ZONAGEN INC
Form 10-Q
November 14, 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 September 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

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 November 4, 2005, there were outstanding 10,079,601 shares of Common Stock, par value $.001 per share, of the Registrant.

ZONAGEN, INC.
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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, 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 nine-month period ended September 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)

	September 30, 2005	December 31, 2004
ASSETS		
Current Assets		
Cash and cash equivalents	$ 3,000	$ 736
Marketable securities	16,053	4,800
Prepaid expenses and other current assets	203	34
Total current assets	19,256	5,570
Fixed Assets, net	21	18
Other assets	564	1,018
Total assets	$ 19,841	$ 6,606
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities		
Accounts payable	$ 440	$ 144
Accrued expenses	181	470
Total current liabilities	621	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	(156)	(234)
Cost of treasury stock, 1,937,035 and 6,997,035 shares, respectively	(5,948)	(21,487)
Deficit accumulated during the development stage	(91,882)	(86,754)
Total stockholders equity	19,220	5,992
Total liabilities and stockholders equity	$ 19,841	$ 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 September 30,		Nine Months Ended September 30,		From Inception (August 20, 1987) through September 30,
	2005	2004	2005	2004	2005
Revenues and other income					
Licensing fees	$	$	$	$	$ 28,755
Product royalties					627
Research and development grants		2	4	118	1,219
Interest income	175	27	456	75	13,582
Gain on disposal of fixed assets					102
Other Income				35	35
Total revenues and other income	175	29	460	228	44,320
Expenses					
Research and development	1,641	929	4,231	1,914	98,491
General and administrative	461	540	1,357	1,268	27,980
Interest expense and amortization of intangibles					388
Total expenses	2,102	1,469	5,588	3,182	126,859
Loss from continuing operations	(1,927)	(1,440)	(5,128)	(2,954)	(82,539)
Loss from discontinued operations					(1,828)
Gain on disposal					939
Net loss before cumulative effect of change in accounting principle	(1,927)	(1,440)	(5,128)	(2,954)	(83,428)
Cumulative effect of change in accounting principle					(8,454)
Net loss	$ (1,927)	$ (1,440)	$ (5,128)	$ (2,954)	$ (91,882)

Loss per share basic and diluted:	$ (0.19)	$ (0.29)	$ (0.54)	$ (0.57)
Shares used in loss per share calculation:				
Basic	10,080	4,993	9,501	5,159
Diluted	10,080	4,993	9,501	5,159

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 September 30,		Nine Months Ended September 30,		From Inception (August 20, 1987) through September 30,
	2005	2004	2005	2004	2005
Cash Flows from Operating Activities					
Net loss	$ (1,927)	$ (1,440)	$ (5,128)	$ (2,954)	(91,882)
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		288		308	1,339
Noncash decrease in accounts payable					(1,308)
Depreciation and amortization	2	3	5	8	3,778
Noncash expenses related to stock-based transactions	26	52	64	52	2,792
Common stock issued for agreement not to compete					200
Series B Preferred Stock issued for consulting services					18
Maturities (purchases) of marketable securities	2,711	2,350	(11,253)	(2,000)	12,482
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	18	137	(170)	149	95
(Decrease) increase in accounts payable and accrued expenses	(108)	(3)	36	(125)	1,845
Decrease (increase) in other assets		(10)	600	274	
Net cash provided by (used in) operating activities	722	1,377	(15,846)	(4,288)	(71,595)

Cash Flows from Investing Activities					
Maturities (purchases) of marketable securities					(28,723)
Capital expenditures	(1)	(6)	(8)	(19)	(2,297)
Purchase of technology rights and other assets	(79)	(30)	(147)	(129)	(2,585)
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	(80)	(36)	(155)	(148)	(31,202)
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	642	1,341	2,264	(18,390)	3,000
Cash and cash equivalents at beginning of period	2,358	1,215	736	20,946	
Cash and cash equivalents at end of period	$ 3,000	$ 2,556	$ 3,000	$ 2,556	$ 3,000

