the Company had approximately \$1.3 million in capitalized patent and patent application costs reflected on its balance sheet. This entire amount relates to patent and patent application costs for Androxal®.

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

#### NOTE 3 — Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2011	December 31, 2010
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Research and development costs	\$ 182	\$ 8
Personnel related costs	70	87
Other	70	34
Patent costs	26	18
<b>Total</b>	<b>\$ 348</b>	<b>\$ 147</b>



#### 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, 2011 and 2010 (in thousands, except per share amounts):

	Three Months Ended Sept. 30,	Nine Months Ended Sept. 30,		
	2011	2010	2011	2010
Net Loss	\$ (3,960 )	\$ (1,184 )	\$ (9,759 )	\$ (3,584 )
Average common shares outstanding	12,315	8,875	11,840	7,763
Basic and diluted loss per share	\$ (0.32 )	\$ (0.13 )	\$ (0.82 )	\$ (0.46 )

Other potential common stock of 5,260,795 common shares underlying stock options and warrants for the period ended September 30, 2011, which include Series A Warrants to purchase 1,749,270 shares of our common stock at an exercise price of \$0.01 and Series B Warrants to purchase 1,690,500 shares of our common stock at an exercise price of \$2.49 issued in our February 8, 2011 public offering, were excluded from the above calculation of diluted loss per share because they were anti-dilutive. Additionally, 538,582 common shares underlying stock options for the period ended September 30, 2010, were also excluded from the above calculation of diluted loss per share because they were anti-dilutive.

On February 28, 2011, our Board of Directors approved, and on June 1, 2011 the stockholders of the Company approved the 2011 Equity Incentive Plan (the “Plan”), which superseded and replaced our then-current two share based compensation plans, the 2000 Non-Employee Directors’ Stock Option Plan and the 2004 Stock Option Plan, subject to stockholder approval. Effective June 1, 2011, 885,000 stock option awards were granted under the Plan to employees and non-employee directors, of which 210,000 stock option awards vested immediately. This resulted in a non-cash charge of \$759,000 in June 2011 and is included in General and Administrative expenses in the Condensed Consolidated Statement of Operations for the nine month period ended September 30, 2011.

#### NOTE 5 — Commitments and Contingencies

Therapeutic uses of our Androxal® product candidate are covered in the United States by four issued U.S. patents and four pending patent applications. Foreign coverage of therapeutic uses of our Androxal® product candidate includes 44 issued foreign patents and 64 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. In our prior filings with the SEC, we have described our request to the U.S. Patent and Trademark Office, or PTO, for re-examination of one of these patents based on prior art. The third party amended the claims in the re-examination proceedings, which led the PTO to determine that the amended claims are patentable in view of those publications under consideration and a re-examination certificate was issued. However, we believe that the amended claims are invalid based on additional prior art publications, and we filed a second request for re-examination by the PTO in light

of a number of these additional publications and other publications cited by the PTO. 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 Board”) which affirmed the rejection of all of the claims. The patent holder subsequently filed a request for rehearing, which led the Board to reverse 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 Board. Principal briefing has been completed. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. Nevertheless, there is no assurance that either patent will ultimately be found invalid over the prior art. If such patents are not invalidated by the PTO we may be required to obtain a license from the holder of such patents in order to develop Androxal® further or attempts may be made to undertake further legal action to invalidate such patents. If such licenses were not available on acceptable terms, or at all, we may not be able to successfully commercialize or out-license Androxal®.

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 — Other Recent and Subsequent Events

On October 27, 2011, the Company’s board of directors (the “Board”) increased the size of the Board from five to six members and elected Dr. Michael Wyllie as a director of the Company to fill the vacancy created by such increase. In connection with Dr. Wyllie’s election to the Board, he was granted an option to purchase 40,000 shares of the Company’s common stock at an exercise price equal to the closing price per share for the Company’s common stock on the Nasdaq Capital Market on the date of such election. Such option will vest and become exercisable at a rate of one-twelfth (1/12) at the end of each quarter for the three (3) year period following the date of Dr. Wyllie’s election to the Board, based on continuing service to the Company.

## 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", "RPRX," "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.

