

REPROS THERAPEUTICS INC.

Form 10-Q

August 03, 2006

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**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 June 30, 2006

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)

76-0233274
(IRS Employer
Identification No.)

2408 Timberloch Place, Suite B-7
The Woodlands, Texas 77380
(Address of principal executive
offices and zip code)
(281) 719-3400

(Registrant's telephone number,
including area code)

Zonagen, Inc.

(Former name, former address and former fiscal year, if changed since report)

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 July 24, 2006, there were outstanding 10,150,962 shares of Common Stock, par value \$.001 per share, of the Registrant.

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(A development stage company)
For the Quarter Ended June 30, 2006
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FACTORS AFFECTING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words may, anticipate, believe, expect, estimate, project, suggest, intend and similar expressions are intended 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, 2005 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.

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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 six-month period ended June 30, 2006 are not necessarily indicative of the results that may be expected for the year ended December 31, 2006. 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, 2005.

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

	June 30, 2006	December 31, 2005
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 1,474	\$ 2,165
Marketable securities	11,035	14,667
Prepaid expenses and other current assets	337	231
Total current assets	12,846	17,063
Fixed Assets, net	73	19
Other assets, net	687	600
Total assets	\$ 13,606	\$ 17,682

LIABILITIES AND STOCKHOLDERS EQUITY

Current Liabilities		
Accounts payable	\$ 784	\$ 338
Accrued expenses	420	389
Total current liabilities	1,204	727

Commitments and 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, 12,082,997 and 12,016,636 shares issued, respectively; 10,145,962 and 10,079,601 shares outstanding, respectively	12	12
Additional paid-in capital	117,590	117,166
Deferred compensation		(130)
Cost of treasury stock, 1,937,035 and 1,937,035 shares, respectively	(5,948)	(5,948)
Deficit accumulated during the development stage	(99,252)	(94,145)
Total stockholders equity	12,402	16,955
Total liabilities and stockholders equity	\$ 13,606	\$ 17,682

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

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

	Three Months Ended		Six Months Ended June		From
	June 30,		30,		Inception
	2006	2005	2006	2005	(August 20,
					1987)
					through
					June 30,
					2006
Revenues					
Licensing fees	\$	\$	\$	\$	\$ 28,755
Product royalties					627
Research and development grants				4	1,219
Interest income	166	173	340	281	14,096
Gain on disposal of fixed assets					102
Other Income					35
Total revenues and other income	166	173	340	285	44,834
Expenses					
Research and development	2,363	1,355	4,171	2,590	104,532
General and administrative	666	465	1,276	896	29,823
Interest expense and amortization of intangibles					388
Total expenses	3,029	1,820	5,447	3,486	134,743
Loss from continuing operations	(2,863)	(1,647)	(5,107)	(3,201)	(89,909)
Income (loss) from discontinued operations					(1,828)
Gain on disposal					939
Net loss before cumulative effect of change in accounting principle	(2,863)	(1,647)	(5,107)	(3,201)	(90,798)
Cumulative effect of change in accounting principle					(8,454)
Net loss	\$ (2,863)	\$ (1,647)	\$ (5,107)	\$ (3,201)	\$ (99,252)
Income (loss) per share basic and diluted:	\$ (0.28)	\$ (0.16)	\$ (0.50)	\$ (0.35)	

Shares used in loss per share
calculation:

Basic	10,146	10,080	10,143	9,208
Diluted	10,146	10,080	10,143	9,208

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

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

	Six Months Ended June		From Inception
	30,		(August 20,
	2006	2005	1987)
			through
			June 30,
			2006
Cash Flows from Operating Activities			
Net loss	\$ (5,107)	\$ (3,201)	(99,252)
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	6	3	3,786
Noncash expenses related to stock-based transactions	351	38	3,168
Common stock issued for agreement not to compete			200
Series B Preferred Stock issued for consulting services			18
Maturities of marketable securities	22,107	9,725	46,932
Purchases of marketable securities	(18,475)	(23,689)	(29,432)
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	(106)	(188)	(38)
(Decrease) increase in accounts payable and accrued expenses	477	143	2,400
Net cash provided by (used in) operating activities	(747)	(17,169)	(73,141)
Cash Flows from Investing Activities			
Maturities (purchases) of marketable securities			(28,723)
Capital expenditures	(60)	(6)	(2,357)
Purchase of technology rights and other assets	(87)	(68)	(2,708)
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

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Proceeds from sale of the assets of FTI			2,250
Increase in net assets held for disposal			(213)
Net cash used in investing activities	(147)	(74)	(31,385)

Cash Flows from Financing Activities

Proceeds from issuance of common stock, net of offering costs		18,180	102,404
(Increase) decrease in prepaid offering costs		600	
Exercise of stock options	203	85	288
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	203	18,865	106,000
Net increase (decrease) in cash and cash equivalents	(691)	1,622	1,474
Cash and cash equivalents at beginning of period	2,165	736	
Cash and cash equivalents at end of period	\$ 1,474	\$ 2,358	\$ 1,474

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

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REPOS THERAPEUTICS INC. AND SUBSIDIARY
(A development stage company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
June 30, 2006
(Unaudited)

NOTE 1 Organization and Operations

Repos Therapeutics Inc., formerly known as Zonagen, 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. Our second product candidate is Androxal, an orally available small molecule compound being developed for the treatment of testosterone deficiency in men.

