ZONAGEN INC
Form 10-Q
July 29, 2005

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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 June 30, 2005

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-1
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 past 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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ

As of July 27, 2005, there were outstanding 10,079,601 shares of Common Stock, par value $.001 per share, of the Registrant.

ZONAGEN, INC.
(A development stage company)
For the Quarter Ended June 30, 2005
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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 (formerly Progenta) 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 , the Company s ability to obtain value from its other technologies, 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, 2004 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, 2005 are not necessarily indicative of the results that may be expected for the year ended December 31, 2005. 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, 2004.

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

	June 30, 2005	December 31, 2004
ASSETS		
Current Assets		
Cash and cash equivalents	$ 2,358	$ 736
Marketable securities	18,764	4,800
Prepaid expenses and other current assets	222	34
Total current assets	21,344	5,570
Fixed Assets, net	22	18
Other assets	485	1,018
Total assets	$ 21,851	$ 6,606
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities		
Accounts payable	$ 530	$ 144
Accrued expenses	200	470
Total current liabilities	730	614
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, 12,016,636 and 11,989,936 shares issued, respectively; 10,079,601 and 4,992,901 shares outstanding, respectively	12	12
Additional paid-in capital	117,194	114,455
Deferred compensation	(182)	(234)
Cost of treasury stock, 1,937,035 and 6,997,035 shares, respectively	(5,948)	(21,487)
Deficit accumulated during the development stage	(89,955)	(86,754)
Total stockholders equity	21,121	5,992
Total liabilities and stockholders equity	$ 21,851	$ 6,606

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 June 30,		Six Months Ended June 30,		From Inception (August 20, 1987) through June 30,
	2005	2004	2005	2004	2005
Revenues and other income					
Licensing fees	$	$	$	$	$ 28,755
Product royalties					627
Research and development grants		53	4	117	1,219
Interest income	173	22	281	48	13,407
Gain on disposal of fixed assets					102
Other Income				35	35
Total revenues and other income	173	75	285	200	44,145
Expenses					
Research and development	1,355	508	2,590	985	96,850
General and administrative	465	294	896	728	27,519
Interest expense and amortization of intangibles					388
Total expenses	1,820	802	3,486	1,713	124,757
Loss from continuing operations	(1,647)	(727)	(3,201)	(1,513)	(80,612)
Loss from discontinued operations					(1,828)
Gain on disposal					939
Net loss before cumulative effect of change in accounting principle	(1,647)	(727)	(3,201)	(1,513)	(81,501)
Cumulative effect of change in accounting principle					(8,454)
Net loss	$ (1,647)	$ (727)	$(3,201)	$(1,513)	$ (89,955)
Loss per share basic and diluted:	$ (0.16)	$ (0.15)	$ (0.35)	$ (0.29)	

Shares used in loss per share calculation:				
Basic	10,080	4,993	9,208	5,242
Diluted	10,080	4,993	9,208	5,242

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 June 30,		Six Months Ended June 30,		From Inception (August 20, 1987) through June 30,
	2005	2004	2005	2004	2005
Cash Flows from Operating Activities					
Net loss	$(1,647)	$ (727)	$ (3,201)	$ (1,513)	(89,955)
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		20		20	1,339
Noncash decrease in accounts payable					(1,308)
Depreciation and amortization	2	3	3	5	3,776
Noncash expenses related to stock-based transactions	34		38		2,766
Common stock issued for agreement not to compete					200
Series B Preferred Stock issued for consulting services					18
Maturities (purchases) of marketable securities	2,777	(250)	(13,964)	(4,350)	9,771
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	16	55	(188)	11	77
(Decrease) increase in accounts payable and accrued expenses	(394)	22	143	(123)	1,952
Decrease (increase) in other assets			600	284	
	788	(877)	(16,569)	(5,666)	(72,318)