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
September 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 biopharmaceutical company focused on the clinical development of new drugs to treat hormonal and reproductive system disorders. Our lead product candidate, Proellex , is an orally active small molecule compound that we are developing for the treatment of uterine fibroids and endometriosis. Our second product candidate, Androxal , is an orally active 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 their 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 September 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 a 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 its product candidate development requirements including preclinical studies and clinical trials of its 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 December 31, 2006. The Company s current 2005 budget and projected 2006 expenses have allotted financial resources to fund the existing CRO contracts for the completion of the Company s three proposed 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 clinical development of its products which it intends to do after initial clinical study data is available, assuming such data is positive. We can not assure that additional funding will be available on acceptable terms, or at all.

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 its 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 September 30, 2005, the Company had an accumulated deficit of $91.9 million. Losses have resulted principally from costs incurred in conducting clinical trials for the Company s product candidates, in research and development activities related to efforts to develop our products and from the associated administrative costs required to support those efforts. Due to various tax regulations, including change in control provisions in the tax code, the value of this tax asset to the Company could be substantially diminished.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

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 Sept. 30,		Nine Months Ended Sept. 30,	
	2005	2004	2005	2004
Net loss, as reported	$ (1,927)	$ (1,440)	$ (5,128)	$ (2,954)
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	26	52	64	52
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(181)	(191)	(591)	(310)
Pro forma net loss	$ (2,082)	$ (1,579)	$ (5,655)	$ (3,212)
Loss per share -				
Basic as reported	$ (0.19)	$ (0.29)	$ (0.54)	$ (0.57)
Basic pro forma	(0.21)	(0.32)	(0.60)	(0.62)
Diluted as reported	(0.19)	(0.29)	(0.54)	(0.57)
Diluted pro forma	(0.21)	(0.32)	(0.60)	(0.62)

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 September 30, 2005. The following weighted average assumptions were used for grants in the three-month period ended September 30, 2004: risk-free interest rate of 3.8%; no expected dividends; expected lives of 6.5 years and expected volatility of 87%. The weighted fair value of options granted for the three-month period ended September 30, 2004 was $2.75. The following weighted average assumptions were used for grants in the nine-month period ended September 30, 2005 and 2004, respectively: risk-free interest rate of 3.9% and 3.5%; no expected dividends; expected lives of 6.1 and 6.5 years and expected volatility of 87% and 89%. The weighted fair value of options granted for the nine-month period ended September 30, 2005 and 2004 was $2.85 and $1.99, 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 September 30, 2005, all securities were classified as trading securities. The cost basis including purchased premium, which approximates fair value, for these securities was $16.1 million and $4.8 million at September 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 September 30, 2005 consist of only short-term investments totaling $16.1 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 September 30, 2005, the Company had approximately $564,000 in internal capitalized patent costs reflected on its balance sheet. Of this amount, $315,000 relates to patents for Proellex, which is being developed as an oral treatment for uterine fibroids and endometriosis, and $249,000 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.

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The following table presents information necessary to calculate earnings per share for the three-month and nine-month periods ended September 30, 2005 and 2004 (in thousands, except per share amounts):

	Three Months Ended Sept. 30,		Nine Months Ended Sept. 30,	
	2005	2004	2005	2004
Net Loss	$ (1,927)	$ (1,440)	$ (5,128)	$ (2,954)
Weighted average common shares outstanding	10,080	4,993	9,501	5,159
Basic loss per share	$ (0.19)	$ (0.29)	$ (0.54)	$ (0.57)
Diluted loss per share	$ (0.19)	$ (0.29)	$ (0.54)	$ (0.57)

Common stock equivalents of 1,710,363 and 1,836,846 for the periods ended September 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.

Immediately following its 2005 Annual Meeting of Stockholders 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 nine-month period ended September 30, 2005. As of September 30, 2005, the Company had 1,710,363 options outstanding, of which 1,039,631 were vested. All outstanding options have exercise prices ranging from $1.70 to $33.25 with a weighted average exercise price of $4.66.