On February 1, 2005 the Company completed its follow-on public offering of 5,060,000 shares of its common stock at \$4.00 per share (which included the underwriters' exercise of its over allotment option for 660,000 shares). The shares offered by the Company were issued out of its existing treasury stock, and the offering resulted in net proceeds to the Company of approximately \$18.2 million.

The Company has experienced negative cash flows from operations since inception and has funded its activities to date primarily from equity financings and corporate collaborations. The Company 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 December 31, 2006. The Company's 2006 budget contains allotted financial resources to fund existing clinical research organization (CRO) contracts for expenses to be incurred through December 31, 2006, relating to the Company's three clinical studies which are the Androxal U.S. Phase III, Proellex U.S. Phase II and the Proellex European Phase II studies. 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 adjust our plans, which will delay the approval process of our product candidates.

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 and conduct clinical trials for additional indications, seek to obtain regulatory approvals and conduct long-term animal safety studies.

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RPRX's results of operations may vary significantly from year to year and quarter to quarter, and depend, among other factors, on the Company's 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 manufacturing, sales and marketing 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 June 30, 2006, the Company had an accumulated deficit of \$99.3 million. Losses have resulted principally from costs incurred in conducting clinical trials for the Company's product candidates, in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. Due to various tax regulations, including change in control provisions in the tax code, the value of this tax asset to the Company could be substantially diminished.

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.

NOTE 2 Stock-based Compensation

The Company has two stock option plans available: the 2000 Non-Employee Directors' Stock Option Plan, or 2000 Plan; and the 2004 Stock Option Plan, or 2004 Plan. As of June 30, 2006, there were 272,935 shares available for grant under the 2004 Plan and 500,000 shares available for grant under the 2000 Plan. The 2000 Plan has an evergreen provision pursuant to which the number of shares available under such plan are automatically increased each year on the day after the Company's Annual Shareholders' Meeting by the number of shares granted during the prior year under such plan (or by one-half percent of the Company's then outstanding common stock, if greater). There are no significant differences between the other provisions of the two plans, other than the length of time the directors have to exercise their options under the 2000 Plan, which is two years from the cessation of service to the Company compared to ninety (90) days for employees. Typically, options are granted with an exercise price per share which is equal to the fair market value per share of common stock on the date of grant. Vesting provisions for each grant are determined by the board of directors and typically vest quarterly over a three year period. All options expire no later than the tenth anniversary of the grant date.

On January 1, 2006, we adopted SFAS No. 123 (revised 2004), Share-Based Payment. We adopted the new statement using the modified prospective method of adoption, which does not require restatement of prior periods. The revised standard eliminated the intrinsic value method of accounting for share-based employee compensation under APB Opinion No. 25, Accounting for Stock-Based Compensation, which we previously used (see pro-forma disclosure of prior period included herein). The revised standard generally requires the recognition of the cost of employee services for share-based compensation based on the grant date fair value of the equity or liability instruments issued. The effect of adoption of the new standard related to stock option

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plans was an additional expense of \$195,000 (\$0.02 per share, basic and diluted) for the three-months ended June 30, 2006, of which \$28,000 was recorded to Research and Development expense and \$167,000 was recorded to General and Administrative expense and \$351,000 (\$0.03 per share, basic and diluted) for the six-months ended June 30, 2006, of which \$53,000 was recorded to Research and Development expense and \$298,000 was recorded to General and Administrative expense. At June 30, 2006, there was \$844,000 of total unrecognized compensation cost related to non-vested stock options. This compensation is expected to be recognized over a weighted-average period of approximately 1 year.

Under SFAS 123(R), we continue to use the Black-Scholes option pricing model to estimate the fair value of our stock options. However, we will apply the expanded guidance under SFAS 123R for the development of our assumptions used as inputs for the Black-Scholes option pricing model for grants issued after January 1, 2006. Expected volatility is determined using historical volatilities based on historical stock prices for a period equal to the expected term. The expected volatility assumption is adjusted if future volatility is expected to vary from historical experience. The expected term of options represents the period of time that options granted are expected to be outstanding and falls between the options vesting and contractual expiration dates. The risk-free interest rate is based on the yield at the date of grant of a zero-coupon U.S. Treasury bond whose maturity period equals the option's expected term. There were 25,000 stock options granted to the Company's Board of Directors for their re-election to the Board at the Company's Annual Meeting held on May 2, 2006. These options have an exercise price of \$12.70 per share which was the closing price of the Company's common stock on the date of grant. There were 20,000 stock options granted to an employee on June 14, 2006 at an exercise price of \$8.41 per share which was the closing price of the Company's common stock on the date of grant. The following assumptions were used for stock option grants: risk-free interest rate of 3.5% to 5.0%; no expected dividends; expected lives of 4.2 to 7 years; and expected volatility of 86% to 90%.

