ZONAGEN INC
Form 10-Q
May 01, 2006

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

(Mark One)

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

**For the quarterly period ended March 31, 2006**

**or**

o **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**

**ZONAGEN, INC.**

(Exact Name of Registrant as Specified in its Charter)

| Delaware | 76-0233274 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (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)

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 þ No o

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 o Accelerated filer o Non-accelerated filer þ

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

As of April 28, 2006, there were outstanding 10,145,962 shares of Common Stock, par value $.001 per share, of the Registrant.

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**ZONAGEN, INC.**
(A development stage company)
For the Quarter Ended March 31, 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, manufacturing uncertainties related to Proellex , 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. Description of Business Business Risks 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 three-month period ended March 31, 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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**ZONAGEN, INC. AND SUBSIDIARY**
(A development stage company)
**CONDENSED CONSOLIDATED BALANCE SHEETS**
(unaudited and in thousands except share amounts)

| | March 31, 2006 | December 31, 2005 |
|---|---|---|
| **ASSETS** | | |
| **Current Assets** | | |
| Cash and cash equivalents | $ 4,587 | $ 2,165 |
| Marketable securities | 10,356 | 14,667 |
| Prepaid expenses and other current assets | 197 | 231 |
| Total current assets | 15,140 | 17,063 |
| **Fixed Assets,** net | 64 | 19 |
| **Other assets** | 638 | 600 |
| Total assets | $ 15,842 | $ 17,682 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| **Current Liabilities** | | |
| Accounts payable | $ 468 | $ 338 |
| Accrued expenses | 304 | 389 |
| Total current liabilities | 772 | 727 |
| **Commitments & Contingencies** | | |
| **Stockholders Equity** | | |
| Undesignated Preferred Stock, $.001 par value, 5,000,000 shares authorized, none issued and outstanding | | |
| Common Stock, $.001 par value, 20,000,000 shares authorized, 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 | 117,395 | 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 | (96,389) | (94,145) |
| Total stockholders equity | 15,070 | 16,955 |
| Total liabilities and stockholders equity | $ 15,842 | $ 17,682 |

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

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

| | Three Months Ended March 31, | | From Inception (August 20, 1987) through March 31, |
|---|---|---|---|
| | **2006** | **2005** | **2006** |
| **Revenues and other income** | | | |
| Licensing fees | $ | $ | $ 28,755 |
| Product royalties | | | 627 |
| Research and development grants | | 4 | 1,219 |
| Interest income | 174 | 108 | 13,930 |
| Gain on disposal of fixed assets | | | 102 |
| Other Income | | | 35 |
| Total revenues and other income | 174 | 112 | 44,668 |
| **Expenses** | | | |
| Research and development | 1,808 | 1,236 | 102,169 |
| General and administrative | 610 | 431 | 29,157 |
| Interest expense and amortization of intangibles | | | 388 |
| Total expenses | 2,418 | 1,667 | 131,714 |
| Loss from continuing operations | (2,244) | (1,555) | (87,046) |
| Loss from discontinued operations | | | (1,828) |
| Gain on disposal | | | 939 |
| Net loss before cumulative effect of change in accounting principle | (2,244) | (1,555) | (87,935) |
| Cumulative effect of change in accounting principle | | | (8,454) |
| **Net loss** | $ (2,244) | $ (1,555) | $ (96,389) |
| **Loss per share basic and diluted** | $ (0.22) | $ (0.19) | |
| Shares used in loss per share calculation: | | | |
| Basic | 10,140 | 8,326 | |
| Diluted | 10,140 | 8,326 | |

