

REPROS THERAPEUTICS INC.

Form 10-Q

May 11, 2009

**Table of Contents**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10-Q**

(Mark One)

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

**For the quarterly period ended March 31, 2009**

**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 a smaller reporting company. See the definitions of large accelerated filer, 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   
(Do not check if a 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 May 4, 2009, there were outstanding 15,174,904 shares of Common Stock, par value \$.001 per share, of the Registrant.

**REPROS THERAPEUTICS INC.**  
(A development stage company)  
For the Quarter Ended March 31, 2009  
**INDEX**

	<b>Page</b>
<b><u>FACTORS AFFECTING FORWARD-LOOKING STATEMENTS</u></b>	<b>3</b>
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<u>Item 1. Financial Statements (unaudited)</u>	4
<u>Unaudited Condensed Consolidated Balance Sheets as of March 31, 2009 and December 31, 2008.</u>	5
<u>Unaudited Condensed Consolidated Statements of Operations for the three months ended March 31, 2009 and 2008 and from Inception (August 20, 1987) through March 31, 2009</u>	6
<u>Unaudited Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2009</u>	7
<u>Unaudited Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2009 and 2008 and from Inception (August 20, 1987) through March 31, 2009</u>	8
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	9
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	25
<u>Item 4. Controls and Procedures</u>	25
<b><u>PART II. OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	26
<u>Item 1A. Risk Factors</u>	26
<u>Item 5. Other Information</u>	26
<u>Item 6. Exhibits</u>	26
<b><u>SIGNATURES</u></b>	<b>28</b>
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	
<u>EX-32.2</u>	

**Table of Contents**

**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 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 raise additional capital on acceptable terms or at all, the continued development of Proellex® and Androxal® and 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 Item 1. Business and Item 1A. Risk Factors included in the Company's Annual Report on Form 10-K for the year ended December 31, 2008 and 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.

**Table of Contents**

**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

The following unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (which include only normal recurring adjustments) considered necessary for a fair statement of the interim periods presented have been included. The year-end balance sheet data was derived from audited financial statements, but does not include all the disclosures required by accounting principles generally accepted in the United States of America. Operating results for the three-month period ended March 31, 2009 are not necessarily indicative of the results that may be expected for the year ended December 31, 2009. 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, 2008.

**Table of Contents**

**REPOS THERAPEUTICS INC. AND SUBSIDIARY**  
(A development stage company)  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(unaudited and in thousands except share and per share amounts)

	<b>March 31, 2009</b>	<b>December 31, 2008</b>
<b>ASSETS</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 12,402	\$ 19,470
Prepaid expenses and other current assets	2,240	1,392
Total current assets	14,642	20,862
<b>Fixed assets, net</b>	23	28
<b>Other assets, net</b>	1,840	1,713
Total assets	\$ 16,505	\$ 22,603
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 5,790	\$ 5,132
Accrued expenses	1,522	1,857
Total current liabilities	7,312	6,989
<b>Commitments &amp; Contingencies (note 6)</b>		
<b>Stockholders Equity</b>		
Undesignated Preferred Stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding		
Common Stock, \$.001 par value, 30,000,000 shares authorized, 17,111,939 shares issued; 15,174,904 shares outstanding	17	17
Additional paid-in capital	169,121	168,787
Cost of treasury stock, 1,937,035 shares	(5,948)	(5,948)
Deficit accumulated during the development stage	(153,997)	(147,242)
Total stockholders equity	9,193	15,614
Total liabilities and stockholders equity	\$ 16,505	\$ 22,603

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

**Table of Contents**

**REPROS THERAPEUTICS INC. AND SUBSIDIARY**  
(A development stage company)  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(unaudited and in thousands except per share amounts)

	<b>Three Months Ended March</b>		<b>From Inception</b>
	<b>31,</b>		<b>(August 20,</b>
	<b>2009</b>	<b>2008</b>	<b>1987)</b>
			<b>through</b>
			<b>March 31,</b>
			<b>2009</b>
<b>Revenues and other income</b>			
Licensing fees	\$	\$	\$ 28,755
Product royalties			627
Research and development grants			1,219
Interest income	3	269	16,296
Gain on disposal of fixed assets			102
Other Income			35
<b>Total revenues and other income</b>	<b>3</b>	<b>269</b>	<b>47,034</b>
<b>Expenses</b>			
Research and development	5,698	6,166	152,966
General and administrative	1,060	797	38,334
Interest expense and amortization of intangibles			388
<b>Total expenses</b>	<b>6,758</b>	<b>6,963</b>	<b>191,688</b>
Loss from continuing operations	(6,755)	(6,694)	(144,654)
Loss from discontinued operations			(1,828)
Gain on disposal of discontinued operation			939
Net loss before cumulative effect of change in accounting principle	(6,755)	(6,694)	(145,543)
Cumulative effect of change in accounting principle			(8,454)
<b>Net loss</b>	<b>\$ (6,755)</b>	<b>\$ (6,694)</b>	<b>\$ (153,997)</b>
<b>Loss per share basic and diluted</b>	<b>\$ (0.45)</b>	<b>\$ (0.52)</b>	
Shares used in loss per share calculation:			
Basic	15,175	12,775	
Diluted	15,175	12,775	

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



Table of Contents

**Repros Therapeutics, Inc. and Subsidiary**  
(A development stage company)  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**  
(unaudited and in thousands except share amounts)

	<b>Common Stock</b>		<b>Additional Paid-in Capital</b>	<b>Treasury Stock</b>		<b>Deficit Accumulated During the Development Stage</b>	<b>Total Stockholders Equity</b>
	<b>Shares</b>	<b>Amount</b>		<b>Shares</b>	<b>Amount</b>		
Balance at December 31, 2008	17,111,939	\$ 17	\$ 168,787	1,937,035	\$ (5,948)	\$ (147,242)	\$ 15,614
Stock based option compensation			334				334
Net loss						(6,755)	(6,755)
Balance at March 31, 2009	17,111,939	\$ 17	\$ 169,121	1,937,035	\$ (5,948)	\$ (153,997)	\$ 9,193