Due to the Company's net operating loss position there are no anticipated windfall tax benefits upon exercise of options.

Prior to the adoption of SFAS 123(R) we recorded deferred compensation in equity for options issued in the money under APB Opinion No. 25. Due to the adoption of SFAS 123(R) on January 1, 2006, we eliminated \$130,000 from deferred compensation to additional paid in capital.

The following table presents the pro-forma effect on net income and earnings per share as if we had applied the fair value recognition of SFAS 123 to stock-based compensation prior to the adoption of SFAS 123(R) during the three-month and six-month periods ended June 30, 2005 (in thousands except per share amounts):

	Three Months Ended June 30, 2005	Six Months Ended June 30, 2005
Net loss, as reported	\$ (1,647)	\$ (3,201)
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	34	38
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(135)	(410)

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	Three Months Ended June 30, 2005	Six Months Ended June 30, 2005
Pro-forma net loss	\$ (1,748)	\$ (3,573)
Loss per share		
Basic as reported	\$ (0.16)	\$ (0.35)
Basic pro-forma	(0.17)	(0.39)
Diluted as reported	(0.16)	(0.35)
Diluted pro-forma	(0.17)	(0.39)

The following table summarizes the Company's stock option activity for the six-months ended June 30, 2006:

	Stock Options	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2005	1,715,363		
Granted	45,000		
Exercised	(66,361)		\$ 337
Forfeited	(176,854)		
Outstanding at June 30, 2006	1,517,148	\$ 4.58	\$ 5,397
Exercisable at June 30, 2006	1,008,775	\$ 4.71	\$ 3,462

The weighted average remaining contractual term of shares exercisable at June 30, 2006 is 6.0 years.

NOTE 3 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 June 30, 2006 all securities were classified as trading securities. The cost basis including purchased premium for these securities was \$11.0 million and \$14.7 million at June 30, 2006 and December 31, 2005, respectively.

Marketable securities as of June 30, 2006 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 4 Patents

As of June 30, 2006, the Company had approximately \$687,000 in internal capitalized patent costs reflected on its balance sheet. Of this amount, \$359,000 relates to patents for Proellex, which is being developed as an oral treatment for uterine fibroids and endometriosis, and \$328,000 relates to patents for Androxal, which is being developed as an oral treatment for testosterone deficiency.

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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 in the same manner as basic loss per share, except that, among other changes, the average share price for the period is used in all cases when applying the treasury stock method of potentially dilutive outstanding options.

The following table presents information necessary to calculate earnings per share for the three-month and six-month periods ended June 30, 2006 and 2005 (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Net Loss	\$ (2,863)	\$ (1,647)	\$ (5,107)	\$ (3,201)
Average common shares outstanding	10,146	10,080	10,143	9,208
Basic loss per share	\$ (0.28)	\$ (0.16)	\$ (0.50)	\$ (0.35)
Diluted loss per share	\$ (0.28)	\$ (0.16)	\$ (0.50)	\$ (0.35)

Other potential common stock of 1,517,148 and 1,710,363 for the periods ended June 30, 2006 and 2005, respectively, were excluded from the above calculation of diluted loss per share since they were antidilutive.

NOTE 6 Stockholders Equity

As of June 30, 2006, the Company had 1,517,148 options outstanding, of which 1,008,775 were vested. All outstanding options have exercise prices ranging from \$2.40 to \$33.25 with a weighted average exercise price of \$4.58. In January 2006, we received \$203,600 from the exercise of 66,361 stock options that were exercised by former Board Members. These options were scheduled to expire on January 14, 2006. An additional 176,854 stock options expired unexercised in the first quarter. As of June 30, 2006 management, employees and outside consultants held 118,000 stock options which are scheduled to expire during 2006 and have exercise prices ranging from \$7.50 to \$8.38 with a weighted average strike price of \$8.34. On July 18, 2006 stock options for 5,000 shares, that were scheduled to expire, were exercised by a consultant.

NOTE 7 Commitments and Contingencies

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

On July 21, 2006, the Company contracted Pharm Olam, a CRO, to conduct a one year open label extension safety study relating to its current U.S. Phase II uterine fibroid clinical study. Patients from this study will be given an opportunity to enroll in the open label extension study which will not begin until the United States Food and Drug Administration (FDA) has given its approval to conduct such study.

