

REPROS THERAPEUTICS INC.

Form 10-Q

November 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 September 30, 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 November 6, 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 September 30, 2007  
INDEX

	<b>Page</b>
<b><u>FACTORS AFFECTING FORWARD-LOOKING STATEMENTS</u></b>	3
<b><u>PART I. FINANCIAL INFORMATION</u></b>	4
<u>Item 1. Financial Statements (unaudited)</u>	
<u>Unaudited Condensed Consolidated Balance Sheets: September 30, 2007 and December 31, 2006</u>	5
<u>Unaudited Condensed Consolidated Statements of Operations:</u> For the three-months and nine-months ended September 30, 2007 and 2006 and from Inception (August 20, 1987) through September 30, 2007	6
<u>Unaudited Condensed Consolidated Statements of Stockholders' Equity</u>	7
<u>Unaudited Condensed Consolidated Statements of Cash Flows:</u> For the nine-months ended September 30, 2007 and 2006 and from Inception (August 20, 1987) through September 30, 2007	8
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	9
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	23
<u>Item 4. Controls and Procedures</u>	23
<b><u>PART II. OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	25
<u>Item 1A. Risk Factors</u>	25
<u>Item 5. Other Information</u>	26
<u>Item 6. Exhibits</u>	26
<b><u>SIGNATURES</u></b>	27
<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 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 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 nine-month period ended September 30, 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**

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

	<b>September 30, 2007</b>	<b>December 31, 2006</b>
<b>ASSETS</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 2,815	\$ 1,136
Marketable securities	25,935	5,600
Prepaid expenses and other current assets	508	225
Total current assets	29,258	6,961
<b>Fixed Assets, net</b>	50	65
<b>Other Assets, net</b>	1,013	823
Total assets	\$ 30,321	\$ 7,849
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 1,756	\$ 1,973
Accrued expenses	1,391	2,086
Total current liabilities	3,147	4,059
<b>Commitments and Contingencies</b>		
<b>Stockholders Equity</b>		
Undesignated Preferred Stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding		
Common Stock, \$.001 par value, 20,000,000 shares authorized, 14,711,939 and 12,087,997 shares issued, respectively; 12,774,904 and 10,150,962 shares outstanding, respectively	15	12
Additional paid-in capital	151,839	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	(118,732)	(108,340)
Total stockholders equity	27,174	3,790
Total liabilities and stockholders equity	\$ 30,321	\$ 7,849

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

**Table of Contents**

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

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>		<b>From Inception</b>
	<b>September 30,</b>		<b>September 30,</b>		<b>(August 20,</b>
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>	<b>1987)</b>
					<b>through</b>
					<b>September 30,</b>
					<b>2007</b>
<b>Revenues</b>					
Licensing fees	\$	\$	\$	\$	\$ 28,755
Product royalties					627
Research and development grants					1,219
Interest income	396	146	1,155	486	15,507
Gain on disposal of fixed assets					102
Other income					35
<b>Total revenues and other income</b>	<b>396</b>	<b>146</b>	<b>1,155</b>	<b>486</b>	<b>46,245</b>
<b>Expenses</b>					
Research and development	3,196	3,073	9,430	7,245	121,703
General and administrative	568	713	2,117	1,989	33,543
Interest expense and amortization of intangibles					388
<b>Total expenses</b>	<b>3,764</b>	<b>3,786</b>	<b>11,547</b>	<b>9,234</b>	<b>155,634</b>
<b>Loss from continuing operations</b>	<b>(3,368)</b>	<b>(3,640)</b>	<b>(10,392)</b>	<b>(8,748)</b>	<b>(109,389)</b>
Loss from discontinued operations					(1,828)
Gain on disposal of discontinued operation					939
<b>Net loss before cumulative effect of change in accounting principle</b>	<b>(3,368)</b>	<b>(3,640)</b>	<b>(10,392)</b>	<b>(8,748)</b>	<b>(110,278)</b>
Cumulative effect of change in accounting principle					(8,454)
<b>Net loss</b>	<b>\$ (3,368)</b>	<b>\$ (3,640)</b>	<b>\$ (10,392)</b>	<b>\$ (8,748)</b>	<b>\$ (118,732)</b>
<b>Loss per share basic and diluted:</b>	<b>\$ (0.26)</b>	<b>\$ (0.36)</b>	<b>\$ (0.84)</b>	<b>\$ (0.86)</b>	
Weighted average shares used in loss per share calculation:					
Basic	12,775	10,150	12,439	10,145	