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

**Table of Contents**

**REPOS THERAPEUTICS INC. AND SUBSIDIARY**  
(A development stage company)  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(unaudited and in thousands)

	<b>Three Months Ended March</b>		<b>From Inception</b>
	<b>31,</b>		<b>(August 20,</b>
	<b>2009</b>	<b>2008</b>	<b>1987)</b>
			<b>through</b>
			<b>March 31,</b>
			<b>2009</b>
<b>Cash Flows from Operating Activities</b>			
Net loss	\$ (6,755)	\$ (6,694)	\$ (153,997)
Gain on disposal of discontinued operations			(939)
Gain on disposal of 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			1,339
Noncash decrease in accounts payable			(1,308)
Depreciation and amortization	17	9	3,899
Noncash expenses related to stock-based transactions	334	192	5,691
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 in prepaid expenses and other current assets	(848)	(387)	(1,938)
Increase (decrease) in accounts payable and accrued expenses	323	723	8,507
Net cash used in operating activities	(6,929)	(6,157)	(138,543)
<b>Cash Flows from Investing Activities</b>			
Change in trading marketable securities		16,087	(191)
Capital expenditures		(2)	(2,371)
Purchase of technology rights and other assets	(139)	(137)	(3,909)
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) provided by investing activities	(139)	15,948	(4,068)

**Cash Flows from Financing Activities**

Proceeds from issuance of common stock, net of offering costs				151,015
Exercise of stock options				363
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				155,013
<b>Net increase (decrease) in cash and cash equivalents</b>	(7,068)	9,791		12,402
<b>Cash and cash equivalents at beginning of period</b>	19,470	1,779		
<b>Cash and cash equivalents at end of period</b>	\$ 12,402	\$ 11,570	\$	12,402

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

**Table of Contents**

**REPOS THERAPEUTICS INC. AND SUBSIDIARY**  
(A development stage company)  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**March 31, 2009**  
(Unaudited)

**NOTE 1 Organization, Operations and Liquidity**

Repos Therapeutics Inc. ( the Company , Repos, or we, us or our ), was organized on August 28, 1987. We are a development stage biopharmaceutical company focused on the development of oral small molecule drugs for major unmet medical needs that treat male and female reproductive disorders.

Our lead development drug, Proellex<sup>®</sup>, is a selective blocker of the progesterone receptor and is being developed for the treatment of symptoms associated with uterine fibroids and endometriosis. We are also developing Proellex as a short course pre-surgical treatment for anemia associated with excessive menstrual bleeding associated with uterine fibroids, or anemia associated with uterine fibroids. There is no currently approved effective long-term orally administered drug treatment for uterine fibroids or endometriosis. In the United States alone, approximately 300,000 women per year undergo a hysterectomy as a result of severe uterine fibroids.

Our second product candidate, Androxal<sup>®</sup>, 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 who want to improve or maintain their fertility and/or sperm function while being treated for low testosterone. In November 2008, we received guidance from the FDA suggesting submission of an Investigational New Drug Application, or IND, to the Division of Metabolic and Endocrine Products, or DMEP, for the investigation of Androxal as a potential treatment for type 2 diabetes. We plan to submit a new IND for this indication to the DMEP as soon as practicable.

Previously we were developing Androxal in the United States to treat testosterone deficiency due to secondary hypogonadism by restoring normal testosterone production in males with functional testes and diminished pituitary function, a common condition in the aging male. Based on a Type C meeting held with the Food and Drug Administration, or FDA, on October 15, 2007 we believe we do not have a clear clinical path to develop Androxal for this indication in the U.S. at this time. Although we believe Androxal could be developed outside of the U.S., due to the limited European market for this indication and our limited internal resources we do not intend to pursue approval outside of the U.S. at this time.

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

On October 2, 2008, we completed a direct registered offering of 2.4 million shares of our common stock at a purchase price of \$6.50 per share for net proceeds after expenses of approximately \$15.6 million pursuant to an effective shelf registration statement.

The Company has used and intends to continue to use the proceeds from the financing to fund its research and development activities, including the ongoing pivotal Phase 3 trials of its lead product candidate, Proellex, as a pre-surgical short course treatment of anemia associated with uterine fibroids and as a chronic treatment of uterine fibroids and its Phase 2 clinical trial for the treatment of endometriosis as well as for working capital and general corporate purposes.

**Table of Contents**

In connection with this sale of our common stock, we filed a Form S-3 shelf registration statement (Reg. No. 333-155265) on November 10, 2008 to cover the issuance of up to 5,000,000 shares in future offerings and up to 1,282,052 shares underlying certain purchase options related to the offering described above. This registration statement, as amended, was declared effective on November 26, 2008 and will remain in effect for three years thereafter unless it is otherwise terminated or the shares underlying such registration statement are exhausted.

As of March 31, 2009, we had accumulated losses of \$154.0 million and had cash and cash equivalents of \$12.4 million. 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 ongoing and planned clinical programs, we will have spent our remaining cash and cash equivalents during the third quarter of 2009 and need to raise additional capital in order to continue our development activities. The uncertainties relating to the foregoing matters raise substantial doubt about our ability to continue as a going concern over the next twelve months.

Our plans are to secure additional cash resources through either the sale of our equity securities or the potential regional out-licensing of Proellex. However, there can be no assurance that we will be successful in obtaining additional capital in amounts sufficient to continue to fund our operations and product development. If we are not able to raise capital through the sale of equity securities or through out-licensing Proellex, or cannot locate an alternative source of financing, the outcome would have a material adverse effect on us and the clinical development of our product candidates. If we are not able to raise adequate capital for our clinical development plans, then we will have to adjust our plans, which will delay the approval process of our product candidates.

Our results of operations may vary significantly from quarter to quarter and year to year, and depend on, among other factors, 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 generally exceeded revenue in any particular period and/or fiscal year.

