

REPROS THERAPEUTICS INC.  
Form 10-Q  
November 10, 2010

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 September 30, 2010

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-15281

REPROS THERAPEUTICS INC.  
(Exact Name of Registrant as Specified in its Charter)

Delaware  
(State or other jurisdiction of  
incorporation or  
organization)

2408 Timberloch Place, Suite B-7  
The Woodlands, Texas 77380  
(Address of principal executive offices  
and zip code)

76-0233274  
(IRS Employer  
Identification No.)

(281) 719-3400  
(Registrant's telephone number,  
including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

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

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

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

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

As of November 4, 2010, there were outstanding 8,930,057 shares of Common Stock, par value \$.001 per share, of the Registrant.

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REPOS THERAPEUTICS INC.  
(A development stage company)

For the Quarter Ended September 30, 2010

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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; its ability to successfully defend itself in the class action lawsuits filed against it; its ability to maintain its listing on the Nasdaq Capital Market; the success of the clinical trials for Proellex® and Androxal® and the reestablishment of safe dosing in clinical trials for Proellex®; having available funding for the continued development of Proellex® and Androxal®; uncertainty related to the Company's ability to obtain approval of the Company's products by the Food and Drug Administration, or FDA, and regulatory bodies in other jurisdictions; uncertainty relating to the Company's patent portfolio and license rights to such patents; 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, 2009.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

The following unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments (which include only normal recurring adjustments) considered necessary for a fair statement of the interim periods presented have been included. The year-end balance sheet data was derived from audited financial statements, but does not include all the disclosures required by accounting principles generally accepted in the United States of America. Operating results for the three month and nine month periods ended September 30, 2010 are not necessarily indicative of the results that may be expected for the year ended December 31, 2010. 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, 2009.

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

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

|  | September 30,<br>2010 | December 31,<br>2009 |
|--|-----------------------|----------------------|
| <b>ASSETS</b>  |                       |                      |
| <b>Current Assets</b>  |                       |                      |
| Cash and cash equivalents  | \$ 4,216              | \$ 1,886             |
| Prepaid expenses and other current assets  | 211                   | 177                  |
| Total current assets   | 4,427                 | 2,063                |
| Fixed assets, net  | 9                     | 12                   |
| Other assets, net  | 1,131                 | 885                  |
| Total assets   | \$ 5,567              | \$ 2,960             |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                       |                      |
| <b>Current Liabilities</b>   |                       |                      |
| Accounts payable   | \$ 1,172              | \$ 2,043             |
| Accrued expenses   | 182                   | 355                  |
| Total current liabilities  | 1,354                 | 2,398                |
| Commitments and contingencies (note 5)   |                       |                      |
| <b>Stockholders' Equity</b>  |                       |                      |
| Undesignated Preferred Stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding   | -                     | -                    |
| Common Stock, \$.001 par value, 75,000,000 shares authorized, 9,042,407 and 6,496,999 shares issued, respectively and 8,930,057 and 6,384,649 shares outstanding, respectively | 9                     | 6                    |
| Additional paid-in capital   | 183,644               | 176,412              |
| Cost of treasury stock, 112,350 shares   | (1,380)               | (1,380)              |
| Deficit accumulated during the development stage   | (178,060)             | (174,476)            |
| Total stockholders' equity   | 4,213                 | 562                  |
| Total liabilities and stockholders' equity   | \$ 5,567              | \$ 2,960             |

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

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

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

|   | Three Months Ended September 30, |             | Nine Months Ended September 30, |             | From Inception<br>(August 20, 1987)<br>through<br>September 30, |
|---|----------------------------------|-------------|---------------------------------|-------------|---|
|   | 2010                             | 2009        | 2010                            | 2009        | 2010  |
| <b>Revenues</b>   |                                  |             |                                 |             |   |
| Licensing fees  | \$ -                             | \$ -        | \$ -                            | \$ -        | \$ 28,755   |
| Product royalties   | -                                | -           | -                               | -           | 627   |
| Research and development grants                                     | -                                | -           | -                               | -           | 1,219   |
| Interest income   | -                                | -           | -                               | 4           | 16,297  |
| Gain on disposal of fixed assets                                    | -                                | -           | -                               | -           | 102   |
| Other Income  | 85                               | -           | 138                             | -           | 720   |
| Total revenues and other income                                     | 85                               | -           | 138                             | 4           | 47,720  |
| <b>Expenses</b>   |                                  |             |                                 |             |   |
| Research and development  | 736                              | 8,282       | 1,950                           | 21,765      | 172,280   |
| General and administrative  | 533                              | 1,962       | 1,772                           | 4,126       | 43,769  |
| Interest expense and amortization of intangibles                    | -                                | -           | -                               | -           | 388   |
| Total expenses  | 1,269                            | 10,244      | 3,722                           | 25,891      | 216,437   |
| Loss from continuing operations                                     | (1,184)                          | (10,244)    | (3,584)                         | (25,887)    | (168,717)   |
| Loss from discontinued operations                                   | -                                | -           | -                               | -           | (1,828)   |
| Gain on disposal of discontinued operation                          | -                                | -           | -                               | -           | 939   |
| Net loss before cumulative effect of change in accounting principle | (1,184)                          | (10,244)    | (3,584)                         | (25,887)    | (169,606)   |
| Cumulative effect of change in accounting principle                 | -                                | -           | -                               | -           | (8,454)   |
| Net loss  | \$ (1,184)                       | \$ (10,244) | \$ (3,584)                      | \$ (25,887) | \$ (178,060)  |
| Loss per share - basic and diluted:                                 | \$ (0.13)                        | \$ (2.64)   | \$ (0.46)                       | \$ (6.77)   |   |
| Weighted average shares used in loss per share calculation:         |                                  |             |                                 |             |   |
| Basic   | 8,875                            | 3,876       | 7,763                           | 3,821       |   |
| Diluted   | 8,875                            | 3,876       | 7,763                           | 3,821       |   |

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

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

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

|  | Common Stock |        | Additional         | Treasury Stock |            | Deficit   | Total                   |
|--|--------------|--------|--------------------|----------------|------------|---|-------------------------|
|  | Shares       | Amount | Paid-in<br>Capital | Shares         | Amount     | Accumulated<br>During the<br>Development<br>Stage | Stockholders'<br>Equity |
| Balance at December 31, 2009   | 6,496,999    | \$ 6   | \$ 176,412         | 112,350        | \$ (1,380) | \$ (174,476)                                      | \$ 562                  |
| Stock based option compensation  | -            | -      | 471                | -              | -          | -   | 471                     |
| Issuance of 96,836 shares of common stock at \$2.88 to \$4.40 per share, as settlement with trade creditors              | 96,836       | -      | 370                | -              | -          | -   | 370                     |
| Issuance of 2,448,572 shares of common stock at a weighted average share price of \$2.77, net of offering costs of \$381 | 2,448,572    | 3      | 6,391              | -              | -          | -   | 6,394                   |
| Net loss   | -            | -      | -                  | -              | -          | (3,584)   | (3,584)                 |
| Balance at September 30, 2010  | 9,042,407    | \$ 9   | \$ 183,644         | 112,350        | \$ (1,380) | \$ (178,060)                                      | \$ 4,213                |

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



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

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

|  | Nine Months Ended September 30, |             | From Inception<br>(August 20, 1987)<br>through<br>September 30, |
|--|---------------------------------|-------------|---|
|  | 2010                            | 2009        | 2010  |
| <b>Cash Flows from Operating Activities</b>  |                                 |             |   |
| Net loss   | \$ (3,584)                      | \$ (25,887) | (178,060)   |
| 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  | -                               | 989         | 2,614   |
| Noncash other income   | (138)                           | -           | (685)   |
| Noncash decrease in accounts payable   | -                               | -           | (1,308)   |
| Depreciation and amortization  | 60                              | 51          | 4,014   |
| Noncash stock-based compensation   | 471                             | 1,110       | 7,112   |
| Common stock issued for agreement not to compete   | -                               | -           | 200   |
| Series B Preferred Stock issued for consulting services  | -                               | -           | 18  |
| Changes in operating assets and liabilities<br>(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   | (34)                            | 1,114       | 91  |
| Increase (decrease) in accounts payable and accrued expenses   | (536)                           | 5,246       | 9,502   |
| Net cash used in operating activities  | (3,761)                         | (17,377)    | (157,456)   |
| <b>Cash Flows from Investing Activities</b>  |                                 |             |   |
| Change in trading marketable securities  | -                               | -           | (191)   |
| Capital expenditures   | (6)                             | -           | (2,377)   |
| Purchase of technology rights and other assets   | (297)                           | (424)       | (4,569)   |
| 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  | (303)                           | (424)       | (4,734)   |
| <b>Cash Flows from Financing Activities</b>  |                                 |             |   |
| Proceeds from issuance of common stock, net of offering costs  | 6,394                           | 869         | 162,399   |

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|  |          |          |          |
|--|----------|----------|----------|
| Exercise of stock options                            | -        | 9        | 372      |
| 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            | 6,394    | 878      | 166,406  |
| Net increase (decrease) in cash and cash equivalents | 2,330    | (16,923) | 4,216    |
| Cash and cash equivalents at beginning of period     | 1,886    | 19,470   | -        |
| Cash and cash equivalents at end of period           | \$ 4,216 | \$ 2,547 | \$ 4,216 |

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

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

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
September 30, 2010  
(Unaudited)

NOTE 1 — Organization, Operations and Liquidity

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 oral small molecule drugs for major unmet medical needs that treat male and female reproductive disorders.

