

REPROS THERAPEUTICS INC.

Form 10-Q

May 09, 2007

Table of Contents

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

(Mark One)

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

For the quarterly period ended March 31, 2007

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 is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):
Large accelerated filer Accelerated filer Non-accelerated filer

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

As of May 1, 2007, there were outstanding 12,774,904 shares of Common Stock, par value \$.001 per share, of the Registrant.

REPROS THERAPEUTICS INC.
(A development stage company)
For the Quarter Ended March 31, 2007
INDEX

	Page
<u>FACTORS AFFECTING FORWARD-LOOKING STATEMENTS</u>	3
<u>PART I. FINANCIAL INFORMATION</u>	4
<u>Item 1. Financial Statements (unaudited)</u>	
<u>Unaudited Condensed Consolidated Balance Sheets: March 31, 2007 and December 31, 2006</u>	5
<u>Unaudited Condensed Consolidated Statements of Operations: For the three-months ended March 31, 2007 and 2006 and from Inception (August 20, 1987) through March 31, 2007</u>	6
<u>Unaudited Condensed Consolidated Statements of Cash Flows: For the three-months ended March 31, 2007 and 2006 and from Inception (August 20, 1987) through March 31, 2007</u>	7
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	8
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	19
<u>Item 4. Controls and Procedures</u>	19
<u>PART II. OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	20
<u>Item 1A. Risk Factors</u>	20
<u>Item 5. Other Information</u>	20
<u>Item 6. Exhibits</u>	20
<u>SIGNATURES</u>	22
<u>Certification of CEO Pursuant to Section 302</u>	
<u>Certification of CFO Pursuant to Section 302</u>	
<u>Certification of CEO Pursuant to Section 1350</u>	
<u>Certification of CFO Pursuant to Section 1350</u>	

Table of Contents

FACTORS AFFECTING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words may, anticipate, believe, expect, estimate, project, suggest, intend and similar expressions are intended forward-looking statements. Such statements are subject to certain risks, uncertainties and assumptions. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, expected, estimated, projected, suggested or intended. These risks and uncertainties include risks associated with the early stage of development of Proellex and Androxal and uncertainty related to the Company's ability to obtain approval of the Company's products by the Food and Drug Administration (FDA) and regulatory bodies in other jurisdictions, the Company's ability to raise additional capital on acceptable terms or at all, uncertainty relating to the Company's patent portfolio, and other risks and uncertainties described in the Company's filings with the Securities and Exchange Commission. For additional discussion of such risks, uncertainties and assumptions, see Item 1. Business and Item 1A. Risk Factors included in the Company's annual report on Form 10-K for the year-ended December 31, 2006 and Part I. Financial Information Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources included elsewhere in this quarterly report on Form 10-Q.

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

The following unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Rule 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all necessary adjustments (which include only normal recurring adjustments) considered necessary for a fair statement of the interim periods presented have been included. The year-end balance sheet data was derived from audited financial statements, but does not include all the disclosures required by accounting principles generally accepted in the United States of America. Operating results for the three-month period ended March 31, 2007 are not necessarily indicative of the results that may be expected for the year ended December 31, 2007. 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, 2006.

Table of Contents

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

	March 31, 2007	December 31, 2006
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 4,592	\$ 1,136
Marketable securities	31,033	5,600
Prepaid expenses and other current assets	383	225
Total current assets	36,008	6,961
Fixed assets, net	61	65
Other assets, net	912	823
Total assets	\$ 36,981	\$ 7,849
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities		
Accounts payable	\$ 1,704	\$ 1,973
Accrued expenses	1,773	2,086
Total current liabilities	3,477	4,059
Commitments & Contingencies		
Stockholders Equity		
Undesignated Preferred Stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding		
Common Stock, \$.001 par value, 20,000,000 shares authorized, 14,711,330 and 12,087,997 shares issued, respectively, 12,774,295 and 10,150,962 shares outstanding, respectively	15	12
Additional paid-in capital	151,428	118,066
Cost of treasury stock, 1,937,035 and 1,937,035 shares, respectively	(5,948)	(5,948)
Deficit accumulated during the development stage	(111,991)	(108,340)
Total stockholders equity	33,504	3,790
Total liabilities and stockholders equity	\$ 36,981	\$ 7,849