We are developing Androxal®, an oral therapy that normalizes testicular function, for the treatment of low testosterone due to secondary hypogonadism. Secondary hypogonadism is associated with obesity and we believe it is among the most common causes of low testosterone in men. It is estimated that 13 million men in the U.S. experience low levels of testosterone, and the condition is becoming recognized with more frequency. In 2010, for the first time, sales of preparations for the treatment of low testosterone exceeded \$1 billion in the U.S. and first tier pharmaceutical companies have entered the low testosterone marketplace.

The Company believes Androxal® is highly differentiated from currently marketed testosterone treatments or those treatments in late stage development because it is an oral therapy and it treats the cause of secondary hypogonadism, which is inadequate pituitary hormones. We believe that by treating the cause of secondary hypogonadism it also has the potential to maintain reproductive status and potentially improve overall metabolic profiles, which we believe may improve the condition of men suffering from Type 2 diabetes. The Company held a Type B meeting with the Food and Drug Administration ("FDA") on November 8, 2010 to discuss the FDA's willingness to review Phase 3 protocols under a Special Protocol Assessment ("SPA"). Although the FDA advised the Company that it may proceed with Phase 3 studies, the FDA recommended that a Phase 2B study in men with secondary hypogonadism, but naïve to testosterone treatment, be conducted if the Company desired the protocols to be reviewed under an SPA. We received Investigational Review Board ("IRB") approval to commence the Phase 2B study of Androxal® in men with secondary hypogonadism in January of 2011, and we have completed enrollment of patients. We hope to have the study completed by the end of 2011.

The Company is also currently conducting a Phase 2 study of the use of Androxal® as a treatment for improving glycemic control in hypogonadal men with Type 2 diabetes. Retrospective analysis of completed Androxal® studies showed that Androxal® improved fasting plasma glucose levels in men with Type 2 diabetes, an improvement not seen in similar subjects using a topical testosterone or placebo. The Company believes this effect is directly related to Androxal®'s ability to normalize the hypothalamic-pituitary-testes pathway and organ function.

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® had shown statistically significant results in previous Phase 2 studies for endometriosis and uterine fibroids. The Company is currently conducting a low dose escalating study as permitted by the FDA, which is intended to determine both signals of efficacy and safety for low oral doses of the drug. The Company has

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recently commenced the last cohort (i.e. 12mg) of such low dose study, which the Company anticipates will be completed by the end of 2011.

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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 shortly will place both programs on a clear late stage clinical development path and a solid position for licensing.

As of September 30, 2011, we had accumulated losses of \$189.0 million, approximately \$7.1 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately \$2.0 million. We believe we have sufficient funding to complete all of the Phase 2 and 2B clinical trials currently underway; however, significant additional capital will be required for us to complete development of either of our product candidates. Based on the current or planned clinical trials, we will need to raise additional capital no later than the second quarter of 2012. 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 completion of the outlined clinical trials; 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. In addition, we are conducting a Phase 2 clinical trial of Androxal® as a potential treatment for improving glycemic control in hypogonadal men with Type 2 diabetes.

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, but is 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 a meeting held with the FDA in the fourth quarter of 2007, however, the FDA determined that improved testosterone levels alone were not sufficient to grant approval for the drug. In the meeting held on November 8, 2010, the FDA changed its position and determined that improved testosterone levels would be sufficient to grant approval for the drug.

We also believe there may be an association between the restoration of normal pituitary function and improvement of metabolic conditions such as Type 2 diabetes. Research has been published which demonstrates that increased insulin resistance, a characteristic implicated in Type 2 diabetes, is associated with the onset of secondary hypogonadism. Based on our own clinical trial screening data, we have found hypogonadism, obesity and Type 2 diabetes to be comorbid conditions in a significant number of men. A retrospective analysis of the clinical trial data from our completed Androxal® studies showed that Androxal® improved fasting plasma glucose levels in men with Type 2 diabetes, suggesting that Androxal® modifies the endocrinologic profile in terms of both hormones and certain metabolic measures. This improvement was not seen in similar subjects using a topical testosterone or placebo. In a large trial conducted by Solvay Pharmaceuticals, AndroGel® was found to have no positive effect on glycemic control in hypogonadal men who were also Type 2 diabetic regardless of how much the exogenous testosterone concentration increased. Contrary to the results seen with exogenous testosterone, Androxal® did exhibit positive effects on glycemic control, and we believe these effects are directly related to Androxal®'s ability to normalize the hypothalamic-pituitary-testes pathway and organ function.