Our accumulated deficit of \$154.0 million primarily relates to costs that were incurred in research and development activities related to efforts to develop our product candidates and from the associated administrative costs required to support those efforts. Due to various tax regulations, including change in control provisions in the tax code, the value of the tax asset created by these accumulated losses can be substantially diminished.

**Recent Accounting Pronouncements**

In September 2006, FASB issued SFAS No. 157, *Fair Value Measurements* which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. FSP 157-2 *Partial Deferral of the Effective Date of Statement 157* (FSP 157-2), deferred the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities to fiscal years beginning after November 15, 2008. The implementation of SFAS No. 157 for financial assets and financial liabilities, effective January 1, 2008, did not have a material impact on our consolidated financial position and results of operations. The implementation of SFAS No. 157 for nonfinancial assets and nonfinancial liabilities did not have a material impact on our consolidated financial position and results of operations.

In April 2008, the FASB issued FSP 142-3, *Determination of the Useful Life of Intangible Assets* ,

**Table of Contents**

(FSP 142-3). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets. FSP 142-3 is effective for fiscal years beginning after December 15, 2008. The implementation of this standard did not have a material impact on our consolidated financial position and results of operations.

**NOTE 2 Marketable Securities**

Management determines the appropriate classification of investments in debt and equity securities at the time of purchase and re-evaluates such designation as of each subsequent balance sheet date. Securities for which the Company has the ability and intent to hold to maturity are classified as held to maturity. Securities classified as trading securities are recorded at fair value. Gains and losses on trading securities, realized and unrealized, are included in earnings and are calculated using the specific identification method. Any other securities are classified as available for sale. Due to the current downturn in the financial markets and as a means of protecting our cash resources, we invest all of our cash resources in either an insured bank account or a money market mutual fund that is backed by U.S. government securities. This money market mutual fund is recorded as cash and cash equivalents in the consolidated balance sheet and is a level one security, as defined by SFAS 157.

**NOTE 3 Patents**

As of March 31, 2009, the Company had approximately \$1,840,000 in capitalized patent costs reflected on its balance sheet. Of this amount, \$809,000 relates to patent costs for Proellex and \$1,031,000 relates to patent costs for Androxal.

**NOTE 4 Accrued Expenses**

Accrued expenses consist of the following (in thousands):

	<b>March 31, 2009</b>	<b>December 31, 2008</b>
Research and development costs	\$ 1,438	\$ 1,573
Payroll		123
Patent costs	8	81
Other	76	80
Total	\$ 1,522	\$ 1,857

**NOTE 5 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 antidilutive and, accordingly, were not included in the computation of diluted loss per share.

**Table of Contents**

The following table presents information necessary to calculate loss per share for the three- month periods ended March 31, 2009 and 2008 (in thousands, except per share amounts):

	<b>Three Months Ended March</b>	
	<b>2009</b>	<b>2008</b>
Net loss	\$ (6,755)	\$ (6,694)
Average common shares outstanding	15,175	12,775
Basic and diluted loss per share	\$ (0.45)	\$ (0.52)

Other potential common stock of 3,430,617 and 1,553,565 common shares underlying stock options for the periods ended March 31, 2009 and 2008, respectively, were excluded from the above calculation of diluted loss per share since they were not dilutive.

**NOTE 6 Commitments and Contingencies**

We are not currently a party to any material legal proceedings.

In December 2008 we committed to the purchase of \$3 million of the bulk active ingredient of Proellex which is to be produced under a new scaled-up amended manufacturing process by Gedeon Richter. Under this Purchase Request, as amended, we paid \$750,000 in Q1, 2009 and \$750,000 in Q2, 2009. As of March 31, 2009 \$1.5 million is reflected under Prepaid Expenses and Other Current Assets on the balance sheet. We are obligated to make two additional payments of \$750,000 each, aggregating \$3 million in total, for the two batches of Proellex. The remaining two payments are due based upon the delivery of finished product by Gedeon Richter, with a payment due no sooner than mid August 2009 and the final payment due no sooner than mid January 2010. We expect to receive this material in the third and fourth quarters of 2009 and will recognize the expense associated with this purchase when this material is received from the manufacturer. This Purchase Request provides that all payments made to Gedeon Richter under the Purchase Request will be returned if they can not meet their obligations under this Purchase Request by March 31, 2010 or a newly mutually agreed upon date.

We have entered into agreements with certain clinical research organizations to conduct our Proellex clinical trials. All of these contracts can be cancelled by us at any time, and we would only be responsible for services rendered through the cancellation period.

Our Androxal product candidate and its uses are covered in the United States by two issued U.S. patents and seven pending patent applications. Foreign coverage of our Androxal product candidate includes 33 issued foreign patents and 69 foreign pending patent applications. The issued patents and pending applications relate to methods and compositions for treating certain conditions including the treatment of testosterone deficiency in men, 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 our request for re-examination by the PTO in light of a number of these additional

**Table of Contents**

publications and other publications cited by the PTO, has been granted. All of the claims have been finally rejected in the re-examination. The patent holder has appealed the rejections and has recently filed a Request for Oral Hearing. 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 Androxal.

On February 18, 2009 the Company's Board of Directors appointed Dr. Paul Lammers as the Company's President. That same day the Company's Board of Directors granted the Chief Executive Officer, the new President and the Chief Financial Officer options to purchase 50,000, 300,000 and 20,000 shares of the Company's common stock, respectively, at the closing price that day of \$8.80 per share under the Company's 2004 Stock Option Plan, or 2004 Plan. At that time the 2004 Plan had 221,326 options available. The remaining 148,674 options will not be effective until the Company's shareholders approve a modification to the 2004 Plan at its next Annual Meeting to be held on May 20, 2009.