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

Table of Contents

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

	Three Months Ended March		From Inception
	31,		(August 20,
	2007	2006	1987)
			through
			March 31,
			2007
Revenues and other income			
Licensing fees	\$	\$	\$ 28,755
Product royalties			627
Research and development grants			1,219
Interest income	318	174	14,670
Gain on disposal of fixed assets			102
Other Income			35
Total revenues and other income	318	174	45,408
Expenses			
Research and development	3,028	1,808	115,301
General and administrative	941	610	32,367
Interest expense and amortization of intangibles			388
Total expenses	3,969	2,418	148,056
Loss from continuing operations	(3,651)	(2,244)	(102,648)
Loss from discontinued operations			(1,828)
Gain on disposal of discontinued operation			939
Net loss before cumulative effect of change in accounting principle	(3,651)	(2,244)	(103,537)
Cumulative effect of change in accounting principle			(8,454)
Net loss	\$ (3,651)	\$ (2,244)	\$ (111,991)
Loss per share basic and diluted	\$ (0.31)	\$ (0.22)	
Weighted average shares used in loss per share calculation:			
Basic	11,756	10,140	
Diluted	11,756	10,140	

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

Table of Contents

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

	Three Months Ended March		From Inception
	31,		(August 20,
	2007	2006	1987)
			through
			March 31,
			2007
Cash Flows from Operating Activities			
Net loss	\$ (3,651)	\$ (2,244)	\$ (111,991)
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			1,339
Noncash decrease in accounts payable			(1,308)
Depreciation and amortization	8		3,806
Noncash expenses related to stock-based transactions	294	156	3,900
Common stock issued for agreement not to compete			200
Series B Preferred Stock issued for consulting services			18
Sales and maturities of marketable securities	4,450	14,112	62,432
Purchases of marketable securities	(29,883)	(9,801)	(64,930)
Changes in operating assets and liabilities (net effects of purchase of businesses in 1988 and 1994):			
Decrease (increase) in receivables			(199)
Decrease (increase) in inventory			(4,447)
Decrease (increase) in prepaid expenses and other current assets	(159)	34	(85)
(Decrease) increase in accounts payable and accrued expenses	(582)	45	4,673
Net cash provided by (used in) operating activities	(29,523)	2,302	(102,900)
Cash Flows from Investing Activities			
Maturities (purchases) of marketable securities			(28,723)
Capital expenditures	(2)	(45)	(2,363)
Purchase of technology rights and other assets	(90)	(38)	(2,934)
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

Edgar Filing: REPROS THERAPEUTICS INC. - Form 10-Q

Increase in net assets held for disposal			(213)
Net cash used in investing activities	(92)	(83)	(31,617)
Cash Flows from Financing Activities			
Proceeds from issuance of common stock, net of offering costs	33,039		135,443
(Increase) decrease in prepaid offering costs			
Exercise of stock options	32	203	358
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 (used in) financing activities	33,071	203	139,109
Net increase (decrease) in cash and cash equivalents	3,456	2,422	4,592
Cash and cash equivalents at beginning of period	1,136	2,165	
Cash and cash equivalents at end of period	\$ 4,592	\$ 4,587	\$ 4,592

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

Table of Contents

REPOS THERAPEUTICS INC. AND SUBSIDIARY
(A development stage company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2007
(Unaudited)

NOTE 1 Organization, Operations and Liquidity

Repos Therapeutics Inc. (the Company , RPRX , or we, us or our) was organized on August 28, 1987 and is a development stage company. We are a biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders. Our lead product candidate, Proellex, is an orally available small molecule compound that we are developing for the treatment of uterine fibroids and endometriosis. We are also developing Androxal, which causes increased testosterone secretion from the testes, for the treatment of testosterone deficiency in men resulting from secondary hypogonadism.

On February 5, 2007 the Company completed a follow-on public offering of 2,610,000 shares of common stock at \$13.75 per share. The net proceeds from the sale of shares of common stock in this offering were approximately \$33.0 million.