Net cash used in operating activities					
Cash Flows from Investing Activities					
Maturities (purchases) of marketable securities					(28,723)
Capital expenditures	(3)	(9)	(6)	(12)	(2,295)
Purchase of technology rights and other assets	(47)	(46)	(68)	(99)	(2,506)
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	(50)	(55)	(74)	(111)	(31,121)
Cash Flows from Financing Activities					
Proceeds from issuance of common stock, net of offering costs			18,180		102,404
Exercise of stock options			85		85
Proceeds from issuance of preferred stock					23,688
Purchase of treasury stock				(13,954)	(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			18,265	(13,954)	105,797
Net increase (decrease) in cash and cash equivalents	738	(932)	1,622	(19,731)	2,358
Cash and cash equivalents at beginning of period	1,620	2,147	736	20,946	
Cash and cash equivalents at end of period	$ 2,358	$1,215	$ 2,358	$ 1,215	$ 2,358

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
June 30, 2005
(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 developm stage company. We are a clinical stage biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders. Our lead product candidate, Proellex (formerly Progenta), 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 then existing treasury stock, and the offering resulted in net proceeds to the Company of approximately $18.2 million. As of June 30, 2005, the Company had 10,079,601 shares outstanding and 1,937,035 shares of treasury stock.

In January 2004, the Company purchased 6,547,635 shares of its common stock (approximately 57% of its then-outstanding common stock) at $2.10 per share in its self tender offer for a total aggregate cost of approximately $14.0 million, inclusive of costs associated with the offer.

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 U.S. Food and Drug Administration (FDA) or other regulatory approvals are obtained. The Company believes that its existing capital resources under its current operating plan will be sufficient to fund the Company s operations through at least the second quarter of 2006. There can be no assurance that changes in our current strategic plans or other events will not result in accelerated or unexpected expenditures.

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.

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As of June 30, 2005, the Company had an accumulated deficit of $90.0 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 can 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.

Recent Accounting Pronouncements

In May 2005, SFAS No. 154, Accounting Changes and Error Corrections replacement of APB Opinion No. 20 and FASB Statement No. 3, (SFAS No. 154) was issued. SFAS No. 154 changes the accounting for and reporting of a change in accounting principle by requiring retrospective application to prior periods financial statements of changes in accounting principle unless impracticable. SFAS No. 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005. The Company does not expect the adoption of SFAS No. 154 to have a material impact on its results of operations, financial position or cash flows.

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004), Share-Based Payment. In March 2005 the SEC issued Staff Accounting Bulletin No. 107 (SAB 107). SAB 107 expresses views of the SEC staff regarding the interaction between SFAS 123(R) and certain SEC rules. SFAS No. 123(R) will require that the compensation cost relating to share-based payment transactions be recognized in financial statements. That cost will be measured based on the fair value of the equity or liability instruments issued. SFAS No. 123(R) covers a wide range of share-based compensation arrangements including share options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. SFAS No. 123(R) replaces FASB Statement No. 123, Accounting for Stock-Based Compensation, and supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees. SFAS No. 123, as originally issued in 1995, established as preferable a fair value-based method of accounting for share-based payment transactions with employees. However, that Statement permitted entities the option of continuing to apply the guidance in APB Opinion No. 25, as long as the footnotes to financial statements disclosed what net income would have been had the preferable fair value-based method been used. Public entities will be required to apply SFAS No. 123(R) as of the first annual reporting period that begins after June 15, 2005. The impact of the adoption of SFAS No. 123(R) based on share-based payments currently awarded to employees is expected to be approximately $0.6 million in additional non-cash compensation expense in 2006.

NOTE 2 Stock-based Compensation

The Company accounts for its stock option plans under APB No. 25 Accounting for Stock

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Issued to Employees. Accordingly, deferred compensation is recorded for stock options based on the excess of the market value of the common stock on the measurement date over the exercise price of the options. This deferred compensation is amortized over the vesting period of each option.