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In addition to general operating obligations, the Company currently has open purchase order commitments and potential future contractual obligations, which both span into and through the year 2008, for the clinical development of both Proellex and Androxal in the amounts of \$5.6 million and \$3.6 million, respectively. The management services agreements for clinical trials are generally cancelable on 30 days notice, although the Company would be responsible for expenses incurred to that point of termination. Included in purchase order commitments is the remaining \$1.1 million of an initial five year, \$1.6 million requirements agreement for the commercial supply of the active pharmaceutical ingredient for our drug Proellex which was entered into on April 26, 2006. The Company paid an up-front and non-refundable \$500,000 payment of that commitment at the time of signing. The Company may incur an additional \$500,000 milestone payment relating to this contract before year-end 2006 depending upon the contractor's ability to reach such milestone specified in the commercial supply agreement. In addition, the Company also has an obligation to purchase a specified amount of bulk Proellex drug if the contractor is successful in supplying that bulk drug by year-end 2006.

The Company amended its current facility lease effective April 1, 2006 for its office/laboratory space in The Woodlands, Texas. The amendment increased the leased space to approximately 7,100 square feet from 4,800 square feet to provide additional space needed for the increase in headcount expected in 2006. This lease amendment increased the Company's obligations under its lease by approximately \$20,000 per year, for a total of \$59,600 per year, for the remainder of the lease term which expires on June 30, 2010. The lease term was not affected as a result of the amendment.

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

The following discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, 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 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. On May 2, 2006, at the Company's Annual Shareholders' Meeting, the Company's shareholders approved a corporate name change from Zonagen, Inc. to Repros Therapeutics Inc. This name change was made to better reflect the Company's focus on the reproductive and hormonal health market.

On February 1, 2005, we completed our follow-on public offering of 5,060,000 shares of our common stock at \$4.00 per share (which included the underwriters' exercise of their over allotment option for 660,000 shares). The shares offered by us were issued out of our then existing treasury stock, and the offering resulted in net proceeds to us of approximately \$18.2 million.

Proellex

Our lead product candidate, Proellex, is an orally active small molecule compound which is being developed to alleviate symptoms associated with both uterine fibroids and endometriosis by selectively blocking the progesterone receptor in women. The National Uterine Fibroid Foundation estimates that possibly 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. We are developing Proellex under an exclusive worldwide license from the National Institutes of Health (NIH).

The current standards of care for uterine fibroids and endometriosis include surgery and treatment with drugs. The most effective drugs on the market are gonadotropin releasing hormone agonists (GnRH) agonists, such as Lupron® (leuprolide acetate). GnRH is a peptide hormone that plays an important role in the regulation of the human reproductive system. Chronic administration of GnRH agonists down regulate the GnRH receptors and block the action of GnRH and its activity in stimulating the pituitary FSH and LH steroid hormone secretions. Lupron is marketed by TAP Pharmaceuticals, a joint venture between Abbott Laboratories and Takeda Chemical Industries, Ltd. Tap Pharmaceuticals reported total Lupron sales of \$698.8 million in 2005 in the United States and Canada for all indications.

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We believe Proellex may have advantages in treating uterine fibroids and endometriosis as compared to treatment with GnRH agonists. Unlike Proellex, GnRH agonists induce a low estrogen, menopausal-like state in women. Because estrogen is necessary for the maintenance of bone mineral density, GnRH agonists tend to promote bone loss and are not recommended to be used for more than six months at a time. When women cease treatment with GnRH agonists, fibroids rapidly regenerate and symptoms associated with endometriosis quickly reappear. We believe Proellex may have advantages over treatment with GnRH agonists because, in our Phase Ib human clinical study and our animal research to date, Proellex maintains a tonic estrogen state and therefore should maintain mineral bone density. We believe Proellex may provide an attractive alternative to surgery because of its potential to treat these conditions in a long-term or chronic fashion, resolving the symptoms that most commonly lead to surgical treatment.

We completed a 28 patient European Phase Ib, 12-week clinical study of Proellex in women with uterine fibroids in late 2004. Results of this study showed significant reduction in uterine fibroid size, pain and bleeding.

The Company's Investigational New Drug (IND) application for its 150 patient U.S. Phase II clinical study with Proellex for the treatment of woman with uterine fibroids became effective in December 2005 and this study is anticipated to be conducted in up to 20 clinical sites. The study is designed to assess both improvement of symptoms associated with uterine fibroids as well as effects on the fibroid itself. The study will test two doses of Proellex versus placebo in a double-blind design over a 12-week duration. Doses to be used in this trial were previously tested in our European Phase Ib, 12-week clinical study of Proellex, in women with uterine fibroids. We hope this study will serve as the first of two required pivotal trials of efficacy and we plan on enrolling the participants of this study into a subsequent long-term open label study. Completion of this study is based on patient enrollment which is currently occurring slower than originally anticipated. As a means of increasing the patient enrollment rate, the Company has embarked on a media advertising campaign that began in July 2006. Although enrollment is slower than anticipated, management still believes that initial interim data from this study will be available by year-end 2006 and we still anticipate submitting a New Drug Application (NDA) in 2008.