Androxal® will be required to undergo the full regulatory approval process, including the current Phase 2B trial, pivotal Phase 3 trial and long-term Open Label Safety Studies 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 in the human body 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 our current Phase 2 trials, and 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 the Company 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. In our 24-patient Phase 2B proof-of-concept clinical trial which was initiated in the second quarter of 2008, we monitored the effects of Androxal® on male fertility and testicular function in patients being treated for low testosterone as compared to Testim®, a popular marketed topical testosterone medication. This trial

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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.

The Company's Phase 2B trial consists of four arms; placebo, two doses of Androxal® and topical testosterone. At baseline the men should exhibit morning testosterone less than 250 ng/dl. The primary endpoint will consist of total testosterone at the end of the three month study compared to baseline. Impact on reproductive status (sperm counts) will be assessed as a safety endpoint. In a previous study, we found a statistically significant improvement in morning testosterone in a subset of men with morning testosterone less than 250 ng/dl and no deterioration of FSH in Androxal®-treated men. However, in the men on topical testosterone, 26 out of the 41 men that completed three months of dosing exhibited FSH levels below the reference limits for the hormone, with 17 below the lower limit of detection.

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. We combined the three studies into one analysis, which has been submitted for FDA review. This analysis provides 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. We have committed to conduct one additional 24 hour study to show that Androxal®'s action in maintaining the normal rhythm is both predictable and dose-dependent. Enrollment is completed in this study and data should be presented by year end 2011.

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.

#### Type 2 Diabetes

Our findings from a retrospective review of the clinical data from our 200 patient non-pivotal Phase 2 clinical trial showed that Androxal® therapy resulted in a significant reduction in mean fasting plasma glucose levels in men with glucose levels greater than 104 mg/dL at the outset of the trial, an outcome not seen in the placebo or AndroGel® arms of this study. Based on these results, in April 2008, we submitted a White Paper to the Division of Reproductive and Urology Products. The data demonstrated that among subjects with a serum glucose of greater than or equal to 105 mg/dL, there was a higher response rate to treatment in the Androxal® group than the placebo or AndroGel® groups, and the reduction in fasting serum glucose in this group was statistically significant. In November 2008, after the FDA reviewed this paper we received guidance from them suggesting that we open an Investigational New Drug Application ("IND") with the Division of Metabolic and Endocrine Products, or DMEP, for the investigation of Androxal® as a potential treatment for Type 2 diabetes. In December 2009, we submitted an IND to DMEP for the investigation of Androxal® for such purpose. On February 1, 2010, we received confirmation from DMEP that our IND was accepted and, as a result, we have initiated our Phase 2 trial. This trial has completed enrollment of 115 men with morning testosterone levels under 300 ng/dl who also have a fasting glucose level between 125 mg and 240 mg per deciliter and glycosylated hemoglobin, or HbA1c, levels between 7% and 9.5% - levels indicative of poor glucose control. Enrolled patients also have been on a stable dose of an oral hypoglycemic agent for at least 2 months. The study consists of splitting the men into three arms, one placebo and two doses of Androxal®, at 12.5 and 25 mg. We will look at changes in fasting glucose and HbA1C levels from baseline, along with changes in testosterone level. On August 3, 2011, the Company announced that top line unaudited results of this study yield statistically significant and clinically relevant reductions in glycosylated hemoglobin ("HbA1c") in men achieving morning testosterone levels >450ng/dl after three months of treatment. The full study results, expected at year end 2011, may differ from this interim analysis.

## 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® enrolling over 750 women, roughly 700 of whom were dosed 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, the Company petitioned the FDA to allow it 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, which we have since commenced and is currently in the last cohort (i.e. 12mg).