We have experienced negative cash flows from operations since inception and have funded our activities to date primarily from equity financings and corporate collaborations. We will continue to 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. We believe that our existing capital resources under our current operating plan will be sufficient to fund our operations through at least the first quarter of 2008. There can be no assurance that changes in our current strategic plans or other events will not result in accelerated or unexpected expenditures.

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

As of March 31, 2007, we had an accumulated deficit of \$112.0 million. Losses 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. Due to various tax regulations, including change in control provisions in the tax code, the value of the tax asset created by these accumulated losses can be substantially diminished. We have recorded a full valuation allowance for all deferred tax assets.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and

Table of Contents

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.

Recent Accounting Pronouncements

In June 2006, the FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48), which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109, Accounting for Income Taxes. FIN 48 establishes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for the Company as of January 1, 2007. The adoption of FIN 48 did not have an impact on the Company's consolidated financial statements.

In September 2006, FASB issued SFAS No. 157, Fair Value Measurements which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. Earlier application is encouraged provided that the reporting entity has not yet issued financial statements for that fiscal year including financial statements for an interim period within that fiscal year. The company is assessing SFAS No. 157 and has not determined yet the impact that the adoption of SFAS No. 157 will have on its result of operations or financial position.

In September 2006, the SEC released Staff Accounting Bulletin No. 108 Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements (SAB 108). SAB 108 provides interpretative guidance on how public companies quantify financial statement misstatements. There have been two common approaches used to quantify such errors. Under an income statement approach, the roll-over method, the error is quantified as the amount by which the current year income statement is misstated. Alternatively, under a balance sheet approach, the iron curtain method, the error is quantified as the cumulative amount by which the current year balance sheet is misstated. In SAB 108, the SEC established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the company's financial statements and the related financial statement disclosures. This model is commonly referred to as a dual approach because it requires quantification of errors under both the roll-over and iron curtain methods. SAB 108 is effective for the Company as of January 1, 2007. The adoption of SAB 108 did not have a material impact on the Company's consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115. This pronouncement permits entities to use the fair value method to measure certain financial assets and liabilities by electing an irrevocable option to use the fair value method at specified election dates. After election of the option, subsequent changes in fair value would result in the recognition

Table of Contents

of unrealized gains or losses as period costs during the period the change occurred. SFAS No. 159 becomes effective as of the beginning of the first fiscal year that begins after November 15, 2007, with early adoption permitted. However, entities may not retroactively apply the provisions of SFAS No. 159 to fiscal years preceding the date of adoption. We are currently evaluating the impact that SFAS No. 159 may have on our financial position, results of operations and cash flows.

NOTE 2 Marketable Securities

Management determines the appropriate classification of investments in debt and equity securities at the time of purchase and re-evaluates such designation as of each subsequent balance sheet date. Securities for which the Company has the ability and intent to hold to maturity are classified as held to maturity. Securities classified as trading securities are recorded at fair value. Gains and losses on trading securities, realized and unrealized, are included in earnings and are calculated using the specific identification method. Any other securities are classified as available for sale. At March 31, 2007, all securities were classified as trading securities. The fair value and cost basis including purchased premium for these securities was \$31.0 million and \$5.6 million at March 31, 2007 and December 31, 2006, respectively.

Marketable securities as of March 31, 2007 consist of only short term investments. The Company's investments typically include corporate bonds and notes, Euro-dollar bonds, taxable auction securities and asset-backed securities. The Company's policy is to require minimum credit ratings of A2/A and A1/P1 with maturities of up to three years. The average life of the investment portfolio may not exceed 24 months.

NOTE 3 Patents

As of March 31, 2007, the Company had approximately \$912,000 in internal capitalized patent costs reflected on its balance sheet. Of this amount, \$442,000 relates to patents for Proellex, which is being developed as an oral treatment for uterine fibroids and endometriosis, and \$470,000 relates to patents for Androxal, which is being developed as an oral treatment for testosterone deficiency.

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 year. 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.

The following table presents information necessary to calculate earnings per share for the three-month periods ended March 31, 2007 and 2006 (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2007	2006
Net Loss	\$ (3,651)	\$ (2,244)
Average common shares outstanding	11,756	10,140
Basic loss per share	\$ (0.31)	\$ (0.22)
Diluted loss per share	\$ (0.31)	\$ (0.22)

Table of Contents

Other potential common stock of 1,535,148 and 1,472,148 for the periods ended March 31, 2007 and 2006, respectively, were excluded from the above calculation of diluted loss per share since they were antidilutive.