**Table of Contents**

**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, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements reflect the Company's current views with respect to future events and financial performance and 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 in such forward-looking statements. The following discussion of financial condition should be read in conjunction with the accompanying consolidated financial statements and related notes.*

**Overview**

Repros Therapeutics Inc. (the Company, Repros, or we, us or our), was organized on August 28, 1987. We are a development stage biopharmaceutical company focused on the development of oral small molecule drugs for major unmet medical needs that treat male and female reproductive disorders.

Our current product pipeline (with the respective status of development) consists of the following:

**Proellex®** (female reproductive health)

Phase 3 three-month pre-surgical treatment for women with anemia due to excessive menstrual bleeding associated with uterine fibroids (anemia associated with uterine fibroids) who may consider having a subsequent hysterectomy

- o Currently conducting two 65-patient, 3-month duration, registration Pivotal Phase 3 clinical trials (ZPU-301 and ZPU-302).
- o In addition to our Pivotal Phase 3 clinical trials, the FDA will require data from 100 patients that have been exposed to Proellex for a six-month period. We will also have to provide the FDA with data accumulated from our other Proellex indications as well as other clinical data.

Phase 3 chronic treatment of symptoms associated with uterine fibroids

- o Currently conducting two 75-patient, 4-month duration, registration Pivotal Phase 3 clinical trials (ZPU-303 and ZPU-304).
- o In addition to our two Pivotal Phase 3 clinical trials, the FDA will require data from 200 patients that have been exposed to Proellex for one year with the final duration of drug exposure to be determined as data from ongoing trials continues to evolve. We will also need to provide the FDA with data from approximately 300 to 600 patients that have been on Proellex for six months. The FDA has suggested a total safety data base of 1,500 patients which may be derived from all of our trials and studies of Proellex for all indications, doses and durations of exposure.

Phase 2 chronic treatment of symptoms associated with endometriosis

- o Finalizing activities associated with our 4-month duration, Phase 2 clinical trial (ZPE-201).
- o We are preparing to request an end of Phase 2 meeting with the FDA that we anticipate could occur mid-year 2009. Pending positive FDA outcome from that meeting and acceptance of clinical protocols, we plan to initiate registration Phase 3 pivotal trials as soon as practicable.

**Table of Contents**

**Androxal®** (male reproductive health)

Phase 2b men being treated for low testosterone levels who want to improve or maintain their fertility and/or sperm number and function

- o Currently conducting a Phase 2b (ZA-201) proof-of-concept clinical trial.

We intend to file an Investigational New Drug Application, or IND, in the second half of 2009 for Androxal as a treatment for diabetes type 2.

Both Proellex and Androxal are considered new chemical entities, which means they are required to comply and meet with full regulatory approval requirements which include pre-clinical animal safety studies; Phase 1, Phase 2 and Pivotal Phase 3 clinical trials; long-term Open Label Safety Studies; manufacturing related activities as well as other requirements requested by the FDA to receive marketing approval for each of our disease indications. In addition, the FDA may request additional clinical data before approval can be obtained.

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 pivotal Phase 3 and long-term Open Label Safety Study data may not agree with these results which will be based upon a significantly larger and more diverse patient population treated for longer periods of time.

**Available Information**

For additional information please visit our Internet site ([www.reprosrx.com](http://www.reprosrx.com)) which makes available free of charge to all interested parties our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, as well as all other reports and schedules filed electronically with the Securities and Exchange Commission, or SEC, as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. Interested parties may also find reports, proxy and information statements and other information on issuers that file electronically with the SEC at the SEC's Internet site (<http://www.sec.gov>).

**Proellex**

Our lead drug, Proellex®, is a selective blocker of the progesterone receptor and is being developed for the treatment of symptoms associated with uterine fibroids and endometriosis. We are also developing Proellex as a short course pre-surgical treatment for anemia associated with uterine fibroids. There is no currently approved effective long-term orally administered drug treatment for uterine fibroids or endometriosis.

The National Uterine Fibroid Foundation estimates that as many as 80% of all women in the United States have uterine fibroids, and one in four of these women have symptoms severe enough to require treatment. In the United States alone, approximately 300,000 women per year undergo a hysterectomy as a result of severe uterine fibroids. According to The Endometriosis Association, endometriosis affects 5.5 million women in the United States and Canada and millions more worldwide.

All clinical development activities relating to Proellex for all indications will be combined and submitted to the FDA to show the overall safety of Proellex. In addition to the clinical trials listed above under each specific indication we have either completed or are currently performing the following clinical development activities:

- o Currently conducting one uterine fibroid 400-patient, 12-month drug treatment duration,

**Table of Contents**

Open Label Safety Trial (ZPU-305) and continuing preparation requirements to conduct a second 400-patient, 8-month drug treatment duration, Open Label Safety Trial (ZPU-306) immediately after ZPU-305 patient randomization is completed.

- o Proellex 12-month uterine fibroid Open Label Safety Trial (ZPU-003ext) completed with patients that rolled over from our prior Phase 2 clinical trial (ZPU-003). Currently conducting a second small 12-month uterine fibroid Open Label Safety Trial (ZPU-003ext2) with rollover patients from (ZPU-003ext).
- o Currently conducting one endometriosis 12-month Open Label Safety Trial (ZPE-201ext) with rollover patients from our U.S. Phase 2 clinical trial (ZPE-201).
- o Proellex Phase 1 clinical trials completed and also ongoing.
- o Proellex animal safety studies completed and also ongoing.
- o Continuing scale-up activities related to manufacturing and production.