In addition, the Company has undertaken two related initiatives presently at the preclinical stage. The first is the exploration of vaginal delivery as an alternative administrative route to bypass first-pass liver effects and reduce systemic exposure. The second is the screening of second generation molecules that do not possess the specific structures the Company believes 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 is allowing us to run a single study to test low doses of Proellex® for signals of safety and efficacy. The new study is testing 5 different doses of Proellex® (1, 3, 6, 9 and 12 mg), with 1 mg being the first dose tested. Each dose will be compared to placebo with weekly assessments of liver function during both the placebo and drug period. Subjects will be dosed with the active drug for 10 weeks, which will allow for adequate time to determine the impact of a given dose on trends in liver function. Each dose is/was tested in up to 12 different subjects and assessment of pharmacokinetic parameters will be 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 monitor 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®.

At September 20, 2011, we began enrolling subjects in the study of the 12mg dose. We believe we can complete the trial by year end 2011. To date, no women in this study have exhibited elevated liver enzymes indicative of an adverse event. Presuming a safe and effective dose is identified and the FDA is in agreement, we believe that we will be able to proceed with large Phase 3 efficacy trials for both uterine fibroids and endometriosis in 2012, subject to available funds, or out-license the product to a major pharmaceutical company. We believe that the evaluation of ovulation and menstrual bleeding patterns in the low dose trial will provide strong evidence for efficacy warranting further development.

### 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. Based on the outcome of dose optimization and vaginal irritation studies and a pre-IND meeting with the FDA, we plan to submit to the FDA an IND for both uterine fibroids and endometriosis by the end of 2011. We believe we will be able to leverage the experience we have gained with the oral dose in the preparation of this IND, and after a single Phase 1/2 study we will be able to test the vaginal product in a pivotal Phase 3 study.

### Second Generation Compound

We believe we understand the cause of the liver toxicity observed at high doses in the prior Phase 3 Proellex® studies. Our hypothesis is that liver adverse events are associated with a specific part of the chemical structure of Proellex®. To that end we have synthesized new but related molecules that we believe are devoid of the specific toxicity-causing part of the chemical structure of Proellex® and initial preclinical screening has begun. If we are successful in identifying such a molecule, we believe we will be able to achieve high oral doses and systemic exposure, opening the path to aggressive anti progestin therapy for conditions such as breast cancer. We expect to have completed our screen of the new molecules sometime in 2012.

### 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) the current escalating low dose study for Proellex® permitted by the FDA, (ii) the ongoing Phase 2B fertility trial for Androxal®, (iii) the ongoing Type 2 diabetes trial for Androxal®, (iv) preclinical assessment of vaginal delivery of Proellex® and (v) completing the initial identification of potential second generation Proellex® molecules. We anticipate that our current liquidity will be sufficient to complete all of these objectives; however, significant additional capital will be required for us to complete development of either of our product candidates or any new product candidates. 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.

## 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, 2010 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, 2011, we had accumulated losses of \$189.0 million, approximately \$7.1 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately \$2.0 million. We believe we have sufficient funding to complete all of the Phase 2 and 2B clinical trials currently underway; however, significant additional capital will be required for us to complete development of either of our product candidates. Based on the current or planned clinical trials, we will need to raise additional capital no later than the second quarter of 2012. 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 completion of the outlined clinical trials; 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](http://www.reprosrx.com). The information on our website or any other website is not incorporated by reference into this quarterly report and does not constitute a part of this quarterly report. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and all amendments to such reports are made available free of charge through the Investor Relations section of our website as soon as reasonably practicable after they have been filed or furnished with the Securities and Exchange Commission.

## General

We have experienced negative cash flows from operations since inception and have funded our activities to date primarily from equity financings and corporate collaborations. Based on our current and planned clinical trials, we will need to raise additional capital no later than the second quarter of 2012. 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 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 completion of the outlined clinical trials; 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.

We currently have 13 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, 2011 and the value of the tax asset associated with these accumulated net operating losses can be substantially diminished in value due to various tax regulations, including change in control provisions in the tax code. The Company's public offerings completed on February 5, 2007, October 2, 2008, September 11, 2009, October 13, 2009, February 8, 2011, the sale and issuance of the ATM Shares and the issuance of unregistered shares as part of various settlement agreements may have created a change of ownership for Federal income tax purposes. The Company has 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®. As of September 30, 2011, other assets consist of capitalized patent and patent application costs in the amount of \$1.3 million. 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 \$28,000 and \$21,000 for the three month periods ended September 30, 2011 and 2010, respectively, and was \$80,000 and \$50,000 for the nine month periods ended September 30, 2011 and 2010, respectively. The entire \$1.3 million in capitalized patents and patent applications relates to Androxal®.