NOTE 5 Stockholders Equity

On February 5, 2007 the Company completed a follow-on public offering of 2,610,000 shares of common stock at \$13.75 per share. The net proceeds from the sale of shares of common stock in this offering were approximately \$33.0 million.

On March 9, 2007 the Company's Board of Directors voted to terminate its current 2000 Employee Stock Purchase Plan.

NOTE 6 Commitments and Contingencies

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

Table of Contents

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

The following discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements reflect the Company's current views with respect to future events and financial performance and are subject to certain risks, uncertainties and assumptions. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated in such forward-looking statements. The following discussion of financial condition should be read in conjunction with the accompanying consolidated financial statements and related notes.

Overview

Repros Therapeutics Inc., (the Company , RPRX, or we, us or our), was organized on August 28, 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 Proellex, a selective blocker of the progesterone receptor in women, for the treatment of uterine fibroids and endometriosis. We are also developing Androxal, for the treatment of testosterone deficiency in men resulting from secondary hypogonadism.

Our lead product candidate, Proellex, is an orally active small molecule which we are developing for two indications: the treatment of uterine fibroids and the treatment of endometriosis. The National Uterine Fibroid Foundation estimates that as many as 80% of all women in the United States have uterine fibroids, and one in four of these women have symptoms severe enough to require treatment. According to The Endometriosis Association, endometriosis affects 5.5 million women in the United States and Canada and millions more worldwide.

In April 2007, we provided top line data from our three-month U.S. Phase 2 clinical trial of Proellex in uterine fibroid patients which showed a statistically significant improvement in our primary endpoint. Women on Proellex experienced a dramatic reduction in their scores on the Pictorial Blood Loss Assessment Chart, or PBAC, which is a validated visual analog scale. Women experienced a reduction from mean scores on the PBAC of over 100 to scores less than 10. The mean scores after three months of dosing for the 25 mg and 12.5 mg dose of Proellex were 6.0 and 16.9, respectively. Women on placebo, on the other hand, exhibited a score of 109.5 after 3 months of treatment. The 12.5 mg and 25 mg doses were statistically superior to placebo with p-values of less than 0.0001 for both. These results were similar for both the modified intent-to-treat group and the group of patients that completed the study. A positive effect of reducing menstrual blood loss was a significant increase in hemoglobin in the Proellex-treated group as a whole but particularly in those subjects with an abnormally low hemoglobin on study entry.

In addition, after three months of treatment, no statistically significant changes in endometrial thickness were detected among the women who underwent ultrasound measurements of endometrial thickness at various time points. This study uses an endometrial thickness cut-off of 14mm after three months of dosing to determine whether or not a woman is allowed to proceed into an ongoing open label study. For those patients that were evaluated, 9 patients at the 12.5 mg dose and 4 patients at the 25 mg dose exhibited an endometrium greater than 14 mm compared to 6 patients on placebo. An expert panel of pathologists will review all of

Table of Contents

the biopsies using criteria adopted by the World Health Organization in addition to a specific classification created for the analysis of the histology in this study.

Both doses of Proellex were well tolerated. The number of adverse events judged to be treatment related by the investigators in the Proellex 12.5 and 25 mg treatment groups were similar in incidence to placebo. The exception was the occurrence of amenorrhea (an expected drug effect) in 78.6% and hot flashes in 16.7% of all Proellex treated patients, respectively. The hot flashes were not dose dependent. The severity of the hot flashes was generally mild to moderate as were the vast majority of the other adverse events. On average, there were no clinically significant changes in other laboratory measurements of safety, including liver enzymes.

In December 2006, we provided a three-month interim analysis of our six-month ongoing European endometriosis Phase 1/2 clinical trial of Proellex. This analysis demonstrated that treatment with the highest dose of Proellex, 50 mg, achieved statistically significant reduction in days of pain compared to treatment with Lupron[®], the current pharmaceutical standard of care for the treatment of endometriosis.