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

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

| | Three Months Ended March 31, | | From Inception (August 20, 1987) through March 31, |
|---|---|---|---|
| | 2006 | 2005 | 2006 |
| **Cash Flows from Operating Activities** | | | |
| Net loss | $ (2,244) | $ (1,555) | $ (96,389) |
| Gain on disposal of discontinued operations | | | (939) |
| Gain on disposal of fixed assets | | | (102) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Noncash financing costs | | | 316 |
| Noncash inventory impairment | | | 4,417 |
| Noncash patent impairment | | | 1,339 |
| Noncash decrease in accounts payable | | | (1,308) |
| Depreciation and amortization | | 1 | 3,780 |
| Noncash expenses related to stock-based transactions | 156 | 4 | 2,973 |
| Common stock issued for agreement not to compete | | | 200 |
| Series B Preferred Stock issued for consulting services | | | 18 |
| Maturities of marketable securities | 14,112 | 3,400 | 38,937 |
| Purchases of marketable securities | (9,801) | (20,140) | (20,758) |
| 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 | 34 | (205) | 102 |
| (Decrease) increase in accounts payable and accrued expenses | 45 | 538 | 1,968 |
| Net cash provided by (used in) operating activities | 2,302 | (17,957) | (70,092) |
| **Cash Flows from Investing Activities** | | | |
| Maturities (purchases) of marketable securities | | | (28,723) |
| Capital expenditures | (45) | (3) | (2,342) |
| Purchase of technology rights and other assets | (38) | (21) | (2,659) |
| Proceeds from sale of PP&E | | | 225 |
| Cash acquired in purchase of FTI | | | 3 |
| Proceeds from sale of subsidiary, less $12,345 for operating losses during 1990 phase-out period | | | 138 |
| Proceeds from sale of the assets of FTI | | | 2,250 |

| | | | |
|---|---|---|---|
| Increase in net assets held for disposal | | | (213) |
| Net cash used in investing activities | (83) | (24) | (31,321) |
| **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 in) financing activities | 203 | 18,865 | 106,000 |
| **Net increase (decrease) in cash and cash equivalents** | 2,422 | 884 | 4,587 |
| **Cash and cash equivalents at beginning of period** | 2,165 | 736 | |
| **Cash and cash equivalents at end of period** | $ 4,587 | $ 1,620 | $ 4,587 |

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

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**ZONAGEN, INC. AND SUBSIDIARY**
(A development stage company)
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**
**March 31, 2006**
(Unaudited)

**NOTE 1 Organization and Operations**

Zonagen, Inc. ( the Company , Zonagen, 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 the existing CRO contracts for expenses to be incurred during 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. The Company will need to obtain additional funding from the capital markets in 2006 to continue the future clinical development of its products. We can not 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 start long-term animal safety studies.

Zonagen 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 new licenses and product development agreements. The timing of our revenues may not match the timing of our associated product development expenses. To date, research and development expenses have generally exceeded revenue in any particular period and/or fiscal year.

As of March 31, 2006, the Company had an accumulated deficit of $96.4 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.

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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 Director Plan; and the 2004 Stock Option Plan, or 2004 Plan. As of March 31, 2006, there were 292,935 options available under the 2004 Plan and 500,000 available 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 provisions of the two remaining plans. 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.

In the first quarter of 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 in the first quarter of 2006, related to stock option plans was an additional expense of $156,000 ($0.02 per share, basic and diluted), of which $26,000 was recorded to Research and Development expense and $130,000 was recorded to General and Administrative expense. At March 31, 2006, there was $651,000 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 1.1 years.

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 option s 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 no stock options granted in the three-month period ended March 31, 2006. The following assumptions were used for stock option grants: risk-free interest rate of 3.5% to 4.0%; no expected dividends; expected lives of 4.2 to 6.4 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 FAS123(R) we recorded deferred compensation in equity for options issued in the money under APB Opinion No. 25. Due to the adoption of FAS 123(R) on January 1, 2006, we eliminated $130,000 from deferred compensation to additional paid in capital.

The following table presents the proforma 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 123R during the three-month period ended March 31, 2005 (in thousands except per share amounts):

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| | Three Months Ended March 31, 2005 |
|---|---|
| Net loss, as reported | $ (1,555) |
| Add: Stock-based employee compensation expense included in reported net income, net of related tax effects | 4 |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | (275) |
| Pro forma net loss | $ (1,826) |
| Loss per share - | |
| Basic as reported | $ (0.19) |
| Basic pro forma | (0.22) |
| Diluted as reported | (0.19) |
| Diluted pro forma | (0.22) |

The following table summarizes the Company s stock option activity for the three-months ended March 31, 2006:

| | Stock Options | Weighted Average Exercise Price | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|
| Outstanding at December 31, 2005 | 1,715,363 | | |
| Granted | | | |
| Exercised | (66,361) | | $ 421 |
| Forfeited | (176,854) | | |
| Outstanding at March 31, 2006 | 1,472,148 | $ 4.39 | $ 7,386 |
| Exercisable at March 31, 2006 | 926,246 | $ 4.85 | $ 4,221 |

The weighted average remaining contractual term of shares exercisable at March 31, 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 March 31, 2006 all securities were classified as trading securities. The cost basis including purchased premium for these securities was $10.4 million and $14.7 million at March 31, 2006 and December 31, 2005, respectively.