The Company has adopted the disclosure requirements of SFAS No. 123, Accounting for Stock-Based Compensation as amended by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure (SFAS 123/148) and has elected not to record related compensation expense in accordance with this statement. Had compensation expense for its stock option plans been determined consistent with SFAS No. 123/148, the Company s net loss and loss per share would have been increased to the following pro forma amounts (in thousands, except for per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Net loss, as reported	$(1,647)	$ (727)	$(3,201)	$(1,513)
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)	(98)	(410)	(118)
Pro forma net loss	$(1,748)	$ (825)	$(3,573)	$(1,631)
Loss per share -				
Basic as reported	$ (0.16)	$(0.15)	$ (0.35)	$ (0.29)
Basic pro forma	(0.17)	(0.17)	(0.39)	(0.31)
Diluted as reported	(0.16)	(0.15)	(0.35)	(0.29)
Diluted pro forma	(0.17)	(0.17)	(0.39)	(0.31)

Under SFAS No. 123/148, the fair value of each option grant was estimated on the date of grant using the Black-Scholes option-pricing model. There were no options granted in the three-month period ended June 30, 2004. The following weighted average assumptions were used for grants in the three-month period ended June 30, 2005: risk-free interest rate of 3.9%; no expected dividends; expected lives of 6.3 years and expected volatility of 87%. The weighted fair value of options granted for the three-month period ended June 30, 2005 was $2.85. The following weighted average assumptions were used for grants in the six-month period ended June 30, 2005 and 2004, respectively: risk-free interest rate of 3.9% and 3.9%; no expected dividends; expected lives of 6.3 and 5.7 years and expected volatility of 87% and 87%. The weighted fair value of options granted for the six-month period ended June 30, 2005 and 2004 was $2.85 and $1.89, respectively.

The Black-Scholes option valuation model and other existing models were developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of and are highly sensitive to subjective assumptions including the expected stock price volatility. The Company s employee

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stock options have characteristics significantly different from those of traded options and changes in the subjective input assumptions can materially affect the fair value estimate.

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 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, 2005, all securities were classified as trading securities. The cost basis including purchased premium, which approximates fair value, for these securities was $18.8 million and $4.8 million at June 30, 2005 and December 31, 2004, respectively.

Short-term marketable securities have a remaining maturity of less than twelve months and long-term marketable securities have a remaining maturity of greater than twelve months. Marketable securities as of June 30, 2005 consist of only short-term investments totaling $18.8 million. 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, 2005, the Company had approximately $485,000 in internal capitalized patent costs reflected on its balance sheet. Of this amount, $302,000 relates to patents for Proellex, which is being developed as an oral treatment for uterine fibroids and endometriosis, and $183,000 relates to Androxal, which is being developed as an oral treatment for testosterone deficiency. The Company is no longer maintaining its patent portfolio for its vaccine adjuvants, prostate cancer vaccines, hCG and zona pellucida immuno-contraceptive vaccines.

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

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three-month periods ended June 30, 2005 and 2004 (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Net Loss	$ (1,647)	$ (727)	$(3,201)	$(1,513)
Average common shares outstanding	10,080	4,993	9,208	5,242
Basic loss per share	$ (0.16)	$ (0.15)	$ (0.35)	$ (0.29)
Diluted loss per share	$ (0.16)	$ (0.15)	$ (0.35)	$ (0.29)

Common stock equivalents of 1,710,363 and 1,290,382 for the periods ended June 30, 2005 and 2004, respectively, were excluded from the above calculation of diluted loss per share since they were antidilutive.

NOTE 6 Stockholders Equity

On June 30, 2005, the Company amended its Rights Agreement dated as of September 1, 1999, as amended, to (i) delete all provisions excluding Lavipharm Corporation and its affiliates from the provisions of the Rights Agreement that were included in an earlier amendment to the Rights Agreement and (ii) extend the expiration date of the Rights Agreement for five years to September 13, 2010.