During the first quarter of 2006, the Company also received approval to start its European Phase II study of Proellex for the treatment of endometriosis. This 40 patient European Phase II study will compare three doses of double blinded Proellex against open label Lupron(R), the current standard of care, for up to six-months of treatment. Completion of this study is based on patient enrollment which is currently occurring slower than originally anticipated. As a means of increasing the patient enrollment rate, the Company is currently adding at least one additional clinical site. Although enrollment is slower than anticipated, management still believes that it will have initial interim 12-week efficacy assessment data by year-end 2006.

Proellex is a new chemical entity which means that the compound will be required to go through the full clinical approval process, including amongst other requirements a two-year carcinogenicity study which is scheduled to begin in the third quarter 2006. The Company previously completed a six-month rat study and a nine-month dog study testing the safety of Proellex.

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Androxal

Our second product candidate, Androxal, is a proprietary orally active small molecule being developed for the treatment of testosterone deficiency in men. Androxal is a once-a-day oral therapy which is designed to restore normal testosterone production in males versus competitive treatments that exogenously replace testosterone.

Testosterone is an important male hormone. Testosterone deficiency in men is linked to several negative physical and mental conditions, including loss of muscle tone, reduced sexual desire, and deterioration of memory and certain other cognitive functions. Testosterone production normally decreases as men age, sometimes leading to testosterone deficiency. According to the Urology Channel, recent estimates show that approximately 13 million men in the U.S. experience testosterone deficiency. Current therapies focus on testosterone replacement by delivering testosterone either through the skin, nasal spray or via injection. The current gold standard in the industry is AndroGel®, with reported sales of approximately \$308 million in 2004 in North America.

We estimate over 70% of men that have low testosterone suffer from secondary hypogonadism. Secondary hypogonadism is caused by failure of the pituitary to provide appropriate hormone signaling to the testis, thereby causing testosterone levels to drop to the point where pituitary secretions fall under the influence of estrogen. In this state, estrogen further suppresses the testicular stimulation from the pituitary. These men are readily distinguished from those that have primary testicular failure via assessment of the levels of secretions of pituitary hormones (i.e., men with primary testicular failure experience elevated secretions of pituitary hormones). Secondary hypogonadism is not relegated only to older men although the condition becomes more prevalent as men age.

During 2004 we completed a 52 patient, 14-day duration, U.S. Phase II clinical study of Androxal in men with secondary hypogonadism. In the study, Androxal exhibited positive effects on inducing restoration of normal testicular function as evidenced by achievement of normal testosterone levels. The drug was well tolerated over the course of the study.

In February 2006, the Company announced results of an open-label study of Androxal in 13 men with normal, borderline or low testosterone. This safety study was undertaken to determine if treatment with Androxal could result in supra-normal levels of testosterone, as observed with some currently available testosterone-replacement therapies. At the conclusion of the trial, following administration of 25mg of Androxal for two weeks, all study subjects, including those that had normal testosterone levels at the start of the study, exhibited average testosterone levels within the normal range.

During the first quarter 2006, we initiated clinical sites for our 200 patient U.S. Phase III clinical study for the treatment of men with testosterone deficiency resulting from secondary hypogonadism. This 200 patient clinical study is being performed under an existing U.S. IND and is anticipated to be conducted in up to 20 clinical sites. The study is designed to assess both the safety of Androxal and its efficacy in restoring normal pituitary and testicular function in men that are hypogonadal due to secondary hypogonadism. This double-blind study will test two doses of Androxal versus placebo and will include an open-label arm of the commercially available drug

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AndroGel®. The dosing is of 24-week duration with an efficacy assessment made at 12-weeks. Completion of this study is based on patient enrollment which is currently occurring slower than originally anticipated. As a means of increasing the patient enrollment rate, the Company has embarked on a media advertising campaign that began in July 2006. Although enrollment is slower than anticipated, management still believes that it will have initial interim 12-week efficacy assessment data by year-end 2006 and we still anticipate submitting an NDA in 2008.

The extension of the U.S. Phase III clinical trial dosing to 24 weeks is to satisfy the U.S. FDA's request regarding the safety of restoring normal testicular function as compared to placebo or the currently approved testosterone replacement therapies. Doses to be used in this U.S. Phase III trial were previously tested in a U.S. Phase II clinical study of 52 patients which was conducted over a 14-day duration. Based on our communications with the FDA, we believe that at least two additional Phase III pivotal studies beyond this current study will be required before an NDA can be submitted.