No options were exercised during the three-month period ended September 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

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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 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 non-cash 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 September 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 $4,128,458 and $3,466,066, respectively, cancelable on 30 days notice.

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

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. GnRH agonists block the action of GnRH and its activity in stimulating steroid hormone secretions. Lupron is marketed by TAP Pharmaceuticals, a joint venture between Abbott Laboratories and Takeda Chemical Industries, Ltd. Abbott reported total Lupron sales of $787.8 million in 2003 in the United States and Canada for all indications.

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, and estrogen is necessary for the maintenance of bone mineral density. Therefore, 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

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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 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. We are currently conducting a six-month rat study and a nine-month dog study testing the safety of Proellex in response to our May 2005 meeting with the U.S. Food and Drug Administration, or FDA, for commencing human clinical trials with Proellex in the U.S. We hope this study may serve as the first of two required pivotal trials of efficacy. The Company completed its 23 volume IND submission which included extensive preclinical animal data supporting the safety of Proellex as well as a final study report for the previously reported trial of Proellex in women with uterine fibroids and delivered the submission to the FDA on November 10, 2005. The Company can not begin its Proellex Phase II clinical study until the FDA has reviewed and accepted the submission. The completion of additional clinical safety studies will be required before a New Drug Application, or NDA, can be submitted. Future studies will start only if this first U.S. study is successfully completed.

We anticipate that we will begin this 150 patient U.S. Phase II clinical study by year end 2005, utilizing up to 20 clinical sites both in the U.S. and abroad. This study is designed to assess both improvement of symptoms associated with uterine fibroids as well as effects on the fibroid itself. The study is expected to be 12-weeks in duration, administering two test doses of Proellex that were previously successfully tested in our prior European Phase Ib clinical study, versus placebo in a double-blind design. Initial data from this study is anticipated during the summer of 2006 and we hope to submit an NDA in 2008.

We also plan to initiate a Phase II clinical trial in Europe with Proellex for the treatment of endometriosis by year end 2005. This study is expected to be six-months in duration and we anticipate that initial three-month interim study data will be available during the summer of 2006.

We have selected Pharm Olam International, a clinical research organization located in Houston, Texas, for our next planned U.S. Phase II clinical study of Proellex for uterine fibroids as well as the European Phase II study for endometriosis. This is the same firm that oversaw our European Phase Ib trial of Proellex for uterine fibroids.

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. This carcinogenicity study is scheduled to begin before year end 2005.

On October 12, 2005 Schering AG announced that it would stop giving its uterine fibroid drug asoprisnil to patients that were in an extension to a late-stage asoprisnil clinical trial due to adverse effects. Based on the limited information provided by Schering AG at the uterine fibroid conference in Bethesda in February of 2005, Zonagen believes that the side effect they observed that resulted in the cessation of dosing was endometrial hyperplasia-like observations. On September 15, 2005 Zonagen released data from a long term primate study that was presented at the 9th World Congress on Endometriosis (data available at Zonagen website, www.zonagen.com) that suggested that Proellex when administered in a chronic fashion is both anti-proliferative and apoptotic on endometrial tissue. Based on these findings Zonagen does not believe that the negative experience of Schering AG with Asoprisnil will be reproduced in Zonagen s long term human studies with Proellex.

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

Testosterone is an important male hormone. Testosterone deficiency in men is linked to several negative physical and mental conditions, including loss of muscle tone, reduced sexual desire, and deterioration of memory and certain other cognitive functions. Testosterone production normally decreases as men age, sometimes leading to testosterone deficiency although this phenomenon is not limited to old men. In studies completed by Zonagen men as young as 26 years of age were effectively treated and restored to a normal testicular state over the course of the study. 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, nose or via injection. The current gold standard in the industry is Androgel®, a topical gel marketed by Solvay Pharmaceuticals, which reported sales of approximately $283 million in 2003 in North America.

Approximately 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.