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

Diluted

12,775

10,150

12,439

10,145

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

6

---



**Table of Contents**

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

	<b>Preferred Stock Shares</b>	<b>Common Stock Shares</b>	<b>Additional Paid-in Capital</b>	<b>Deferred Compensation</b>	<b>Treasury Stock Shares</b>	<b>Stock Amount</b>	<b>Development Stage</b>	<b>Deficit Accumulated During the</b>	<b>Total Stockholders Equity</b>
Balance at December 31, 2006	\$	12,087,997	\$ 12	\$ 118,066	\$	1,937,035	\$ (5,948)	\$ (108,340)	\$ 3,790
Exercise of options to purchase common stock for cash, January and April @ \$2.40 & \$8.00 per share		13,942		37					37
Issuance of 2,610,000 shares of common stock at \$13.75 per share									
February 5, 2007		2,610,000	3	33,552					33,555
Offering Costs FAS 123(R)				(502)					(502)
stock option compensation				686					686
Net loss							(10,392)		(10,392)
	\$	14,711,939	\$ 15	\$ 151,839	\$	1,937,035	\$ (5,948)	\$ (118,732)	\$ 27,174

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

**Table of Contents**

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

	<b>Nine Months Ended</b>		<b>From Inception</b>
	<b>September 30,</b>		<b>(August 20,</b>
	<b>2007</b>	<b>2006</b>	<b>1987)</b>
			<b>through</b>
			<b>September 30,</b>
			<b>2007</b>
<b>Cash Flows from Operating Activities</b>			
Net loss	\$ (10,392)	\$ (8,748)	(118,732)
Gain on disposal of discontinued operations			(939)
Gain on disposal of assets			(102)
Adjustments to reconcile net loss to net cash used in operating activities:			
Noncash financing costs			316
Noncash inventory impairment			4,417
Noncash patent impairment			1,339
Noncash decrease in accounts payable			(1,308)
Depreciation and amortization	25	12	3,823
Noncash expenses related to stock-based transactions	686	570	4,292
Common stock issued for agreement not to compete			200
Series B Preferred Stock issued for consulting services			18
Sales and maturities of marketable securities	26,810	29,957	84,792
Purchases of marketable securities	(47,145)	(23,040)	(82,192)
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	(284)	(26)	(210)
(Decrease) increase in accounts payable and accrued expenses	(912)	1,184	4,343
Net cash provided by (used in) operating activities	(31,212)	(91)	(104,589)
<b>Cash Flows from Investing Activities</b>			
Maturities (purchases) of marketable securities			(28,723)
Capital expenditures	(3)	(62)	(2,364)
Purchase of technology rights and other assets	(196)	(136)	(3,040)
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)

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

Net cash used in investing activities	(199)	(198)	(31,724)
<b>Cash Flows from Financing Activities</b>			
Proceeds from issuance of common stock, net of offering costs	33,053		135,457
(Increase) decrease in prepaid offering costs			
Exercise of stock options	37	241	363
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 by) financing activities	33,090	241	139,128
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>1,679</b>	<b>(48)</b>	<b>2,815</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>1,136</b>	<b>2,165</b>	
<b>Cash and cash equivalents at end of period</b>	<b>\$ 2,815</b>	<b>\$ 2,117</b>	<b>\$ 2,815</b>

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

**Table of Contents**

**REPROS THERAPEUTICS INC. AND SUBSIDIARY**  
(A development stage company)  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**September 30, 2007**  
(Unaudited)

**NOTE 1 Organization, Operations and Liquidity**

Repros Therapeutics Inc., ( the Company , Repros , RPRX, we, us or our ), was organized on August 28, are a development stage biopharmaceutical company focused on the development of small molecule therapeutics for reproductive system disorders that have significant market potential and are currently underserved. We are developing our lead product Proellex<sup>®</sup>, which is a selective blocker of the progesterone receptor, for the treatment of uterine fibroids and endometriosis and intend to expand our product development indications with Proellex by pursuing an indication as a short course treatment of anemia due to excessive menstrual bleeding associated with uterine fibroids. We intend to develop Androxal , for the treatment of fertility preservation and improvement in patients that want to preserve their fertility while being treated for low testosterone associated with secondary hypogonadism. In addition, we also intend to develop Androxal for the treatment of men with idiopathic adult onset hypogonadotropic hypogonadism ( AIHH ) associated with glycemic and lipid dysregulation.