On June 21, 2005, the Company issued options to purchase an aggregate of 60,000 shares of its common stock to its Board of Directors, including (i) an initial grant of an option to purchase 40,000 shares to one Director as a result of his initial election to the Board and (ii) options to purchase an aggregate of 20,000 shares to its four existing non-employee directors due to their re-election to the Board of Directors. The single initial stock option grant for 40,000 shares will vest quarterly over a three year period. The re-election option grants for 20,000 shares will vest immediately following the 2006 Annual Meeting of Stockholders. All grants have an exercise price of $3.71, which was the fair market value of the Company s common stock on the date of grant.

A total of 129,783 options with exercise prices ranging from $2.40 to $33.25 have expired or were cancelled during the six-month period ended June 30, 2005. As of June 30, 2005, the Company had 1,710,363 options outstanding, of which 967,123 were vested. All outstanding options have exercise prices ranging from $1.70 to $33.25 with an average exercise price of $4.67.

No options were exercised during the three-month period ended June 30, 2005. The Company received $85,000, from prior employees, for the exercise of options to purchase 26,700 shares of common stock for the three-month period ended March 31, 2005 that were due to expire during that quarter.

On March 29, 2004, the Compensation Committee approved grants to the Company s executive officers for incentive options to purchase 79,486 shares of its common stock and also granted incentive options to purchase 17,504 shares to non-executive employees. Vesting of these

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options was tied to attaining certain milestones and all options were granted at an exercise price of $2.72, the fair market value of the Company s common stock on the date of grant. The Company recorded compensation expense as performance milestones were achieved for these incentive options. Five of the ten milestones were met resulting in compensation expense for the year ended December 31, 2004 of $55,000 under these incentive option grants. Three additional milestones were met resulting in additional compensation expense of $8,000 during the three month period ended June 30, 2005. The two remaining performance milestones expired without being met.

NOTE 7 Commitments and Contingencies

As of June 30, 2005, 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 $1,798,100 and $995,400, respectively.

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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 conjuction 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 clinical stage biopharmaceutical company focused on the development of new drugs to treat hormonal and reproductive system disorders.

Our lead product candidate is Proellex (formerly Progenta), an orally available small molecule compound being developed for the treatment of uterine fibroids and endometriosis. We are developing Proellex under an exclusive, worldwide license from the National Institutes of Health (NIH). Proellex is being developed to alleviate adverse symptoms associated with both uterine fibroids and endometriosis by selectively blocking the progesterone receptor in women. We believe Proellex may be an attractive alternative treatment to the current standards of care for uterine fibroids and endometriosis, which include surgery and treatment with gonadotropin releasing hormone agonists, or GnRH agonists, such as Lupron®. Unlike Proellex, GnRH agonists induce a low estrogen, menopausal-like state in women, and estrogen is necessary for the maintenance of bone mineral density. Therefore, GnRH agonists tend to promote bone loss and cannot be used for more than six months at a time. When women cease treatment with GnRH agonists, the fibroids rapidly regenerate and symptoms associated with endometriosis quickly reappear. 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 invasive therapies. We believe Proellex may also be effective as a pre-surgical treatment for uterine fibroids.

During February 2005 the Company presented initial results from a European Phase Ib clinical study with Proellex, which studied the drug s safety and efficacy when administered for three months to women diagnosed with uterine fibroids. The results indicated that Proellex may be safe and have the potential to significantly reduce fibroid size. The Company believes it has sufficient data from this trial to adequately select dose for an advanced efficacy U.S. trial. On May 20, 2005, Zonagen held a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) for the purpose of obtaining FDA guidance on filing an IND for an efficacy trial and commencing this efficacy trial by year end 2005. The meeting was constructive and the FDA laid out many of the requirements that would need to be met before an IND could be opened to allow the Company to begin its efficacy study as well as guidance on the endpoints

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that may be required for the study. The Company is currently addressing those issues which include among other things three-months of animal safety data from two different species. We are currently conducting a six-month dog study and a nine-month rat study testing the safety of Proellex and have used some of the animals in each study, known as peel-offs, for this three-month data requirement. The three-month dosing peel-off portion was completed in July 2005, and we are currently analyzing that data and preparing an animal safety data report to submit to the FDA.