Our portfolio of products includes:

Androxal®

• As a treatment for men of reproductive age with low testosterone levels that spares fertility, unlike testosterone replacement therapy; and

- As a treatment for type 2 diabetes

Proellex®

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

As of September 30, 2010, we had accumulated losses of \$178.1 million, approximately \$4.2 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately \$1.4 million. The amount of cash on hand is not sufficient to fund the (i) escalating dose study for Proellex® permitted by the FDA, (ii) Phase 2B and upcoming Phase 3 hypogonadism trials for Androxal®, (iii) type 2 diabetes trial for Androxal®, (iv) preclinical assessment of vaginal delivery of Proellex® and (v) second generation Proellex® molecules. Based on these current and planned clinical trials, we will need to raise additional capital no later than the first quarter of 2011. We continue to explore potential additional financing and capital raising alternatives to provide additional funds to enable us to continue to develop our two product candidates through completion of 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. Significant additional funding will be required for us to continue development of either of our product candidates. Additionally, as discussed in Note 5, we have various pending legal proceedings that could adversely impact us. The foregoing and other matters raise substantial doubt about our ability to continue as a going concern.

On October 14, 2010, the Company effected a one-for-four reverse stock split of its common stock. The split-adjusted shares of the Company's common stock began trading on the Nasdaq Capital Market on October 15, 2010. The one-for-four reverse stock split converted all shares of the Company's common stock issued and outstanding, plus all outstanding stock options and the number of shares of common stock available for issuance under the Company's approved stock plans. The number of authorized shares of common stock was not affected by the reverse split. The reverse split enabled the Company to meet the continued listing rules of the Nasdaq Capital Market as evidenced by the Compliance Letter received from Nasdaq on October 29, 2010. All share and per share amounts have been

retroactively adjusted to reflect the reverse stock split for all periods presented.

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.

#### NOTE 2 — Patents and Patent Applications

As of September 30, 2010, the Company had approximately \$1.1 million in capitalized patent and patent application costs reflected on its balance sheet. This entire amount relates to patent and patent application costs for Androxal®.

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

#### NOTE 3 — Accrued Expenses

Accrued expenses consist of the following (in thousands):

|                         | September 30, 2010 |     | December 31, 2009 |     |
|-------------------------|--------------------|-----|-------------------|-----|
| Personnel related costs | \$                 | 103 | \$                | 181 |
| Other                   |                    | 69  |                   | 159 |
| Patent costs            |                    | 10  |                   | 15  |
| Total                   | \$                 | 182 | \$                | 355 |

#### 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 antidilutive and, accordingly, were not included in the computation of diluted loss per share. Additionally, on October 14, 2010, the Company effected a one-for-four reverse stock split of its common stock. The split-adjusted shares of the Company's common stock began trading on the Nasdaq Capital Market on October 15, 2010. All share and per share amounts have been retroactively adjusted to reflect the reverse stock split for all periods presented.

The following table presents information necessary to calculate loss per share for the three month and nine month periods ended September 30, 2010 and 2009 (in thousands, except per share amounts):

|                                   | Three Months Ended Sept. 30, |             | Nine Months Ended Sept. 30, |             |
|-----------------------------------|------------------------------|-------------|-----------------------------|-------------|
|                                   | 2010                         | 2009        | 2010                        | 2009        |
| Net Loss                          | \$ (1,184)                   | \$ (10,244) | \$ (3,584)                  | \$ (25,887) |
| Average common shares outstanding | 8,875                        | 3,876       | 7,763                       | 3,821       |
| Basic and diluted loss per share  | \$ (0.13)                    | \$ (2.64)   | \$ (0.46)                   | \$ (6.77)   |

Other potential common stock of 538,582 and 552,402 common shares underlying stock options for the periods ended September 30, 2010 and 2009, respectively, were excluded from the above calculation of diluted loss per share because they were not dilutive.



## NOTE 5 — Commitments and Contingencies

Therapeutic uses of our Androxal® product candidate are covered in the United States by four issued U.S. patents and four pending patent applications. Foreign coverage of therapeutic uses of our Androxal® product candidate includes 40 issued foreign patents and 75 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 metabolic syndrome and conditions associated therewith, and the treatment of infertility in hypogonadal men. Androxal® (the trans-isomer of clomiphene) is purified from clomiphene citrate. A third party individual holds two issued patents related to the use of an anti-estrogen such as clomiphene citrate and others for use in the treatment of androgen deficiency and disorders related thereto. In our prior filings with the SEC, we have described our request to the U.S. Patent and Trademark Office, or PTO, for re-examination of one of these patents based on prior art. The third party amended the claims in the re-examination proceedings, which led the PTO to determine that the amended claims are patentable in view of those publications under consideration and a re-examination certificate was issued. However, we believe that the amended claims are invalid based on additional prior art publications, and we filed a second request for re-examination by the PTO in light of a number of these additional publications and other publications cited by the PTO. The request was granted and all of the claims were finally rejected by the PTO in the re-examination. The patent holder appealed the rejections to the PTO Board of Patent Appeals and Interferences (“the Board”) which affirmed the rejection of all of the claims. The patent holder subsequently filed a request for rehearing, which led the Board to reverse the rejections of several dependent claims in view of those publications under consideration. The patent holder has filed a Notice of Appeal to the Federal Circuit contesting the rejections maintained by the Board. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. Nevertheless, there is no assurance that either patent will ultimately be found invalid over the prior art. If such patents are not invalidated by the PTO we may be required to obtain a license from the holder of such patents in order to develop Androxal® further or attempts may be made to undertake further legal action to invalidate such patents. If such licenses were not available on acceptable terms, or at all, we may not be able to successfully commercialize or out-license Androxal®.

On August 7, 2009, R.M. Berry filed a putative class action lawsuit naming the Company, Joseph Podolski, Paul Lammers, and Louis Ploth, Jr. as defendants. The lawsuit is pending in the United States District Court for the Southern District of Texas, Houston Division. The lawsuit, styled R.M. Berry, on Behalf of Himself and all Others Similarly Situated v. Repros Therapeutics, Inc., Joseph Podolski, Paul Lammers, and Louis Ploth, Jr., alleges that the defendants made certain misleading statements related to the Company’s Proellex® drug. Among other claims, the lawsuit contends that the defendants misrepresented the side effects of the drug related to liver function, and the risk that these side effects could cause a suspension of clinical trials of Proellex®. The lawsuit seeks to establish a class of shareholders allegedly harmed by the misleading statements, and asserts causes of action under the Securities Exchange Act of 1934. On August 14, 2009, a lawsuit making similar allegations and naming the same defendants was also filed in the United States District Court for the Southern District of Texas. This suit is styled Josephine Medina, Individually and On Behalf of all Others Similarly Situated v. Repros Therapeutics, Inc., Joseph Podolski, Paul Lammers, and Louis Ploth, Jr. On September 25, 2009, a lawsuit also making allegations similar to those in the Berry action, and naming the same defendants, was filed in the United States District Court for the Southern District of Texas. That lawsuit is styled Shane Simpson, Paul Frank and Clayton Scobie, on Behalf of Themselves and all Others Similarly Situated v. Repros Therapeutics, Inc., Joseph Podolski, Paul Lammers, and Louis Ploth, Jr. The lawsuits have now been consolidated, and lead plaintiffs appointed. On January 27, 2010, the lead plaintiffs filed a Consolidated Class Action Complaint styled In re Repros Therapeutics, Inc. Securities Litigation, Civil Action No. 09 Civ. 2530 (VDG). The lawsuit names Repros Therapeutics, Inc., Joseph Podolski, Paul Lammers, and Louis Ploth, Jr. as defendants. The allegations in the Consolidated Class Action Complaint are substantially the same as those contained in the prior complaints, and focus on the claim that the defendants deliberately withheld information concerning the negative side-effects of Proellex® related to liver function. Plaintiffs seek to establish a class action for all persons who “purchased or otherwise acquired Repros common stock between July 1, 2009, and August 2, 2009.” No discovery has yet occurred in the matter. Defendants filed a motion to dismiss the Consolidated Class Action

Complaint on March 15, 2010. Briefing has been completed on that motion, but the court has not yet ruled on it. An estimate of the possible loss or range of losses in connection with the lawsuits cannot be made at this time.



