REPROS THERAPEUTICS INC.
Form 10-Q
August 13, 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 June 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 The Woodlands, Texas 77380	76-0233274

(State or other jurisdiction of incorporation or organization)	(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 August 6, 2012, there were outstanding 14,833,989 shares of Common Stock, par value $.001 per share, of the Registrant.

REPROS THERAPEUTICS INC.

(A development stage company)

For the Quarter Ended June 30, 2012

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FACTORS AFFECTING FORWARD-LOOKING STATEMENTS

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

	June 30, 2012	December 31, 2011
ASSETS		
Current Assets		
Cash and cash equivalents	$9,939	$4,565
Prepaid expenses and other current assets	245	99
Total current assets	10,184	4,664
Fixed assets, net	37	15
Other assets, net	1,727	1,385
Total assets	$11,948	$6,064
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$1,199	$1,145
Accrued expenses	241	253
Total current liabilities	1,440	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, 14,946,339 and 12,470,694 shares issued, respectively and 14,833,989 and 12,358,344 shares outstanding, respectively	15	12
Additional paid-in capital	209,147	197,769
Cost of treasury stock, 112,350 shares	(1,380)	(1,380)
Deficit accumulated during the development stage	(197,274)	(191,735)
Total stockholders' equity	10,508	4,666
Total liabilities and stockholders' equity	$11,948	$6,064

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

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

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

	Three Months Ended June 30,		Six Months Ended June 30,		From Inception (August 20, 1987) through June 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	2,178	2,267	3,644	3,747	185,560
General and administrative	922	1,418	1,896	2,053	49,989
Interest expense and amortization of intangibles	-	-	-	-	388
Total expenses	3,100	3,685	5,540	5,800	235,937
Loss from continuing operations	(3,100)	(3,684)	(5,539)	(5,799)	(187,931)
Loss from discontinued operations	-	-	-	-	(1,828)
Gain on disposal of discontinued operation	-	-	-	-	939
Net loss before cumulative effect of change in accounting principle	(3,100)	(3,684)	(5,539)	(5,799)	(188,820)
Cumulative effect of change in accounting principle	-	-	-	-	(8,454)

Net loss	$ (3,100)	$ (3,684)	$ (5,539)	$ (5,799)	$ (197,274)
Loss per share - basic and diluted:	$ (0.21)	$ (0.30)	$ (0.38)	$ (0.50)	
Weighted average shares used in loss per share calculation:					
Basic	14,826	12,296	14,404	11,598	
Diluted	14,826	12,296	14,404	11,598	

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 Shares	Amount	Additional Paid-in Capital	Treasury Stock Shares	Amount	Deficit Accumulated During the Development Stage	Total Stockholders Equity
Balance at December 31, 2011	12,470,694	$12	$197,769	112,350	$(1,380)	$(191,735)	$4,666
Stock based option compensation	-	-	1,022	-	-	-	1,022
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 option to purchase common stock for cash @ $4.80 per share	8,333	-	40	-	-	-	40
Exercise of 3,675 Series B Warrants to purchase common stock for cash @ $2.49 per share	3,675	-	9	-	-	-	9
Net loss	-	-	-	-	-	(5,539)	(5,539)
Balance at June 30, 2012	14,946,339	$15	$209,147	112,350	$(1,380)	$(197,274)	$10,508

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)

	Six Months Ended June 30,		From Inception (August 20, 1987) through June 30,
	2012	2011	2012
Cash Flows from Operating Activities			
Net loss	$(5,539)	$(5,799)	(197,274)
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	68	54	4,224
Noncash stock-based compensation	1,022	1,159	10,555
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	(147)	130	57
Increase (decrease) in accounts payable and accrued expenses	(5)	361	9,565
Net cash used in operating activities	(4,601)	(4,095)	(173,012)
Cash Flows from Investing Activities			
Change in trading marketable securities	-	-	(191)
Capital expenditures	(28)	(15)	(2,421)
Capitalization of technology rights and other assets	(356)	(108)	(5,312)
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	(384)	(123)	(5,521)
Cash Flows from Financing Activities			
Proceeds from issuance of common stock, net of offering costs	10,310	11,509	184,413
Exercise of stock options & warrants	49	3	424
Proceeds from a shareholder transaction	-	-	327
Proceeds from issuance of preferred stock	-	-	23,688
Purchase of treasury stock	-	-	(21,487)
Proceeds from issuance of notes payable	-	-	2,839
Principal payments on notes payable	-	-	(1,732)
Net cash provided by financing activities	10,359	11,512	188,472
Net increase (decrease) in cash and cash equivalents	5,374	7,294	9,939
Cash and cash equivalents at beginning of period	4,565	2,957	-
Cash and cash equivalents at end of period	$9,939	$10,251	$ 9,939

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

June 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.

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 January 3, 2012, we announced the completion of a low dose study to demonstrate both safety and signals of efficacy in low oral doses of Proellex®. Additionally, the Food and Drug Administration (“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.