We currently do not have reliable estimates regarding the timing of our Proellex clinical trials. The length of time required to complete Phase 1, Phase 2 and Phase 3 clinical trials and long-term open label safety studies may vary substantially according to factors relating to the particular clinical trial, such as the type and intended use of the drug candidate, the clinical trial design and the ability to enroll suitable patients. We have had difficulty recruiting patients into our Proellex clinical trials primarily due to the various test procedures that are required for a patient to be treated for these three indications, which includes multiple biopsies. In addition, patients being treated for anemia associated with uterine fibroids were previously scheduled to have hysterectomies post treatment and we have found that both patients and doctors did not want to be a part of those clinical trials due to this requirement. We have recently removed this requirement and will leave this procedure up to the patient and their physician. Notwithstanding the uncertainty described above, we currently estimate completion of our Proellex projects and the submission of a NDA under the following timelines:

Pre-surgical treatment of anemia associated with uterine fibroids	2010
Treatment of symptoms associated with uterine fibroids	Late 2010-2011
Treatment of symptoms associated with endometriosis	2011

In 1999, we licensed rights to Proellex from the National Institutes of Health, or NIH, under an exclusive, worldwide license in the field of treatment of human endocrinologic pathologies or conditions in steroid sensitive tissues which expires upon the expiration of the last licensed patent. Under the terms of the agreement, we are obligated to meet developmental milestones as outlined in a commercial development plan. This development plan outlines a preclinical and clinical program leading to the stated objective of submitting an NDA for regulatory approval of Proellex for a first indication by June 30, 2009. We have requested a meeting with the NIH to amend such date along with certain other milestones prior to such deadline. Although we believe we have a good working relationship with the NIH and even though the NIH has amended our agreement on several other occasions for similar reasons, no assurance can be given that such date or milestones will be revised.

**Androxal**

Our second product candidate, Androxal<sup>®</sup>, 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 who want to improve or maintain their fertility and/or sperm function while being treated for low testosterone. During the second quarter of 2008, we initiated a Phase 2b proof-of-concept clinical trial (ZA-201) for this new indication in which we are monitoring the effects of Androxal on male fertility and testicular function in patients being treated for low testosterone as compared to Testim<sup>®</sup>, a popular marketed topical



**Table of Contents**

testosterone medication. We anticipate holding an end of Phase 2 meeting with the FDA during the second half of 2009. At this time it is too early in the clinical development process to estimate when or even if a NDA will be filed with Androxal for this indication.

In April 2008, we submitted a White Paper, based on the results from a previously conducted non-pivotal Phase 2 clinical trial (ZA-003) with Androxal® for the treatment of testosterone deficiency due to secondary hypogonadism, to the Division of Reproductive and Urology Products. The data we believe demonstrated that in subjects with a serum glucose of greater than or equal to 105mg/dL, there was a statistically significant reduction in fasting serum glucose and a higher response rate to treatment in the Androxal®-group than the placebo or Androgel® groups. In November 2008, after the FDA reviewed this paper we received guidance from them suggesting that we open a new IND with the Division of Metabolic and Endocrine Products, or DMEP, for the investigation of Androxal as a potential treatment for type 2 diabetes. We plan to submit a new IND for this indication to the DMEP in the second half of 2009. We anticipate conducting a Phase 2b proof-of-concept clinical trial with Androxal after feedback from the FDA. At this time it is too early in the clinical development process to estimate when or even if a NDA will be filed with Androxal for this indication. This new indication replaces our previously announced plan to develop Androxal in men with adult-onset idiopathic hypogonadotropic hypogonadism, or AIHH, with concomitant plasma glucose and lipid elevations, all of which are components of Metabolic Syndrome.

We were previously developing Androxal in the United States to treat testosterone deficiency due to secondary hypogonadism by restoring normal testosterone production in males with functional testes and diminished pituitary function, a common condition in the aging male. Based on a Type C meeting held with the FDA on October 15, 2007 we believe that we do not have a clear clinical path to develop Androxal for this indication in the U.S. at this time. Although we believe Androxal could be developed outside of the U.S., due to the limited European market for this indication and our limited internal resources we do not intend to pursue approval outside of the U.S. at this time.

**General**

On February 18, 2009, Repros Board of Directors appointed Dr. Paul Lammers as the Company's new President. Joseph Podolski will remain as the Company's Chief Executive Officer and as a director.

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

The clinical development of pharmaceutical products is a complex undertaking, and many products that begin the clinical development process do not obtain regulatory approval. The costs associated with our clinical trials may be impacted by a number of internal and external factors, including the number and complexity of clinical trials necessary to obtain regulatory approval, the number of eligible patients necessary to complete our clinical trials and any difficulty in enrolling these patients, and the length of time to complete our clinical trials. Given the uncertainty of these potential costs, we recognize that the total costs we will incur for the clinical development of our product candidates may exceed our current estimates. We do, however, expect these costs to increase in year 2009 as compared to year 2008 as we continue with later-stage clinical trials, increase patient randomization into our larger open label safety clinical trials, potentially initiate new clinical trials for additional indications and seek to obtain regulatory approvals. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations.

As with most biotechnology companies with drug candidates in development, the path to

**Table of Contents**

marketing approval by the FDA, and comparable foreign agencies for each such candidate, is long and uncertain. The regulatory process, both domestically and abroad, is a multi-year process with no certainty when and if a drug candidate will be approved for commercial use. The development path for a particular drug candidate typically includes a variety of clinical trials. While we have a general estimate of the timeframe for our clinical trials, the actual anticipated completion dates for each of our drug candidates are uncertain. The length of time for a clinical trial may vary substantially according to factors relating to the particular clinical trial, such as the type and intended use of the drug candidate, the clinical trial design and the ability to enroll suitable patients. For example, we have revised our original estimates for clinical trial completion and related NDA dates on several occasions over the past several years based on data received from our clinical trials to date. In addition, it may be necessary to undertake additional unanticipated clinical trials during the development path.

We will not receive any revenue from commercial sales unless we, or a potential partner, complete the clinical development process, obtain regulatory approval, and successfully commercialize one or more of our product candidates. Similarly, we do not have a reasonable basis to predict when or if material net cash inflows from the commercialization and sale of our drug candidates will occur. To date, we have not commercialized any of our drug candidates to any material extent and in fact may never do so.

Our results of operations may vary significantly from quarter to quarter and year to year, and depend on, among other factors, 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 generally exceeded revenue in any particular period and/or fiscal year.