On March 1, 2010, we were served with a lawsuit where we were named as a co-defendant along with one of our clinical regulatory service providers (“CRO”) relating to the Proellex® clinical trial study. The lawsuit was filed in the State of Tennessee, 30th Judicial District Chancery Court at Memphis by an investigator and claims that the CRO did not pay it amounts owing to it relating to the Proellex® study. We did not engage the investigator and under our agreement with the CRO, we believe the CRO is responsible for any such costs or damages regarding such lawsuit. Pursuant to a Settlement Agreement and Mutual Release entered into in October 2009, such CRO, on behalf of itself and its agents, released us from all claims which could be asserted by them against us. We believe such release covers the claims set forth in this lawsuit. The CRO failed to respond to the lawsuit, and a default judgment was entered against it in the amount of \$172,901.29. We intend to vigorously defend any and all claims asserted by the investigator. An estimate of the possible costs or expenses to defend ourselves in this matter or risk of exposure under the litigation cannot be made at this time.

NOTE 6 — Other Recent Events, Including Subsequent Events

Between November 30, 2009 and March 31, 2010, we entered into settlement agreements and mutual releases (the “Prior Settlement Agreements”) with certain of our creditors, pursuant to which we issued an aggregate of 352,459 shares of common stock and paid an aggregate of \$140,572 in cash as payment in full for our then-outstanding liabilities to such creditors. On April 8, 2010, we entered into an additional settlement agreement and mutual release (together with the Prior Settlement Agreements, the “Settlement Agreements”) with a creditor, pursuant to which we issued 34,885 shares of common stock (together with the shares issued under the Prior Settlement Agreements, the “Settlement Shares”) and paid \$8,721 in cash as payment in full for our then-outstanding liability to such creditor. The Settlement Shares were issued by the Company pursuant to Section 4(2) and /or Rule 506 of Regulation D promulgated under the Securities Act of 1933, as amended. Pursuant to the Settlement Agreements, we filed a registration statement to register the Settlement Shares on June 9, 2010, which was declared effective by the SEC on June 25, 2010, and we agreed to use our best efforts to maintain such registration statement until all such Settlement Shares registered thereunder to such creditors have been sold or for a period of one year, whichever comes first.

In addition to the Settlement Agreements, we settled with several of our creditors during the second and third quarter of 2010, in an amount less than our then-outstanding liabilities to such creditors. These settlements resulted in recognition of \$85,000 and \$138,000 in other income for the three and nine month periods ended September 30, 2010, respectively, on the Condensed Consolidated Statement of Operations.

On February 12, 2010, we entered into an Equity Distribution Agreement (the “Equity Distribution Agreement”) with Ladenburg Thalmann & Co. Inc. (“Ladenburg”), pursuant to which we may issue and sell from time to time through Ladenburg, as sales agent and/or principal, shares of our common stock having an aggregate offering price of up to \$10 million (the “ATM Shares”). Ladenburg is not required to sell on our behalf any specific number or dollar amount of the ATM Shares, but Ladenburg, upon acceptance of written instructions from us, agreed to use its commercially reasonable efforts consistent with its customary trading and sales practices, to sell the ATM Shares up to the amount specified, and otherwise in accordance with the terms of a placement notice delivered to Ladenburg. We have no obligation to sell any ATM Shares under the Equity Distribution Agreement, and may at any time suspend sales under the Equity Distribution Agreement, provided that such suspension shall not affect either party’s obligations with respect to the ATM Shares sold prior to the receipt of notice of such suspension. Ladenburg receives a commission of 4% of the gross sales price of all ATM Shares sold through it under the Equity Distribution Agreement. The ATM Shares are issued pursuant to our shelf registration statement on Form S-3, as amended (File No. 333-163648). Between July 1, 2010 and September 30, 2010, we have sold an aggregate of 277,164 ATM Shares at a weighted average share price of \$1.51, for proceeds of approximately \$401,000, net of expenses. Cumulative through September 30, 2010, we have sold 2,448,572 ATM Shares at a weighted average share price of \$2.77, for proceeds of approximately \$6.4 million, net of expenses. Pursuant to General Instruction I.B.6. of Form S-3, we may not sell more than one-third of the aggregate market value of our common stock held by non-affiliates during a period of 12

calendar months immediately prior to, and including, the date of such sale of such common stock. Due to this limitation, we announced on August 3, 2010 that we have suspended this ATM offering of Company securities.

On November 1, 2010, we were notified by The Department of the Treasury that our application submitted requesting certification for qualified investment in a qualifying therapeutic discovery project under section 48D of the Internal Revenue Code was accepted. As a result, we have been awarded a grant in the amount of \$244,479. It is anticipated that proceeds from this grant will be received late in November 2010.

On November 8, 2010, we had a Type B meeting with the FDA. In that meeting the FDA recommended that we conduct a Phase 2B study in men with secondary hypogonadism but naïve to testosterone treatment before moving into Phase 3. The FDA opined further that such a Phase 2B study would provide for a more solid data base for design of Phase 3 studies and eventual approval of such studies under a Special Protocol Assessment (“SPA”). The FDA did note “the Division agrees in general with the outline of your program for the development of enclomiphene” (Androxal®).

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion contains forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act") that involve risk and uncertainties. Any statements contained in this quarterly report that are not statements of historical fact may be forward-looking statements. When we use the words "may," "anticipates," "believes," "plans," "expects" and similar expressions, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. The following discussion of financial condition should be read in conjunction with the accompanying consolidated financial statements and related notes.

Repros Therapeutics Inc.

Repros Therapeutics Inc. ("the Company", "RPRX," "Repros", or "we," "us" or "our") was organized on August 20, 1987. We are a development stage biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders.

We are developing Androxal®, an oral therapy that normalizes testicular function, for the treatment of low testosterone due to secondary hypogonadism. Secondary hypogonadism is most commonly associated with aging and the Company believes it is the most common cause of low testosterone in men. It is estimated that 13 million men in the U.S. experience low levels of testosterone. In 2009, for the first time, sales of testosterone preparations for the treatment of low testosterone exceeded \$1 billion worldwide and first tier pharmaceutical companies entered the low testosterone marketplace as evidenced by the acquisition of Solvay Pharmaceuticals and the subsequent active marketing of its AndroGel® product by Abbott Laboratories. Eli Lilly and Company also entered into a licensing agreement for a late stage topical testosterone treatment.

The Company believes Androxal® is highly differentiated from currently marketed testosterone treatments or those treatments in late stage development. Androxal® is the only oral therapy for treating low testosterone which is approaching Phase 3 studies. The Company had a Type B meeting with the FDA on November 8, 2010 to discuss protocols for such Phase 3 studies. In the meeting, the FDA recommended that a Phase 2B study in men with secondary hypogonadism but naïve to testosterone treatment be conducted before moving into Phase 3. The Company is also currently conducting a Phase 2 study of the use of Androxal® in the treatment of type 2 diabetes in hypogonadal men. Retrospective analysis of completed Androxal® studies showed that Androxal® improved fasting plasma glucose levels in men with type 2 diabetes. Hypogonadism and type 2 diabetes are comorbid conditions in a significant number of men. This improvement was not seen in similar subjects using a topical testosterone or placebo. The Company believes this effect is directly related to Androxal®'s ability to normalize the hypothalamic-pituitary-testes pathway and organ function.