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, 2011.

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

### Accrued Expenses

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

### R&D Expense

Research and development, or R&D, expenses include salaries and related employee expenses, contracted regulatory affairs activities, insurance coverage for clinical trials and prior product sales, contracted research and consulting fees, facility costs, amortization of capitalized patent costs and internal research and development supplies. We expense research and development costs in the period they are incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research on our behalf.

## Share-Based Compensation

On February 28, 2011, our Board of Directors approved, and on June 1, 2011 the stockholders of the Company approved the 2011 Equity Incentive Plan (the “Plan”), which superseded and replaced our then-current two share based compensation plans, the 2000 Non-Employee Directors’ Stock Option Plan and the 2004 Stock Option Plan, subject to stockholder approval. 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.

Effective June 1, 2011, 885,000 stock option awards were granted under the Plan to employees and non-employee directors, of which 210,000 stock option awards vested immediately. This resulted in a non-cash charge of \$759,000 in June 2011 and is included in General and Administrative expenses in the Condensed Consolidated Statement of Operations for the nine month period ended September 30, 2011.

## Income Taxes

Our losses from inception to date have resulted principally from costs incurred in conducting clinical trials and in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. We have recorded a deferred tax asset for our net operating losses (“NOL”); however, as the Company has incurred losses since inception, and since there is no certainty of future profits, a valuation allowance has been provided in full on our deferred tax assets in the accompanying consolidated financial statements. If the Company has an opportunity to use this NOL to off-set tax liabilities in the future, the use of this asset would be restricted based on Internal Revenue Service, state and local NOL use guidelines. The Company’s public offerings completed on February 5, 2007, October 2, 2008, September 11, 2009, October 13, 2009, February 8, 2011, the sale and issuance of the ATM Shares and the issuance of unregistered shares as part of various settlement agreements may have created a change of ownership for Federal Income tax purposes. The Company has 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, 2011 and 2010

#### Revenues and Other Income

Total revenues and other income decreased to zero for the three month period ended September 30, 2011 as compared to \$85,000 for the same period in the prior year and decreased to \$1,000 for the nine month period ended September 30, 2011 as compared to \$138,000 for the same period in the prior year. The decrease for the three month and nine month periods ended September 30, 2011 was primarily due to a decrease of \$85,000 and \$138,000, respectively, in non-cash other income related to debt relief from settlements with certain vendors in the second and third quarters of 2010.

#### Research and Development Expenses

Research and development (“R&D”) expenses include contracted services relating to our clinical product development activities which include preclinical studies, clinical trials, regulatory affairs and bulk manufacturing scale-up activities and bulk active ingredient purchases for preclinical and clinical trials primarily relating to our two products in clinical development, which are Androxal® and Proellex®. Research and development expenses also include internal operating expenses relating to our general research and development activities. R&D expenses increased 339% or approximately \$2.5 million to \$3.2 million for the three month period ended September 30, 2011 as compared to \$736,000 for the same period in the prior year. Our primary R&D expenses for the three month periods ended September 30, 2011 and 2010 are shown in the following table (in thousands):

	Three-months ended Sept. 30, 2011	Three-months ended Sept. 30, 2010	Variance	Change (%)
Research and Development				
Androxal® clinical development	\$ 2,138	\$ 163	\$ 1,975	1,212 %
Proellex® clinical development	277	262	15	6 %
Payroll and benefits	421	159	262	165 %
Operating and occupancy	398	152	246	162 %
Total	\$ 3,234	\$ 736	\$ 2,498	339 %

R&D expenses increased 258% or approximately \$5.0 million to \$7.0 million for the nine month period ended September 30, 2011 as compared to \$2.0 million for the same period in the prior year. Our primary R&D expenses for the nine month periods ended September 30, 2011 and 2010 are shown in the following table (in thousands):

	Nine-months ended Sept. 30, 2011	Nine-months ended Sept. 30, 2010	Variance	Change (%)
Research and Development				
Androxal® clinical development	\$ 4,366	\$ 177	\$ 4,189	2,367 %
Proellex® clinical development	820	844	(24 )	(3 )%
Payroll and benefits	875	421	454	108 %
Operating and occupancy	919	508	411	81 %
Total	\$ 6,980	\$ 1,950	\$ 5,030	258 %