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 \$33.1 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 June 30, 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 September 30, 2007, we had an accumulated deficit of \$118.7 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

**Table of Contents**

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 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 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. 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 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 statements.

**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 September 30, 2007, all securities were classified as trading securities. The fair value and cost basis including purchased premium for these securities was \$25.9 million and \$5.6 million at September 30, 2007 and December 31, 2006, respectively.

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

**Table of Contents**

the investment portfolio may not exceed 24 months. As of September 30, 2007 our investments have a monthly staggered maturity that does not exceed August 4, 2008.

Marketable securities consist of the following (in thousands):

	<b>September 30, 2007</b>	<b>December 31, 2006</b>
Corporate Bonds	\$ 11,032	\$ 900
Certificates of Deposit	5,503	4,550
Taxable Auction Securities	5,265	3,137
Medium and Short Term Notes	3,137	998
Euro Dollar Bonds	998	150
Total	\$ 25,935	\$ 5,600

**NOTE 3 Patents**

As of September 30, 2007, the Company had approximately \$1,013,000 in internal capitalized patent costs reflected on its balance sheet. Of this amount, \$420,000 relates to patent costs for Proellex and \$593,000 relates to patent costs for Androxal.

**NOTE 4 Accrued Expenses**

Accrued expenses consist of the following (in thousands):

	<b>September 30, 2007</b>	<b>December 31, 2006</b>
Research and development costs	\$ 1,113	\$ 1,686
Payroll	40	123
Patent Costs	238	150
Other	150	127
Total	\$ 1,391	\$ 2,086

**NOTE 5 Loss Per Share**

Basic loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the 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 of diluted loss per share.

**Table of Contents**

The following table presents information necessary to calculate loss per share for the three-month and nine-month periods ended September 30, 2007 and 2006 (in thousands, except per share amounts):

	<b>Three Months Ended Sept.</b>		<b>Nine Months Ended Sept. 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Net Loss	\$ (3,368)	\$ (3,640)	\$ (10,392)	\$ (8,748)
Average common shares outstanding	12,775	10,150	12,439	10,145
Basic and diluted loss per share	\$ (0.26)	\$ (0.36)	\$ (0.84)	\$ (0.86)

Other potential common stock of 1,576,815 and 1,532,148 for the periods ended September 30, 2007 and 2006, respectively, were excluded from the above calculation of diluted loss per share since they were antidilutive.

**NOTE 6 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 \$33.1 million.

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

**NOTE 7 Commitments and Contingencies**

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

**NOTE 8 Subsequent Event**

As of November 8, 2007, there has been no material decline in the value of the marketable securities since September 30, 2007.

**Table of Contents**

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

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

**Overview**

Repros Therapeutics Inc., (the Company, Repros, RPRX, we, us or our), was organized on August 28, 2007 and is a development stage biopharmaceutical company focused on the development of small molecule therapeutics for reproductive system disorders that have significant market potential and are currently underserved. We are developing our lead product Proellex®, which is a selective blocker of the progesterone receptor, for the treatment of uterine fibroids and endometriosis and intend to expand our product development indications with Proellex by pursuing an indication as a short course treatment of anemia due to excessive menstrual bleeding associated with uterine fibroids. We intend to develop Androxal, for the treatment of fertility preservation and improvement in patients that want to preserve their fertility while being treated for low testosterone associated with secondary hypogonadism. In addition, we also intend to develop Androxal for the treatment of men with idiopathic adult onset hypogonadotropic hypogonadism (AIHH) associated with glyceic and lipid dysregulation.

**Proellex**

Our lead product candidate, Proellex, is an orally active small molecule which we have been developing for two indications: the oral treatment of uterine fibroids and the oral treatment of endometriosis. Repros intends to expand its development activities relating to Proellex by also developing it as an oral treatment for anemia due to excessive menstrual bleeding associated with uterine fibroids.

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.