We are also developing Proellex®, an orally administered selective blocker of the progesterone receptor in women, for the treatment of uterine fibroids and endometriosis. Uterine fibroids and endometriosis affect millions of women of reproductive age in the U.S. Repros was conducting large Phase 3 studies for Proellex® in uterine fibroids based on significant success in Phase 2 studies and was preparing to move to Phase 3 trials in endometriosis; however, during the third quarter of 2009, liver toxicity associated with the high dose of Proellex® in such studies became apparent. At such time, the Proellex® program was placed on full clinical hold by the FDA. Recently the FDA upgraded the full hold to a partial hold to allow Repros to conduct a low dose oral study of Proellex® after the Company completed an analysis of the incidence and severity of the liver toxicity observed at the higher doses of the drug. All women that experienced liver toxicity and returned for follow-up visits returned to normal after dosing was stopped with no overnight hospitalization necessary. The Company has commenced the low dose study to determine both signals of

efficacy and safety for low oral doses of the drug. In addition to the low dose study, the Company has commenced two related preclinical programs: vaginal delivery of Proellex® to avoid first pass liver effects and second generation molecules that do not possess the structures Repros believes resulted in the liver toxicity observed.

Repros believes both of its product candidates have exhibited strong efficacy results in every study completed to date and the studies presently underway or scheduled to start shortly will place both programs on a clear late stage clinical development path and a solid position for licensing.

As of September 30, 2010, we had accumulated losses of \$178.1 million, approximately \$4.2 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately \$1.4 million. The amount of cash on hand is not sufficient to fund each of the clinical trials currently planned for our two drug candidates, Proellex® and Androxal®. Based on these planned clinical trials, we will need to raise additional capital no later than the first quarter of 2011. We continue to explore potential additional financing alternatives 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. Significant additional capital will be required for us to complete development of either of our product candidates. The foregoing and other matters raise substantial doubt about our ability to continue as a going concern.

Androxal®

#### Product Overview

Our primary product candidate, Androxal®, is a single isomer of clomiphene citrate and is an orally active proprietary small molecule compound. We are developing Androxal® for men of reproductive age with low testosterone levels. Unlike testosterone replacement, Androxal® does not induce an infertile state while being treated for low testosterone. In addition, we are performing an investigation of Androxal® as a potential treatment for type 2 diabetes.

Testosterone is an important male hormone. Testosterone deficiency in men is linked to several negative physical and mental conditions, including loss of muscle tone, reduced sexual desire, and deterioration of memory and certain other cognitive functions. Testosterone production normally decreases as men age, sometimes leading to testosterone deficiency. According to the Urology Channel, recent estimates show that approximately 13 million men in the United States experience testosterone deficiency. The leading therapy is AndroGel®, a commercially available testosterone replacement cream marketed by Abbott Laboratories for the treatment of low testosterone, which we believe has had and continues to have significant sales in North America.

Based on our own clinical trial screening data, we believe over 70% of men that have low testosterone suffer from secondary hypogonadism, caused by failure of the pituitary to provide appropriate hormone signaling to the testes, which we believe causes testosterone levels to drop to the point where pituitary secretions fall under the influence of estrogen. In this state, we also believe that estrogen further suppresses the testicular stimulation from the pituitary. These men are readily distinguished from those that have primary testicular failure via assessment of the levels of secretions of pituitary hormones (i.e., men with primary testicular failure experience elevated secretions of pituitary hormones). Secondary hypogonadism is not relegated only to older men although the condition becomes more prevalent as men age.

Confounding this condition further, men with secondary hypogonadism often have both low testosterone and exhibit other metabolic changes such as obesity and type 2 diabetes, among other signs. Our clinical trial data suggests that Androxal® modifies the endocrinologic profile in terms of both hormones and certain metabolic measures.

Retrospective analysis of completed Androxal® studies showed that Androxal® improved fasting plasma glucose levels in men with type 2 diabetics. Hypogonadism and type 2 diabetes are comorbid conditions in a significant number of men. This improvement was not seen in similar subjects using a topical testosterone or placebo. The Company believes this effect is directly related to Androxal®'s ability to normalize the hypothalamic-pituitary-testes pathway and organ function.



We believe Androxal® may have advantages over current therapies for the treatment of low testosterone due to secondary hypogonadism because it is designed as an oral therapy that acts centrally to restore testicular function and hence normal testosterone in the body, as compared to currently approved products that simply replace diminished testosterone either through injections, nasal spray or the application of a gel or cream containing testosterone over a percentage of body area. We believe Androxal® will be superior to the existing administration of exogenous testosterone products used to normalize testosterone as only Androxal® has the property of restoring both LH (luteinizing hormone) and FSH (follicle stimulating hormone) levels. LH and FSH are the pituitary hormones that stimulate testicular testosterone and sperm production, respectively.

Androxal® is considered a new chemical entity by the FDA which means that the compound will be required to undergo the full regulatory approval process. We must still meet additional clinical requirements including pre-clinical, Phase 1, Phase 2, pivotal Phase 3 trials and long-term Open Label Safety Studies as well as other requirements. Although Androxal® is considered a new chemical entity for purposes of requirements for approval, it is closely related chemically to the drug, Clomid®, which is approved for use in women to treat certain infertility disorders. The FDA has indicated that testicular tumors, gynecomastia and adverse ophthalmologic events, which have been reported in males taking Clomid®, are potential risks that should be included in informed consent forms for our Androxal® clinical trials. We do not believe that Androxal® will present with the same adverse events given its reduced half-life in the human body as compared to Clomid®. In our preclinical studies and our clinical trials to date, we have observed no evidence of any of these events except for certain ophthalmologic events in our preclinical dog study at doses significantly higher than those administered in the clinical trials.

All clinical trial results are subject to review by the FDA, and the FDA may disagree with our conclusions about safety and efficacy. We caution that the results discussed herein are based on data from non-pivotal trials and that our future Phase 2 trials, pivotal Phase 3 and long-term Open Label Safety Trial data may not agree with these results which will be based upon significantly larger and more diverse patient populations treated for longer periods of time.

#### Fertility Sparing Treatment for Secondary Hypogonadism

On August 9, 2010, we announced that the FDA has notified us that they will allow us to conduct two Phase 3 trials for Androxal® in men with low testosterone subject to protocol review by the FDA. On November 8, 2010, we had a Type B meeting with the FDA to discuss protocols for such Phase 3 studies. In the meeting, the FDA recommended that a Phase 2B study in men with secondary hypogonadism but naïve to testosterone treatment be conducted before moving into Phase 3. The FDA further opined that such a Phase 2B study would provide for a more solid data base for design of Phase 3 studies and eventual approval of such studies under an SPA. During the second quarter of 2008, we initiated a 24-patient Phase 2b proof-of-concept clinical trial (ZA-201) for a new indication in which we monitored the effects of Androxal® on male fertility and testicular function in patients being treated for low testosterone as compared to Testim®, a popular marketed topical testosterone medication. On October 6, 2009 we announced that Androxal® was able to maintain sperm counts in men being treated for their low testosterone levels. Testim® resulted in suppressed sperm levels while men were being treated with that topical gel.

Given that there is currently an acceptable treatment regimen for men with low testosterone, there is significant uncertainty as to whether or not an additional approach such as Androxal® would be approved by the FDA or accepted in the market. Even if we reach an agreement with the FDA regarding trial design and number of subjects required for the safety data base is resolved, we do not believe that a new drug application (“NDA”) can be submitted at any time before 2013.





## Type 2 Diabetes

Our findings from a retrospective review of the clinical data from our 200 patient non-pivotal Phase 2 clinical trial (ZA-003) showed that Androxal® therapy resulted in a significant reduction in mean fasting plasma glucose levels in men with glucose levels >104 mg/dL, an outcome not seen in the placebo or AndroGel® arms of this study. Based on these results, in April 2008, we submitted a White Paper to the Division of Reproductive and Urology Products. The data 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 in mellitus. In December 2009, we submitted a new IND to DMEP for the investigation of Androxal® for such purpose. On February 1, 2010, we received confirmation from the DMEP that our new IND was accepted and, as a result, we have initiated our Phase 2 trial. The Company believes it has sufficient cash to complete an interim analysis of the study around the end of the first quarter of 2011; however, completion of such study is subject to additional funding which, as discussed previously, is uncertain.

## Proellex®

### Product Overview

Proellex®, our product candidate for female reproductive health, is a new chemical entity that acts as a selective blocker of the progesterone receptor and is being developed for the treatment of symptoms associated with uterine fibroids and endometriosis. There is currently no FDA-approved orally administered drug for the long-term treatment of uterine fibroids or endometriosis. The National Uterine Fibroids Foundation estimates that 80% of all women in the U.S. have uterine fibroids, and one in four of these women have symptoms severe enough to require treatment. According to the Endometriosis Association, endometriosis affects 5.5 million women in the U.S. and Canada and millions more worldwide.

The current standards of care for uterine fibroids and endometriosis include surgery and treatment with drugs. The most effective drugs on the market are gonadotropin releasing hormone agonists (GnRHa) such as Lupron®. GnRHa's induce a low estrogen, menopausal-like state and promote bone loss and are not recommended for use for more than six months.