For a discussion of the risks and uncertainties associated with the timing and costs of completing the development and commercialization of the Company's drug candidates, see the section titled "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2008.

As of March 31, 2009, the Company had an accumulated deficit of \$154.0 million and had cash and cash equivalents of \$12.4 million. 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 ongoing and planned clinical programs, we will have spent our remaining cash and cash equivalents during the third quarter of 2009 and need to raise additional capital in order to continue our development activities. It is possible that our current clinical trial activities will be more costly and take longer than we anticipate; accordingly, there can be no assurance that additional capital will not be necessary prior to the time anticipated. We believe that we will secure sufficient capital to continue our ongoing and planned clinical programs assuming that the results of our current ongoing clinical trials with Proellex are favorable. If the results of these trials are unfavorable, there can be no assurance that the Company will be successful in obtaining additional capital in amounts sufficient to continue to fund its operations, which outcome would have a material adverse effect on the Company. The uncertainties relating to the foregoing matters raise substantial doubt about our ability to continue as a going concern over the next twelve months.

We have 11 full-time employees that utilize the services of contract research organizations, contract manufacturers and various consultants to assist us in performing clinical and regulatory services for the clinical development of our products. We are substantially dependent on our various contract groups to adequately perform the activities required to obtain regulatory approval of our products.

We have accumulated net operating losses through March 31, 2009 and the value of the tax asset associated with these accumulated net operating losses can be substantially diminished in value to us due to

**Table of Contents**

various tax regulations, including change in control provisions in the tax code. 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, among other things, on 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, our and our partners' ability to realize value from our research and development programs through the commercialization of those products and raising sufficient funds to finance our activities. There can be no assurance that we will be able to achieve profitability or that profitability, if achieved, can be sustained.

**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.

*Investments*

Management determines the appropriate classification of investments in debt and equity securities at the time of purchase and re-evaluates such designation as of each subsequent balance sheet date. Debt securities for which we have the ability and intent to hold to maturity are classified as held to maturity. Securities we designate as trading securities are recorded at fair value. Gains and losses on trading securities, realized and unrealized, are included in earnings and are calculated using the specific identification method. Any other securities are classified as available for sale. Due to the volatility of the financial markets at March 31, 2009, we had no marketable securities and held our cash in either an insured bank account or a money market mutual fund backed by U.S. Securities.

*Capitalized Patent Costs*

We capitalize the cost associated with building our patent library for Proellex and Androxal. As of March 31, 2009, other assets consist of capitalized patent costs in the amount of \$1,840,000. Patent costs, which include legal and application costs related to the patent portfolio, are being amortized over 20 years, or the lesser of the legal or the estimated economic life of the patent. Amortization of patent costs was \$12,000 and \$3,000 in the first quarter ended March 31, 2009 and 2008, respectively. Of the \$1,840,000 in capitalized patents, \$809,000 related to Proellex patents and \$1,031,000 related to Androxal patents.

We review capitalized patent 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 capitalized patent costs are not impaired as of March 31, 2009.

*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.

**Table of Contents**

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, we are expanding the level of our clinical trials and related services. As a result, we anticipate that our estimated accruals for clinical services will be more material to our operations in future periods. 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 and internal research and development supplies. We expense research and development costs in the period they are incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform research on our behalf.

*Share-Based Compensation*

We had two stock-based compensation plans at March 31, 2009, the 2000 Non-Employee Directors Stock Option Plan, or 2000 Director Plan and the 2004 Stock Option Plan, or 2004 Plan. We account for our stock-based compensation plans under FASB Statement No. 123(R), Share-Based Payments ( SFAS 123(R) ). SFAS 123(R) 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. Under SFAS 123(R), we use the Black-Scholes option pricing model to estimate the fair value of our stock options. Expected volatility is determined using historical volatilities based on historical stock prices for a period equal to the expected term. The expected volatility assumption is adjusted if future volatility is expected to vary from historical experience. The expected term of options represents the period of time that options granted are expected to be outstanding and falls between the options vesting and contractual expiration dates. The risk-free interest rate is based on the yield at the date of grant of a zero-coupon U.S. Treasury bond whose maturity period equals the option s expected term.

*Income Taxes*

Our losses from inception to date have resulted principally from costs incurred in conducting clinical trials and in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. Under SFAS No. 109, Accounting for Income Taxes, a net operating loss ( NOL ), requires the recognition of deferred tax assets. 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.

**RECENT ACCOUNTING PRONOUNCEMENTS**

In September 2006, FASB issued SFAS No. 157, Fair Value Measurements which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. FSP



**Table of Contents**

157-2 Partial Deferral of the Effective Date of Statement 157 (FSP 157-2), deferred the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities to fiscal years beginning after November 15, 2008. The implementation of SFAS No. 157 for financial assets and financial liabilities, effective January 1, 2008, did not have a material impact on our consolidated financial position and results of operations. The implementation of SFAS No. 157 for nonfinancial assets and nonfinancial liabilities did not have a material impact on our consolidated financial position and results of operations.

In April 2008, the FASB issued FSP 142-3, Determination of the Useful Life of Intangible Assets, (FSP 142-3). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets. FSP 142-3 is effective for fiscal years beginning after December 15, 2008. The implementation of this standard did not have a material impact on our consolidated financial position and results of operations.

**Results of Operations**

*Comparison of the three-month periods ended March 31, 2009 and 2008*

*Revenues and Other Income*

Total revenues and other income, which was comprised of interest income for the three month periods ended March 31, 2009 and 2008, decreased 99% to \$3,000 for the three month period ended March 31, 2009 as compared to \$269,000 for the same period in the prior year. This decrease was primarily due to lower combined cash, cash equivalents and marketable securities balances and reduced interest rate yields that have occurred as we moved our cash investments solely into a money market mutual fund.