Initial review of our special protocol assessment (SPA) for a Phase III pivotal study of efficacy was completed by the FDA. Unlike testosterone replacement therapies in which efficacy can be shown through mere elevation of testosterone levels back to normal ranges, the FDA has noted that Androxal must demonstrate a benefit over placebo on a relevant clinical endpoint. We intend to comply with the FDA's request, develop a validated clinical test and revise our proposed Phase III pivotal efficacy protocol to incorporate the FDA's other suggestions. We anticipate that this study will begin in 2007, subject to available funding and timely and successful completion of our initial Phase III study.

Androxal is considered a new chemical entity by the FDA which means that the compound will be required to go through the full clinical approval process, which will include amongst other requirements a two-year carcinogenicity study. A revised two-year carcinogenicity study is scheduled to begin in the third quarter 2006. The Company previously completed a six-month rat study and a nine-month dog study testing the safety of Androxal.

All clinical trial results relating to both 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.

Our Androxal product candidate is covered by eight pending patent applications in the United States and 19 foreign pending patent applications. These applications relate to methods and materials for treating certain conditions including the treatment of testosterone deficiency in men. Androxal is purified from clomiphene citrate. A third party holds two issued patents related to the use of an anti-estrogen such as clomiphene citrate 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 (the PTO) for re-examination of one of these patents based on prior art. The third party amended the claims in the reexamination proceedings, which has since led the PTO to determine that the amended claims are patentable in view of those publications under consideration and a reexamination certificate was issued. However, we believe that the amended claims are invalid based on, among other things, additional prior art publications not yet considered by the PTO and we have successfully sought reexamination of this patent in light of a number of these additional publications. We also believe that the second of these two patents is invalid in view of published prior art not considered by the PTO and for other reasons. Nevertheless, there is no assurance that either patent will ultimately be found invalid over the prior art. If such patents are not invalidated, we may be required to obtain a license from the holder of such patents in order to develop Androxal further. If such licenses were not available on acceptable terms or at all, we may not be able to develop or commercialize Androxal.

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Phentolamine Products

We are continuing our limited development assessment and out-licensing efforts relating to our phentolamine-based product candidates, including VASOMAX[®], which had previously been approved for marketing in several countries in Latin America for the treatment of male erectile dysfunction, or MED. VASOMAX is currently on partial clinical hold in the United States but is not on clinical hold in any other country. During the first quarter 2006, we met with the Ministry of Health in Mexico regarding our second generation phentolamine-based products for the treatment of erectile dysfunction: Bimexes[®], an oral therapy for men with mild to moderate impotence, and ERxin[®], an injectable therapy for the treatment of severe erectile dysfunction. Initial assessment of the outcome from a meeting held with the Mexican Ministry of Health in the first quarter 2006, suggests that both drugs could potentially be approved in Mexico after completion of a successful single positive controlled registration trial to the satisfaction of the Mexican Ministry of Health. A decision to proceed with Mexican approval trials for Bimexes or ERxin is heavily dependent on having the necessary capital available. Mexico is viewed as the gold standard for regulatory efforts in Latin America. Approval in Mexico can potentially lead to approvals in other Latin American countries. For example, VASOMAX, our former lead erectile dysfunction drug was approved in seven additional countries in Latin America after approval in Mexico. The current Latin American market for erectile dysfunction therapies now exceeds \$230 million.

Employees and Consultants

We currently have six 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

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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.

Results of Operations

Three-Month and Six-Month Periods Ended June 30, 2006 and 2005

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 June 30, 2006 decreased to \$166,000 as compared to \$173,000 for the same period in the prior year and increased to \$340,000 for the six-month period ended June 30, 2006 as compared to \$285,000 for the same period in the prior year.

Research and development grant revenues for the six-month period ended June 30, 2006 were zero as compared to \$4,000 for the same period in the prior year. Grant revenue relates to an \$836,441 Phase II Small Business Innovative Research (SBIR) grant that was awarded to us in 2002 for the development of Proellex as an oral treatment for endometriosis. This SBIR grant has come to its anticipated conclusion and is essentially depleted.

Interest income decreased 4% to \$166,000 for the three-month period ended June 30, 2006, as compared to \$173,000 for the same period in the prior year and increased 21% to \$340,000 for the six-month period ended June 30, 2006 as compared to \$281,000 for the same period in the prior year. The decrease in interest income for the three-month period ended June 30, 2006 as compared to the same period in the prior year is primarily due to lower cash balances. The increase in interest income for the six-month period ended June 30, 2006 as compared to the same period in the prior year is primarily due to an increase in interest rates.