All Proellex® studies completed to date exhibited strong efficacy signals for both uterine fibroids and endometriosis. Up until the summer of 2009, all side effects exhibited in the studies were considered manageable and the benefit of Proellex® far outweighed the risk. Unfortunately, in Phase 3 efficacy and larger Phase 3 safety studies in diverse populations, a small but alarming number of subjects exhibited serious adverse effects associated with elevated liver enzymes. As a result of such findings, the FDA placed Proellex® on full clinical hold until certain questions could be answered by the Company. Included in these questions were determination of the fate of women that exhibited elevated liver enzymes after dosing was stopped and an assessment of the conditions that led to the observed adverse effects. Fortunately, all women that experienced elevated liver enzymes and returned for follow-up visits returned to baseline conditions with no overnight hospitalization necessary. A comprehensive analysis of all the subjects that experienced such serious adverse effects determined that only those subjects that were exposed to the 50mg dose of the drug for any period of time exhibited such outcome. Based on these findings, the Company petitioned the FDA to lift the full clinical hold to allow it to conduct a low dose study to demonstrate both safety and signals of efficacy in doses up to 12mg administered per day. The FDA upgraded the full clinical hold to a partial hold to allow the low dose study to be conducted. The Company has since commenced the low dose study to determine both signals of

efficacy and safety for low oral doses of the drug. In addition, the Company has undertaken two related initiatives presently at the pre-clinical stage. The first is the exploration of vaginal delivery as an alternative administrative route to bypass first-pass liver effects and reduce systemic exposure. The second is to begin screening of second generation molecules that do not possess the specific structures the Company believes induced the liver toxicity exhibited at higher doses of Proellex®.

### Low Dose Study

As a result of the liver toxicity exhibited by Proellex® in our previous Phase 2 and 3 clinical trials studying endometriosis and uterine fibroids, respectively, all ongoing clinical trial activities have been put on partial hold by the FDA. Pursuant to the terms of such partial clinical hold, the FDA has allowed us to run a single study under the new partial clinical hold status. The new low dose study is designed to explore both safety and signals of efficacy in an escalating dose fashion. The new study will test 5 different doses of Proellex® (1, 3, 6, 9 and 12 mg) with 1 mg being the first dose tested. Each dose will be compared to placebo with weekly assessments of liver function during both the placebo and drug period. Higher doses will not be studied until we are confident that it is safe to proceed to the next dose and have reported the safety findings to the FDA. Subjects will be dosed with the active drug for 10 weeks, which will allow for adequate time to determine the impact of a given dose on trends in liver function. Each dose will be tested in up to 12 different subjects and assessment of pharmacokinetic parameters will be obtained at the start of dosing and the end of the dosing period to determine overall and maximum drug exposure for a given dose. We will also monitor changes in menstrual bleeding patterns and ovulation as well as changes in endometrial thickness. The FDA requires that an independent Drug Safety Monitoring Board be established and that the informed consent clearly state the liver toxicity previously experienced with Proellex®.

In a 120 patient study of Proellex® as a treatment of uterine fibroids conducted in the United States (roughly 40 subjects per arm), both a 12.5 and 25 mg dose of Proellex® were compared to placebo. In this study each of the 12.5 and 25 mg doses achieved highly statistically significant results when compared to placebo when menstrual bleeding was assessed ( $p < 0.0001$ ). The two doses also achieved highly statistically significant improvement in quality of life measures using the Uterine Fibroid Symptom Quality of Life questionnaire developed and validated by Georgetown University and used in the development of device like treatments of uterine fibroids such as uterine artery embolization. There was no statistical difference in efficacy measures between the two doses. Importantly, in the Phase II US trial a significant percentage of women stopped menstruating. Over 80% of women on both the 12.5 and 25 mg doses exhibited no menses during the three month trial, whereas all women on placebo exhibited at least one menses. We believe that the evaluation of ovulation and menstrual bleeding patterns in the low dose trial will provide strong evidence for efficacy warranting further development.

We have manufactured the initial 1 mg dose of Proellex® capsules and have recently begun dosing subjects. We believe we can complete the trial within approximately 18 months after first dose. Presuming a safe and effective dose is identified and the FDA is in agreement, we anticipate that we will be able to proceed with large efficacy trials for both uterine fibroids and endometriosis, subject to available funds, or outlicense of the product to a major pharmaceutical company.

### Vaginal Administration

We are assessing vaginal administration of Proellex® to avoid first pass liver effects and achieve higher reproductive tract concentrations of the drug while minimizing systemic exposure. Initial in vivo animal studies look promising and should a subsequent animal study confirm efficacy signals at substantially lower doses than oral administration we intend to open a new Investigational New Drug Application (“IND”) for both uterine fibroids and endometriosis. We believe this new IND will be able to leverage the experience we have gained with the oral dose and after a single Phase I/II study we will be able to move to Phase III. We plan on completing our preclinical proof-of-concept work around the end of 2010 and submit a new IND if warranted.

## Second Generation Compound

We believe we understand the cause of the liver toxicity observed at high doses in the Proellex® studies. Our hypothesis is that liver adverse events are associated with a specific part of the chemical structure of Proellex®. To that end we have synthesized new, but related molecules that are devoid of the specific toxicity causing structure and initial preclinical screening has begun. If we are successful in identifying such a molecule, we believe we will be able to achieve high oral doses and systemic exposure opening the path to aggressive anti progestin therapy for conditions such as breast cancer. We hope to have completed our screen of the new molecules during the third quarter of 2011, subject to additional funding.

## Other Products

We continue limited out-licensing efforts for our phentolamine-based product candidates, including VASOMAX®, which had previously been approved for marketing in several countries in Latin America for the treatment of male erectile dysfunction under the brand name, Z-Max. VASOMAX® is currently on partial clinical hold in the U.S.

## Business Strategy

We plan to focus our clinical program on the (i) new escalating dose study for Proellex® permitted by the FDA, (ii) Phase 2B and upcoming Phase 3 fertility trials for Androxal®, (iii) type 2 diabetes trial for Androxal®, (iv) preclinical assessment of vaginal delivery of Proellex® and (v) second generation Proellex® molecules. Based on our currently available funds and outstanding obligations, we will need to raise additional funds no later than the first quarter 2011 in order to continue development ourselves of such product candidates. We will continue to explore corporate partnering opportunities for assistance in the clinical development funding and commercialization of our products, as appropriate; however, there can be no assurance that an acceptable corporate partnering opportunity will be successfully completed.

## Risks Affecting Us

Our business is subject to numerous risks as discussed more fully in "Item 1A. Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2009 and the section entitled "Risk Factors" in this quarterly report. We are investigating a variety of sources for raising capital. No assurance can be given that we will be successful in obtaining financing on acceptable terms or at all. We anticipate that if we are able to secure financing, that such financing will result in significant dilution of the ownership interests of our current stockholders and may provide certain rights to the new investors senior to the rights of our current stockholders, including but not limited to voting rights and rights to proceeds in the event of a sale or liquidation of the Company. In the event that we are unable to obtain adequate financing to meet our future needs, we will pursue other options, including but not limited to, reductions of expenses, sale of the Company, sale or license of a portion or all of our assets or the liquidation of the Company.

In addition, we have not received regulatory approval for any of our product candidates, have not successfully earned any significant commercial revenues from any of our product candidates and may never launch either of our product candidates. If we do not successfully commercialize any of our product candidates, we will be unable to achieve our business objectives. In addition, the reported results of our clinical trials completed to date may not be indicative of results that will be achieved in later-stage clinical trials involving larger and more diverse patient populations. As of September 30, 2010, we had accumulated losses of \$178.1 million, approximately \$4.2 million in cash and cash equivalents, and our accounts payable and accrued expenses were approximately \$1.4 million. The amount of cash on hand is not sufficient to fund each of the clinical trials currently planned or in process for our two drug candidates, Proellex® and Androxal®. Based on these current or planned clinical trials, we will need to raise additional capital no

later than the first quarter of 2011. The foregoing and other matters raise substantial doubt about our ability to continue as a going concern and we expect to continue to incur significant losses over the next several years, and we may never become profitable. Our financial statements do not include any adjustments that might result from the outcome of these uncertainties.