Repros has a scheduled end of Phase 2 Type B meeting with the Food and Drug Administration (FDA) on November 30, 2007 to discuss the future clinical development pathway of Proellex for the treatment of uterine fibroids. During that meeting Repros intends to propose the initiation of clinical trials for a new indication as a short course treatment of anemia due to excessive menstrual bleeding associated with uterine fibroids. There can be no assurance that the FDA will accept this proposal. If the FDA accepts such proposal during the November 30, 2007 meeting, Repros anticipates initiating a U.S. Phase 3 clinical trial with Proellex for the treatment of both uterine fibroids and anemia during the first half of 2008. Repros initiated a U.S. Phase 2 clinical trial with Proellex for the treatment of endometriosis during the third quarter of 2007 and continues to



**Table of Contents**

conduct a one-year open label safety study for the treatment of uterine fibroids which currently consists of 33 patients. We anticipate providing interim data from this open label study during the first quarter of 2008.

If the proposed clinical trials are successful, we intend to submit a New Drug Application ( NDA ) for Proellex relating to the treatment of anemia due to excessive menstrual bleeding associated with uterine fibroids at year-end 2008 and intend to submit a NDA with Proellex for the treatment of uterine fibroids during the second half of 2009. We also intend to submit a NDA for Proellex for the treatment of endometriosis by year-end 2009.

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. In June 2007, we provided top-line data from our six-month European Phase 1/2 study which indicated that Proellex demonstrated superior efficacy when compared to the pharmaceutical standard of care in the treatment of endometriosis. In July 2007 we provided endometrial biopsy findings from our U.S. three-month and European six-month studies of Proellex in the treatment of uterine fibroids and endometriosis, respectively, indicating that the effects on the endometrium were benign. These clinical trials demonstrated statistically significant efficacy in the treatment of both conditions along with a reduction of pain associated with endometriosis and a reduction of bleeding in uterine fibroids patients.

**Androxal**

Our second product candidate, Androxal, is an orally active proprietary small molecule compound which we intend to develop as a treatment for the improvement or maintenance of fertility and sperm status in hypogonadal men of reproductive age who are interested in maintaining their fertility while being treated for low testosterone associated with secondary hypogonadism. We also intend to develop Androxal for the treatment of blood glucose and lipid elevations associated with AIHH. Previously the Company was developing Androxal in the United States to treat testosterone deficiency due to secondary hypogonadism by restoring normal testosterone production in males with functional testes and diminished pituitary function, a common condition in the aging male. The Company believes that Androxal can continue to be developed outside of the United States for the treatment of testosterone deficiency due to secondary hypogonadism.

Repros met with the FDA on October 15, 2007 in a Type C meeting to discuss the future development of Androxal. Subject to the receipt of final minutes from the FDA October 15, 2007 meeting the Company believes that the outcome of that meeting is that the FDA is willing to consider a proposal to develop Androxal as a treatment for the improvement or maintenance of fertility and sperm status in hypogonadal men of reproductive age that want to preserve their fertility while being treated for low testosterone associated with secondary hypogonadism as well as for the treatment of AIHH associated with glycemic and lipid dysregulation. Contrary to the Company's prior approach, the FDA considers a patient's testosterone level as an insufficient primary endpoint for an Androxal pivotal Phase 3 clinical trial. Furthermore, the FDA will not permit the Company to use quality of life ( QOL ) scales (such as the DeRogatis Interview for Sexual Functioning scale and the Male Sexual Dysfunction Survey scale, two scales the Company previously used in its clinical trials) to be used as a primary endpoint as the Company previously intended. In addition, the FDA considers the avoidance of side effects due to testosterone replacement therapy as an unacceptable basis for approval of Androxal.

**Table of Contents**

The Company intends to submit two white papers to the FDA. One white paper will be submitted for the commencement of a Phase 2b study in an academic setting to elucidate Androxal's effect on fertility. The second white paper will be for the commencement of a Phase 2b study in an academic setting to elucidate Androxal's effect on metabolic dysregulation of blood glucose, cholesterol and triglycerides in men with AIHH and for the FDA to consider whether the current Investigational New Drug Application ( IND ) should be moved to the FDA's endocrine division. Both proposed Phase 2b studies are expected to be small studies that are anticipated to begin during the first half of 2008 and are anticipated to last approximately 12 months. Subsequent to the completion and success of each of the proposed Phase 2b clinical trials the Company intends to submit a protocol to begin a pivotal Phase 3 trial for both of these indications. Data relating to the findings of Androxal's beneficial effect on fertility and as a treatment for AIHH associated with glycemic and lipid dysregulation was discovered after a prospective review of our clinical data. There can be no assurance that clinical trials performed for these two new indications will be successful.