We recently completed a 52 patient, 14-day Phase II study of Androxal in the U.S. in men with secondary hypogonadism. In the study, Androxal successfully induced restoration of normal testicular function as evidenced by achievement of normal testosterone levels. The drug was well tolerated over the course of the study. We believe that our Phase II study has shown that Androxal blocks estrogen in this depleted testosterone environment, causing renewed normal secretions of important pituitary hormones that result in restoration of normal testicular function. This phenomenon is in marked contrast to the effect that currently approved testosterone replacement therapies have on men that suffer from secondary hypogonadism. We believe that the administration of exogenous testosterone to men suffering from secondary hypogonadism actually makes the underlying condition worse by further suppressing pituitary hormones even beyond that which was imposed by estrogen.

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We intend to begin a U.S. Phase III clinical trial designed primarily to collect additional safety data on Androxal for the treatment of testosterone deficiency by year end 2005 in approximately 200 patients, using up to 20 clinical sites in both the U.S. and abroad. Initial study data is anticipated to be available during the summer of 2006 and we anticipate including this study in an NDA for Androxal in 2008. We believe that it is important to begin to compile the long term safety data base for Androxal that will be necessary for NDA submission and to demonstrate the safety and benefits of Androxal in men that have low testosterone due to secondary hypogonadism. We plan to design the Phase III protocol to compare the safety and performance of Androxal to the leading approved therapy, Androgel as well as placebo.

The proposed 200 patient U.S. Phase III Androxal study is designed to assess safety as well as improvement in testosterone levels and certain clinical symptoms associated with low testosterone in men diagnosed with secondary hypogonadism. The study will test two doses of Androxal versus placebo, in a double-blind design, and Androgel in an open label arm. Androgel will be dosed per manufacturer recommendations. The study is of 24-week duration with a three month assessment built into the trial. The 24 week duration is dependent upon successful completion of an ongoing six month rodent and nine month dog study. The in-life portion of both animal studies is expected to be completed during December of 2005 and data will be submitted to the FDA within a few months thereafter. Pending outcomes from both current six-month rat and nine-month dog studies, results from this Phase III study and subsequent FDA concurrence, patients may be rolled over into a long-term open-label trial in order to assess the continued safety and efficacy of Androxal. Doses to be used in this trial were previously tested in our prior U.S. Phase II study.

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 libido, in a Phase III efficacy study, tests that measure these endpoints must be validated. We intend to comply with the FDA s request, develop a validated clinical test and revise our proposed Phase III pivotal efficacy protocol to incorporate the FDA s other suggestions. We anticipate that this study will begin in 2006, subject to available funding and successful completion of the Phase III study.

We believe that Androxal has the potential to be the only therapy that addresses the root cause of secondary hypogonadism, that is, restoration of normal pituitary secretions leading to normal testicular function. In the first planned Phase III study, we hope to further demonstrate these favorable characteristics of Androxal in a clinical trial that is both placebo and positive controlled.

Based on our communications with the FDA, we believe that at least two additional Phase III pivotal studies beyond the currently planned study will be required before an NDA can be submitted. 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. This two-year carcinogenicity study was initiated in September 2005.

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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 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, or 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 led the PTO to determine that the amended 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 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.

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.

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

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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.

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. There can be no assurance that we will be able to create any value from developing or out-licensing our phentolamine-based product candidates.

Results of Operations

Three Month and Nine Month Periods Ended September 30, 2005 and 2004

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

Revenues and other income. Total revenues and other income for the three-month period ended September 30, 2005 increased to $175,000 as compared to $29,000 for the same period in the prior year and increased to $460,000 for the nine-month period ended September 30, 2005 as compared to $228,000 for the same period in the prior year.

Research and development grant revenues for the three-month period ended September 30, 2005 were zero as compared to $2,000 for the same period in the prior year and were $4,000 for the nine-month period ended September 30, 2005 as compared to $118,000 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

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treatment for endometriosis. This SBIR grant has come to its anticipated conclusion and is essentially depleted.