## Corporate Information

We were organized as a Delaware corporation in August 1987. Our principal executive offices are located at 2408 Timberloch Place, Suite B-7, The Woodlands, Texas, 77380, and our telephone number is (281) 719-3400. We maintain an internet website at [www.reprosrx.com](http://www.reprosrx.com). The information on our website or any other website is not incorporated by reference into this quarterly report and does not constitute a part of this quarterly report. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K and all amendments to such reports are made available free of charge through the Investor Relations section of our website as soon as reasonably practicable after they have been filed or furnished with the Securities and Exchange Commission.

## Recent Developments

On October 14, 2010, the Company effected a one-for-four reverse stock split of its common stock. The split-adjusted shares of the Company's common stock began trading on the Nasdaq Capital Market on October 15, 2010. The one-for-four reverse stock split converted all shares of the Company's common stock issued and outstanding, plus all outstanding stock options and the number of shares of common stock available for issuance under the Company's approved stock plans. The number of authorized shares of common stock was not affected by the reverse split. The reverse split enabled the Company to meet the continued listing rules of the Nasdaq Capital Market as evidenced by the Compliance Letter received from Nasdaq on October 29, 2010. All share and per share amounts have been retroactively adjusted to reflect the reverse stock split for all periods presented.

## General

We have experienced negative cash flows from operations since inception and have funded our activities to date primarily from equity financings and corporate collaborations. Based on our current and planned clinical trials, we will need to raise additional capital no later than the first quarter of 2011 in order to continue our development activities. It is possible that our current and planned clinical trial activities will be more costly and take longer than we anticipate; accordingly, there can be no assurance that additional capital will not be necessary prior to the time anticipated. We believe that we will secure sufficient capital to continue our ongoing and planned clinical programs assuming that the results of our current or planned clinical trials with Androxal® and Proellex® are favorable. If the results of these trials are unfavorable, there can be no assurance that 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. Our financial statements do not include any adjustments that might result from the outcome of these uncertainties.

We have 6 full time employees. We utilize the services of contract research organizations, contract manufacturers and various consultants to assist us in performing clinical and regulatory services for the clinical development of our products. The current salary reduction program we adopted during 2009 and which we revised in May 2010 to 25% of salary, other than the CEO who is at 50%, could have a negative impact on our ability to retain our employees. We are substantially dependent on our various contract groups to adequately perform the activities required to obtain regulatory approval of our products.

We have accumulated net operating losses through September 30, 2010 and the value of the tax asset associated with these accumulated net operating losses can be substantially diminished in value due to various tax regulations, including change in control provisions in the tax code. The Company's public offerings completed on February 5, 2007, October 2, 2008, September 11, 2009, October 13, 2009, the sale and issuance of the ATM Shares and the issuance of unregistered shares as part of the settlement agreements we have entered into with certain of our creditors since October of 2009 may have created a change of ownership for Federal Income tax purposes. The Company has not undertaken a study to determine if this has occurred. A change in ownership for Federal Income tax purposes may

result in a limitation on the use of net operating loss and tax credit carryforwards in future periods.



Losses have resulted principally from costs incurred in conducting clinical trials for our product candidates, in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. There can be no assurance that we will be able to successfully complete the transition from a development stage company to the successful introduction of commercially viable products. Our ability to achieve profitability will depend on, among other things, successfully completing the clinical development of our products in a reasonable time frame and at a reasonable cost, obtaining regulatory approvals, establishing marketing, sales and manufacturing capabilities or collaborative arrangements with others that possess such capabilities, and, if applicable, our partners' ability to realize value from our research and development programs through the commercialization of those products and raise sufficient funds to finance our activities. There can be no assurance that we will be able to achieve profitability.

#### Critical Accounting Policies and the Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

#### Capitalized Patent and Patent Application Costs

We capitalize the cost associated with building our patent library for Androxal®. As of September 30, 2010, other assets consist of capitalized patent and patent application costs in the amount of \$1.1 million. Patent costs, which include legal and application costs related to the patent portfolio, are being amortized over 20 years, or the lesser of the legal or the estimated economic life of the patent. Amortization of patent costs was \$21,000 and \$13,000 for the three month periods ended September, 30, 2010 and 2009, respectively, and was \$50,000 and \$39,000 for the nine month periods ended September 30, 2010 and 2009, respectively. The entire \$1.1 million in capitalized patents and patent applications relates to Androxal®.

We review capitalized patent and patent application costs for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment exists when estimated undiscounted cash flows expected to result from the patent are less than its carrying amount. The impairment loss recognized represents the excess of the patent cost as compared to its estimated fair value. We believe that our remaining capitalized patent and patent application costs are not impaired as of September 30, 2010.

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

#### Accrued Expenses

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

costs incurred. Based on our current and planned clinical trials for Androxal® and Proellex® and our current financial condition, further development of our product candidates is dependent on our ability to raise additional capital. As a result, we anticipate that our estimated accruals for clinical services will be significantly reduced in future periods. However, subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our balance sheet and results of operations.

## R&D Expense

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

## Share-Based Compensation

We had two stock-based compensation plans at September 30, 2010, the 2000 Non-Employee Directors' Stock Option Plan, or 2000 Director Plan, and the 2004 Stock Option Plan, or 2004 Plan. Accounting for stock based compensation generally requires the recognition of the cost of employee services for share-based compensation based on the grant date fair value of the equity or liability instruments issued. We use the Black-Scholes option pricing model to estimate the fair value of our stock options. Expected volatility is determined using historical volatilities based on historical stock prices for a period equal to the expected term. The expected volatility assumption is adjusted if future volatility is expected to vary from historical experience. The expected term of options represents the period of time that options granted are expected to be outstanding and falls between the options' vesting and contractual expiration dates. The risk-free interest rate is based on the yield at the date of grant of a zero-coupon U.S. Treasury bond whose maturity period equals the option's expected term.

## Income Taxes

Our losses from inception to date have resulted principally from costs incurred in conducting clinical trials and in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. We have recorded a deferred tax asset for our net operating losses ("NOL"); however, as the Company has incurred losses since inception, and since there is no certainty of future profits, a valuation allowance has been provided in full on our deferred tax assets in the accompanying consolidated financial statements. If the Company has an opportunity to use this NOL to off-set tax liabilities in the future, the use of this asset would be restricted based on Internal Revenue Service, state and local NOL use guidelines. The Company's public offerings completed on February 5, 2007, October 2, 2008, September 11, 2009, October 13, 2009, the sale and issuance of the ATM Shares and the issuance of unregistered shares as part of the settlement agreements we entered into with certain of our creditors since October of 2009 may have created a change of ownership for Federal Income tax purposes. The Company has not undertaken a study to determine if this has occurred. A change in ownership for Federal Income tax purposes may result in a limitation on the use of net operating loss and tax credit carryforwards in future periods.

## Results of Operations

Comparison of the three-month and nine-month periods ended September 30, 2010 and 2009

### Revenues and Other Income

Total revenues and other income increased to \$85,000 for the three month period ended September 30, 2010 as compared to zero for the same period in the prior and increased to \$138,000 for the nine month period ended September 30, 2010 as compared to \$4,000 for the same period in the prior year. The increase for the three and nine month periods ended September 30, 2010 was primarily due to an increase of \$85,000 and \$138,000, respectively, in non-cash other income related to debt relief from settlements with certain vendors in the second and third quarters of 2010.



## Research and Development Expenses

Research and development, or R&D, expenses include contracted services relating to our clinical product development activities which include preclinical studies, clinical trials, regulatory affairs and bulk manufacturing scale-up activities and bulk active ingredient purchases for preclinical and clinical trials primarily relating to our two products in clinical development, which are Androxal® and Proellex®. Research and development expenses also include internal operating expenses relating to our general research and development activities. R&D expenses decreased 91% or approximately \$7.5 million to \$736,000 for the three month period ended September 30, 2010 as compared to \$8.3 million for the same period in the prior year. Our primary R&D expenses for the three month periods ended September 30, 2010 and 2009 are shown in the following table (in thousands):

|                                | Three-months<br>ended<br>September 30, 2010 | Three-months<br>ended<br>September 30, 2009 | Variance   | Change<br>(%) |
|--------------------------------|---|---|------------|---------------|
| Research and Development       |   |   |            |               |
| Operating and occupancy        | \$ 152                                      | \$ 1,551                                    | \$ (1,399) | (90)%         |
| Payroll and benefits           | 159   | 344   | (185)      | (54)%         |
| Androxal® clinical development | 163   | 64  | 99         | 153%          |
| Proellex® clinical development | 262   | 6,323                                       | (6,061)    | (99)%         |
| Total                          | \$ 736                                      | \$ 8,282                                    | \$ (7,546) | (91)%         |