In June 2007 we provided top-line results from our six-month U.S. non-pivotal Phase 3 study of Androxal . This trial demonstrated statistically significant increases in testosterone levels versus placebo, without suppression of luteinizing hormone ( LH ) and non-inferiority on all measured outcomes to AndroGel. We are currently conducting a U.S. one-year open label safety trial for patients that completed the Androxal U.S. Phase 3 clinical trial. Currently, there are 79 patients enrolled in this clinical trial.

**Table of Contents**

Our current product pipeline is summarized below:

<b>Product Candidate</b>	<b>Indication</b>	<b>Current Phase of Development</b>	<b>Estimate of Completion of Current Phase and Future Clinical Development(1)</b>
<b>Proellex</b>	-Uterine fibroids	-U.S. Phase 2 clinical trial (3-month study) data reported (2Q2007)	-FDA end of Phase 2 meeting is scheduled for November 30, 2007
		-U.S. Open Label Safety Study (12-month)	-Ongoing U.S. Open Label Safety Study (33 patients as of October 2007), interim extension data anticipated (1Q2008)
	-Anemia associated with uterine fibroids	-Begin to conduct clinical trials pending outcome of November 30, 2007, FDA meeting	-Initiate proposed U.S. Phase 3 pivotal trial pending November 30, 2007, FDA meeting outcome (1H2008)  -Submit Proellex proposed NDA for uterine fibroids (2H2009)
-Endometriosis	-European Phase 1/2 clinical trial (6-month study) - top-line data reported (2Q2007)	-Initiate Phase 3 studies pending outcome of November 30, 2007, FDA meeting (1H2008)  -Submit proposed Proellex NDA for anemia (YE2008)	
		-Initiated 75 patient U.S. Phase 2 clinical trial (3Q2007)	-Initiate proposed Phase 3 trials in (2H2008)  -Submit Proellex proposed NDA for endometriosis (YE2009)

**Table of Contents**

<b>Product Candidate</b>	<b>Indication</b>	<b>Current Phase of Development</b>	<b>Estimate of Completion of Current Phase and Future Clinical Development(1)</b>
<b>Androxal</b>	-Male Secondary Hypogonadism	-We are no longer seeking this indication in the U.S. in lieu of AIHH and fertility described below but will continue to seek this indication in non-U.S. markets	-FDA Type C meeting held October 15, 2007
		-Non-pivotal U.S. Phase 3 (6-month study) top-line data reported (2Q2007)	
		-U.S. Open Label Safety Study (12-month)	-Ongoing U.S. Open Label Safety Study (79 patients as of October 2007)
	AIHH and concomitant glycemic and lipid elevations	-Submit White Paper to FDA then begin Phase 2b clinical trial in men with AIHH	-Conduct Phase 2b clinical trial (1H2008)
			-Initiate proposed U.S. Phase 3 pivotal trials pending positive results from AIHH Phase 2b trial and FDA acceptance of clinical protocols (1H2009)
	-Male Secondary Hypogonadism and preservation of fertility	-Submit White Paper to FDA then begin Phase 2b clinical trial showing improvement and maintenance of fertility and sperm count in hypogonadal men	-Conduct Phase 2b clinical trial (1H2008)
			-Initiate proposed U.S. Phase 3 pivotal trials pending positive results from fertility Phase 2b trial and FDA acceptance of clinical protocols (1H2009)

**Table of Contents**

(1) The information in the column labeled Estimate of Completion of Current Phase and Future Clinical Development contains forward-looking statements regarding timing of completion of product development phases. The successful development of our product candidates is highly uncertain. Estimated completion dates and expenses can vary significantly for each product candidate and are difficult to predict. The actual timing of completion of those phases could differ materially from the estimates provided in the table. We currently have no collaborators on the development of any of our product candidates.

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.

We intend to seek strategic non-U.S. out-licensing or other corporate partnering opportunities with respect to Androxal to permit us to offset expenses associated with 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.