The increase in R&D expenses for both the three and nine month periods ended September 30, 2011 is primarily due to the increased clinical development expenses related to Androxal® as a result of the ongoing Phase 2b study in men with secondary hypogonadism and the Phase 2 study as a potential treatment for improving glycemic control in hypogonadal men with Type 2 diabetes. Payroll and benefits expenses increased due to increased headcount and the discontinuation of the salary reduction program put in place in August 2009 for all salaried R&D employees. Additionally, operating and occupancy expenses increased due to an increase in costs related to our patent portfolio. Based on our current and planned clinical trials, it is anticipated that R&D expenses will continue to increase at approximately the same rate for the remainder of the year.

To date through September 30, 2011 we have incurred approximately \$19.1 million for the development of Androxal® and approximately \$57.1 million for the development of Proellex®. These accumulated costs exclude any internal operating expenses.

#### General and Administrative Expenses

General and administrative expenses ('G&A") increased 36% or approximately \$193,000 to \$726,000 for the three month period ended September 30, 2011 as compared to \$533,000 for the same period in the prior year. Our primary G&A expenses for the three month period ended September 30, 2011 and 2010 are shown in the following table (in thousands):

	Three-months ended Sept. 30, 2011	Three-months ended Sept. 30, 2010	Variance	Change (%)
General and Administrative				
Payroll and benefits	\$ 469	\$ 155	\$314	203 %
Operating and occupancy	257	378	(121 )	(32 )%
Total	\$ 726	\$ 533	\$193	36 %

G&A payroll and benefits expenses include salaries, 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 \$299,000 for the three month period ended September 30, 2011 as compared to \$79,000 for the same period in the prior year. Additionally, salaries for the three month period ended September 30, 2011 were \$150,000 as compared to \$68,000 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 for all salaried employees other than Mr. Podolski, the Company's President and CEO, and Mr. Podolski's salary was revised to a 25% reduction on January 1, 2011.

G&A operating and occupancy expenses, which include expenses to operate as a public company, decreased 32% or approximately \$121,000 to \$257,000 for the three month period ended September 30, 2011 as compared to \$378,000 for the same period in the prior year. The decrease is primarily due to a decrease in professional services.

G&A expenses increased 57% or approximately \$1.0 million to \$2.8 million for the nine month period ended September 30, 2011 as compared to \$1.8 million for the same period in the prior year. Our primary G&A expenses for the nine month period ended September 30, 2011 and 2010 are shown in the following table (in thousands):

	Nine-months ended Sept. 30, 2011	Nine-months ended Sept. 30, 2010	Variance	Change (%)
General and Administrative				
Payroll and benefits	\$ 1,762	\$ 460	\$1,302	283 %
Operating and occupancy	1,018	1,312	(294 )	(22 )%
Total	\$ 2,780	\$ 1,772	\$1,008	57 %

G&A payroll and benefits expenses include salaries, 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 \$1.3 million for the nine month period ended September 30, 2011 as compared to \$230,000 for the same period in the prior year. Non-cash stock based compensation includes a charge of \$759,000 in June 2011 associated with 210,000 stock option awards issued under the 2011 Equity Incentive Plan approved by the stockholders of the Company on June 1, 2011, which vested immediately upon stockholders' approval. Additionally, salaries for the nine month period ended September 30, 2011 were \$380,000 as compared to \$197,000 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 for all salaried employees other than Mr. Podolski, the Company's President and CEO, and Mr. Podolski's salary was revised to a 25% reduction on January 1, 2011.

G&A operating and occupancy expenses, which include expenses to operate as a public company, decreased 22% or approximately \$294,000 to \$1.0 million for the nine month period ended September 30, 2011 as compared to \$1.3 million for the same period in the prior year. The decrease is primarily due to a decrease in professional services.