R&D expenses decreased 91% or approximately \$19.8 million to \$1.9 million for the nine month period ended September 30, 2010 as compared to \$21.8 million for the same period in the prior year. Our primary R&D expenses for the nine month periods ended September 30, 2010 and 2009 are shown in the following table (in thousands):

|                                | Nine-months<br>ended<br>September 30, 2010 | Nine-months<br>ended<br>September 30, 2009 | Variance    | Change<br>(%) |
|--------------------------------|--|--|-------------|---------------|
| Research and Development       |  |  |             |               |
| Operating and occupancy        | \$ 508                                     | \$ 2,026                                   | \$ (1,518)  | (75)%         |
| Payroll and benefits           | 421  | 1,170                                      | (749)       | (64)%         |
| Androxal® clinical development | 177  | 775  | (598)       | (77)%         |
| Proellex® clinical development | 844  | 17,794                                     | (16,950)    | (95)%         |
| Total                          | \$ 1,950                                   | \$ 21,765                                  | \$ (19,815) | (91)%         |

The decrease in R&D expenses is primarily due to the decreased clinical development expenses related to Proellex® as a result of the discontinuation of all clinical trials in August 2009 due to the FDA's clinical hold on Proellex®. R&D expenses were further decreased by the decreased clinical development expenses related to Androxal® due to the completion of a Phase 2b proof-of-concept clinical trial in 2009. Additionally, payroll and benefits expenses decreased due to reduced headcount and the salary reduction program put in place in August 2009 and revised in May 2010.

To date through September 30, 2010 we have incurred approximately \$14.5 million for the development of Androxal® and approximately \$56.0 million for the development of Proellex®. These accumulated costs exclude any internal operating expenses. We have received confirmation from the Division of Metabolic and Endocrine Products ("DMEP") that our new IND was accepted for the investigation of Androxal® as a potential treatment for type 2 diabetes. As a result, we have initiated a Phase 2 trial. In addition, we are developing Androxal® as a treatment for men of reproductive age with low testosterone. The FDA has recently notified us that they will allow us to conduct two Phase 3 trials for Androxal® in men of reproductive age with low testosterone subject to protocol review by the FDA. We had a Type B meeting on November 8, 2010 to review our Phase 3 protocols with the FDA. In the meeting, the FDA recommended that a Phase 2B study in men with secondary hypogonadism but naïve to testosterone

treatment be conducted before moving into Phase 3. Prior to the clinical hold on further Proellex® development in August 2009, we were developing Proellex® for three indications which included a pre-surgical treatment of anemia associated with uterine fibroids, a chronic treatment of symptoms associated with uterine fibroids and as a chronic treatment of symptoms associated with endometriosis. In June 2010, the FDA notified us that the full clinical hold on Proellex® had been revised to a partial clinical hold to allow us to run a single study to explore both safety and signals of efficacy in an escalating dose fashion.

## General and Administrative Expenses

General and administrative expenses, or G&A, decreased 73% to approximately \$533,000 for the three month period ended September 30, 2010 as compared to \$2.0 million for the same period in the prior year. Our primary G&A expenses for the three month period ended September 30, 2010 and 2009 are shown in the following table (in thousands):

|                            | Three-months<br>ended<br>September 30, 2010 | Three-months<br>ended<br>September 30, 2009 | Variance   | Change<br>(%) |
|----------------------------|---|---|------------|---------------|
| General and Administrative |   |   |            |               |
| Payroll and benefits       | \$ 155                                      | \$ 767                                      | \$ (612)   | (80)%         |
| Operating and occupancy    | 378   | 1,195                                       | (817)      | (68)%         |
| Total                      | \$ 533                                      | \$ 1,962                                    | \$ (1,429) | (73)%         |

G&A payroll and benefits expenses include salaries, bonuses, relocation expense, severance costs, non-cash stock option compensation expense and fringe benefits. Included in payroll and benefits expense is a charge for non-cash stock option expense of \$79,000 for the three month period ended September 30, 2010 as compared to \$266,000 for the same period in the prior year. Additionally, salaries for the three month period ended September 30, 2010 were \$68,000 as compared to \$307,000 for the same period in the prior year. The decrease in salaries is primarily due to a decrease in headcount and the salary reduction program put in place in August 2009 and revised in May 2010.

G&A operating and occupancy expenses, which include expenses to operate as a public company, decreased 68% to \$378,000 for the three month period ended September 30, 2010 as compared to \$1.2 million for the same period in the prior year. The decrease is primarily due to a decrease in professional services.

G&A expenses decreased 57% to approximately \$1.8 million for the nine month period ended September 30, 2010 as compared to \$4.1 million for the same period in the prior year. Our primary G&A expenses for the nine month period ended September 30, 2010 and 2009 are shown in the following table (in thousands):

|                            | Nine-months<br>ended<br>September 30, 2010 | Nine-months<br>ended<br>September 30, 2009 | Variance   | Change<br>(%) |
|----------------------------|--|--|------------|---------------|
| General and Administrative |  |  |            |               |
| Payroll and benefits       | \$ 460                                     | \$ 1,862                                   | \$ (1,402) | (75)%         |
| Operating and occupancy    | 1,312                                      | 2,264                                      | (952)      | (42)%         |
| Total                      | \$ 1,772                                   | \$ 4,126                                   | \$ (2,354) | (57)%         |

Included in payroll and benefits expense is a charge for non-cash stock option expense of \$230,000 for the nine month period ended September 30, 2010 as compared to \$711,000 for the same period in the prior year. Additionally, salaries for the nine month period ended September 30, 2010 were \$197,000 as compared to \$870,000 for the same period in the prior year. The decrease in salaries is primarily due to a decrease in headcount and the salary reduction program put in place in August 2009 and revised in May 2010.

G&A operating and occupancy expenses decreased 42% to \$1.3 million for the nine month period ended September 30, 2010 as compared to \$2.3 million for the same period in the prior year. The decrease is primarily due to a decrease in professional services and consulting expenses.

#### Off-Balance Sheet Arrangements

As of September 30, 2010, the only off-balance sheet arrangement we have is the operating lease relating to our facility.

#### Liquidity and Capital Resources

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

On February 12, 2010, we entered into an Equity Distribution Agreement (the "Equity Distribution Agreement") with Ladenburg Thalmann & Co. Inc. ("Ladenburg"), pursuant to which we may issue and sell from time to time through Ladenburg, as sales agent and/or principal, shares of our common stock having an aggregate offering price of up to \$10 million (the "ATM Shares"). Ladenburg is not required to sell on our behalf any specific number or dollar amount of the ATM Shares, but Ladenburg, upon acceptance of written instructions from us, agreed to use its commercially reasonable efforts consistent with its customary trading and sales practices, to sell the ATM Shares up to the amount specified, and otherwise in accordance with the terms of a placement notice delivered to Ladenburg. We have no obligation to sell any ATM Shares under the Equity Distribution Agreement, and may at any time suspend sales under the Equity Distribution Agreement, provided that such suspension shall not affect either party's obligations with respect to the ATM Shares sold prior to the receipt of notice of such suspension. Ladenburg receives a commission of 4% of the gross sales price of all ATM Shares sold through it under the Equity Distribution Agreement. The ATM Shares are issued pursuant to our shelf registration statement on Form S-3, as amended (File No. 333-163648). Between July 1, 2010 and September 30, 2010, we have sold an aggregate of 277,164 ATM Shares at a weighted average share price of \$1.51, for proceeds of approximately \$401,000, net of expenses. Cumulative through September 30, 2010, we have sold 2,448,572 ATM Shares at a weighted average share price of \$2.77, for proceeds of approximately \$6.4 million, net of expenses. Pursuant to General Instruction I.B.6. of Form S-3, we may not sell more than one-third of the aggregate market value of our common stock held by non-affiliates during a period of 12 calendar months immediately prior to, and including, the date of such sale of such common stock. Due to this limitation, we announced on August 3, 2010 that we have suspended this ATM offering of Company securities.

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 \$4.2 million as of September 30, 2010 as compared to \$1.9 million as of December 31, 2009. All cash and cash equivalents as of September 30, 2010 and December 31, 2009 were held in an account backed by U.S. government securities.

Net cash of approximately \$3.8 million and \$17.4 million was used in operating activities during the nine month period ended September 30, 2010 and 2009, respectively. The major use of cash for operating activities through the third quarter of 2010 was to fund our operations and pay down our accounts payable and accrued expenses. Cash used in investing activities through the third quarter of 2010 was approximately \$303,000 primarily for capitalized patent and patent application costs for Androxal®. Cash provided by financing activities through the third quarter of 2010 was approximately \$6.4 million due to the 2,448,572 ATM Shares sold at a weighted average share price of \$2.77.