*Research and Development Expenses*

Research and development, or R&D, expenses include contracted services relating to our clinical product development activities which include preclinical studies, clinical trials, regulatory affairs and bulk manufacturing scale-up activities and bulk active ingredient purchases for preclinical and clinical trials primarily relating to our two products in clinical development, which are Proellex and Androxal. Research and development expenses also include internal operating expenses relating to our general research and development activities. R&D expenses decreased 8% or approximately \$468,000 to \$5.7 million for the three month period ended March 31, 2009 as compared to \$6.2 million for the same period in the prior year. Our primary R&D expenses for the three month periods ended March 31, 2009 and 2008 are shown in the following table (in thousands):

<b>Research and Development</b>	<b>Three-months March 31, 2009</b>	<b>Three-months March 31, 2008</b>	<b>Variance</b>	<b>Change (%)</b>
Proellex clinical development	\$ 4,717	\$ 4,640	\$ 77	2%
Androxal clinical development	347	970	(623)	(64)%
Payroll and benefits	416	235	181	77%
Operating and occupancy	218	321	(103)	(32)%
Total	\$ 5,698	\$ 6,166	\$ (468)	(8)%

To date through March 31, 2009 we have incurred approximately \$41.5 million for the development of Proellex and approximately \$13.9 million for the development of Androxal. These accumulated costs exclude any internal operating expenses. We are currently developing Proellex for three indications which include a pre-surgical treatment of anemia associated with uterine fibroids, a chronic treatment of

**Table of Contents**

symptoms associated with uterine fibroids and as a chronic treatment of symptoms associated with endometriosis. We are currently developing Androxal as a treatment for men with low testosterone that want to maintain or improve their fertility and sperm function. In addition, we are exploring the feasibility of developing Androxal as a treatment for Type 2 diabetes. Prior to 2008, we were developing Androxal as a treatment for men with low testosterone due to secondary hypogonadism.

*Proellex*

Proellex clinical development expenses remained relatively constant at \$4.7 million for the three month period ended March 31, 2009 as compared to \$4.6 million for the same period in the prior year. Although the Proellex clinical development expenses remained constant, the detail of the expenses is shown in the following table (in thousands):

<b>Proellex Clinical Development</b>	<b>Three-months March 31, 2009</b>	<b>Three-months March 31, 2008</b>	<b>Variance</b>	<b>Change (%)</b>
Clinical trials	\$ 4,063	\$ 3,658	\$ 405	11%
Preclinical studies	222	743	(521)	(70)%
Formulation and dosage	343	111	232	209%
Other	89	128	(39)	(30)%
Total	\$ 4,717	\$ 4,640	\$ 77	2%

Prior to 2008 we were developing Proellex for two indications which included a chronic treatment of symptoms associated with uterine fibroids and endometriosis. During the first quarter of 2008 we filed an IND with Proellex for a new indication as a short course pre-surgical treatment of anemia associated with uterine fibroids. Proellex clinical expenses for the three month periods ended March 31, 2009 and 2008 include Phase 1, Phase 2, Phase 3 and long-term Open Label Safety study activities.

Preclinical study expenses reflect animal safety activities required by the FDA to file a NDA. Formulation and dosage expenses reflect activities associated with the bulk scale-up and purchase of active drug to conduct clinical trials and to meet any potential future NDA submission requirements.

*Androxal*

Androxal clinical development expenses decreased 64% or approximately \$623,000 to \$347,000 for the three month period ended March 31, 2009 as compared to \$970,000 for the same period in the prior year. The decrease in Androxal clinical development expenses is shown in the following table (in thousands):

<b>Androxal Clinical Development</b>	<b>Three-months March 31, 2009</b>	<b>Three-months March 31, 2008</b>	<b>Variance</b>	<b>Change (%)</b>
Clinical trials	\$ 59	\$ 236	\$ (177)	(75)%
Preclinical studies	258	718	(460)	(64)%
Formulation and dosage		14	(14)	(100)%
Other	30	2	28	1400%
Total	\$ 347	\$ 970	\$ (623)	(64)%

Prior to 2008 we were developing Androxal as a treatment for testosterone deficiency due to secondary hypogonadism by restoring normal testosterone production in males with functional testes. As a result of a Type C meeting held with the Food and Drug Administration, or FDA, on October 15, 2007 we believe that we do not have a clear clinical path to develop Androxal for this indication in the U.S. at this



**Table of Contents**

time and discontinued clinical efforts for that indication except for the continuation of a long-term Open Label Safety study that was already underway and we believe could be used as safety data for our other indications. During 2008 we initiated a clinical development program with Androxal as a treatment for men being treated for low testosterone that want to maintain or improve their sperm function during treatment.

Clinical trial expenses during the three month period ended March 31, 2009 primarily reflect a Phase 2b proof-of-concept clinical trial. Clinical trial expenses during the three month period ended March 31, 2008 primarily reflect a long-term Open Label Safety study. Preclinical study expenses for both three month periods ended March 31, 2009 and 2008 reflect animal safety activities required by the FDA to file a NDA.

*Payroll and Benefits*

R&D payroll and benefit expenses include salaries, non-cash stock option compensation expense and fringe benefits which increased 77% or approximately \$181,000 to \$416,000 for the three month period ended March 31, 2009 as compared to \$235,000 for the same period in the prior year. This increase is primarily due to an increase in headcount and an increase in non-cash stock option compensation of \$74,000. Included in payroll and benefit expense is a charge for non-cash stock option expense of \$142,000 for the three month period ended March 31, 2009 as compared to \$68,000 for the same period in the prior year.

*Operating and Occupancy*

R&D operating and occupancy decreased 32% or approximately \$103,000 to approximately \$218,000 for the three month period ended March 31, 2009 as compared to \$321,000 for the same period in the prior year. The decrease is primarily due to a decrease in clinical development related consulting expenses of approximately \$71,000.