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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 74% to approximately \$2.4 million for the three-month period ended June 30, 2006 as compared to approximately \$1.4 million for the same period in the prior year and increased 61% to \$4.2 million for the six-month period ended June 30, 2006 as compared to \$2.6 million for the same period in the prior year. The increase in R&D expenses for the three-month period ended June 30, 2006 as compared to the same period in the prior year is primarily due to an increase in manufacturing activities associated with the development of a commercially viable source of bulk Proellex and the purchase of bulk Proellex for clinical activities and an increase in non-cash stock compensation expense of \$21,000 due to the adoption of SFAS No. 123(R) offset by a reduction in preclinical activities. The increase in R&D expenses for the six-month period ended June 30, 2006 as compared to the same period in the prior year is primarily due to an increase of \$1.7 million in our current clinical activities offset by a reduction of \$532,000 in preclinical activities relating to the development programs for Proellex and Androxal. In addition, there was an increase in personnel costs of \$48,000 and an increase in non-cash stock compensation expense of \$44,000 due to the adoption of SFAS No. 123(R).

General and Administrative Expenses. General and administrative expenses increased 43% to \$666,000 for the three-month period ended June 30, 2006 as compared to \$465,000 for the same period in the prior year and increased 42% to approximately \$1.3 million for the six-month period ended June 30, 2006 as compared to \$896,000 for the same period in the prior year. The increase in expenses for the three-month period ended June 30, 2006 as compared to the same period in the prior year is primarily due to an increase in non-cash stock compensation expense of \$140,000 due to the adoption of SFAS No. 123(R) and an increase in investor relations costs of \$47,000. The increase in expenses for the six-month period ended June 30, 2006 as compared to the same period in the prior year is primarily due to an increase in non-cash stock compensation expense of \$270,000 due to the adoption of SFAS No. 123(R) and an increase in investor relations costs of \$120,000.

Liquidity and Capital Resources

We had cash, cash equivalents and marketable securities of approximately \$12.5 million at June 30, 2006 as compared to \$16.8 million at December 31, 2005. This decrease in cash is primarily due to an increase in costs related to our clinical development programs for Androxal and Proellex and associated administrative costs.

We believe that our existing capital resources under our current operating plan will be sufficient to fund our operations through at least December 31, 2006. The Company's 2006 budget contains allotted financial resources to fund the existing CRO contracts for expenses to be incurred through December 31, 2006, relating to the Company's three clinical studies which are the Androxal U.S. Phase III, Proellex U.S. Phase II and the Proellex European Phase II studies. 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,

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then we will have to adjust our plans, which will delay the 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.

On July 21, 2006, the Company contracted to conduct a one year open label extension safety study relating to its current U.S. Phase II uterine fibroid clinical study. This open label extension study will not begin until the FDA has given its approval to conduct such study.

In addition to general operating obligations, the Company currently has open purchase order commitments and potential future contractual obligations, which both span into and through the year 2008, for the clinical development of both Proellex and Androxal in the amounts of \$5.6 million and \$3.6 million, respectively, generally cancelable on 30 days notice, although the Company would be responsible for expenses incurred to that point of termination. Included in purchase order commitments is the remaining \$1.1 million of a \$1.6 million agreement for the commercial supply of the active pharmaceutical ingredient for our drug Proellex which was entered into on April 26, 2006. The Company paid an up-front and non-refundable \$500,000 payment of that commitment at the time of signing. The Company may incur additional payments relating to this contract before year-end 2006 depending on the success of the commercial supply agreement and delivery of bulk compound.

The Company amended its current facility lease effective April 1, 2006. This lease amendment increased the Company's obligations under its lease by approximately \$20,000 per year, for a total of \$59,600 per year, for the remainder of the lease term which expires on June 30, 2010.

As of June 30, 2006, we had an accumulated deficit of \$99.3 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 for VASOMAX, our previous lead product candidate for the oral treatment of male erectile dysfunction, in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. We have financed our operations primarily with proceeds from public offerings and private placements of equity securities, funds received under collaborative agreements and SBIR grants. We will require substantial additional capital to further develop Proellex as an oral treatment for uterine fibroids and endometriosis and Androxal as an oral treatment for testosterone deficiency and to pursue commercialization efforts of the Company's phentolamine products should the decision be made to do so.

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,

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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 and defending and enforcing any patent claims and other intellectual property rights; changes in economic, regulatory or competitive conditions of our planned business; and additional costs associated with being a publicly-traded company. Estimates about the adequacy of funding for our activities are based on certain assumptions, 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 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 \$12.5 million at June 30, 2006. 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 June 30, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

On September 21, 2005, the SEC extended the compliance dates related to Section 404 of the Sarbanes-Oxley Act for non-accelerated filers. Under this extension a company that is not required to file its annual and quarterly reports on an accelerated basis (non-accelerated filer) must begin to comply with the internal control over financial reporting requirements for its first fiscal year ending on or after July 15, 2007. We anticipate that we will become an accelerated filer in 2006 and therefore we would be required to comply with these requirements for the year ending December 31, 2006.

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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, 2005 in response to Item 1A. Risk Factors to Part I of Form 10-K for the fiscal year ended December 31, 2005.

We currently rely on third-party manufacturers and other third parties for production of our product candidates, and our dependence on these manufacturers may impair the development of our product candidates.