We have experienced negative cash flows from operations since inception. We will require substantial funds for research and development, including preclinical studies and clinical trials of our product candidates, and to commence sales and marketing efforts if appropriate, if the FDA or other regulatory approvals are obtained. Based on our current and planned clinical activities, we will need to raise additional capital no later than the first quarter of 2011 under our Equity Distribution Agreement with Ladenburg, to the extent allowed, or seek additional funding in the public or private capital markets through corporate collaborations or other financing vehicles in order to continue our development activities. There can be no assurance that any such funding will be available to us on favorable terms or at all. If we are successful in obtaining additional financing, the terms of such financing may have the effect of diluting or adversely affecting the holdings or the rights of holders of our common stock. It is possible that our clinical trial activities will be more costly and take longer than we anticipate; accordingly, there can be no assurance that additional capital will not be necessary prior to the time anticipated. Our capital requirements will depend on many factors, which are discussed in detail in “Item 1A. Risk Factors” to Part I of Form 10-K for the fiscal year ended December 31, 2009. Additionally, as discussed in Note 5, there is a third party individual patent holder that claims priority over our patent application for Androxal®. The uncertainties relating to the foregoing matters raise substantial doubt about our ability to continue as a going concern.

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

### Item 3. Quantitative and Qualitative Disclosures About Market Risk

**Interest Rate Risk.** We had cash and cash equivalents of approximately \$4.2 million at September 30, 2010 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 Accounting Officer have concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e)) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), were effective as of September 30, 2010.

#### Changes in Internal Control over Financial Reporting

In connection with the evaluation described above, we identified no change in internal control over financial reporting that occurred during the quarter ended September 30, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II - OTHER INFORMATION

### Item 1. Legal Proceedings

On August 7, 2009, R.M. Berry filed a putative class action lawsuit naming the Company, Joseph Podolski, Paul Lammers, and Louis Ploth, Jr. as defendants. The lawsuit is pending in the United States District Court for the Southern District of Texas, Houston Division. The lawsuit, styled R.M. Berry, on Behalf of Himself and all Others Similarly Situated v. Repros Therapeutics, Inc., Joseph Podolski, Paul Lammers, and Louis Ploth, Jr., alleges that the defendants made certain misleading statements related to the Company's Proellex® drug. Among other claims, the lawsuit contends that the defendants misrepresented the side effects of the drug related to liver function, and the risk that these side effects could cause a suspension of clinical trials of Proellex®. The lawsuit seeks to establish a class of shareholders allegedly harmed by the misleading statements, and asserts causes of action under the Securities Exchange Act of 1934. On August 14, 2009, a lawsuit making similar allegations and naming the same defendants was also filed in the United States District Court for the Southern District of Texas. This suit is styled Josephine Medina, Individually and On Behalf of all Others Similarly Situated v. Repros Therapeutics, Inc., Joseph Podolski, Paul Lammers, and Louis Ploth, Jr. On September 25, 2009, a lawsuit also making allegations similar to those in the Berry action, and naming the same defendants, was filed in the United States District Court for the Southern District of Texas. That lawsuit is styled Shane Simpson, Paul Frank and Clayton Scobie, on Behalf of Themselves and all Others Similarly Situated v. Repros Therapeutics, Inc., Joseph Podolski, Paul Lammers, and Louis Ploth, Jr. The lawsuits have now been consolidated, and lead plaintiffs appointed. On January 27, 2010, the lead plaintiffs filed a Consolidated Class Action Complaint styled In re Repros Therapeutics, Inc. Securities Litigation, Civil Action No. 09 Civ. 2530 (VDG). The lawsuit names Repros Therapeutics, Inc., Joseph Podolski, Paul Lammers, and Louis Ploth, Jr. as defendants. The allegations in the Consolidated Class Action Complaint are substantially the same as those contained in the prior complaints, and focus on the claim that the defendants deliberately withheld information concerning the negative side-effects of Proellex® related to liver function. Plaintiffs seek to establish a class action for all persons who "purchased or otherwise acquired Repros common stock between July 1, 2009, and August 2, 2009." No discovery has yet occurred in the matter. Defendants filed a motion to dismiss the Consolidated Class Action Complaint on March 15, 2010. Briefing has been completed on that motion, but the court has not yet ruled on it. An estimate of the possible loss or range of losses in connection with the lawsuits cannot be made at this time.

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.

Therapeutic uses of our Androxal® product candidate are covered in the United States by four issued U.S. patents and four pending patent applications. Foreign coverage of therapeutic uses of our Androxal® product candidate includes 40 issued foreign patents and 75 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 metabolic syndrome and conditions associated therewith, and the treatment of infertility in hypogonadal men. Androxal® (the trans-isomer of clomiphene) is purified from clomiphene citrate. A third party individual holds two issued patents related to the use of an anti-estrogen such as clomiphene citrate and others for use in the treatment of androgen deficiency and disorders related thereto. In our prior filings with the SEC, we have described our request to the U.S. Patent and Trademark Office, or PTO, for re-examination of one of these patents based on prior art. The third party amended the claims in the re-examination proceedings, which led the PTO to determine that the amended claims are patentable in view of those publications under consideration and a re-examination certificate was issued. However, we believe that the amended claims are invalid based on additional prior art publications, and we filed a second request for re-examination by the PTO in light of a number of these additional publications and other publications cited by the PTO. The request was granted and all of the claims were finally rejected by the PTO in the re-examination. The patent holder appealed the rejections to the PTO Board of Patent Appeals and Interferences (“the Board”) which affirmed the rejection of all of the claims. The patent holder subsequently filed a request for rehearing, which led the Board to reverse the rejections of several dependent claims in view of those publications under consideration. The patent holder has filed a Notice of Appeal to the Federal Circuit contesting the rejections maintained by the Board. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. Nevertheless, there is no assurance that either patent will ultimately be found invalid over the prior art. If such patents are not invalidated by the PTO we may be required to obtain a license from the holder of such patents in order to develop Androxal® further or attempts may be made to undertake further legal action to invalidate such patents. If such licenses were not available on acceptable terms, or at all, we may not be able to successfully commercialize or out-license Androxal®.

#### 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, 2009 in response to “Item 1A. Risk Factors” to Part I of Form 10-K.

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

None

#### Item 3. Defaults Upon Senior Securities.

None

#### Item 4. (Removed and Reserved).

#### Item 5. Other Information

None

#### Item 6. Exhibits

3.1(a) Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.3 to the Company's Registration Statement on Form SB-2 (No. 33-57728-FW), as amended ("Registration Statement")).

- 3.1(b) Certificate of Amendment to the Company's Restated Certificate of Incorporation, dated as of May 2, 2006 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K as filed with the Securities and Exchange Commission (the "Commission") on May 2, 2006).
- 3.1(c) Certificate of Amendment to the Company's Restated Certificate of Incorporation, as amended, dated as of December 16, 2008 (incorporated by reference to Exhibit 3.1(d) to the Company's Current Report on Form 8-K as filed with the Commission on December 23, 2008).
- 3.1(d) Certificate of Designation of Series One Junior Participating Preferred Stock dated September 2, 1999 (incorporated by reference to Exhibit A to Exhibit 4.1 to the Company's Registration Statement on Form 8-A as filed with the Commission on September 3, 1999).
- 3.1(e) Certificate of Amendment to Restated Certificate of Incorporation, dated as of November 18, 2009. Exhibit 3.1(e) to the Company's Current Report on Form 8-K dated November 19, 2009 is incorporated herein by reference.
- 3.1(f) Certificate of Amendment to Restated Certificate of Incorporation, dated October 14, 2010. Exhibit 3.1(f) to the Company's Current Report on Form 8-K dated October 14, 2010 is incorporated herein by reference.

- 3.2 Restated Bylaws of the Company (incorporated by reference to Exhibit 3.4 to the Registration Statement).
- 4.7 Sixth Amendment to Rights Agreement, dated September 9, 2010, between the Company and Computershare Trust Company, N.A. Exhibit 4.7 to the Company's Current Report on form 8-K dated September 9, 2010 is incorporated herein by reference.
- 10.1\* Second Amendment to Lease, effective as of July 1, 2010, between the Company and Columbia Texas 2408 Timberloch Industrial, L.P.
- 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 Accounting 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 Accounting Officer).
- \* Filed herewith.

SIGNATURES

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

REPROS THERAPEUTICS INC.

Date: November 10, 2010

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

Date: November 10, 2010

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