We are currently conducting a U.S. and a European one-year safety trial for patients that have completed either the Proellex U.S. Phase 2 or the European Phase 1/2 trials. Fifty-eight patients from the U.S. Phase 2 trial have rolled into the one-year open label extension study. We anticipate that completed patients from the European Phase 1/2 trial will begin to roll into the one-year open label trial during the second quarter 2007. We intend to begin a U.S. Phase 2 trial with Proellex for the treatment of endometriosis in Q3, 2007 and a U.S. Phase 3 trial with Proellex for the treatment of uterine fibroids in Q4, 2007.

Our second product candidate, Androxal, is an orally active proprietary small molecule compound designed to treat testosterone deficiency due to secondary hypogonadism by restoring normal testosterone production in males with functional testes and diminished pituitary function, a common condition in the aging male. According to the Urology Channel, recent estimates show that approximately 13 million men in the United States experience testosterone deficiency. The current gold standard in the industry is AndroGel[®], with reported sales in North America of approximately \$282 million in 2005. Estimated sales of all androgens in North America in 2006 is approximately \$570 million.

We have completed a U.S. Phase 1 clinical trial and in December 2006, we provided a three-month interim analysis from our ongoing six-month non-pivotal U.S. Phase 3 trial of Androxal. Both trials demonstrated statistically significant increases in testosterone levels versus placebo, without suppression of luteinizing hormone (LH). In our current U.S. Phase 3 trial, at three-months, Androxal restored testosterone levels to the normal range in over 80% of patients treated. We intend to provide top-line data from this six-month clinical trial in Q3, 2007. We are currently enrolling completed patients from this clinical trial into a one-year open label safety trial. We intend to initiate our first pivotal U.S. Phase 3 clinical trial in Q4, 2007.

All clinical trial results, including those related to Proellex and Androxal, are subject to review by the FDA, and the FDA may disagree with our conclusions about safety and efficacy. We caution that results obtained in early stage clinical trials may be reversed by the results of later stage clinical trials with significantly larger and more diverse patient populations treated for longer periods of time.

Table of Contents

We refer you to our Annual Report on Form 10-K for the year ended December 31, 2006 and to our Current Reports on Forms 8-K filed since we filed such Form 10-K for additional details relating to our clinical trials and preclinical studies.

We intend to seek strategic out-licensing or other corporate partnering opportunities with respect to Androxal to permit us to continue to fund our clinical trial programs. In addition, we also are continuing to seek strategic out-licensing opportunities with respect to our phentolamine-based products for the treatment of sexual dysfunction. As a result, we have maintained our patent portfolio for these products so that they will continue to be attractive to potential third party licensees.

We have not generated any substantial revenue from the commercial sale of any of our current product candidates. We will not receive any revenue from commercial sales unless we complete the clinical trial process, obtain regulatory approval, and successfully commercialize one or more of our product candidates. We cannot be certain when or if any net cash inflow from any of our current product candidates will commence.

We have experienced negative cash flows from operations since inception and have funded our activities to date primarily from equity financings and corporate collaborations. We believe that our existing capital resources under our current operating plan will be sufficient to fund our operations through at least March 31, 2008. There can be no assurance that changes in our current strategic plans or other events will not result in accelerated or unexpected expenditures.

We may need to raise additional capital through the sale of equity securities and/or through partnerships to continue the clinical development of our products. If we are not able to raise capital through the sale of equity securities, or cannot locate an alternative source of financing, the outcome would have a material adverse effect on us and the clinical development timeline of our product candidates. If we are not able to raise adequate capital for our clinical development plans, then we will have to adjust our plans, which will delay the approval process of our product candidates.

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

On February 5, 2007, we completed a follow-on public offering of 2,610,000 shares of our common stock at a purchase price of \$13.75 per share. As a result of the offering, we received approximately \$33.0 million in net proceeds which we intend to use to continue our clinical development of Proellex and Androxal.

Effective January 8, 2007, we voluntarily withdrew the listing of our common stock from

Table of Contents

NYSE Arca, Inc., formerly the Pacific Exchange, in order to streamline administrative requirements and reduce expenses.