The Company hopes that this efficacy trial may be the first pivotal trial of two required pivotal trials. This trial is still subject to among other things the FDA s review of our European Phase Ib data, clinical trial protocol, and three-month preclinical animal safety studies. We believe that initial study data will be available mid-year 2006 and anticipate filing a New Drug Application (NDA) for Proellex, for the treatment of uterine fibroids in the year 2008. We also plan to begin a Phase II clinical trial in Poland for Proellex for the treatment of endometriosis by year end 2005 with initial study data also available mid-year 2006. The FDA deems Proellex to be a new chemical entity.

Our second product candidate is Androxal, an orally available small molecule compound being developed for the treatment of testosterone deficiency in men. Androxal, our proprietary compound, is designed to restore normal testosterone production in males with functional testes and diminished pituitary function, a condition commonly referred to as andropause.

We have completed a 14-day dosing Phase I/II clinical trial in the United States with Androxal for the treatment of men with testosterone deficiency and have submitted a full study report to the FDA. We met with FDA staff members on November 10, 2004 to review our clinical plan for the approval of Androxal. The FDA agreed to review the protocols for our trials in a timely fashion under a special protocol assessment (SPA). We intend to begin a Phase III clinical trial with Androxal in the United States for the treatment of testosterone deficiency by year end 2005, subject to review by the FDA of our clinical trial protocol, clinical study endpoints and successful completion of our current three-month preclinical animal safety studies. We are currently conducting a six-month dog study and a nine-month rat study to test the safety of Androxal and have peeled-off some of the animals in each study to meet our current three-month data requirement. The three-month dosing peel-off portion was completed in July 2005, and we are currently analyzing that data and preparing an animal safety data report to submit to the FDA. We believe that initial study data will be available mid-year 2006 from this Phase III trial. We anticipate filing a NDA for Androxal for the treatment of testosterone deficiency in the year 2008. The FDA deems Androxal to be a new chemical entity.

Both Proellex and Androxal are considered new chemical entities by the FDA which means that both compounds will be required to go through the full clinical approval process, which will include amongst other requirements a two-year carcinogenicity study. We must provide the FDA with additional data from lengthy animal studies before long-term human studies may be initiated in the United States and a NDA may be submitted. The Company s current six month dog and nine-month rat animal safety studies are expected to provide both safety data to support the initiation of the Company s U.S. efficacy study with Proellex and U.S. Phase III study with Androxal for initiation by year end 2005 as well as provide some additional safety data that could be used toward the support of future longer-term human studies.

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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 the 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 (PTO) for re-examination of this third party s patent based on prior art. The third party has since amended the claims in the reexamination proceedings, which may lead to the PTO finding that the claims are patentable in view of the publications under consideration. We believe that the amended claims are invalid based on, among other things, additional prior publications not yet considered by the PTO. We intend to seek further reexamination of the third party s patent in light of a number of these publications. There is no assurance that the patent ultimately will be reversed. If such patent is not cancelled, 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 currently have five full-time employees and utilize the services of contract research organizations, contract manufacturers and various consultants to assist us in performing regulatory services for 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.

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 its 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.

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.

The Company has limited financial resources and personnel and anticipates that it will need to raise additional capital and hire a significant number of employees in order to be able to successfully develop each of its current product candidates through the clinical trials and to be able to market them, should regulatory approval be obtained, on a worldwide basis. Alternatively, the Company may elect to partner with a larger and more experienced

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pharmaceutical company with better resources for one or more of its product candidates and/or target indications. As a result, the Company believes that an out-license of one or more of its 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 not be entered into by us.