*General and Administrative Expenses*

General and administrative expenses, or G&A, increased 33% to approximately \$1.1 million for the three month period ended March 31, 2009 as compared to \$797,000 for the same period in the prior year. Our primary G&A expenses for the three month period ended March 31, 2009 and 2008 are shown in the following table (in thousands):

<b>General and Administrative</b>	<b>Three- months March 31, 2009</b>	<b>Three- months March 31, 2008</b>	<b>Variance</b>	<b>Change (%)</b>
Payroll and benefits	\$ 475	\$ 346	\$ 129	37%
Operating and occupancy	585	451	134	30%
Total	\$ 1,060	\$ 797	\$ 263	33%

G&A payroll and benefit expense include salaries, bonuses, non-cash stock option compensation expense and fringe benefits. Included in payroll and benefit expense is a charge for non-cash stock option expense of \$192,000 for the three month period ended March 31, 2009 as compared to \$124,000 for the same period in the prior year. Additionally, salaries for the three month period ended March 31, 2009 were \$238,000 as compared to \$192,000 for the same period in the prior year.

G&A operating and occupancy expenses, which include expenses to operate as a public company, increased 30% or approximately \$134,000 to \$585,000 for the three month period ended March 31, 2009 as

**Table of Contents**

compared to \$451,000 for the same period in the prior year. The increase is primarily due to an increase in professional services of \$126,000.

**Off-Balance Sheet Arrangements**

As of March 31, 2009, we did not have any off-balance sheet arrangements except one operating lease.

**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 October 2, 2008, we completed a direct registered offering of 2.4 million shares of our common stock at a purchase price of \$6.50 per share for net proceeds after expenses of approximately \$15.6 million pursuant to an effective shelf registration statement.

In November 2008, we filed a Form S-3 shelf registration statement (Reg. No. 333-155265) to register up to 6,282,052 shares of our common stock, which includes 1,282,052 shares related to certain purchase options related to the offering described above and an additional 5 million shares for future offerings. This registration statement was declared effective on November 26, 2008 and remains effective for three years after such date unless earlier terminated or expired.

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 \$12.4 million as of March 31, 2009 as compared to cash, cash equivalents and marketable securities of \$19.5 million as of December 31, 2008.

Net cash of approximately \$6.9 million and \$6.2 million was used in operating activities during the first quarter of 2009 and 2008, respectively. The major use of cash for operating activities during the first quarter of 2009 was to fund our clinical development programs and associated administrative costs.

We have experienced negative cash flows from operations since inception and have funded our activities to date primarily from equity financings and corporate collaborations. 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 ongoing and planned clinical programs, we will have spent our remaining cash and cash equivalents during the third quarter of 2009 and need to raise additional capital in order to continue our development activities. There can be no assurance that changes in our current strategic plans or other events will not result in accelerated or unexpected expenditures.

Our capital requirements will depend on many factors, including the costs and timing of seeking regulatory approvals of our products; the problems, delays, expenses and complications frequently encountered by development stage companies; the progress of our preclinical and clinical activities; the costs associated with any future collaborative research, manufacturing, marketing or other funding arrangements; our ability to obtain regulatory approvals; the success of our potential future sales and marketing programs; the cost of filing, prosecuting and defending and enforcing any patent claims and other intellectual property rights; changes in economic, regulatory or competitive conditions of our planned business; and additional costs associated with being a publicly-traded company. Estimates about the adequacy of funding for our activities are based on certain assumptions, that the development and regulatory approval of our products can be completed at projected costs; and that product approvals and

**Table of Contents**

introductions will be timely and successful. There can be no assurance that changes in our research and development plans, acquisitions or other events will not result in accelerated or unexpected expenditures. To satisfy our capital requirements, we may seek to raise additional funds in the public or private capital markets. We may seek additional funding through corporate collaborations and other financing vehicles. 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 over the next twelve months.

Our results of operations may vary significantly from quarter to quarter and year to year, and depend, among other factors, on our ability to raise additional capital on acceptable terms or at all, on our ability to be successful in our clinical trials, the regulatory approval process in the United States and other foreign jurisdictions and the ability to complete 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 generally 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 \$12.4 million at March 31, 2009 which is held in an account backed by U.S. government securities. Although this cash account is subject to fluctuations in interest rates and market conditions, no significant gain or loss on this account is expected to be recognized in earnings. We do not invest in derivative securities.

**Item 4. Controls and Procedures**

*Disclosure Controls and Procedures*

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e)) under the Securities Exchange Act of 1934, as amended (the Exchange Act), were effective as of March 31, 2009.

*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 March 31, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents****PART II OTHER INFORMATION****Item 1. Legal Proceedings**

We are not currently a party to any material legal proceedings.

Our Androxal product candidate and its uses are covered in the United States by two issued U.S. patents and seven pending patent applications. Foreign coverage of our Androxal product candidate includes 33 issued foreign patents and 69 foreign pending patent applications. The issued patents and pending applications relate to methods and compositions for treating certain conditions including the treatment of testosterone deficiency in men, 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 our request for re-examination by the PTO in light of a number of these additional publications and other publications cited by the PTO, has been granted. All of the claims have been finally rejected in the re-examination. The patent holder has appealed the rejections and has recently filed a Request for Oral Hearing. 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 Androxal.

**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, 2008 in response to Item 1A. Risk Factors to Part I of Form 10-K.

**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).

**Table of Contents**

- 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).
- 3.2 Restated Bylaws of the Company (incorporated by reference to Exhibit 3.4 to the Registration Statement).
- 10.1 Employment Agreement dated February 18, 2009 between the Company and Paul Lammers, M.D., M.Sc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on February 24, 2009).
- 10.2 Third Amendment to Employment Agreement dated effective March 11, 2009 between the Company and Joseph S. Podolski (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on March 17, 2009).
- 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.



**Table of Contents**

**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: May 11, 2009

By: /s/ Joseph S. Podolski

Joseph S. Podolski  
Chief Executive Officer and Director  
(Principal Executive Officer)

Date: May 11, 2009

By: /s/ Louis Ploth, Jr.

Louis Ploth, Jr.  
Chief Financial Officer, Director and  
Secretary  
(Principal Financial and Accounting  
Officer)