#### Off-Balance Sheet Arrangements

As of September 30, 2011, 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, 2011 and September 30, 2011 we have sold an aggregate of 286,187 ATM Shares at a weighted average share price of \$2.90, for proceeds of approximately \$831,000, net of expenses. Between July 1, 2011 and September 30, 2011, no ATM Shares were sold. Cumulative through September 30, 2011, we have sold 2,734,760 ATM Shares at a weighted average share price of \$2.79, for proceeds of approximately \$7.2 million, net of expenses. Pursuant to General Instruction I.B.6. of Form S-3, we may not sell more than one-third of the aggregate market value of our common stock held by non-affiliates during a period of 12 calendar months immediately prior to, and including, the date of such sale of such common stock.

On February 8, 2011, we completed an underwritten public offering (the “Public Offering”) of 690,000 units (including the exercise of the underwriter’s over-allotment option), consisting of an aggregate of 2,760,000 shares of our common stock, Series A Warrants to purchase 2,070,000 shares of our common stock and Series B Warrants to purchase 1,690,500 shares of our common stock, at a price per unit of \$17.15. Each unit consisted of four shares of our common stock, Series A Warrants exercisable for three shares of our common stock at an exercise price of \$0.01 per share and Series B Warrants exercisable for 2.45 shares of our common stock at an exercise price of \$2.49 per share. Net proceeds to us, after offering expenses, were approximately \$10.7 million. The fair value of the Series A and Series B Warrants was determined using a Black-Scholes model with the following assumptions: risk-free interest rate of 0.18%; no dividend yield; volatility of 131.66% and an expected term of six months. This resulted in a fair value of the Series A and Series B Warrants of approximately \$5.4 million, which has been recorded in Additional Paid-In Capital on our Condensed Consolidated Balance Sheet. To date, 320,730 shares of our common stock have been issued from the exercise of the Series A Warrants at \$0.01 per share.

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 \$7.1 million as of September 30, 2011 as compared to \$3.0 million as of December 31, 2010. All cash and cash equivalents as of September 30, 2011 and December 31, 2010 were held in an account backed by U.S. government securities.



Net cash of approximately \$7.1 million and \$3.8 million was used in operating activities during the nine month period ended September 30, 2011 and 2010, respectively. The major use of cash for operating activities through September 30, 2011 was to fund our operations, partially offset by an increase in current liabilities. Cash used in investing activities during the nine month period ended September 30, 2011 was approximately \$262,000 primarily for capitalized patent and patent application costs for Androxal®. Cash provided by financing activities during the nine month period ended September 30, 2011 was approximately \$11.5 million primarily due to the Public Offering and the 286,187 ATM Shares sold at a weighted average share price of \$2.90.

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 2012. 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. 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. 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, 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 new 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 \$7.1 million at September 30, 2011 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 realized 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, 2011.

##### 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, 2011 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 four issued U.S. patents and four pending patent applications. Foreign coverage of therapeutic uses of our Androxal® product candidate includes 44 issued foreign patents and 64 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. In our prior filings with the SEC, we have described our request to the U.S. Patent and Trademark Office, or PTO, for re-examination of one of these patents based on prior art. The third party amended the claims in the re-examination proceedings, which led the PTO to determine that the amended claims are patentable in view of those publications under consideration and a re-examination certificate was issued. However, we believe that the amended claims are invalid based on additional prior art publications, and we filed a second request for re-examination by the PTO in light of a number of these additional publications and other publications cited by the PTO. 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 Board”) which affirmed the rejection of all of the claims. The patent holder subsequently filed a request for rehearing, which led the Board to reverse 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 Board. Principal briefing has been completed. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. Nevertheless, there is no assurance that either patent will ultimately be found invalid over the prior art. If such patents are not invalidated by the PTO we may be required to obtain a license from the holder of such patents in order to develop Androxal® further or attempts may be made to undertake further legal action to invalidate such patents. If such licenses were not available on acceptable terms, or at all, we may not be able to successfully commercialize or out-license Androxal®.

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, 2010 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.

None

Item 3. Defaults Upon Senior Securities.

None

Item 4. (Removed and Reserved).

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+ Employment Agreement dated August 1, 2011 by and between the Company and Katherine A. Anderson. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on August 4, 2011 is incorporated herein by reference.

31.1\* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).

31.2\* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).

32.1\* Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).

32.2\* Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).

\* Filed herewith.

+ Management contract or compensatory plan.

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 10, 2011

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

Date: November 10, 2011

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