The Company is continuing its limited out-licensing efforts relating to its 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 Europe. There can be no assurance that the Company will be able to create any value from out-licensing activities of its phentolamine-based product candidates.

Results of Operations

Three Month and Six Month Periods Ended June 30, 2005 and 2004

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

Revenues and other income. Total revenues and other income for the three-month period ended June 30, 2005 increased to $173,000 as compared with $75,000 for the same period in the prior year and increased to $285,000 for the six-month period ended June 30, 2005 as compared to $200,000 for the same period in the prior year.

Research and development grant revenues for the three-month period ended June 30, 2005 were zero as compared to $53,000 for the same period in the prior year and were $4,000 for the six-month period ended June 30, 2005 as compared to $117,000 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 the Company 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 686% to $173,000 for the three-month period ended June 30, 2005, as compared to $22,000 for the same period in the prior year and increased 485% to $281,000 for the six-month period ended June 30, 2005 as compared to $48,000 for the same period in the prior year. This increase is primarily due to the increase in marketable securities as a result of the Company completing its follow-on public offering on February 1, 2005 in which it received approximately $18.2 million in net proceeds, and an increase in interest rates.

Other revenue included in the six-month period ended June 30, 2004 of $35,000 was from the sale of some of the Company s preclinical phentolamine data that is to be used for a purpose

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that does not compete with the Company s sexual dysfunction technologies.

Research and Development Expenses. Research and development (R&D) expenses include contracted research, regulatory affairs activities and preclinical and clinical study development expenses. R&D expenses increased 167% to $1.4 million for the three-month period ended June 30, 2005 as compared to $508,000 for the same period in the prior year and increased 163% to $2.6 million for the six-month period ended June 30, 2005 as compared to $985,000 for the same period in the prior year. The increase in R&D expenses for the three-month period ended June 30, 2005 as compared to the same period in the prior year is primarily due to an increase of $440,000 and $480,000 related to the Company s clinical development programs for Proellex and Androxal, respectively, partially offset by a decrease of $52,000 in costs associated with the Company s SBIR grant funded R&D. The increase in R&D expenses for the six-month period ended June 30, 2005 as compared to the same period in the prior year is primarily due to an increase of $939,000 and $772,000 related to the Company s clinical development programs for Proellex and Androxal, respectively, partially offset by a decrease of $112,000 in costs associated with the Company s SBIR grant funded R&D.

General and Administrative Expenses. General and administrative expenses increased 58% to $465,000 for the three-month period ended June 30, 2005 as compared to $294,000 for the same period in the prior year and increased 23% to $896,000 for the six-month period ended June 30, 2005 as compared to $728,000 for the same period in the prior year. Expenses for the first quarter 2005 were $431,000 as compared to $465,000 for the second quarter. The increase in expenses for the three-month period ended June 30, 2005 is primarily due to an increase in costs associated with investor relations in the amount of $62,000, legal and accounting services in the amount of $56,000 and non-cash stock option compensation expense in the amount of $28,000. The increase in expenses for the six-month period ended June 30, 2005 is primarily due to an increase in costs associated with strategic administrative fees in the amount of $61,000, investor relations in the amount of $55,000, legal and accounting services in the amount of $35,000 and non-cash stock option compensation expense in the amount of $28,000 partially offset by a $27,000 decrease in directors and officers insurance.

Liquidity and Capital Resources

The Company had cash, cash equivalents and marketable securities of approximately $21.1 million at June 30, 2005 as compared to $5.5 million at December 31, 2004. This increase in cash is due to the February 1, 2005 completion of our public offering of 5,060,000 shares of common stock in which we received net proceeds of approximately $18.2 million. We believe that our existing capital resources under our current operating plan will be sufficient to fund our operations through at least the second quarter of 2006. 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 of marketable investment securities of $2.8 million, we used $2.0 million during the three-month period ended June 30, 2005 for operating activities; and excluding purchases of marketable investment securities of $14.0 million, we used $2.6 million during the