Our Androxal product candidate and its uses are covered in the United States by eight pending patent applications and one issued U.S. patent. Foreign coverage of our Androxal product candidate includes seven issued foreign patents and 55 foreign pending patent applications and one PCT application. The issued patents and pending applications relate to methods and compositions for treating certain conditions including the treatment of testosterone deficiency in men, the treatment of men with idiopathic adult onset hypogonadotropic hypogonadism ( AIHH ) associated with glycemic and lipid dysregulation and the treatment of infertility in hypogonadal men. Androxal (the trans isomer of clomiphene) is purified from clomiphene citrate. A third party individual holds two issued patents related to the use of an anti-estrogen such as clomiphene citrate and others for use in the treatment of androgen deficiency and disorders related thereto. In our prior filings with the SEC, we have described our request to the U.S. Patent and Trademark Office, or PTO, for re-examination of one of these patents based on prior art. The third party amended the claims in the re-examination proceedings, which led the PTO to determine that the amended claims are patentable in view of those publications under consideration and a re-examination certificate was issued. However, we believe that the amended claims are invalid based on additional prior art publications, and our request for re-examination by the PTO in light of a number of these additional publications and other publications cited by the PTO, has been granted. In June, 2007, the PTO issued a final Office action in the re-examination, rejecting all of the claims. The patent holder has responded to the final rejections and has filed a notice of appeal. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO. Nevertheless, there is no assurance that either patent will ultimately be found invalid over the prior art. If such patents are not invalidated by the PTO we may be required to obtain a license from the holder of such patents in order to develop Androxal further or attempts may be made to undertake further legal action to invalidate such patents. If such licenses were not available on acceptable terms or at all, we may not be able to successfully commercialize Androxal.

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

**Table of Contents**

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 June 30, 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 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 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 \$33.1 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 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

**Table of Contents**

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 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. 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 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 statements.



**Table of Contents****Results of Operations***Three-Month and Nine-Month Periods Ended September 30, 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 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 September 30, 2007 increased to \$396,000 as compared to \$146,000 for the same period in the prior year and increased to \$1.2 million for the nine-month period ended September 30, 2007 as compared to \$486,000 for the same period in the prior year.

Interest income increased 171% to \$396,000 for the three-month period ended September 30, 2007, as compared to \$146,000 for the same period in the prior year and increased 138% to \$1.2 million for the nine-month period ended September 30, 2007 as compared to \$486,000 for the same period in the prior year. The increase in interest income for the three-month and nine-month periods ended September 30, 2007 as compared to the same periods 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 \$33.1 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 4% to approximately \$3.2 million for the three-month period ended September 30, 2007 as compared to \$3.1 million for the same period in the prior year and increased 30% to approximately \$9.4 million for the nine-month period ended September 30, 2007 as compared to \$7.2 million for the same period in the prior year. Although the R&D expenses for the three-month period ended September 30, 2007 remained relatively constant as compared to the same period in the prior year, the Company had a decrease in our current clinical and preclinical activities of \$206,000, partially offset by an increase in manufacturing activities of \$135,000, an increase in personnel costs of \$85,000 and an increase in consulting services of \$58,000. The increase in R&D expenses for the nine-month period ended September 30, 2007 as compared to the same period in the prior year is primarily due to an increase of \$1.5 million in our current clinical and preclinical activities, an increase in personnel costs of \$241,000, an increase in consulting of \$179,000, an increase in non-cash stock compensation expense of \$94,000 and an increase in legal expenses of \$56,000 related to our patent portfolio.

*General and Administrative Expenses.* General and administrative expenses decreased 20% to \$568,000 for the three-month period ended September 30, 2007 as compared to \$713,000 for the same period in the prior year and increased 6% to approximately \$2.1 million for the nine-month period ended September 30, 2007 as compared to \$2.0 million for the same period in the prior

**Table of Contents**

year. The decrease in general and administrative expenses for the three-month period ended September 30, 2007 as compared to the same period in the prior year is primarily due to a decrease in professional services costs of \$123,000, a decrease in non-cash stock compensation expense of \$39,000 and a decrease of \$27,000 in costs associated with meeting the requirements of Section 404 of the Sarbanes-Oxley Act, partially offset by an increase in strategic administrative fees of \$23,000. The increase in general and administrative expenses for the nine-month period ended September 30, 2007 as compared to the same period in the prior year is primarily due to an increase in personnel costs of \$91,000, an increase in strategic administrative fees of \$73,000, partially offset by a decrease in professional services of \$91,000.