Interest income increased 548% to $175,000 for the three-month period ended September 30, 2005, as compared to $27,000 for the same period in the prior year and increased 508% to $456,000 for the nine-month period ended September 30, 2005 as compared to $75,000 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.

Other revenue included in the nine-month period ended September 30, 2004 of $35,000 was from the sale of some our preclinical phentolamine data that is to be used for a purpose that does not compete with our sexual dysfunction technologies.

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 72% to $1.6 million for the three-month period ended September 30, 2005 as compared to $929,000 for the same period in the prior year and increased 121% to $4.2 million for the nine-month period ended September 30, 2005 as compared to $1.9 million for the same period in the prior year. The increase in R&D expenses for the three-month period ended September 30, 2005 as compared to the same period in the prior year is primarily due to an increase of $732,000 and $274,000 related to our clinical development programs for Androxal and Proellex, respectively, partially offset by a decrease of $281,000 in costs associated with the 2004 write-off of our patent portfolio related to our vaccine adjuvants and prostate cancer vaccines. The increase in R&D expenses for the nine-month period ended September 30, 2005 as compared to the same period in the prior year is primarily due to an increase of $1.5 million and $1.2 million related to our clinical development programs for Androxal and Proellex, respectively, partially offset by a decrease of $337,000 in costs associated with the 2004 write-off of our patent portfolio related to our vaccine adjuvants, prostate cancer vaccines and hCG immuno-contraceptive vaccine.

General and Administrative Expenses. General and administrative expenses decreased 15% to $461,000 for the three-month period ended September 30, 2005 as compared to $540,000 for the same period in the prior year and increased 8% to $1.4 million for the nine-month period ended September 30, 2005 as compared to $1.3 million for the same period in the prior year. The decrease in expenses for the three-month period ended September 30, 2005 is primarily due to a decrease in costs associated with potential funding activities in the amount of $117,000, offset by an increase in costs associated with strategic administrative fees in the amount of $25,000. The increase in expenses for the nine-month period ended September 30, 2005 is primarily due to an increase in costs associated with strategic administrative fees in the amount of $86,000, personnel costs in the amount of $47,000, legal and accounting services in the amount of $43,000 and investor relations costs in the amount of $37,000, offset by a decrease in costs associated with potential funding activities in the amount of $117,000 and a $27,000 decrease in directors and officers insurance.

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Liquidity and Capital Resources

We had cash, cash equivalents and marketable securities of approximately $19.1 million at September 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 December 31, 2006. The Company s current 2005 budget and projected 2006 expenses have allotted financial resources to fund the existing CRO contracts for the completion of the Company s three proposed 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 clinical development of its products which it intends to do after initial clinical study data is available, assuming such data is positive. 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 of marketable investment securities of $2.7 million, we used $2.0 million during the three-month period ended September 30, 2005 for operating activities; and excluding purchases of marketable investment securities of $11.3 million, we used $4.6 million during the nine-month period ended September 30, 2005. The major uses of cash for operating activities during the three-month period ended September 30, 2005 was to fund our clinical development programs and administrative costs of approximately $1.9 million and to pay our accounts payable and current liabilities. The major uses of cash for operating activities during the nine-month period ended September 30, 2005 was to fund our clinical development programs and associated administrative costs of approximately $5.1 million and to prepay the majority of our 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 $80,000 and $155,000 in the three-month and nine-month periods ended September 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 nine-month period ended September 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 September 30, 2005, 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 $4,128,458 and $3,466,066, respectively, which commitments are cancelable on thirty days notice.

As of September 30, 2005, we had an accumulated deficit of $91.9 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 are not currently committing any significant additional resources toward the development of VASOMAX, although certain development assessment studies are being considered. 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.

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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 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 $19.1 million at September 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, 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 insuring that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the required time periods.

In connection with the evaluation described above, we identified no change in internal control over financial reporting that occurred during the fiscal quarter ended September 30, 2005 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 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: November 11, 2005

By: /s/ Joseph S. Podolski

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

Date: November 11, 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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INDEX TO EXHIBITS

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