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six-month period ended June 30, 2005. The major uses of cash for operating activities during the three-month period ended June 30, 2005 was to fund the Company s clinical development programs and administrative costs of approximately $1.8 million and to pay the Company s accounts payable and current liabilities. The major uses of cash for operating activities during the six-month period ended June 30, 2005 was to fund the Company s clinical development programs and associated administrative costs of approximately $3.5 million and to prepay the majority of the Company s insurance policies offset by a decrease in other assets related to the costs associated with the follow-on public offering completed in February 2005. Cash used in investing activities was $50,000 and $74,000 in the three-month and six-month periods ended June 30, 2005, respectively, primarily for investments in technology rights related to our Proellex and Androxal patent portfolios. Cash provided by financing activities was approximately $18.3 million in the six-month period ended June 30, 2005, relating to the follow-on public offering which was completed in February 2005 and the exercise of 26,700 stock options in the three-month period ended March 31, 2005. As of June 30, 2005, in addition to general operating obligations, the Company also had current open purchase order commitments relating to the clinical development of both Proellex and Androxal in the amounts of $1,798,100 and $995,400, respectively.

As of June 30, 2005, we had an accumulated deficit of $90.0 million. The Company has incurred losses since its inception and expects 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 do not currently intend to commit any additional resources toward the development of VASOMAX. 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 our oral treatment for uterine fibroids and endometriosis and Androxal for the oral treatment of testosterone deficiency.

Our capital requirements will depend on many factors, including the costs and timing of seeking regulatory approvals of the Company s products; the problems, delays, expenses and complications frequently encountered by development stage companies; the progress of the Company s preclinical and clinical activities; the costs associated with any future collaborative research, manufacturing, marketing or other funding arrangements; the Company s ability to obtain regulatory approvals; the success of the Company s 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 the Company s planned business; and additional costs associated with being a publicly-traded company. Estimates about the adequacy of funding for the Company s activities are based on certain assumptions, including the assumption that the development and regulatory approval of the Company s 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 the Company s research and development plans, acquisitions or other events will not result in accelerated or unexpected expenditures. To satisfy its capital requirements, the Company may seek to raise additional funds in the public or private capital markets. The Company may seek additional funding through corporate collaborations and other financing vehicles. There can be

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no assurance that any such funding will be available to the Company on favorable terms or at all. If the Company is 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 the Company s common stock.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. Cash, cash equivalents and investments were approximately $21.1 million at June 30, 2005. These assets were primarily invested in investment grade corporate bonds and commercial paper with maturities of less than 18 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.

Recent Accounting Pronouncements

Please see Note 1 to our condensed consolidated financials statements included in Item 1 of this filing.

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, the Company s Chief Executive Officer and Chief Financial Officer have concluded that the Company s 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 insuring that the information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the required time periods.

In connection with the evaluation described above, the Company identified no change in internal control over financial reporting that occurred during the fiscal quarter ended June 30, 2005 that has materially affected, or is reasonably likely to materially affect, the Company s 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 4. Submission of Matters to a Vote of Security Holders

The 2005 Annual Meeting of the Company s Stockholders was held on June 21, 2005 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	9,380,062	33,000
Louis Ploth, Jr.	9,374,511	38,551
Daniel F. Cain	9,376,112	36,950
Jean Fourcroy, M.D., Ph.D., M.P.H.	9,375,561	37,501
Jeffrey R. Harder, J.D.	9,374,312	38,750
Nola Masterson.	9,354,361	58,701
David Poorvin, Ph.D.	9,354,161	58,901

(2) Approval of the appointment of PricewaterhouseCoopers LLP as the Company s independent registered public accounting firm for the fiscal year ending December 31, 2005.

For 9,387,161	Against 19,801	Abstain 6,100

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.

ZONAGEN, INC.

Date: July 29, 2005

By: /s/ Joseph S. Podolski

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

Date: July 29, 2005

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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