Marketable securities as of March 31, 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.

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**NOTE 4 Patents**

As of March 31, 2006, the Company had approximately $638,000 in internal capitalized patent costs reflected on its balance sheet. Of this amount, $348,000 relates to patents for Proellex, which is being developed as an oral treatment for uterine fibroids and endometriosis, and $290,000 relates to Androxal, which is being developed as an oral treatment for testosterone deficiency.

**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 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 periods ended March 31, 2006 and 2005 (in thousands, except per share amounts):

| | Three Months Ended March 31, | |
|---|---|---|
| | **2006** | **2005** |
| Net loss | $ (2,244) | $ (1,555) |
| Weighted average common shares outstanding | 10,140 | 8,326 |
| Basic loss per share | $ (0.22) | $ (0.19) |
| Weighted average common and dilutive potential common shares outstanding: | | |
| Weighted average common shares outstanding | 10,140 | 8,326 |
| Diluted loss per share | $ (0.22) | $ (0.19) |

Other potential common stock of 1,472,148 and 1,685,397 for the periods ended March 31, 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 March 31, 2006, the Company had 1,472,148 options outstanding, of which 926,246 were vested. All outstanding options have exercise prices ranging from $2.40 to $33.25 with a weighted average exercise price of $4.39. In January 2006, we received $203,600 from the exercise of 66,361 stock options that were exercised by former Board Members. Additional stock options also held by former Board Members of 176,854 expired unexercised on January 14, 2006. Management, employees and outside consultants hold 118,000 stock options which are also

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scheduled to expire during 2006. These options have exercise prices ranging from $7.50 to $8.38 with a weighted average strike price of $8.34.

**NOTE 7 Commitments and Contingencies**

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

As of March 31, 2006, in addition to general operating obligations, the Company also had open purchase order commitments for clinical development of both Proellex and Androxal in the amounts of $4.8 million and $3.2 million, respectively, cancelable on 30 days notice, although the Company would be responsible for expenses incurred to that point of termination. In addition as of April 26th the Company also entered into a $1.6 million agreement for the commercial supply of the active pharmaceutical ingredient for its drug Proellex of which $500,000 was paid up-front and non-refundable.

The Company amended its current facility lease effective April 1, 2006 for its office/laboratory space in The Woodlands, Texas. The amendment increased the 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. See Factors Affecting Forward-Looking Statements included elsewhere in this quarterly report on Form 10-Q. The following discussion of financial condition should be read in conjunction with the accompanying consolidated financial statements and related notes.*

**Overview**

Zonagen, Inc. ( the Company , Zonagen, or we, us or our ) was organized on August 28, 1987 and is a develop stage company. We are a biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders. The Board of Directors recently approved changing the company s name to Repros Therapeutics Inc. in order to more appropriately reflect the Company s focus on the reproductive and hormonal health technology market. We anticipate that the name change will be effective immediately after our 2006 annual meeting, subject to stockholder approval.

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.

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, or 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, or 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 downregulate 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, or 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. Initial data from this study is not expected before fourth quarter 2006 and we hope to submit an 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 European Phase II study will enroll 40 women and compare three doses of double blinded Proellex against open label Lupron(R), the current standard of care, for up to six-months of treatment. Initial interim three-month data from this six-month study is not expected before the fourth quarter of 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 2006. The Company previously completed a six-month rat study and a nine-month dog study testing the safety of Proellex.

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

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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 25 mg 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. The double-blind study will test two doses of Androxal versus placebo and will include an open-label arm of the commercially available drug Androgel®. The dosing is of 24-week duration with an efficacy assessment made at 12 weeks. Initial data after 12 weeks of dosing is not expected before fourth quarter 2006. The extension of the 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 and we hope to submit an NDA in 2008.

Initial review of our special protocol assessment (SPA) for a Phase III pivotal study of efficacy has been 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 clinical endpoint such as improvement in libido and the associated emotional distress. The FDA has suggested that prior to using certain endpoints proposed by us in our SPA filing, such as reduced stress, in a Phase III efficacy study, tests that measure these endpoints must be validated. We intend to

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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 late 2006 or early 2007, subject to available funding 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 will be initiated in 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 an issued patent 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 this third party s patent 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 are seeking further reexamination of the third party s patent in light of a number of these additional publications. Nevertheless, there is no assurance that the patent ultimately will be found invalid over the prior art. If such patent is not invalidated, we may be required to obtain a license from the holder of such patent in order to develop Androxal further. If such license were not available on acceptable terms or at all, we may not be able to develop or commercialize Androxal.