Employees and Consultants

We currently have seven full-time employees and utilize the services of contract research organizations, contract manufacturers and various consultants to assist us in performing regulatory, clinical development and manufacturing activities related to the clinical development of our products. We are highly dependent on our various contract organizations to adequately perform the activities required to obtain regulatory approval of our products and to complete development and manufacturing thereof.

Research and Development

The clinical development of pharmaceutical products is a complex undertaking, and many products that begin the clinical development process do not obtain regulatory approval. The costs associated with our clinical trials may be impacted by a number of internal and external factors, including the number and complexity of clinical trials necessary to obtain regulatory approval, the number of eligible patients necessary to complete our clinical trials and any difficulty in enrolling these patients, and the length of time to complete our clinical trials. Given the uncertainty of these potential costs, we are unable to estimate the total costs we will incur for the clinical development of our product candidates over those costs currently projected. We do, however, expect these costs to increase substantially in future periods as we continue later-stage clinical trials, initiate new clinical trials for additional indications and seek to obtain regulatory approvals. Any failure by us to obtain, or any delay in obtaining, regulatory approvals could cause our research and development expenditures to increase and, in turn, have a material adverse effect on our results of operations.

We have limited financial resources and personnel and anticipate that we will need to raise additional capital and hire additional key employees in order to be able to successfully develop each of our current product candidates through clinical trials and to be able to market them, should regulatory approval be obtained, on a worldwide basis. Alternatively, we may elect to partner with a larger and more experienced pharmaceutical company with better resources for one or more of our product candidates and/or target indications. As a result, we believe that an out-license of one or more of our product candidates could occur at some point in the future, and discussions are held from time to time with potential partners to explore possible arrangements; however, there can be no assurance that such an agreement will be entered into by us.

Recent Accounting Pronouncements

In June 2006, the FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes (FIN 48), which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109, Accounting for Income Taxes. FIN 48 establishes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for the

Table of Contents

Company as of January 1, 2007. The adoption of FIN 48 did not have an impact on the Company's consolidated financial statements.

In September 2006, FASB issued SFAS No. 157, Fair Value Measurements which defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. Earlier application is encouraged provided that the reporting entity has not yet issued financial statements for that fiscal year including financial statements for an interim period within that fiscal year. The company is assessing SFAS No. 157 and has not determined yet the impact that the adoption of SFAS No. 157 will have on its result of operations or financial position.

In September 2006, the SEC released Staff Accounting Bulletin No. 108 Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements (SAB 108). SAB 108 provides interpretative guidance on how public companies quantify financial statement misstatements. There have been two common approaches used to quantify such errors. Under an income statement approach, the roll-over method, the error is quantified as the amount by which the current year income statement is misstated. Alternatively, under a balance sheet approach, the iron curtain method, the error is quantified as the cumulative amount by which the current year balance sheet is misstated. In SAB 108, the SEC established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the company's financial statements and the related financial statement disclosures. This model is commonly referred to as a dual approach because it requires quantification of errors under both the roll-over and iron curtain methods. SAB 108 is effective for the Company as of January 1, 2007. The adoption of SAB 108 did not have a material impact on the Company's consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115. This pronouncement permits entities to use the fair value method to measure certain financial assets and liabilities by electing an irrevocable option to use the fair value method at specified election dates. After election of the option, subsequent changes in fair value would result in the recognition of unrealized gains or losses as period costs during the period the change occurred. SFAS No. 159 becomes effective as of the beginning of the first fiscal year that begins after November 15, 2007, with early adoption permitted. However, entities may not retroactively apply the provisions of SFAS No. 159 to fiscal years preceding the date of adoption. We are currently evaluating the impact that SFAS No. 159 may have on our financial position, results of operations and cash flows.

Results of Operations

Three-Month Periods Ended March 31, 2007 and 2006

Our results of operations may vary significantly from quarter to quarter and year to year, and depend on, among other factors, our ability to be successful in our clinical trials, the regulatory approval process in the United States and other foreign jurisdictions and the ability to complete new licenses and product development agreements. The timing of our revenues may

Table of Contents

not match the timing of our associated product development expenses. To date, research and development expenses have generally exceeded revenue in each particular period and/or fiscal year.

Revenues and other income. Total revenues and other income for the three-month period ended March 31, 2007 increased to \$318,000 as compared to \$174,000 for the same period in the prior year.