**Liquidity and Capital Resources**

We had cash, cash equivalents and marketable securities of approximately \$28.8 million at September 30, 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 \$33.1 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 to fund operations through at least June 30, 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 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 September 30, 2007, we had an accumulated deficit of \$118.7 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 Small Business Innovative Research ( SBIR ) grants. We are actively developing Proellex for the treatment of uterine fibroids and endometriosis and we intend to expand our product development indications with Proellex by pursuing an indication as a short course treatment of anemia due to excessive

**Table of Contents**

menstrual bleeding associated with uterine fibroids. We intend to develop Androxal for the treatment of fertility preservation and improvement in patients that want to preserve their fertility while being treated for low testosterone associated with secondary hypogonadism. In addition, we also intend to develop Androxal for the treatment of men with idiopathic adult onset hypogonadotropic hypogonadism ( AIHH ) and concomitant glycemic and lipid dysregulation. We believe we have enough funds to continue such development through at least June 30, 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 marketable securities were approximately \$28.8 million at September 30, 2007. These assets were primarily invested in investment grade corporate bonds and commercial paper with maturities less than twelve months. We do not invest in derivative securities. Our portfolio is subject to fluctuations in interest rates and market conditions. Although we have not experienced any significant fluctuations in the fair values of our marketable securities, there can be no assurance we would not experience a material decrease in interest income due to changes in interest rates or a material change in fair value in the event of a change in interest rates and/or an adverse change in the credit quality of an issuer of securities that we hold.

**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.

**Table of Contents**

In connection with the evaluation described above, we identified no change in internal control over financial reporting that occurred during the fiscal quarter ended September 30, 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**

The information presented below updates, and should be read in conjunction with, the risk factors and information disclosed in the registrant's Form 10-K for the fiscal year ended December 31, 2006 in response to Item 1A. Risk Factors to Part I of Form 10-K for the fiscal year ended December 31, 2006.

Delays in the commencement of preclinical studies and clinical trials testing of our current and potential product candidates could result in increased costs to us and delay our ability to generate revenues.

Our product candidates will require continued preclinical studies and extensive clinical trials prior to the submission of a regulatory application for commercial sales. We intend to initiate Phase 3 trials for Proellex for the treatment of both uterine fibroids and endometriosis and as a short course treatment of anemia due to excessive menstrual bleeding associated with uterine fibroids, an indication for which we have not yet conducted any studies. In addition, we intend to initiate pivotal Phase 3 trials for Androxal for men with AIHH associated with glycemic and lipid dysregulation and fertility, two indications for which we have not yet conducted studies. The initiation of all of these studies are subject to a November meeting with the FDA, in the case of Proellex, and acceptance by the FDA of our position in two separate white papers that have not yet been submitted, in the case of Androxal. We have limited experience conducting clinical trials for these product candidates. Because of this limited experience and the fact that we are still awaiting approval by the FDA of our approaches, we do not know whether any of these future planned clinical trials will begin on time, if at all. Delays in the commencement of preclinical studies and clinical trials could significantly increase our product development costs and delay any product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to denial of regulatory approval of a product candidate.

The commencement of clinical trials can be delayed for a variety of reasons, including delays in:  
demonstrating sufficient safety and efficacy in past clinical trials to obtain regulatory approval to commence a further clinical trial;

reaching agreements on acceptable terms with prospective contract manufacturers for manufacturing sufficient quantities of a product candidate; and

obtaining institutional review board approval to conduct a clinical trial at a prospective site.

In addition, the commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the availability of effective treatments for the relevant disease, and the eligibility criteria for the clinical trial.

**Table of Contents**

**Item 5. Other Information**

None

**Item 6. Exhibits**

- 31.1\* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).
- 31.2\* Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).
- 32.1\* Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer).
- 32.2\* Certification furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).

\* Filed herewith.

**Table of Contents**

**SIGNATURES**

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

**REPROS THERAPEUTICS INC.**

Date: November 9, 2007

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

Date: November 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)

27

---

**Table of Contents**

**Exhibit Index**

- 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.