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 Q1, 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 Q1, 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. Our Board of Directors is evaluating its options before proceeding with Mexican approval

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trials for Bimexes or Erxin. Mexico is viewed as the gold standard for regulatory efforts in Latin America. Approval in Mexico can 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.

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 groups to adequately perform the activities required to obtain regulatory approval of our products and to complete development and manufacturing thereof.

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

We have limited financial resources and personnel and anticipate that we will need to raise additional capital and hire a significant number of employees in order to be able to successfully develop each of our current product candidates through the 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 its 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 Periods Ended March 31, 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

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development expenses have generally exceeded revenue in each particular period and/or fiscal year.

*Revenues and other income*. Total revenues and other income for the three-month period ended March 31, 2006 increased to $174,000 as compared to $112,000 for the same period in the prior year.

Research and development grant revenues for the three-month period ended March 31, 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 increased 61% to $174,000 for the three-month period ended March 31, 2006, as compared to $108,000 for the same period in the prior year. This increase is primarily due to the increase in marketable securities as a result of the completion of our follow-on public offering on February 1, 2005 in which we received approximately $18.2 million in net proceeds, and an increase in interest rates.

*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 46% to approximately $1.8 million for the three-month period ended March 31, 2006 as compared to approximately $1.2 million for the same period in the prior year. This increase in R&D expenses is primarily due to an increase of $351,000 and $145,000 related to our clinical development programs for Androxal and Proellex, respectively, and an increase in non-cash stock compensation expense of $23,000 due to the adoption of SFAS No. 123(R).

*General and Administrative Expenses*. General and administrative expenses increased 42% to $610,000 for the three-month period ended March 31, 2006 as compared to $431,000 for the same period in the prior year. This increase in expenses is primarily due to an increase in non-cash stock compensation expense of $130,000 due to the adoption of SFAS No. 123(R) and an increase in investor relations costs of $74,000, offset by a decrease in costs associated with strategic administrative fees in the amount of $35,000.

**Liquidity and Capital Resources**

We had cash, cash equivalents and marketable securities of approximately $14.9 million at March 31, 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 during 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. The Company will

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need to obtain additional funding from the capital markets in 2006 to continue the future clinical development of its products. We can not 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 start long-term animal safety studies.

Excluding maturities and purchases of marketable investment securities of $4.3 million, we used $2.0 million during the three-month period ended March 31, 2006 for operating activities. The major uses of cash for operating activities during the three-month period ended March 31, 2006 was to fund our clinical development programs and administrative costs of approximately $2.2 million and to pay our accounts payable and current liabilities. Cash used in investing activities was $83,000 in the three-month period ended March 31, 2006, primarily for the purchase of capital assets and capitalized costs related to our Proellex and Androxal patent portfolios. Cash provided by financing activities was approximately $203,000 in the three-month period ended March 31, 2006, relating to the exercise of 66,361 stock options. As of March 31, 2006, in addition to general operating obligations, we also had current open purchase order commitments primarily relating to the clinical development of both Proellex and Androxal in the amounts of $4.8 million and $3.2 million, respectively, which commitments are cancelable on thirty days notice, although the Company would be responsible for expenses incurred to that point of termination.

As of March 31, 2006, we had an accumulated deficit of $96.4 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 Board of Directors elect 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, marketing or other funding arrangements; our ability to obtain regulatory approvals; the success of our potential future sales and marketing programs; the cost of filing, prosecuting and defending and enforcing any patent claims and other intellectual property rights; changes in economic, regulatory or competitive conditions of our planned business; and additional costs associated with being a publicly-traded company. Estimates about the adequacy of funding for our activities are based on certain assumptions, including the assumption that the development and regulatory approval of our products can be completed at projected costs and that product

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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 $14.9 million at March 31, 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 March 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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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**

There were no material changes from risk factors as previously disclosed in the registrant s Form 10-K for the fiscal year ended December 31, 2005 in response to Item 1A. to Part I of Form 10-K.

**Item 5. Other Information**

None

**Item 6. Exhibits**

10.1 Amendment to Lease, dated March 17, 2006

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.

**ZONAGEN, INC.**

Date: May 1, 2006

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

Date: May 1, 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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**Index to Exhibits**

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