Interest income increased 83% to \$318,000 for the three-month period ended March 31, 2007, as compared to \$174,000 for the same period in the prior year. The increase in interest income for the three-month period ended March 31, 2007 as compared to the same period in the prior year is primarily due to an increase in marketable securities as a result of the completion of the Company's follow-on public offering on February 5, 2007 in which we received approximately \$33.0 million in net proceeds.

Research and Development Expenses. Research and development (R&D) expenses primarily include clinical regulatory affairs activities and preclinical and clinical study development expenses. R&D expenses increased 67% to approximately \$3.0 million for the three-month period ended March 31, 2007 as compared to approximately \$1.8 million for the same period in the prior year. The increase in R&D expenses for the three-month period ended March 31, 2007 as compared to the same period in the prior year is primarily due to an increase of \$982,000 in our current clinical activities, an increase in personnel costs of \$81,000, an increase in legal expenses of \$58,000 and an increase of \$46,000 in non-cash stock option compensation.

General and Administrative Expenses. General and administrative expenses increased 54% to \$941,000 for the three-month period ended March 31, 2007 as compared to \$610,000 for the same period in the prior year. The increase in expenses for the three-month period ended March 31, 2007 as compared to the same period in the prior year is primarily due to an increase in non-cash stock compensation expense of \$91,000, an increase in personnel costs of \$67,000, an increase in investor relations costs of \$59,000, an increase in strategic administrative fees of \$40,000, an increase in professional services of \$37,000 and an increase of \$23,000 in costs associated with meeting the requirements of Section 404 of the Sarbanes-Oxley Act.

Liquidity and Capital Resources

We had cash, cash equivalents and marketable securities of approximately \$35.6 million at March 31, 2007 as compared to \$6.7 million at December 31, 2006. This increase in cash is primarily due to the completion of our follow-on public offering of 2,610,000 shares on February 5, 2007 in which we received approximately \$33.0 million in net proceeds. On September 5, 2006 we filed a Form S-3 shelf registration statement with the Securities and Exchange Commission for up to 5,000,000 shares of common stock of which we have utilized 2,610,000 leaving us with 2,390,000 available shares.

Depending upon the timing of certain clinical activities, we believe our cash resources will be sufficient until at least March 31, 2008. We will need to raise additional capital through the sale of equity securities and/or through partnerships to continue the clinical development of our products. If we are not able to raise capital through the sale of equity securities, or cannot locate

Table of Contents

an alternative source of financing, the outcome would have a material adverse effect on us and the clinical development timelines of our product candidates. If we are not able to raise adequate capital for our clinical development plans, then we will have to reduce capital expenditures, which will delay the development and approval process of our product candidates. We cannot assure that additional funding will be available on acceptable terms, or at all.

There can be no assurance that changes in our current strategic plans or other events will not result in accelerated or unexpected expenditures. We expect clinical and preclinical development expenses to increase substantially in future periods as we continue later-stage clinical trials, initiate new clinical trials for additional indications, seek to obtain regulatory approvals and conduct long-term animal safety studies.

As of March 31, 2007, we had an accumulated deficit of \$112.0 million. We have incurred losses since our inception and expect to continue to incur losses for the foreseeable future. Inception to date losses have resulted principally from costs incurred in conducting clinical trials and for research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. We have financed our operations primarily with proceeds from public offerings and private placements of equity securities, funds received under collaborative agreements and SBIR grants. We are actively developing Proellex for the treatment of uterine fibroids and endometriosis and Androxal for the treatment of testosterone deficiency in men with secondary hypogonadism and believe we have enough funds to continue such development through March 31, 2008. We will need substantial additional capital in order to continue such development beyond such date.