Currently, we do not have the ability internally to manufacture the product candidates that we need to conduct our clinical trials. To date, other than some initial amounts from the National Institutes of Health (NIH), we have obtained all of our supply of Proellex for our clinical trials primarily from Bridge Organics pursuant to purchase orders on an as needed basis. We have identified a new manufacturer and recently entered into a long-term supply contract with such manufacturer for the production of Proellex. Pursuant to the terms of this long-term supply contract, we are required, with certain limited exceptions, to purchase all of our future requirements of Proellex from this single supplier for a five year period, to the extent such supplier is able to satisfy our requirements. If the new supplier is unable to supply sufficient quantities of Proellex as provided in the long-term supply contract or fails to remedy a default of a different material provision of the long-term supply contract, the long-term supply agreement is immediately terminable upon our written notice.

We have no long-term contract with suppliers of Androxal. We have obtained all of our supply of Androxal to date from BioVectra. We have not faced any material problems with BioVectra in supplying us with our necessary quantities of Androxal for our clinical trials and anticipate utilizing them for commercial production if Androxal is approved. There are numerous other suitable manufacturers capable of manufacturing Androxal.

For the foreseeable future, we expect to continue to rely on third-party manufacturers and other third parties to produce, package and store sufficient quantities of Proellex, Androxal and any future product candidates for use in our clinical trials. These product candidates are complicated and expensive to manufacture. If our third-party manufacturers fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our product candidates. While we may be able to identify replacement third-party manufacturers or develop our own manufacturing capabilities for these product candidates, this process would likely cause a delay in the availability of our product candidates and an increase in costs. In addition, third-party manufacturers may have a limited number of facilities in which our product candidates can be produced, and any interruption of the

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operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available product candidates.

We also depend on outside vendors for the supply of the active pharmaceutical ingredients and raw materials used to produce our product candidates. Although we believe there are numerous third-party suppliers available, if our current third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we were unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have our product candidates manufactured and to conduct preclinical testing and clinical trials of our product candidates would be adversely affected.

Our product candidates have only been manufactured in small quantities to date, and we may face delays or complications in manufacturing quantities of our product candidates in sufficient quantities to meet the demands of late stage clinical trials and marketing.

We cannot assure that we will be able to successfully increase the manufacturing capacity or scale-up manufacturing volume per batch, whether on our own or in reliance on third-party manufacturers, for any of our product candidates in a timely or economical manner, or at all. To date our non-phentolamine-based product candidates have been manufactured exclusively by third parties in small quantities for pre-clinical and clinical trials. We have arranged for the production of significantly larger quantities of Proellex, and we will need to arrange for the production of significantly larger quantities of Androxal, for future clinical trials and for future commercial sale in the event that such product candidates are approved by the FDA or foreign regulatory bodies. Significant scale-up of manufacturing may require certain additional validation studies, which the FDA must review and approve. If we or our third-party manufacturers are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in supply of that product candidate.

We may incur increased costs as a result of laws and regulations relating to corporate governance matters.

Laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the Securities and Exchange Commission and by NASDAQ, will result in increased costs to us as we evaluate the implications of any new rules and respond to their requirements. Since our public float exceeded \$75 million at the end of our second fiscal quarter ended June 30, 2006, we will become an accelerated filer and be subject to additional regulatory requirements, including Section 404 of Sarbanes-Oxley which will require us to include in our annual report for the period ending December 31, 2006 a report by management on our internal control over financial reporting and an accompanying auditor's report. The additional costs and efforts to do so could be substantial. New rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. We cannot predict or estimate

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the amount of the additional costs we may incur or the timing of such costs to comply with such new rules and regulations.

Item 4. Submission of Matters to a Vote of Security Holders

The 2006 Annual Meeting of the Company's Stockholders was held on May 2, 2006 to consider and vote upon the following proposals:

(1) Election of Directors. The following individuals were nominated and elected as directors, with the following number of shares voted for and withheld with respect to each director.

	For	Withheld
Joseph S. Podolski	8,962,317	14,224
Louis Ploth, Jr.	8,960,507	16,034
Daniel F. Cain	8,959,249	17,292
Jean Fourcroy, M.D., Ph.D., M.P.H.	8,959,659	16,882
Jeffrey R. Harder, J.D.	8,952,609	23,932
Nola Masterson	8,959,517	17,024
David Poorvin, Ph.D.	8,959,659	16,882

(2) To approve an amendment to the Company's Restated Certificate of Incorporation to change the name of the Company to Repros Therapeutics Inc. .

For 8,630,084

Against 343,457

Abstain 3,000

(3) Approval of the appointment of PricewaterhouseCoopers LLP as the Company's independent registered public accounting firm for the fiscal year-ending December 31, 2006.

For 8,945,301

Against 12,352

Abstain 19,158

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).

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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: August 3, 2006

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

Date: August 3, 2006

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

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Exhibit Index

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|------|---|
| 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). |