Our product development pipeline is summarized in the table below:

Product Candidate (Indication) Status Next Expected Milestone(s)

Androxal®		
		Commence Phase 3 pivotal study (Q3 2012)
Secondary Hypogonadism	Phase 3	
		Commence DEXA study (Q3 2012)
Proellex®		
		Complete Phase 2 study (vaginal delivery) (Q4 2012)
Uterine Fibroids	Phase 2	
		Commence Phase 3 study (vaginal delivery) (Q1 2013)
Endometriosis		Commence Phase 2 study (oral delivery) (Q3 2012)
	Phase 2	

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. Through the May 9, 2012 meeting, we had safety data for approximately 70 subjects for one year and 150 subjects for six months. 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 and are expected to be initiated in the third quarter of 2012. Additionally, we began enrolling men into a 500 subject open label safety study in June 2012 and will begin 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 quarter of 2014.

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. The FDA has agreed to update the full clinical hold to a partial clinical hold once an agreement is reached on the design of a Phase 2 study protocol. This, however, does not affect Proellex®-V, the proprietary vaginal delivery formulation of telapristone acetate which has its own unique pharmacodynamics and is being studied under a separate IND. 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 in the treatment of uterine fibroids and we intend to report the study results around the end of the year. 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.

As of June 30, 2012, we had accumulated losses of $197.3 million, approximately $9.9 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $1.4 million. We anticipate that our current liquidity will be sufficient to continue these planned studies into the second quarter of 2013; however, significant additional capital will be required for us to complete the studies and development of either of our product candidates. 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.

NOTE 2 — Patents and Patent Applications

As of June 30, 2012, we had approximately $1,727,000 in capitalized patent and patent application costs reflected on its balance sheet. Of this amount, $1,523,000 relates to patent and patent application costs for Androxal® and $204,000 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):

	June 30, 2012	December 31, 2011
Patent costs	$99	$ 51
Other	73	45
Research and development costs	44	87
Personnel related costs	25	70
Total	$241	$ 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 six month periods ended June 30, 2012 and 2011 (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Net Loss	$(3,100)	$(3,684)	$(5,539)	$(5,799)
Average common shares outstanding	14,826	12,296	14,404	11,598
Basic and diluted loss per share	$(0.21)	$(0.30)	$(0.38)	$(0.50)

Potential common stock of 5,362,348 and 5,144,172 common shares underlying stock options and warrants for the periods ended June 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 June 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 June 30, 2012 and 2011, are Series B Warrants to purchase 1,686,825 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.

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 seven pending patent applications. Foreign coverage of therapeutic uses of our Androxal® product candidate includes 52 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

Under the terms of the Series B Warrants issued in our February 8, 2011 public offering, we may require the exercise of all of the Series B Warrants if our common stock trades at or above $8.00 per share for a period of at least 20 trading days of 30 consecutive trading days, on sixty days notice. In the event that a Holder of Series B Warrants is restricted from exercising the Warrants pursuant to the terms of Section 6(e) of the Warrant Agreement (which provides for certain beneficial ownership limitations), the Holder is required to use commercially reasonable efforts to sell shares of Common Stock of the Company held by such Holder to the extent necessary to allow such Holder to exercise the Series B Warrants without the restrictions of such Section 6(e). On July 3, 2012, our common stock reached this price threshold. Currently, there are 1,686,825 Series B Warrants outstanding with an exercise price of $2.49 per share.

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 and are expected to be initiated in the third quarter of 2012. Additionally, we began enrolling men into a 500 subject open label safety study in June 2012 and will begin 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 quarter of 2014.

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. The FDA has agreed to update the full clinical hold to a partial clinical hold once an agreement is reached on the design of a Phase 2 study protocol.

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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 2010, 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") and are expected to be initiated in the third quarter of 2012. Additionally, we began enrolling men into a 500 subject open label safety study in June 2012 and will begin enrolling men into a one year dual-energy X ray absorptiometry ("DEXA") study in the third quarter of 2012.

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 July 16, 2012, we announced that we held a teleconference with the FDA to discuss the development of oral Proellex® as a treatment for endometriosis. The FDA has agreed to update the full clinical hold to a partial clinical hold once an agreement is reached on the design of a Phase 2 study protocol. We intend to commence a Phase 2 low dose oral administration study for endometriosis in the third quarter of 2012.

The FDA has accepted an Investigational New Drug Application ("IND") for vaginally delivered Proellex® and, as a result, we commenced a Phase 2 vaginal administration study for uterine fibroids in the first quarter of 2012. At the end of July 2012, we satisfied our enrollment requirement of subjects for the Phase 2 study and intend to report the 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 in the first quarter of 2013. 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®		
		Commence Phase 3 pivotal study (Q3 2012)
Secondary Hypogonadism	Phase 3	
		Commence DEXA study (Q3 2012)
Proellex®		
		Complete a Phase 2 study (vaginal delivery) (Q4 2012)
Uterine Fibroids	Phase 2	
		Commence Phase 3 study (vaginal delivery) (Q1 2013)
Endometriosis		Commence Phase 2 study (oral delivery) (Q3 2012)
	Phase 2	

As of June 30, 2012, we had accumulated losses of $197.3 million, approximately $9.9 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately $1.4 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. We anticipate that our current liquidity will be sufficient to continue these planned studies into the second quarter of 2013; however, significant additional capital will be required for us to complete the studies and development of either of our product candidates. 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