Our capital requirements will depend on many factors, including the costs and timing of seeking regulatory approvals of our products; the problems, delays, expenses and complications frequently encountered by development stage companies; the progress of our preclinical and clinical activities; the costs associated with any future collaborative research, manufacturing, marketing or funding arrangements; our ability to obtain regulatory approvals; the success of our potential future sales and marketing programs; the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; changes in economic, regulatory or competitive conditions of our planned business; and additional costs associated with being a publicly-traded company. Estimates about the adequacy of funding for our activities are based on certain assumptions, including the assumption that the development and regulatory approval of our products can be completed at projected costs and that product approvals and introductions will be timely and successful. There can be no assurance that changes in our research and development plans, acquisitions or other events will not result in accelerated or unexpected expenditures. To satisfy our capital requirements, we may seek to raise additional funds in the public or private capital markets. We also may seek additional funding through corporate collaborations and other financing vehicles. There can be no assurance that any such funding will be available to us on favorable terms or at all. If we are successful in obtaining additional financing, the terms of such financing may have the effect of diluting or adversely affecting the holdings or the rights of the holders of our common stock.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. Cash, cash equivalents and investments were approximately \$35.6

Table of Contents

million at March 31, 2007. These assets were primarily invested in investment grade corporate bonds and commercial paper with maturities of less than 6 months, which are classified as Trading Securities. We do not invest in derivative securities. Although our portfolio is subject to fluctuations in interest rates and market conditions, no significant gain or loss on any security is expected to be recognized in earnings due to the expected short holding period.

Item 4. Controls and Procedures

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

In connection with the evaluation described above, we identified no change in internal control over financial reporting that occurred during the fiscal quarter ended March 31, 2007 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

There were no material changes from risk factors as previously disclosed in the registrant's Form 10-K for the fiscal year ended December 31, 2006 in response to Item 1A. to Part I of Form 10-K.

Item 5. Other Information

None

Item 6. Exhibits

- 10.1 Employment Agreement between the Company and Dr. Andre van As dated March 7, 2007. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on March 8, 2007 is incorporated herein by reference.
- 10.2 Fourth Amendment to PHS Patent License Agreement, as amended, dated December 9, 2003 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on March 20, 2007 is incorporated herein by reference.
- 10.3 Waiver to PHS Patent License Agreement, as amended, dated March 8, 2007 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services. Exhibit 10.2 to the Company's Current Report on Form 8-K as filed with the Commission on March 20, 2007 is incorporated herein by reference.
- 10.4** Fifth Amendment to PHS Patent License Agreement, as amended, dated March 15, 2007 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services. Exhibit 10.3 to the Company's Current Report on Form 8-K as filed with the Commission on March 20, 2007 is incorporated herein by reference.
- 31.1* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).
- 31.2* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).
- 32.1* Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).
- 32.2* Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).

* Filed herewith.

Table of Contents

** Portions of this exhibit have been omitted based on a request for confidential treatment pursuant to Rule 24b-2 of the Exchange Act. Such omitted portions have been filed separately with the Commission.

Table of Contents

SIGNATURES

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

REPROS THERAPEUTICS INC.

Date: May 9, 2007

By: /s/ Joseph S. Podolski

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

Date: May 9, 2007

By: /s/ Louis Ploth, Jr.

Louis Ploth, Jr.
Vice President Business Development, Chief
Financial Officer, Director and Secretary
(Principal Financial and Accounting Officer)

22

Table of Contents

Exhibit Index

- 10.1 Employment Agreement between the Company and Dr. Andre van As dated March 7, 2007. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on March 8, 2007 is incorporated herein by reference.
- 10.2 Fourth Amendment to PHS Patent License Agreement, as amended, dated December 9, 2003 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services. Exhibit 10.1 to the Company's Current Report on Form 8-K as filed with the Commission on March 20, 2007 is incorporated herein by reference.
- 10.3 Waiver to PHS Patent License Agreement, as amended, dated March 8, 2007 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services. Exhibit 10.2 to the Company's Current Report on Form 8-K as filed with the Commission on March 20, 2007 is incorporated herein by reference.
- 10.4** Fifth Amendment to PHS Patent License Agreement, as amended, dated March 15, 2007 between the Company and certain agencies of the United States Public Health Service within the Department of Health and Human Services. Exhibit 10.3 to the Company's Current Report on Form 8-K as filed with the Commission on March 20, 2007 is incorporated herein by reference.
- 31.1* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).
- 31.2* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).
- 32.1* Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).
- 32.2* Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).

* Filed herewith.

** Portions of this exhibit have been omitted based on a request for confidential treatment pursuant to Rule 24b-2 of the Exchange Act. Such omitted portions have been filed separately with

the
Commission.